Exploring the Acceptability of an International Patient Safety Learning System: An Exploratory Sequential Mixed Methods Approach

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Summary

Since the publication of influential documents on the inadvertent effects of healthcare provision on patient safety, there has been a growing interest in strategies to monitor adverse events and analyse these data. While efforts have been made to collate data across healthcare settings, particularly on a local or national level, there remain challenges to effective organisational learning on safety data. Other safety-critical industries, such as aviation and nuclear power, have made advances in establishing international learning systems that collate, analyse and devise preventative measures for implementation. However, this approach is lacking in healthcare, potentially leading to avoidable patient harm and missed opportunities for practice and safety improvement.

This thesis draws on existing data from healthcare and safety-critical industries to consider how an international patient safety learning system (PSLS) can be designed and the acceptability of such a system to healthcare professionals. A systematic review of the literature from safety-critical industries is used to guide a theoretical understanding of key gaps and opportunities in healthcare system development. This is followed by a rigorous evaluation of the components, functions and processes within an international PSLS, guided by experts across safety-critical industries. Using the framework of Benn et al. (2009), the findings of a modified online Delphi study are used to inform the development of a framework for an international PSLS. This includes the purposes, functions, features and key learning outcomes of the system.

Finally, the developed framework is examined to establish the potential use of the system in practice. Specifically, a national case study is used to develop and test the prospective acceptability of the international PSLS in the Kuwaiti healthcare context. These findings may be expanded and built on to further explore the feasibility and implementation of such a system and its value across international healthcare safety learning.

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Abbreviations

AIMS	Australian Incident Monitoring System
COVID-19	Coronavirus disease 2019
IAEA	International Atomic Energy Agency
ICAO	International Civil Aviation Organization
ICD	International Classification of diseases
ICPS	International Classification for Patient Safety
IOGP	International Association of Oil & Gas Producers
IOM	Institute of Medicine
IRLS	Incident Reporting and Learning System
MIM PS	Minimal Information Model for Patient Safety
MMS	The Measurement and Monitoring of Safety framework
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health Research
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
OECD	Organisation for Economic Co-operation and Development
PDSA	Plan, Do, Study, Act cycle
PSLS	Patient Safety Learning system
RCA	Root Cause Analysis
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

Chapter 1 – Introduction

1.1 Patient safety in healthcare

The purpose of this thesis is to consider how learning about patient safety is shared and disseminated in the healthcare industry, with a focus on the development of an international incident reporting and learning system (IRLS). This chapter provides an overview of the evolution of the discipline of patient safety in modern clinical practice and the nature of what constitutes a patient safety incident. It will also outline the concepts and classes of information that can be identified following an incident. Furthermore, the importance of the reliability and capability of learning from patient safety data is considered, within the context of the need for sharing learning and actions to mitigate risk to patients at a national and international level. The chapter concludes with an outline of the key aims and objectives of the PhD thesis and an evaluation of the methods used to achieve these aims and objectives.

1.1.1 Defining patient safety

Patient safety is an important concept in contemporary healthcare practice (Vincent, 2011). The introduction of a clear concept of patient safety in the field of healthcare reflected the increasing complexity of the health system itself (Carayon & Wood, 2009). This includes advances in technology, interventions, and care processes, which may have advantages for the health of the individual, but which may also be associated with creating or heightening the risk of harm (Nolan, 2000). It has been suggested that health systems (and processes of patient care within those systems) have become increasingly complex, and that this complexity increases the risk of patient harm (Carayon & Wood, 2009). Complex systems have multiple interactions between professionals, institutions, and processes, which may increase the risk of harm, particularly if this complex system is not aligned with safe practices (Ambwani et al., 2019). How patient safety is defined within such a system plays an important role in identifying strategies to ensure harm is reduced in practice. The definition of patient safety may therefore be considered to reflect the need for harm reduction in practice.

The World Health Organization (WHO) (WHO, 2021) proposed a definition of patient safety in its simplest terms as the prevention of errors and adverse effects to patients associated with health care. In a more nuanced version of the definition of patient safety, it is recognised that the term reflects a healthcare discipline that focuses on preventing and reducing risks, errors and harm during healthcare provision (WHO, 2021). The need for

these preventative and risk reduction strategies is the basis for continuous improvement through learning from errors and adverse events in practice (WHO, 2005a). Importantly, within the more expansive definition of patient safety, multiple terms appear that have been conflated or confused within academic literature and in practice, such as risk, harm, errors, and incidents (Nolan, 2000; WHO, 2005a; Vincent, 2011).

The WHO (2009) technical report on a conceptual framework for the classification of patient safety provides some clarity regarding how terminology may be used and defined in relation to patient safety. Within the technical report, patient safety is defined as a reduction of the risk of unnecessary harm associated with healthcare to an acceptable minimum. This definition raises further questions regarding the nature of risk and harm to patients, with a focus on unnecessary risk. It suggests that certain risks or degrees of risk may be preventable in nature, which forms a pragmatic basis for the potential for creating interventions to reduce risk (Carayon & Wood, 2009). Furthermore, the concept of an acceptable minimum is intended to reduce the need for complete elimination of risk, which may be considered an unrealistic goal (Wachter, 2010). Rather, risk should be reduced to the degree that is consistent with current knowledge, resources, and care contexts and considered relative to the risk of non-treatment or other interventions. However, viewing risk reduction in this manner is complex and may limit the application of this definition across healthcare settings; the need for risk reduction to reflect local circumstances and for different levels of risk to be considered acceptable in different settings may arguably facilitate inequalities in care (Wachter, 2010). Therefore, even when patient safety definitions are developed using systematic approaches, they may remain open to some interpretation and criticism based on how they may be applied in practice.

Risk reduction needs to be further understood in terms of how patient outcomes are conceptualised and the underlying causes of these outcomes. Firstly, the concept of harm suggests that a patient has experienced physically, socially, or psychologically deleterious effects whilst receiving interventions of treatment for underlying conditions. A harmful incident (adverse event) is an incident that causes harm to the patient (WHO, 2009a). However, incidents do not necessarily have to cause harm, but may be classified as near misses or no-harm incidents. While patient safety as a discipline has typically focused on reducing harm based on the assessment of incidents that have caused harm, there is increasing recognition of the need to identify near misses and no-harm incidents to ensure effective harm reduction (Clarke, 2006).

Finally, the concept of errors in practice needs to be considered in relation to patient safety (McNutt et al., 2002). Errors may be defined as a failure to carry out a planned action as intended or recommended, or the adoption of an incorrect plan in healthcare (WHO, 2009a). Errors include instances where an individual acts by doing the wrong thing or through omission (failing to do the right thing) and may be associated with harm (Hurwitz & Sheikh, 2011). Fundamentally, errors increase the risk (probability of an incident occurring) to patients, and targeted efforts to enhance patient safety have often focused on individual practitioner errors as they are perceived to be a driver of risk and harm (Mannion & Braithwaite, 2017). However, as considered in the following section, patient safety has evolved over time to take into account that an individual error-focused approach to safety may not be as effective as wider attempts to consider the wider system-level influences on the individual and related changes upstream of the incident often needed in practice to mitigate future similar incidents.

1.1.2 An history of patient safety in healthcare

1.1.2.1 Healthcare as a source of harm

The potential for healthcare interventions to have a negative influence on patient experience or to cause harm to an individual has been recognised since the time of ancient Greece (Shortell & Singer, 2008). Within the observations of ancient Greek practitioners of healthcare, the term ‘iatrogenic’ emerged as a recognition that doctors/healers (iatros) may create (genesis) illnesses or harm through their actions (Shortell & Singer, 2008). Despite this early recognition of the potential for harm due to healthcare practice and interventions, it was not until the 1990s that international attention focused on patient safety as a concept in the way it is understood in clinical practice today (Leape et al., 1991; Bates et al., 1995). During the intervening centuries, advances in healthcare practice and intervention techniques led to an expanding potential to improve health and prevent illness, although the balance of risk and benefit of interventions was often not considered an important issue (Waring et al., 2016). Indeed, until the modern age, healthcare interventions were viewed as a means of managing an illness, and their use was uniformly considered preferential to allowing the natural course of illness with a risk of harm considered an unfortunate, but acceptable, consequence of the aim to improve health.

As medicine advanced, and societal views towards health, harm and prevention also changed over time, healthcare provision has become a professional industry, tasked with managing and preventing illness in more sophisticated ways, while having an increased

level of professionalism and accountability towards the patient (Waring et al., 2016). As noted by DuPree et al. (2011), a code of professionalism can be used to instil values and attitudes aligned with care that meets the needs of patients, promoting a culture of safety within the hospital setting. Part of this culture is the recognition that the risk of harm caused by any form of medical intervention or medical error should be minimised during routine care and that healthcare professionals have a duty to accept responsibility and to be accountable for errors and lapses in safe care (DuPree et al., 2011). Over time, this level of accountability and the need for professional practice centred on reducing the risk of harm has advanced, following the quantification of these risks and lapses in safety several decades earlier.

1.1.2.2 Emergence of the modern patient safety movement

In 1999, the United States-based Institute of Medicine (IOM) report *'To Err is Human'* attracted international attention to the issue of patient safety in healthcare (IOM, 1999). The report concluded 44,000-98,000 American patients died each year due to preventable errors in hospitals (IOM, 1999). At this time, the finding raised international concerns regarding the methods used to intervene and the standards of care received by patients in the hospital setting. Furthermore, it emphasised the challenges associated with defining, measuring and improving patient safety in practice, given the complexity of the healthcare system as a whole (IOM, 1999). The publication of 'Crossing the Quality Chasm' by the IOM (now the National Academy of Medicine) followed and defined quality in terms of six dimensions: safety, effectiveness, patient-centredness efficiency, equity, and timeliness (IOM, 2001). These dimensions formed a basis for how to improve healthcare systems to ensure an optimal level of quality was achieved, including patient safety.

Subsequent to these reports at the turn of the millennium, there has been a wide body of literature focused on evaluating the occurrence of patient safety incidents and recognising the need for improvements in patient safety within healthcare (Wachter, 2004; Waring et al., 2016). These publications have variably focused on the incidence of patient safety incidents in practice (Chatburn et al., 2018), the need for a safety culture (i.e., a shared set of beliefs, values and practices that are aligned with patient safety practices) within healthcare settings (Shaw, 2004) and the need for improved reporting of safety incidents in practice (Bird, 2005).

In the United Kingdom (UK), the National Patient Safety Agency (NPSA) was formed in 2001 (Department of Health, National Health Service, 2001), and a focused effort to commission studies and guidelines to promote safety within healthcare followed. This

wider acknowledgement of the need for patient safety was broadly accepted in the academic community and among practitioners and was viewed as a means of improving standards of care (Waring et al., 2016). Furthermore, patients and patient advocates welcomed the focus on safety as a key aspect of the care experience and a person-focused approach to care provision (Pronovost et al., 2016). However, the patient safety movement was not without initial resistance, with some authors suggesting that inconsistent definitions of patient safety and errors in practice reflected a lack of empirical investigation of these phenomena (Stelfox et al., 2006; Dekker et al., 2011),

Another source of opposition to the patient safety movement was the view that safety was a wider aspect of quality improvement, which was already an ongoing process within large healthcare organisations (Wears, 2012). Indeed, the definition of quality improvement proposed on an international level (WHO, 2016) is inclusive of the need to promote safety in care, whereby the risk of harm is minimised for the individual patient and more broadly to reflect the experiences and outcomes of patients within an organisation. Quality improvement was already an established process prior to the establishment of the NPSA in the UK, suggesting that measures to improve safety were already recognised and pursued in practice (Stelfox et al., 2006). However, it can be argued that a more focused acknowledgement of the need for patient safety, rather than the multiple elements of care quality that are targeted by quality improvement processes, had the potential to galvanise research in this context, while promoting the specific importance of safety as a concept and practice goal (Wears, 2012).

1.1.2.3 Current policies and standards of patient safety

Emerging from initial controversies over the patient safety movement, a wide range of policies and international standards have emerged to guide quality improvement, with the safety of patients at the heart of quality improvement. The WHO has been a primary leader in international patient safety developments (WHO, 2005a; WHO, 2009a; WHO, 2021). Most recently, this includes the publication of a global action plan for patient safety for 2021-2030. Importantly, this action plan emphasises the need for analysis and sharing of data to generate learning, with the translation of evidence into actionable and measurable improvement.

The Organisation for Economic Co-operation and Development (OECD) has also emerged as a key organisation in advocating for patient safety too. A joint statement on care quality by the WHO, World Bank and OECD (2018) emphasised the need for a global approach to improving quality in healthcare and the strategies that are needed to achieve this outcome.

Recently, the OECD (2020) published a paper on system governance towards improved patient safety, noting how learning needs to be from successes as well as failures, with learning not limited to adverse events in practice, but from the routine application of interventions and systems to minimise harm to patients. Furthermore, this paper highlights the importance of governance across the healthcare sector, not only in hospitals and clinical settings, with a focus on external accreditation, inspections of safety processes, and learning based on outcomes, with a transition in cultures from blame and fear towards openness and transparency in approaches to safety. This aligns with the WHO (2021) action plan for 2021-2030, which recommended that instilling a safety culture into healthcare systems is crucial to supporting learning and policy development in practice. Furthermore, appreciation of human factors, or the individual situated within a socio-technical context, is paramount to improving safety.

Rather than enacting guidelines and measures for the system as a whole, human factors appreciation can provide a basis for participatory approaches, person-centred safety development and design-driven approaches that support learning and wider aspects of safety improvement (WHO, 2021). Consequently, patient safety has emerged as a more transparent issue in healthcare settings and should be firmly embedded in practice, rather than considered an additional or specialist requirement or reactive approach to incidents across the health system.

Guidelines and their use in practice rely not only on their publication and dissemination, but also on the patient safety literacy of the healthcare workforce and the availability of training to enact those guidelines in practice (Sujan et al., 2019). Education and training programmes are now widely used in healthcare settings and form a key part of training. The WHO (2009) patient safety curriculum was initially published for use in medical schools and was more widely disseminated across higher education for healthcare professionals following an update in 2011 (WHO, 2011). This curriculum is an important contributor to patient safety, as it clarifies key terms and concepts related to quality improvement, safety science, and human factors, which may not be widely recognised by faculty members with clinical backgrounds. The curriculum focuses on patient safety content, as well as three high-risk areas where adverse event rates are high: infection control, procedures and interventions, and medication management (WHO, 2011). Advantages of the curriculum include the flexibility of application in practice, with faculty able to select topics of greatest relevance to the context of education, providing a basis for flexibly introducing safety topics within education (Sujan et al., 2019). Patient safety has

evolved to become an element of healthcare professional education, informed by policy, research evidence, and WHO leadership at an international level (Howarth et al., 2021). However, variability in the design and content of patient safety education is notable, and standardisation of patient safety education is lacking, suggesting challenges to integrating safety into healthcare curricula and motivating educators to engage in safety learning (Howarth et al., 2021). Furthermore, it should be noted that there should be a balance between consistency and discipline-specific patient safety education (e.g., patient safety education of a surgeon would be different from that of a nurse or a pharmacist due to the different nature of their work).

Similarly, it is recognised that patients should play a key role in patient safety and quality improvement. This has been recognised for decades (IOM, 2001), and increasingly there has been a move toward establishing patient advocacy groups and co-designing patient safety measures whereby patients and healthcare staff collaborate (Ward et al., 2018). The WHO (2021) notes that scientific expertise and patient experiences are needed to drive improvements in safety. Aligning safety initiatives based on scientific evidence with patient experiences can enhance adherence or buy-in to those measures and may improve the potential for positive attitudes towards safety improvement (WHO, 2021). Therefore, safety improvement has evolved from a conceptualised systematic approach to implementing guidelines based on evidence towards a more nuanced strategy that involves an appreciation of patient factors, experiences and attitudes to drive actionable and measurable interventions in practice (WHO, 2021).

Given that a multitude of factors have been linked to patient safety and that multiple stakeholders may play a role in promoting safe practice or are influenced by such practice, there is evident complexity in patient safety as a discipline. However, at the core of patient safety is the need to drive improvement in safety based on learning related to identified risks and incidents. The concept of learning within patient safety is fundamental in guiding how data are collected, analysed, interpreted, and then utilised to promote changes in practice to reduce safety risks. The following section provides further insights into how learning has been considered in seminal documents related to patient safety and from wider industries that focus on safety-critical processes.

1.2 Safety and learning across industries

1.2.1 Safety learning in seminal healthcare publications

Seminal publications related to patient safety (IOM, 1999; IOM, 2001) sought not only to report the high incidence of adverse events within healthcare settings, but to highlight the need to learn from these incidents to improve future practice. The specific focus on learning within these reports included a need to share learning among health delivery systems and to integrate learning within the way systems operate, with measurement and analysis of data driving quality improvement (IOM, 2001). Similar reports were noted in the UK, such as *'An Organisation with a Memory'*, emphasising the nature of preventable harm to patients and driving a renewed focus on the need for patient safety as a focused national priority (Department of Health, 2000). While there were sporadic improvements in patient safety processes and recognition of aspects of safety within healthcare prior to these publications, these are considered landmark publications for the rise in interest in the study, analysis, and improvement of patient safety at an organisational level within healthcare (Stelfox et al., 2006).

The focus on learning within these publications was largely based on retrospective analysis of reported incidents and then monitoring to drive changes in the future, with evidence used to create guidelines and dissemination focused on guideline availability in practice (IOM, 2011). While this may be broadly consistent with learning approaches in patient safety today, learning in patient safety has advanced over time and now reflects a more nuanced appreciation of incident analysis and an understanding of healthcare as a complex socio-technical system (WHO, 2005a; Health Quality Ontario, 2017; WHO, 2021). Such a system is comprised of multiple socio-technical dimensions suck as workflow, people, organisational policies, communication, and external rules and regulations (Sittig & Singh, 2010).

An important concept to consider when learning is the notion of a learning system, which reflects a wider approach to learning beyond the learning an individual may complete (i.e., standard pedagogical models) (Woolf et al., 2015). The learning system suggests a structured approach to learning that can be implemented across individuals or organisations (Lafreniere et al., 2013). By considering the role of learning systems in guiding learning outside of healthcare, including in wider safety-critical industries, the application of these systems to the patient safety context in healthcare may be appreciated. The next section includes an overview of safety-critical industries and how

they are defined, followed by an analysis of learning processes and systems within these industries.

1.2.2 Defining safety-critical industries

Safety-critical industries include the nuclear power industry, offshore oil platforms, commercial aviation and other forms of transportation (e.g., rail network), and chemical manufacturing plants (Wears, 2012). Falla (1997) defines safety-critical industries as those where the highest level of safety integrity is needed, where a malfunction would lead to serious consequences. These industries have also been defined as complex socio-technical systems comprising multiple professional roles and societal and technical artefacts (Wears, 2012). If these definitions are considered together, then one might perceive a safety-critical industry as any industry comprising technology, people, and organisations, where safety is important due to the consequences of malfunction or failure, including serious injury, harm, loss of life, or damage to the wider environment. Understanding how these industries approach safety, including identification, measurement, analysis, and dissemination of safety-related learning, has important implications for learning. Sharing learning from these industries and evaluating the relevance to healthcare contexts can be considered an important aspect of understanding how learning from safety incidents in healthcare may be improved in practice.

Two of the most widely evaluated safety-critical industries are the nuclear power industry and the commercial aviation industry (Amalberti et al., 2005; Hollnagel et al., 2015; Chatburn et al., 2018). This reflects the degree to which these industries encapsulate the need for stringent safety requirements to prevent harm to a large number of individuals from a single incident. Indeed, Wears (2012) suggests that safety-critical industries have two key properties: mass, where large numbers of people may be injured or killed due to safety failures, and dread, where dangers associated with the industry are perceived to be out of the control of the individuals at risk of harm. Therefore, a nuclear incident at a power plant fulfils these criteria, and an aviation incident may also meet these criteria. A high level of safety regulation is therefore associated with both industries to avoid mass harm and to manage dread associated with the potential for safety malfunction or failures (Chatburn et al., 2018).

Learning within these industries focuses on outcomes that may be related to healthcare practice. These outcomes include a focus on incidents, errors, accidents, and disasters. Such incidents often affect large numbers of individuals but happen infrequently, which contrasts with healthcare settings, where safety issues often affect individual patients or

small groups, but with a much greater frequency than incidents in other industries (Chatburn et al., 2018). Learning from incidents is, however, considered to be advanced in safety-critical industries and provides a model from which healthcare industries may develop a deeper appreciation of the learning process, as considered in the remainder of this section.

1.2.3 Influence of other industries on safety in healthcare

The recognition of safety and the prevention of harm across safety-critical industries has had an influence on the healthcare industry over the past few decades (Wears, 2012). Power production and aviation industry safety standards were typically reviewed and standardised in response to a root cause analysis of critical incidents (including nuclear powerplant failures or disasters, airline crashes, and other mass casualty incidents) (Wears, 2012). The approaches used to identify the cause of safety incidents were diverse in these contexts and highlighted not only the concept of individual error (i.e., a mistake attributed to a single person), but the wider systemic nature of errors and the potential for failings (Liston et al., 2017). Analysis of major incidents, therefore, led to an approach that shifted from a focus on individual error and blame towards a wider strategy to improve systems, prevent the capacity for errors, and ensure fail-safes and checks to identify sources of error are in place to prevent their impact on eventual outcomes and people (Liston et al., 2017).

The lessons learned from other industries have been applied to the healthcare industry, which was traditionally based on an error identification approach focusing on the individual prescriber or practitioner (Spurgeon et al., 2019). The aviation industry, in particular, has been compared with the healthcare industry in terms of the development of safety initiatives consistent with a safety-critical industry (Patankar, 2020). Parallels between the aviation industry and healthcare industry are numerous, including the standardised nature of many processes, the potential for harm if procedures are not followed accurately, and the broad reach of both industries in terms of individuals affected by lapses in safety (Gerstle, 2018). Accordingly, the use of specific safety measures from the aviation industry has been recommended in healthcare contexts. Most notably, the WHO Surgical Safety Checklist has been applied in practice with the use of a structured checklist to ensure that surgical processes are reliably completed according to a clear sequence of stages (Haynes et al., 2009; Vincent & Amalberti, 2015). Checklists are widely used in the aviation industry to ensure that complicated machinery is maintained and operates according to an optimal function, where outcomes of each component and their interaction

can be predicted based on a logical understanding of the process as a whole (Patankar, 2020). The use of checklists affords a standard of assessment for complicated processes (e.g., aircraft suitability for flight) and designates dedicated time and personnel to complete this form of assessment routinely (Spurgeon et al., 2019).

It is important to acknowledge the differences between the aviation and healthcare industries, however. Indeed, these differences may impact the degree to which standards of safety may apply to each industry and the transferability of checklists and other tools to prevent safety incidents from occurring (Spurgeon et al., 2019). As noted above, aviation is based on complicated machinery characterised by components and stages that may be linked to an optimal outcome under all circumstances (Kapur et al., 2015). This is not a complex system, which is defined as a system that emerges, often organically, where individual elements of that system interact in a disordered manner, out of which a robust order is generated (Hart, 2004). In complex systems, there is a lack of linearity between components of the system, unlike mechanical components that are designed to engage in a reliable sequence to generate a specific outcome (Hart, 2004).

In contrast, healthcare is a complex system, where a reliable prediction of processes and stages for use in one patient cannot be established; individualised care is necessary to meet patient needs and improve outcomes (Kapur et al., 2015). In a complex system, the origin of a patient safety incident does not merely derive from a predictable failure in one component of an ordered sequence but may arise from an interplay of technical, organisational, environmental, or human error (or, most commonly, a combination of these errors) (Tanguy et al., 2016). Indeed, an error, such as an incorrect medication dose administered to a patient, may be the result of improper dispensing of a drug, environmental factors (e.g., distractions in the dispensary), human error in failing to check the drug or patient details, or numerous other factors, all leading to the same outcome (Marino et al., 2000). The complexity of the factors contributing to an error in healthcare highlights the challenges in applying aviation industry standards and practices to the healthcare setting, including the use of procedures and checklists that are designed to ensure adherence to sequential or predictable processes. While the WHO checklist may be a suitable application of the standardised method of assessing a procedure in practice, the use of checklists in other contexts may be limited, given the complexity of the healthcare process (Haynes et al., 2009; Chatburn et al., 2018). Indeed, checklists are generally reserved for simple, predictable, and standardised care processes and cannot

easily be applied to the whole episode of patient care, interactions of team members, or evolving nature of standards and practice in healthcare (Clay-Williams & Colligan, 2015).

While these limitations may apply to the use of safety tools and standardisation of processes, it is likely that, when used in context, these checklists may provide a basis for improving patient safety (Clay-Williams & Colligan, 2015). The standardisation of processes and procedures can form an important aspect of preventing the chance of specific, systematic errors from occurring, while not necessarily eliminating errors due to complex causes (Tanguy et al., 2016).

The following section broadens the consideration of how safety is considered across industries and then applied to the healthcare industry, by focusing on other crucial aspects of safety: incident reporting and learning systems.

1.3 The learning system

1.3.1 Defining a learning system

The emphasis on patient safety within the field of healthcare came at a time when systems thinking was already an established model that had been widely discussed from cognitive, organisational, and engineering perspectives (Waterson, 2009). Systems theories and system theory thinking is a marked departure from the focus on human errors (and associated blame) that typified a response to identified safety lapses or incidents in practice (Cooper et al., 2017). While human errors undeniably play a role in the potential for lapses in safety (e.g., a lack of concentration leading to error), there is a wider appreciation of the human as part of a larger system within systems theory thinking (Cooper et al., 2017). Consequently, to focus on the human error alone and seek to correct circumstances that led to an error through individual naming and blaming can be considered ineffective at addressing the underlying systemic factors that may have led to the safety incident or allowed for the effects of human error to potentially harm the patient (Waterson, 2009).

The use of systems theory can be considered an ecological approach to understanding the factors that influence a phenomenon or outcome (Hofmeyer & Marck, 2008). Ecological theory notes the interaction of multiple hierarchies or levels within the occurrence of incidents, including the individual, friends and family, the wider community, and other influences, such as the government and other environmental influences (Marck, 2005). Systems may be defined as having a clear structure and function, with the intention of producing a clear outcome; notably, inter-related components that operate together to

achieve a common goal (Hughes et al., 2015). Specifically, systems may be considered learning environments, with the term ‘learning system’ used to highlight how learning may be achieved on a system-wide level.

A learning system may be viewed as any approach to learning that operates on the level above the individual (micro-level) (Lindberg et al., 2010). The term is prone to variable definitions, depending on the specific context in which it is evaluated, either reflecting an accumulation or aggregation of artefacts (tools or objects) that form an environment in which learning may occur (Koper, 2004). Alternatively, or in addition to, it can reflect learning is facilitated between individuals or groups of individuals in a systematic manner (Soller, 2001). Common to both definitions is the general recognition that a system of learning should have key components that integrate to facilitate learning at the macro- or meso-level (Drupsteen & Guldenmund, 2014). The meso-level reflects organisational factors within a learning environment while the macro-level highlights how learning modes may be situated in varying contexts (Manniche & Testa, 2018). Learning and innovation within organisations have been characterised by a framework that suggests that different learning modes (micro-level) should be situated within varying contexts (macro-level) and delineated by choices made by the organisation (meso-level) to form an integrated approach to innovation within an organisation (Manniche & Testa, 2018). Therefore, learning within a system (or organisation) requires that multiple levels of influence are considered to drive learning outputs, such as innovations, local guidelines, and policy.

Various attempts at defining a system of learning or an organisational approach to learning in relation to safety have been noted in the literature (Lindberg et al., 2010; Le Coze, 2013; Drupsteen & Guldenmund, 2014). Learning from incidents, accidents, and disasters, in particular, is of relevance to the patient safety field and is a rich area of academic study, with several models of learning systems emerging from various industries (Margaryan et al., 2017). In this instance, a learning system is defined as a stepwise approach to learning by most authors, based on varying levels of literature review and analysis of theories (Lindberg et al., 2010; Le Coze, 2013). The stages or components of a learning system include the learner, learning process, and learning product (Le Coze, 2013). Furthermore, an analysis of theories and models by Drupsteen and Guldenmund (2014) highlights that a learning system comprises a clear process of information/data collection (such as incident reporting), analysis of existing and new data (such as incident reports), development of lessons learned from this analysis, and then dissemination and storage of these lessons or associated outputs. This ‘systems approach’ therefore incorporates distinct stages that

may be followed sequentially to link reporting of incidents to the dissemination of outcomes, forming a learning process (Margaryan et al., 2017).

The main aspects of learning systems noted above will now be considered individually, highlighting how the various stages and requirements of a learning system may be achieved across industries and organisations.

1.3.2 Inputs: incident reporting and data collection

Within the healthcare context, a similar strategy to that seen in other safety-critical industries exists, where identification of particularly relevant sources of information or data relating to patient safety is considered crucial in establishing the cause of adverse events, isolating remedial factors, and in analysing current standards of practice (Vincent et al., 2013). However, it has been acknowledged that there is little clear consensus regarding the core dimensions of safety that should be measured and monitored in practice (Pronovost et al., 2009; Vincent et al., 2013). While standardisation of key safety data may be important, it should also be considered that individual organisations (including healthcare organisations or systems) should tailor safety data measurement and monitoring according to their capacity and unique characteristics (Chatburn et al., 2018). Strategies to enact a routine approach to safety measurement and monitoring and to allow for individual organisations within healthcare systems to successfully adopt such practices are considered important to connect safety aspirations with practice realities (Sauro et al., 2020).

The healthcare system may also be considered unique when compared to other safety-critical industries, with the recognition that dynamic elements exist when evaluating risk and safety in healthcare settings, which complicate how terminology is adopted and applied in safety contexts (Leape, 2015). Importantly, it is recognised by Vincent and Amalberti (2015) that safety in the healthcare industry is unique, in that it presents a ‘moving target’ in terms of conceptualisation and measurement, which is another challenge to the use of standard definitions and measures. As healthcare interventions and techniques advance, and standards of care improve, conceptualisations of harm and avoidability become modified, unlike in other industries where safety is a constant concept, even when advances in standards, practices, and technology occur (Cook & Rasmussen, 2005). Indeed, one need only assess the definition of patient safety incidents in healthcare over the past two decades to appreciate how concepts of harm and avoidability have changed. For instance, the risk of healthcare-associated infections (iatrogenic infections) was largely considered an unfortunate consequence of care but had an inevitability

associated with it prior to and during the 1980s. However, as an understanding of underlying mechanisms grew, and methods for infection prevention and control advanced, healthcare-associated infections are now considered a key threat to patient safety, given the potential to avoid such infections (Burke, 2003). Therefore, safety and harm are evolving concepts in the field of healthcare, and this suggests the importance of updating definitions and concepts over time, based on advances in the field and the emergence of new standards of care.

The evolving nature of the field of patient safety has led to challenges in maintaining clear definitions of terminology and standards of safety in practice. Consequently, this has led to challenges in measuring safety incidents and monitoring patient safety in healthcare contexts, as definitions need to be clear and specific safety standards consistent to ensure accurate measurement and monitoring (Leotsakos et al., 2014). The development of safety reporting systems and strategies to monitor patient safety are considered essential to promoting optimal care and preventing the risk of harm to the individual and the wider population of patients (Leotsakos et al., 2014).

Different data sources may be used for different purposes in the context of safety measurement and monitoring (Morello et al., 2013). Routinely collected data on specific adverse outcomes of patient safety incidents are commonly viewed as key sources of data in healthcare, including rates of adverse drug events, mortality rates, and other metrics that quantify the occurrence of safety incidents, near-misses, or other factors involved in safety incidents (Vincent et al., 2014). These data are often derived from administrative records and reviews of incidents, based on reporting of incidents by members of staff, clinical audits, or routine evaluation of outcomes (Wong et al., 2010). These data may be valuable in maintaining a record of safety in practice, but they remain controversial regarding their potential to galvanise improvements in safety (Wong et al., 2010). This controversy stems from how learning from measurement has been associated with a limited impact on changing unprofessional behaviours (Hickson et al., 2007) and non-compliance with accepted safety practices (Wachter & Pronovost, 2009; Edwards, 2017). Therefore, data on past incidents and their analysis may not always necessarily provide a basis for robust learning and behaviour change that improves safety in the future (Vincent et al., 2014).

Other types of data and data sources may also contribute to measuring and monitoring safety in healthcare (Vincent et al., 2014). These include observations, informal conversations, complaints, inquests, investigations underpinned by methods like root

cause analysis, and collaborative approaches to identifying safety lapses and/or underlying factors relating to safety incidents (Vincent et al., 2014). In contrast to routinely collected safety metrics, these data sources more broadly assess possible types of incidents and may provide a different focus to routinely collected adverse event records and administrative data (Vincent et al., 2013). However, optimal assessment of patient safety should rely on multiple data sources and integration of incident data and incident reporting in combination with more in-depth analyses of the outcomes, possible causes, and case details associated with incidents or near misses, allowing for a comprehensive approach to safety evaluation (Morello et al., 2013).

Data collection is only one aspect of pursuing patient safety in practice, as data collected without any further analysis merely provides a report of what went wrong and does not facilitate learning and prevention of likely contributory factors linked to the observed incidents. The data collected as part of a learning process should be standardised and clearly defined to facilitate consistency in organisational learning (Lindberg et al., 2010). This is considered further in the following section, where analysis of data is considered in the learning system.

1.3.3 Analysis of data

1.3.3.1 Analytical methods and frameworks

Collecting data is only one part of assessing the safety of healthcare practice and providing an opportunity for learning (Wakefield & Jorm, 2009). The use and evaluation of data within a clear framework is essential to guide learning (Vincent et al., 2013). Within the aviation and power production industries, in particular, analysis of specific incidents involving multiple casualties formed the basis for driving analysis of safety data and strategies to improve safety (Donaldson et al., 2017). As the causes of incidents may be diverse in nature, analysis of the underlying causes of adverse events is crucial to determining the key factors that may be involved and targeted from an organisational perspective (Vincent et al., 2013).

The Measuring and Monitoring Safety (MMS) framework was devised by Vincent et al. (2013) as a means of combining academic research with practical experiences to guide organisational practice regarding safety measurement and monitoring in healthcare. Five principal dimensions were identified in this framework to guide patient safety data collection and analysis: safety of care in the past; reliability of clinical systems and processes; safety of care today; safety of care in the future; and the response and

improvement capacity of the organisation (Vincent et al., 2013). Implementation and assessment of the MMS programme suggest that the framework may be useful in guiding the conceptualisation of safety and the need for active monitoring (Chatburn et al., 2018).

The framework also provides an emphasis on inquiry rather than assurance, where assessments and metrics used to standardise processes are less important than the need to continuously question and analyse safety across all levels of an organisation (Chatburn et al., 2018). In this context, the distinction between inquiry and assurance (or compliance) is important, as both approaches have relative advantages and disadvantages when assessing safety. Assurance or compliance has the advantage of providing clear standards or guidance for processes associated with safety, allowing safety to be monitored through the achievement of these standards; this is a clear, quantifiable process that is relatively easy to implement in practice (Sauro et al., 2020). However, this approach may lead to an overreliance on these guidelines or standards, leading to a less nuanced and reflective approach to safety. Unless these standards are optimised in practice, overreliance may be associated with false reassurance of safe practice (Chatburn et al., 2018).

In contrast, an approach linked to inquiry promotes a more mindful and inquisitive perspective on safety in practice, as noted by managers in the study by Chatburn et al. (2018). The nature of scientific inquiry is to ask questions, change the types of the question being asked, analyse the need for specific types of data, and critically evaluate the outcomes of such an inquiry (Shendell-Falik et al., 2007). Consequently, this approach has the advantage of providing a more proactive approach to engaging with safety, rather than through the achievement of targets, potentially assisting managers and other staff in linking observations to practical improvements in safety outcomes (Duckett & Jorm, 2019). However, this approach may be considered more complex and open to interpretation, given the need for inquiry-based interpretation of data outside of the use of standardised targets and guidance alone (Sauro et al., 2020). With respect to the MMS, the measures of safety used within this framework may be open to interpretation, and data sources and analysis of data may remain an important source of heterogeneity in the application of safety frameworks at an organisational level (Sauro et al., 2020). Therefore, the MMS has advantages and disadvantages in practice, reflecting the adoption of an inquiry-based approach to safety evaluation.

1.3.3.2 Standardisation of data for analysis

In addition to the use of an analytical framework, one of the most important aspects of the analysis of data is ensuring that data are consistently defined and standardised, which permits aggregation and wider-level analysis of data (Gagnon, 2011). This is widely seen in aviation industries and nuclear power industries, where data are collected on a national and international basis. Such data are uniformly defined and consistently categorised, facilitating clear analysis of data from any setting, while also ensuring that the analysis can be understood and implemented across these settings (Falconer et al., 2019).

For instance, the Aviation Safety Reporting System (ASRS) is the oldest voluntary incident reporting programme for aviation and collects reports from aviation events in the United States (Tanguy et al., 2016). These reports are simple narratives, comprising a range of descriptors regarding the context of the incident and the outcomes. Analysing descriptive prose in this manner requires strategies to categorise data, and the ASRS employs a strategy whereby the grouping of descriptors is linked to specific entities (a logical grouping) related to the aircraft, events or assessments. Rather than adopting standard English, the reports utilise a range of abbreviations for common terms (e.g., ACFT for aircraft) which can remove ambiguity and allows for automated analysis of reports to identify key descriptors, events, or outcomes. Other systems in place for aviation reporting have similar strategies to facilitate the analysis of descriptive text into taxonomic blocks (Karanikas & Passenier, 2019). The use of abbreviations that have standardised meaning, captured within hierarchies related to specific entities or grouping of descriptors can facilitate automated analysis of these data. Furthermore, natural language processing techniques and text mining are increasingly used in these reports on an international basis to ensure that language barriers in reporting are minimised, based on standardisation and definition of key terms in different languages and attempts to utilise abbreviations and other common codes for specific terms and events (Tanguy et al., 2016). Consequently, these reporting systems and methods for analysing data have been seen as a standard for safety-critical industries (Hedge & Rosketh, 2020).

Within the context of healthcare, the WHO (2021) has recognised that for learning to be facilitated from the evaluation of incidents in practice, there needs to be a standardised taxonomy and clarity in concepts and definitions. These concepts include adverse events, errors, patient safety incidents, harm, and never events, as noted in Table 1.1. Standardised terminology can be considered essential to structure any approaches that aim to define and target patient safety in practice (Falconer et al., 2019). However,

although key definitions are available and broadly apply to healthcare practice, research, and policy contexts (Table 1.1), many concepts may be overlapping or interrelated in nature (Falconer et al., 2019). This section considers how the standardisation of definitions and development of a clear taxonomy can facilitate learning in patient safety, while also highlighting challenges in implementing this approach in healthcare practice to date.

Table 1.1 Definitions and concepts associated with patient safety in healthcare (Adapted from WHO, 2009a)

Key safety concepts	Definition
Adverse events	Something that happens to or involves a patient and is associated with adverse effects, including harm or the potential for harm (WHO, 2009a).
Error	Failure to complete a planned action as intended; application of an incorrect plan (WHO, 2009a).
Patient safety incident	An event or circumstance that could have resulted in, or did result in, unnecessary harm to the patient (WHO, 2009a).
Harm	Impairment of structure or function of the body; deleterious effects arising from disease, injury and other causes; harm may be psychological, physical or social (WHO, 2009a).
Never events	Serious incidents that are wholly preventable as strong systemic barriers are widely available and should be implemented by all healthcare providers (NHS Improvement, 2018).
Near miss	An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention (WHO, 2009b).

Numerous attempts have been made to develop clear and consistent definitions for patient safety incidents in healthcare to overcome a lack of empirical classification and investigation of these issues (Runciman et al., 2009). The WHO World Alliance for Patient Safety (WHO, 2005a) provided a unique opportunity for clarity of definitions, as noted in Table 1.1. Consequent to the WHO consensus report, the International Classification for Patient Safety (ICPS) was developed (Sherman et al., 2009), which represented key concepts used to understand patient safety incidents, along with a Minimal Information Model for Patient Safety (MIM PS), defining the essential information that ought to be included in every patient safety incident report (WHO, 2014a; Carson-Stevens et al., 2015; WHO, 2018a). The main aim of the ICPS is to allow for patient safety information to be categorised into a standard set of concepts with agreed definitions and preferred terms (Donaldson, 2009). Following on from these terms and standardised concepts, the MIM PS represents a strategy to utilise these preferred terms and definitions to allow for systematic collection and analysis of data relating to patient safety (WHO, 2014a).

Despite the value in clarifying definitions in this manner, the WHO consensus report has failed to have an impact on practice, given persistent variations in definitions used in practice and a lack of agreement on definitions in the wider research community (Vincent & Amalberti, 2016). It is acknowledged that, within the wider literature and in practice, safety terminology remains inconsistent, which can be associated with challenges in implementing effective safety research and quality improvement approaches (Yu et al., 2005; Vincent & Amalberti, 2016). For instance, if the terminology is not consistent, then the application of terms can vary across settings, leading to inconsistencies in the way incidents are recorded, resources are prioritised to investigate issues in more detail, and/or the potential scope of learning and related possible solutions to mitigate future incidents.

1.3.3.3 Specific analytical strategies and techniques

Incident reporting is a descriptive process whereby the details of a near miss or adverse event are recorded with specific details of the clinical contexts, antecedents, and consequences of the incident in question (Hagley et al., 2019). Some form of learning is needed from an incident report to move beyond an approach that merely counts or collates incidents (Hagley et al., 2019). The root cause analysis (RCA) method has been widely employed in research and practice to facilitate this form of learning, and it is based on three key questions: What happened? Why did it happen? How can this be prevented from happening again? (Hagley et al., 2019).

The process is considered a form of structured feedback to enable learning. The process often uses a range of tools or structures, depending on the setting, including data collection, identification of causal factors, identification of a root cause, and then the development of recommendations/implementation of solutions (Kellogg et al., 2017). The RCA process is estimated to take more than 20 person-hours to complete, and, given the rate at which incidents occur in practice, this would not be feasible for all safety incidents or near misses (Wu et al., 2008; Peerally et al., 2017). Consequently, the use of RCA is often reserved for more severe incidents where harm has occurred, leaving a potentially large number of near misses or minimal harm events to go under-investigated (Peerally et al., 2017).

It has been proposed that the use of incident report analysis, in various formats, may provide an alternative to RCA processes for a large number of safety incidents (Hagley et al., 2019). A concise incident analysis method has been proposed, which is performed by a small group and guided by a checklist to question the causes of an incident and the risk factors that can be addressed in the future (Pham et al., 2016). Other approaches are also

used in practice, and, while diverse in nature, they tend to have common features distinguishing them from RCA. These features include a shorter time to complete, completion by a multidisciplinary team rather than third parties, and variations in the distribution or communication of learnings from the analysis (Pham et al., 2016; Hagley et al., 2019).

It should be noted that incident analyses often focus on environments where small clinical teams operate, where analysis and learning are focused on a discrete set of processes or professionals, rather than system-wide errors and large multi-disciplinary teams derived from multiple healthcare settings (Hagley et al., 2019). The use of incident analysis tools should be considered carefully depending on their relevance to evaluating small clinical teams or system-wide errors.

For instance, the Learning From Defect (LFD) tool was developed to systematically guide clinical teams to improve performance in the context of a Comprehensive Unit-based Safety Programme (CUSP) (Pronovost et al., 2006a). The use of the LFD by CUSP teams is based on an evaluation of one defect per month, with all staff involved in the defect participating in the investigation (Pitts et al., 2017). While this tool has shown benefits in promoting learning in a small team environment and improvement in safety culture, it has not been evaluated in wider contexts and system-wide defects or incidents in practice, which may limit its applicability to multidisciplinary and system-wide problems (Timmel et al., 2010; Pitts et al., 2017; Hagley et al., 2019). Therefore, the nature of investigation facilitated by the tool and the characteristics of the tool itself may inform the utility in practice, with tools showing potential benefits as part of a tiered approach to incident analysis based on levels of harm to ensure cost-effectiveness and feasibility of analysis in practice (Hagley et al., 2019).

Both the RCA and other forms of incident analysis provide benefits over basic incident reporting with limited analysis; they provide a set of analyses and outcomes that facilitate learning from the incident rather than just reporting the details of the incident (Khaleghzadegan et al., 2020). It is not considered sufficient to identify errors and incidents in practice and to record these as episodes of compromised patient safety, as this may be viewed as a metric without the addition of any learning potential or in-depth analysis of how incidents occur (Morello et al., 2013). There is no certainty that a reported safety incident, without associated analysis of contributory factors, leads to improvement in safety in practice. The potential to learn from an incident relies on sufficient analysis and the development of actionable recommendations and solutions to identified issues, ideally

with a cyclical approach to learning in place to ensure the quality improvement process is engaged effectively (Bagian et al., 2001).

A focus on reporting incidents and learning from those incidents is crucial in healthcare organisations, and there is a need to evaluate the strategies that can be used to facilitate these processes, including how tools such as incident analyses and RCA can be implemented effectively and outcomes used to improve practice and safety (Hagley et al., 2019). Reporting and learning processes need to be expanded and developed in line with other industries where safety issues have emerged and have been curbed largely in a systematic manner (Chatburn et al., 2018).

1.3.4 Knowledge management: dissemination and exchange

Milton (2010) has devised a four-way classification system for how lessons may be learnt from experience, representing different approaches to knowledge dissemination. This is presented in Figure 1.1. This classification involves two distinct dimensions, with formal and informal methods of knowledge dissemination applied and connect versus collect approaches used. The collect approach implies that knowledge is recorded in a repository, which may be accessed by a user, while the connect approach implies direct communication between individuals (verbal or written) (Milton, 2010). Formal approaches may be highly structured and operate according to a defined framework compared to unstructured, 'bottom-up' approaches that may be informal. Examples of dissemination strategies aligned with these dimensions are noted in Figure 1.1.

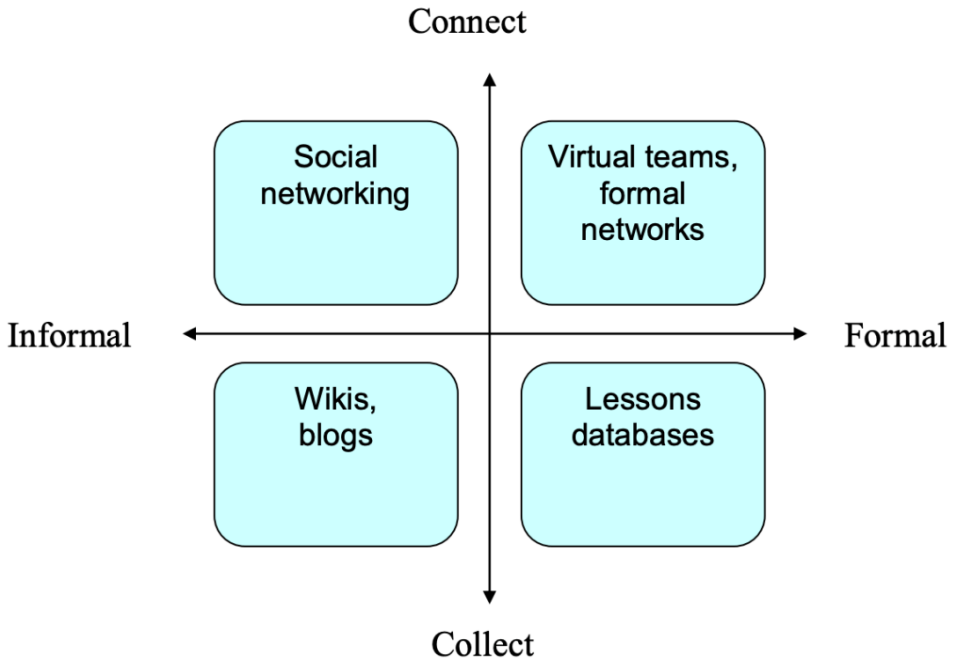

Figure 1.1 Milton's classification of knowledge dissemination approaches (Milton, 2010)

This model has been evaluated in relation to health and safety literature, commerce, government, and wider industries, with specific reflection on when different dissemination strategies may be most appropriate to facilitate learning. An informal connect strategy may include social networking to some degree, including the formation of communities of practice (Curran et al., 2011). These communities have regular contact between members, with the goal of disseminating key knowledge across the community. The communities of practice approach is considered particularly effective for knowledge dissemination when needed between diverse groups, across geographic locations, or organisational boundaries (Lafreniere et al., 2013). However, debates over the optimal size of communities to facilitate knowledge dissemination effectively are noted, with larger communities holding a greater database of knowledge, but smaller communities facilitating convergence and interactions between members more easily (Curran et al., 2011; Woolf et al., 2015).

Other knowledge dissemination strategies within the model include the use of virtual teams and networks, blogs and written information posted locally or within a central repository, and formal lessons and databases of information, which may be accessed by relevant users based on need (Kothari et al., 2015). Technology-facilitated learning environments, including e-learning and online forms, may provide an opportunity to connect communities of practice and promote rapid dissemination of information (Gruppen et al., 2019). Furthermore, these online learning environments may be used to promote discussions and knowledge generation among professionals, promoting critical analysis and interpretation of information, which can refine learning (Gruppen et al., 2019). Different types of knowledge dissemination may therefore be employed, allowing for flexibility to suit dissemination styles to the organisation and characteristics of users (Kingston, 2012).

Innovation networks have also been proposed as a key dissemination strategy for learning in healthcare (Ingram et al., 2015). These networks represent collaboration and communication between different professional groups or agencies, with an aim to improve processes and develop innovations in practice (Quigley et al., 2019). Innovation networks can comprise a range of professional groups, as well as government or public stakeholders, reducing the siloed approach to information management and knowledge generation towards a more collaborative and diverse approach. Dissemination of learning within innovation networks has been evaluated in the literature (Ingram et al., 2015; McPherson et al., 2015; Quigley et al., 2019), suggesting that the interactions and

processes adopted within these networks may contribute to innovative change and adaptations to promote safety.

With regards to safety learning, all of these dissemination strategies may be relevant at different points and in different contexts. For instance, the production of databases of information and lessons/training would be appropriate where prevention of risk can be promoted by adherence to standards and guidance (Prinsloo et al., 2017). NPSA medication safety outputs and alerts formed one key dissemination strategy within the UK health system, for example, which was associated with improved medication safety (Lankshear et al., 2011). In contrast, local dissemination of information and risk assessments may be suited to communities of practice or targeted repositories, where information can be accessed by staff (Kingston, 2012).

Regardless of the knowledge dissemination technique or strategy, other characteristics of knowledge dissemination (or transfer and exchange) have been identified as fundamental to the learning process (Gagnon, 2011). These include the need to target a specific audience effectively and to ensure that the knowledge disseminated is in a format that will be accepted and utilised by the targeted group (Mitton et al., 2007). Indeed, dissemination of information is of little value unless the target end-users will have use for that information and can implement changes based on that information (Gagnon, 2011). As noted by Lankshear et al. (2011) in their evaluation of NPSA patient safety alerts, these may have more limited value in changing practice or informing safety learning where communication within healthcare settings is poor, particularly from senior staff to more junior staff. Where access to learning is limited due to organisational deficiencies, this can compromise learning opportunities for frontline staff.

Therefore, within the different categories of knowledge dissemination, there is a need to appreciate the format of the knowledge being disseminated and to link this to the users/audience and their needs and capabilities in utilising that knowledge to inform practice and its improvement.

Dissemination strategies also need to be considered based on the level at which they may influence practice. As noted previously, learning in safety may be influenced by human factors (Carayon et al., 2014). Certainly, while systematic approaches to addressing safety may be implemented (i.e., guidance on a process or a checklist), learning cannot be effective without appreciating how the individual is situated within the wider system (Watt et al., 2019). Indeed, human factors include how organisations and environments are designed to optimise use and safety outcomes, how communication works within

organisations, how multiple systems (patient-level, organisation-level, and wider systems) interact to influence safety, and how learning need to be continuous and refined according to person-centred approaches (WHO, 2021). Consequently, the dissemination of knowledge may be influenced by individual needs and the design of the wider organisation or system.

The values and principles of learning in recent guidelines and policy documents, such as the WHO (2021) Global Patient Safety Action Plan for 2021-2030, highlight the need for clear outputs and knowledge dissemination strategies. Rather than focusing on learning as an individual process for practitioners, wider organisational approaches are needed that take context into account and provide a basis for developing learning outputs that drive quality improvement. How this learning is applied and disseminated remains an important issue in practice, with the need to adapt dynamic systems and human factors to improve capabilities or to form a barrier to risk (e.g., guideline development), both potentially playing a role in practice (Woodward, 2019).

1.4 Incident reporting and learning systems in healthcare

1.4.1 Incident reporting and learning systems

The learning systems approach discussed in the previous sections highlights the need for a structured approach to learning about patient safety. It is suggested that elements of a learning system include the need for methods for accurate reporting of incidents, analysis of incidents, and dissemination of knowledge to stakeholders within the system. In the healthcare setting, the use of incident reporting and learning approach is viewed as a practical system which can be implemented to promote learning from incidents (WHO, 2009a).

One of the major components of safety systems within the aviation industry is the development of the ASRS in the United States (Mahajan, 2010). This system was considered essential to the improvement in the safety record of aviation, and there have been clear benefits, including the potential to improve safety, increase transparency, standardise processes, and promote the identification and management of risk factors and errors in processes at an early stage, associated with the adoption of such a system across the industry (Pham et al., 2013). The broader implications of the use of incident reporting systems across safety-critical industries have been reported, cementing these systems as key aspects of improving the safety of workers and consumers (Pham et al., 2013).

1.4.2 Importance of an incident reporting culture

Reporting systems provide a means to identify risks, allowing organisations to implement interventions that can reduce these risks and their impact on processes or outcomes

(Pham et al., 2013). The core elements of quality within an organisation or industry include the structure (resources, training, environment), processes (stages used to complete tasks and meet the needs of clients), and outcomes (Donabedian, 2005). In a similar manner, the incident reporting process should take into account the strategy in place, the context of the organisation (including the culture of that organisation), the operational processes, and the intended outcomes that can be expected from the reporting system (Mahajan, 2010). Indeed, the use of an incident reporting system is reliant not only on the introduction of a clear set of guidelines or resources to facilitate reporting but is also dependent on several factors, including a culture consistent with incident reporting (Mahajan, 2010).

Organisational culture may be defined as a shared set of values or beliefs across the organisation, reflecting the priorities and relationships between staff across all levels of the organisation (El-Jardali et al., 2011). A culture consistent with safety incident reporting should be transparent, accepting of the existence of safety issues and free from blame (Richter et al., 2015). This may be challenging to achieve in practice, as often incidents are under-reported for fear of blame or concerns over the potential repercussions facing the individual from a professional or legal perspective (Richter et al., 2015). Promoting a blame-free approach to reporting incidents requires strong management and leadership, with a transparent approach to discussing incidents and promoting organisational learning (IOM, 1999). This has been evidenced in multiple industries, where a hierarchical reporting structure and the use of formal systems allow for openness and minimal blame in reporting incidents (El-Jardali et al., 2011). Therefore, establishing a culture consistent with incident reporting is as important as having these systems in place, if not more important to the success of overall safety initiatives in practice (Pham et al., 2013).

A culture aligned with incident reporting may have an important influence on the quality and consistency with which data are collected and analysed within a learning system (crucial elements to generating learning outputs). It is also noted that healthcare settings may lack the ability to aggregate large amounts of data where existing systems are focused on local areas or lack the ability to aggregate data across various settings or data sources. Learning is partly reliant on the quantity of information available to the individual or organisation, suggesting that efforts to increase data collection and to aggregate data effectively may be required to facilitate an effective IRLS.

1.4.3 Incident aggregation and learning in healthcare

Patient safety incident reporting systems have been established for close to 20 years, but there remain challenges to appreciating their role in quantifying harm associated with healthcare practice and in care improvement opportunities or processes (Howell et al., 2017). Many of the promises associated with the introduction of incident reporting systems in healthcare may have been based on a misunderstanding of the potential benefits and applications of these systems, in terms of the potential to influence safety outcomes (Pham et al., 2013). Indeed, Pham et al. (2013) provide a comprehensive evaluation of the appropriate use and expected benefits of these systems in healthcare, while also highlighting areas where limitations prevent the use of these systems for specific purposes relating to safety monitoring and measurement.

The limitations of incident reporting systems include the lack of potential to measure safety (error rates), and limitations relating to the costs and quantity of data generated through such systems without a clear indication of how interventions may improve safety outcomes (Pham et al., 2013). Indeed, under-reporting of safety incidents automatically provides a limit to the potential for such systems to provide accurate quantifications of safety incidents in practice (Mitchell et al., 2016). The nature of the incident reporting process is that this is a non-random sampling of incidents that is prone to bias and inconsistency across practitioners and care settings, precluding easy tracking of incidents over time and valid quantitative comparisons of institutions or settings (Pham et al., 2013).

Although there are limitations to the use of incident reporting systems in healthcare, there are clear benefits and opportunities in the context of safety evaluation and improvement that should be a clear focus of practitioners and policymakers across organisations (Pham et al., 2013). The expected benefits of incident reporting systems are the potential for characterising and improving the safety of patients (Pham et al., 2013). Specifically, the value of these systems may be seen in the identification of unsafe practices or processes that facilitate harm directly or indirectly (Pronovost et al., 2006b). Furthermore, the use of these systems may have benefits based on the aggregation of data and experiences for uncommon conditions, where individual incident analysis may not provide a robust basis for appreciating safety due to the uncommon nature of the conditions. The reporting of a single incident has the potential to impact care for hundreds or thousands of patients; the aim is not to capture all incidents (particularly as many are not reported), but to utilise reporting incidents as a basis for learning across settings and contexts (Chatburn et al., 2018).

The aggregation of cases may also provide additional benefits when applied across a specific context, such as the occurrence of multiple instances of surgery performed at the wrong site (Pham et al., 2013). Accumulation of these single cases found that poor communication and lack of standardised procedures were associated with almost all cases, forming the basis for promoting improvements in systems that could prevent future occurrences of this type of incident. To obtain these data otherwise would have been challenging in a single institution over time (given the low rate of occurrence of wrong-site surgery), highlighting the value of aggregating information across settings through such reporting systems (Pham et al., 2013). Where incident reporting systems are implemented in conjunction with optimised strategies to promote learning from these incidents, they also have the potential to share lessons within and across organisations and promote a patient safety culture (Carson-Stevens et al., 2016).

Within the healthcare setting, incident reporting systems are often limited in scope and applied on local levels. This limits the possibility for national and international learning, with the aggregation of data across nations and healthcare settings. Challenges relating to the potential for expansion of learning to incorporate IRLSs that have a broader scope, including international practice, are considered in the following section.

1.4.4 Alternatives to incident reporting systems

While incident reporting systems may be an important source of data to generate learning for patient safety, other data sources may also be valuable in this process (Morello et al., 2013). Broadly, it may be considered that data sources diverge regarding their focus on specific incidents (i.e., within incident reports) or sources of data describing general issues on safety, often from a single institution (Boxwala et al., 2004). While data on specific incidents may be largely derived from incident reporting systems, other sources include root cause analysis reports, departmental case reviews (e.g., morbidity and mortality reviews), malpractice claims (e.g., Medical Defence Union [MDU] database) and electronic patient data surveillance. These reports have various limitations and advantages in the context of learning about patient safety. For instance, malpractice claims may provide a specific insight into the most severe safety incidents, with demonstrable value in patient safety risks in anaesthesia and adverse drug events (Mello et al., 2020). However, the correlation between claims and quality in care may be questioned, with a poor correlation between a claim and care quality (Boxwala et al., 2004). Other data sources, such as case reviews within a department, may be valuable in promoting a critical, peer-led discussion of safety, which addresses issues related to decision-making, planning and uncertainty in

diagnostic or treatment pathways, but can be biased due to the nature of self-reporting of these incidents (Benassi et al., 2017). One of the challenges with these data sources is the potential to integrate their findings into a cohesive learning output, given the variations in how data are collected, the details included within reports, and the forum in which these data are analysed or discussed (Morello et al., 2013).

The focus on specific incidents ultimately rests on how effective those incidents are reported, which may be prone to sources of bias based on self-reporting expectations, cultures of safety, and additional structural factors (Vincent et al., 2014). In contrast to follow-on data often collected after an incident is reported, data from other methods like the Failure Mode Effects and Analysis (FMEA) technique can support proactive evaluation of vulnerabilities in a process or system (Spath, 2003). The FMEA methodology involves analysis of different failure modes for a process or system, listing vulnerabilities and remedial actions that may be implemented (Spath, 2003). Similarly, tools and methods adapted from safety-critical industries, including fault hazard analysis and simulation models (Simsekler & Qazi, 2022), may be used to identify systemic vulnerabilities that may be linked to the potential for safety incidents (Anjalee et al., 2021). The use of FMEA in practice may be guided and complemented by systems mapping approaches and structured brainstorming to determine key inputs for the analysis (Simsekler et al., 2019). One evaluation of these inputs suggests that they have value in identifying risks in an organisation but that they may limit the potential to identify new risks not anticipated in the initial system diagram (Simsekler et al., 2019). A systematic review of FMEA in identifying risks found 33 studies suggesting that the approach can be valuable in identifying system errors but that it is time-consuming and subjective in nature (Anjalee et al., 2021). Therefore, the use of investigative approaches, such as FMEA, may play a role in proactive risk identification but may not be sufficient alone to anticipate all risks or to consistently define improvements needed to prevent safety incidents. Finally, it should be considered that other data sources may be used to inform learning at an organisational level. These data sources include patient satisfaction data (surveys or complaints data), health services research, data on diagnostic test utilisation, and quality assurance data, including observations of practice and clinical activities (e.g., trauma resuscitation) (Boxwala et al., 2004; Fauconnier et al., 2020). While these data sources may be particularly valuable in local-level learning and analysis of safety incidents, they are highly heterogeneous in terms of content and format, which may preclude their transferability or scalability to national settings (Boxwala et al., 2004).

1.4.5 International learning

The potential for international learning in the context of patient safety reporting systems is considered a key element of the drive towards wider improvements in safety practice (Hegarty et al., 2020). While not all features of healthcare can be considered transferable across nations (e.g., depending on income, resources, and local disease priorities), broader concepts of safety and reporting of incidents to promote safety in practice are considered internationally transferable (Hegarty et al., 2020). International learning reflects the potential for learning across multiple sites and settings, while also enabling a clear analysis of local, national, and international factors that relate to patient safety (Hickey et al., 2017). The potential for patient safety data and research to be applied from one context to another, including across nations, relies on the use of standardised approaches to defining safety and quality improvement processes (Hickey et al., 2017). Furthermore, linkage of international data sources and tools used for the assessment of patient safety and improvement initiatives can provide a powerful data set for the promotion of consistent, evidence-based change in healthcare practice (Hegarty et al., 2020).

Variations in the definition and terminology associated with safety incident reporting have recently been observed in the international literature (Hegarty et al., 2020). These variations may represent missed opportunities for learning on an international level, which is a significant barrier to improvements in patient safety (Hegarty et al., 2020). Furthermore, appreciation of concepts of safety across cultures and societies is needed to understand how safety data may be obtained, analysed, and used to implement change on an international basis (Steven et al., 2019). Therefore, further appreciation of strategies to promote international standardisation of incident reporting (i.e., a shared taxonomy) and learning about patient safety risks in healthcare can be considered essential to advancing the field.

The problematic nature of international learning has been recognised by the WHO, and strategies to promote collaboration and dissemination of learning have been proposed (WHO, 2021). The WHO Collaborating Centres are designated research institutes that engage in activities supporting WHO programmes at a global level (WHO, 2021). These centres form networks specific to set initiatives, including radiation protection, nursing and midwifery, and patient safety. The Canadian Patient Safety Institute (CPSI) is one prominent WHO Collaborating Centre focused on patient safety and patient engagement (CPSI, 2021). This centre plays a key role in developing policy, strategy, and technical advances across 800 WHO collaborating centres globally (CPSI, 2021). The CPSI focuses

on collecting, collating and disseminating information, standardising terminology, developing technology and innovations, and coordinating and disseminating research training and learning internationally. The development of patient safety tools and resources are among the key outputs of the CPSI (2021), which contributes to the potential for learning across WHO centres. However, the CPSI has a limited remit outside of Canada, and the body may be limited in influencing legislation, policy, regulations, standards, and public engagement with regard to safety improvement. The CPSI also lacks the ability to collate international data in safety to devise learning using routine data sets which are accessible across low, middle and high-income nations.

Other attempts at promoting international learning from safety incidents include pharmacovigilance approaches, such as the WHO (2014) pharmacovigilance systems and networks. These are designed to identify rare medication errors or adverse events based on aggregating data internationally. The WHO pharmacovigilance programme has a goal of coordinating and collating data on an international basis, while other organisations (e.g., World Alliance for Patient Safety and the International Medication Safety Network) aim to use data to promote medication safety. These systems are effective in identifying rare errors or adverse events but may be more limited beyond these areas, based on local resources, implementation and expertise variations internationally (van Eekeren et al., 2018). Indeed, the degree to which pharmacovigilance data may guide safety learning can vary significantly across nations and regions, suggesting limitations in equating these systems to a theoretical international IRLS (van Eekeren et al., 2918). Patient safety and learning systems need to focus on critical incidents and the structures of reporting, collation of data, analysis of data and learning to emerge from these analyses (Health Quality Ontario, 2017). As neither the CPSI nor pharmacovigilance networks meet all of these criteria, there remains a need for such a system in practice. Therefore, current strategies on a global level attempt to overcome some specific challenges to international data collection and learning, although their effectiveness in promoting the dissemination of learning remains largely unclear at the international level.

1.5 Gaps in the knowledge base

This chapter illustrates that safety is a complex topic across industries and advocates the importance of learning about risk to inform the development of solutions to help mitigate future harm. Learning systems play an important role in developing safe practice across industries, and their development and success in the healthcare industry remain unclear from a safety perspective. This is particularly true with regards to an international IRLS,

which shows promise in safety-critical industries like nuclear power and aviation for improving safety worldwide. Apparent challenges linked to the development of these systems include a lack of consistency in the data collected as part of a learning system in patient safety and a lack of standardisation of terminology across nations. Furthermore, a clear link between data collected, analysis of data, and the development of knowledge dissemination strategies that have an impact on practice remains elusive. There is also a lack of guidance on how such systems may be developed at an international level, which has led to an absence of theoretical bases to explore the concepts in healthcare focused on safety.

1.6 Aims and objectives of the PhD

The aims of the PhD are to:

1. Explore how safety-critical industries learn from safety incidents and how they share their learning at the international level.
2. Explore the purpose and key requirements for an international safety learning system in healthcare.
3. Explore the acceptability in terms of barriers and enablers for an international patient safety learning system.

To achieve these aims, the following objectives are defined for this PhD project:

1. Map out key features and requirements of existing learning systems in safety-critical industries.
2. Identify key factors that enable the transfer of actionable learning in healthcare industries at the international level.
3. Outline the purpose and anticipated challenges and opportunities for an international patient safety learning system.
4. Outline the requirements, design and acceptability of an international patient safety learning system.
5. Propose areas for future research and development for pilot testing of an international patient safety learning system.

1.7 Philosophical paradigm

The philosophical paradigm underlying the strategy to address the PhD aims and objectives will be considered on the basis of the background literature considered in this chapter and the various theoretical perspectives, as considered below.

Consideration of an appropriate paradigm for research may be guided by an appreciation of various types of paradigms and their implications for knowledge generation and understanding (Denzin & Lincoln, 2011). Relativist paradigms are those that suggest that knowledge only exists as a subjective experience and that there is no tangible reality outside of our thoughts (Killam, 2013). Consequently, relativist paradigms emphasise that reality cannot be separated from our subjective experience of it (Guba & Lincoln, 2005). While the relativist paradigm may allow for an appreciation of the value of experiences and subjectivity in numerous contexts, this does not align with the empirical nature of safety observations and learning in practice.

Although safety cultures and practices may be influenced by subjective factors, the fundamental design of a learning system should be empirical in nature to provide a basis for consistent, valid learning, based on evidence and clear analysis. Indeed, a non-relativist paradigm assumes that knowledge exists objectively or for a specified purpose, whereby knowledge can be absolute in nature, observable and directly assessed with some degree of independence from context or interpretation (subjectivity) (Levers, 2013). The adoption of a non-relativist paradigm suggests that an objective approach to assessing reality may be the basis for an investigation of the phenomenon of patient safety (Callingham & Hay, 2018).

Philosophical paradigms that are non-relativist in nature include positivism and pragmatism (Callingham & Hay, 2018). The distinction between positivism and pragmatism largely rests in the pursuit of objective truth, which is universal in nature (positivism) or relative to practical use (pragmatism). While positivism holds that truth is absolute in nature and is consistent regardless of contextual influences (e.g., culture, interpretation), the pragmatic approach acknowledges that truth is characterised by its consequences in terms of serving a useful purpose, supporting an experiential value to the application of this truth (Shaw et al., 2010).

As patient safety is a complex field, reflecting multiple risk factors and interactions between humans and systems, positivism may be inadequate in appreciating the complexity of reality, including both objective and subjective experiences and complex

contextual influences on knowledge generation and understanding (Levers, 2013). The pragmatic paradigm may be of greatest value in appreciating how knowledge may be understood and applied directly for practical purposes (Shaw et al., 2010). The field of patient safety is also driven by the practical need for improved outcomes, rejecting the value of empirical approaches to identifying truth which may have little practical application (Lamont & Waring, 2015). To ensure a practical application of knowledge, the pragmatic paradigm may be favoured, as this is intended to generate outcomes that can be directly applied in reality and have a use in practice (Callingham & Hay, 2018).

To determine the type of pragmatism that may be of greatest value in the context of appreciating patient safety, the limitations of the models of Reason (Figure 1.2) and Rasmussen (Figure 1.3) may be considered. Importantly, these theoretical models of error or patient safety emphasise the need to address gaps in safety practices at various levels of an organisation, based on the potential for gaps leading to adverse outcomes.

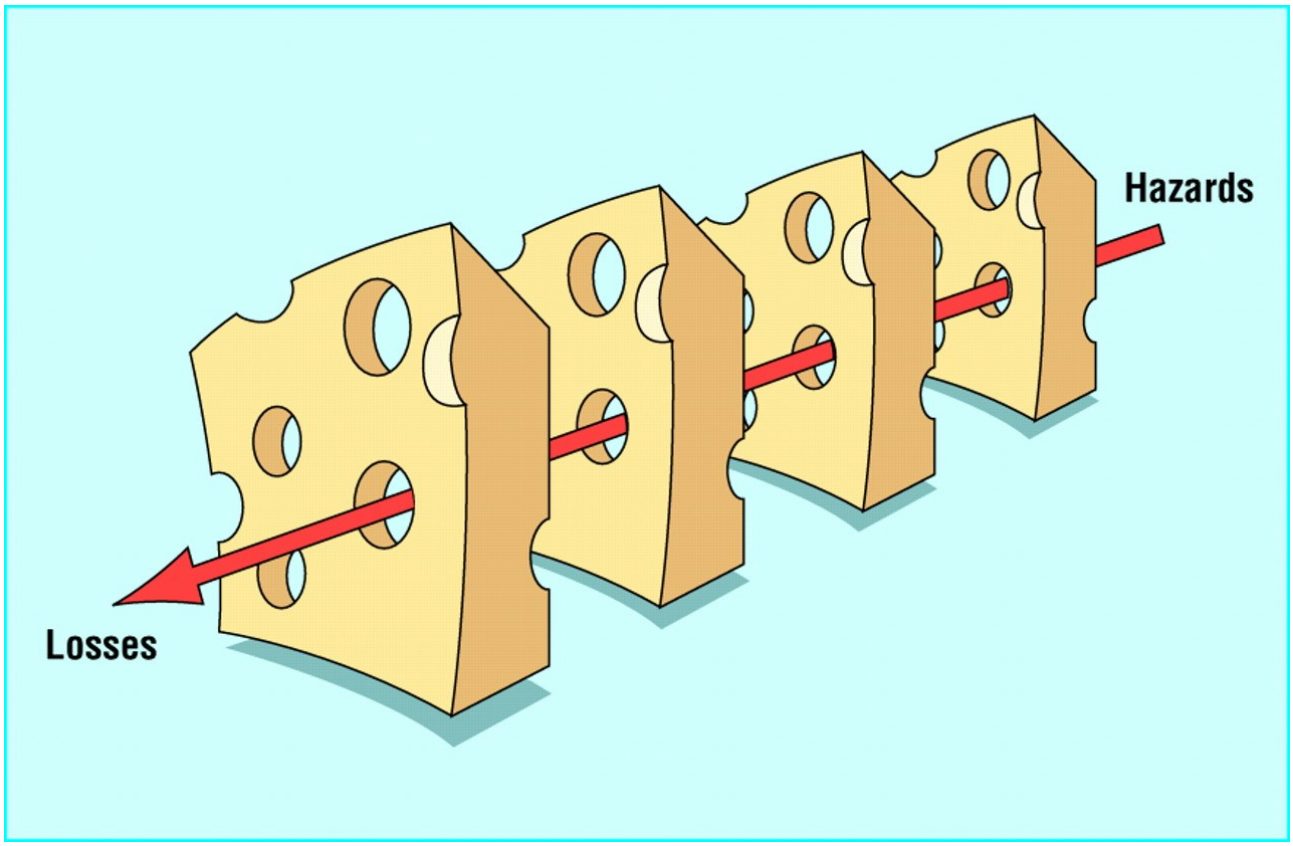

Figure 1.2 Reason's Swiss Cheese Model (Reason, 2000) [permission license number 5437030143537]

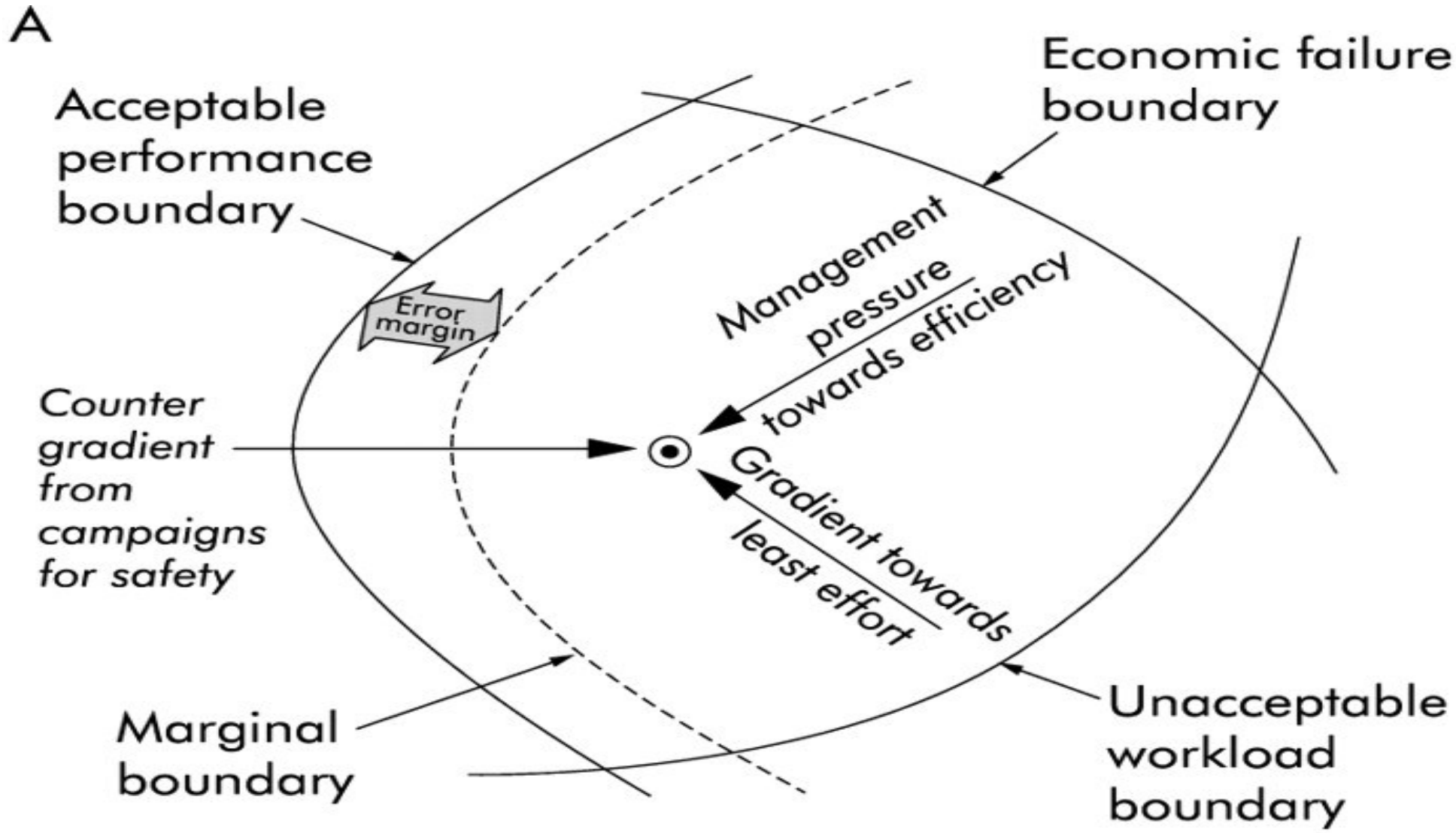

Figure 1.3 Rasmussen's Dynamic Safety Model, (Cook & Rasmussen, 2005) [permission license number 5440930948089]

Table 1.2 outlines a brief description and the strengths of Reason and Rasmussen's models.

Table 1.2 Description and strengths of Reason and Rasmussen's models (Adopted from Wiegmann et al, 2022; Stein & Heiss, 2015; Cook & Rasmussen, 2005; Rasmussen, 2003; Reason, 2000; Rasmussen, 1997)

Model	Description	Strengths
Reason's Swiss Cheese Model	- Based on the theory of active and latent failures. - Safety barriers across levels within a sociotechnical system are represented by four individual slices of cheese. - Holes in the cheese represent absent or failed barriers at each level. A window of opportunity for an accident or patient safety incident to occur is present when holes across each level of the system line up.	- Within a range of industries, including healthcare, it is commonly used to guide RCA and safety efforts. Intended to address and mitigate holes in each layer of cheese that could, or did, lead to an adverse event before causing harm in the future by helping safety professionals identify holes in each layer of cheese.
Rasmussen's Dynamic Safety Model	- Illustrates the feasible operating space for a sociotechnical system within three boundaries surrounding the systems operating point. - The three boundaries are acceptable performance, unacceptable workload and economic failure boundary. - The gradients that drive operations away from the workload and economic failure boundaries and towards the unacceptable performance/accident boundary influence the location of the operating point. As the distance from the unacceptable performance boundary increases, the risk of an accident falls.	- Helps organisations to keep the operating point away from the boundary of acceptable performance to prevent accidents. - A marginal boundary that marks the acceptable limit of operations is produced over time. - As long as the operating point stays within the marginal boundary, the accident risk is deemed acceptably low. The social norms of the organisation are violated by a deliberate crossing of the marginal boundary.

One of the challenges with adopting this line of reasoning is that it would seem to suggest an inherent need to standardise the systems approach to patient safety, with guidelines and fail-safes representing stable interventions that serve to minimise the potential effects of error (Pedersen, 2016). However, this approach makes a broad assumption that the healthcare system is in itself a stable, linear system. This stability (and associated predictability) is a necessary assumption if a specific operating standard or practice is to be introduced and expected to lead to a clear reduction in safety lapses over time. However, this has been challenged by the realisation that healthcare systems are complex systems and under a state of constant change, marked by advances in technology, changes in patient needs, modifications in available interventions and adoption of quality improvement cycles (Pedersen, 2016). Rather, a shift towards appreciating the resilience or adaptive capacities of healthcare organisations has been seen in the literature (Barasa et al., 2018; Anderson et al., 2020).

Where a system is in a constant state of flux or change, it can be argued that the implementation of a standardised approach to safety may be ineffective, as this overlooks the changing nature of the organisation (Pedersen, 2017). Healthcare does undergo dramatic changes in this manner, across the interventions used as well as the cultures and attitudes of the healthcare organisation, but there is also a notable degree of stability within the delivery of healthcare (Pedersen, 2017). Therefore, the understanding of stability and change in this context may be seen to be complicated, with stability and instability co-existing within this context (Pedersen, 2017). This challenge has been reflected in the work of Dewey (1998), who proposed that dichotomies of this nature should be largely eliminated to increase an understanding of the world (Dewey, 1998). This form of pragmatism has been adopted in recent years (Pedersen et al., 2017; Anderson et al., 2020) as a way of challenging existing preconceptions about how patient safety is understood.

Rather than assuming a healthcare system is a stable, linear system, consideration of the dynamic nature of the system has implications for understanding safety, and developing and applying safety interventions. Interventionist approaches and system engineering approaches acknowledge adaptive, flexible and fluid systems exist and that systems change over time (Pedersen, 2016). The nature of healthcare is such that in many instances, the individualised nature of the care of a patient may be unsuitable for applying broad safety interventions and approaches, requiring physicians to act promptly and adequately in a situation of doubt or uncertainty, with a disposition of safety more important than the application of rigid rules, measures or guidelines (Mesman, 2008). While this is a complex perspective to consider in safety practice, the appreciation of nuanced aspects of the complexity of the healthcare system and care delivery processes can be valuable in appreciating safety beyond a conceptual application of interventions in a static system (Pedersen, 2016). Therefore, pragmatism is the adopted philosophical paradigm for the present PhD project, in order to appreciate the reality and practical nature of healthcare stability and change and how this relates to patient safety.

1.8 Methodological approach

This PhD will adopt a mixed methods approach (combining the use of multiple data collection and analysis strategies), incorporating both qualitative and quantitative data. The use of different methodological approaches is justified on the basis of the defined objectives of the project and the sequential nature of data collection, aggregation and synthesis. An exploratory, sequential design was the most robust way to examine how safety-critical industries learn from safety incidents and share that learning, followed by the analysis of the potential for international reporting and learning approaches and the acceptability of any proposed strategies in healthcare. Figure 1.4 shows the sequential exploratory mixed methods design for the PhD.

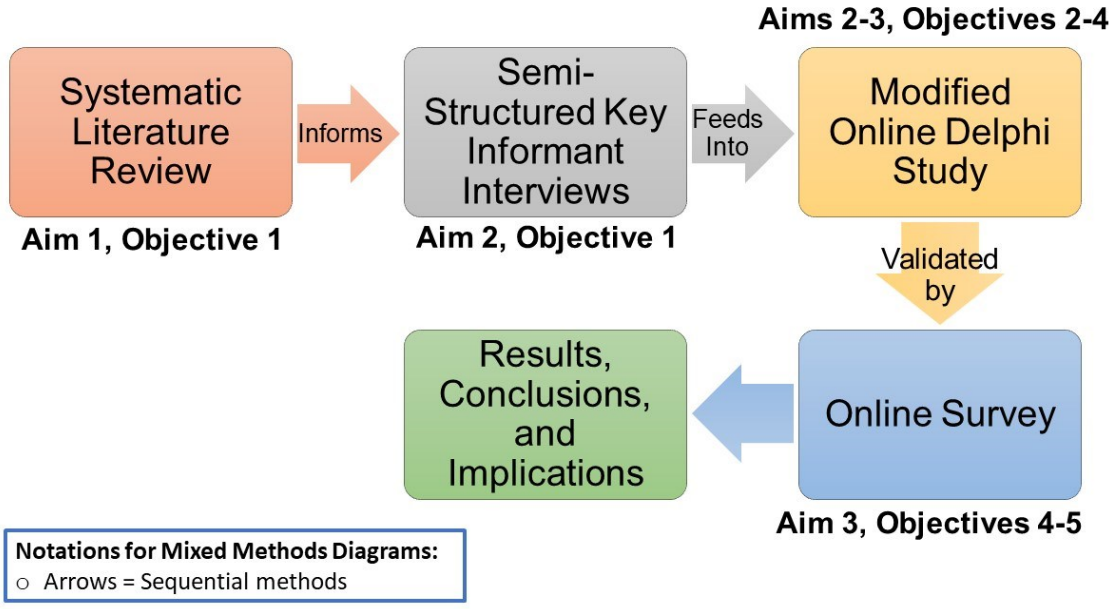

Figure 1.4 Sequential exploratory mixed methods design (Creswell & Clark, 2018)

Four proposed methods are suggested for the thesis, and justification for each method is provided in relation to specific aims and objectives of the PhD, defined in section 1.6. These four methods are as follows: a systematic literature review; semi-structured key informant interviews; an online modified Delphi study; and an online survey. Each of these methods is considered briefly and described in more detail in later chapters, with justification for how they meet the aims and objectives of the PhD project.

The systematic literature review will address aim 1, objective 1 and is intended to explore how safety-critical industries learn from safety incidents and how they share their learning at the international level. This includes exploring the purpose and key requirements for an international IRLS. The review will incorporate a systematic search of academic and grey

literature from safety-critical industries, including healthcare, with the use of the framework analysis method of Ritchie and Spencer (1994) to analyse data. The semi-structured interviews are intended to address aim 2, objective 1 and add depth to knowledge and understanding to gaps apparent in the literature included in the systematic review. The semi-structured key informant interviews will be conducted with experts (including patients) from safety-critical industries, including healthcare, with a focus on developing an in-depth understanding of the purpose and key requirements for an international patient safety IRLS.

Next, to address aims 2 and 3, and objectives 2–4, the online modified Delphi study is intended to gain consensus from a broader panel of international healthcare experts (including patients) about the key requirements and feasibility, in terms of barriers and enablers, of an international IRLS.

Finally, an online survey of end-users was selected as a means of extending the validation offered by the Delphi study concerning the key requirements and feasibility, in terms of acceptability, of an international IRLS, managing aim 3 and objectives 4 and 5. Taken together, these methods are therefore sequential in nature and offer an exploratory, pragmatic approach to developing a framework for an international patient safety IRLS for the healthcare industry. Finally, the discussion chapter provides an opportunity to draw together and compare the perspectives and findings in previous chapters, highlighting opportunities and challenges for future research and practice.

Chapter 2 – Incident reporting and learning systems in safety-critical industries: a systematic literature review

2.1 Introduction

This chapter reports on how safety-critical industries learn from safety incidents at the international level, given the use of different Incident Reporting and Learning Systems (IRLS) across various safety-critical industries. An IRLS is broadly defined as a system designed to share information between organisations/centres on an international level to promote learning that may prevent similar incidents in the future. Given their evolution over the past two decades in healthcare, this chapter is an opportunity to systematically analyse knowledge and understanding accrued about IRLSs in safety-critical industries to consider lessons learnt for the healthcare context.

This chapter aims to synthesise and critically analyse the background literature on safety reporting and learning, with an analysis of experiences and observations seen in safety-critical industries. Discussion of these findings will be used to relate observations to the healthcare setting, which provides an opportunity to focus these findings on the context of patient safety learning and reporting from complex healthcare systems. Furthermore, the concept of international safety and learning systems will be considered, building in particular on key ideas and functions evident from national and/or local data analyses in the literature.

2.1.1 Background to safety reporting and learning

Over the past decade, efforts to collect data on patient safety incidents and healthcare-associated incidents have emerged internationally. The landmark reports, *To Err is Human* and (Institute of Medicine [IOM], 1999) *An Organisation with a Memory* (Department of Health, 2000) at the turn of the millennium, helped the health profession, its organisations, and its professionals realise that healthcare organisations are burdened with a significant level of risk to patients. In England and Wales, this realisation led stakeholders from government and healthcare agencies to establish the National Patient Safety Agency (NPSA) in 2001 and the National Reporting and Learning System (NRLS) in 2003. Over time, this has led to increased awareness of the factors underlying incidents in healthcare, as well as a clear need to promote reliable safety reporting and associated learning (Vincent et al., 2013). Healthcare is also learning from other safety-critical industries, such as aviation and petrochemical plants, which have made efforts to identify their own prevalent risks. This has been achieved through the reporting of incidents and, in turn,

identifying learning to inform efforts to create a safer environment by addressing apparent issues. Undoubtedly, adopting this approach for the healthcare industry requires clarity of the methods, tools and indicators that may be applied to evaluate patient safety (Vincent et al., 2013).

Industries such as aviation and aerospace travel, railway, and nuclear power report remarkable successes from routinely using incident reporting systems to guide safety at a local, national, and international level. For example, the Aviation Safety Reporting System (ASRS), which is operated by the National Aeronautics and Space Administration (NASA) in the United States, have reported successful safety alerting examples, and its model has been applied to the international aviation community (NASA, 2018). A specific example would be when the International Civil Aviation Organization (ICAO) adopted an Aircraft Accident and Incident Investigation procedure, which is an international civil aviation safety learning system (ICAO, 2016). This international system generates learning from reports of accidents and incidents that are shared via a common database, as discussed in Chapter 1.

Despite the intention to mirror this success in healthcare (Institute of Medicine, 1999), there is little academic investigation of the effectiveness of reporting and learning systems to improve patient safety through a process of organisational learning and improvement, based on a lack of identified studies that have demonstrated objective outcomes of such systems (Stavropoulou et al., 2015). Some of the key features of databases used to facilitate safety and safety-associated learning in safety-critical industries are attractive to healthcare settings and the potential for transferability of data across nations. This includes the development of shared taxonomies (schemes of classification) and coding structures based on numerical data or codes to standardise incident identification and reporting (Landrigan et al., 2010). A common taxonomy applied in this manner has the potential to overcome variations in spoken language across nations, as discussed in Chapter 1 (World Health Organization [WHO], 2009). Standardisation of incident characteristics and reporting also facilitates consistency in the investigation of these incidents and reporting any resulting learning (WHO, 2005b). On an international basis, learning between nations can be facilitated by adopting this type of system, due to the benefits of standardisation, coding, and comprehension across cultures and languages (Weisz & Nannestad, 2021).

Incident reporting and learning systems are considered important in facilitating safe practice on a wider organisational level. A number of national healthcare organisations

have founded incident reporting systems. The success of incident reporting in improving safety, although apparent in aviation and other safety-critical industries, is yet to be seen in healthcare systems. While local-level improvements in safety may be observed, it has been suggested that there are limitations to what can be achieved by existing IRLSs in healthcare (Stavropoulou et al., 2015). Studies have suggested that incident reporting systems can have specific benefits for policy and guideline development. For instance, Wong et al. (2013) identified 15 practice changes, including guideline updates, that emerged directly from patient safety incident reports in Moorfields Eye Hospital and implied that such changes had improved safety. Similarly, Anderson et al. (2013) found that safety incident reporting in an acute care and mental health hospital in London led to a range of policy changes. However, there is a general lack of data demonstrating not only the effectiveness of these changes in practice (in terms of improving patient safety) but also the use of incident reporting systems to promote learning at an organisational level in healthcare (Stavropoulou et al., 2015).

Healthcare leaders have considered the benefits of the use of IRLS in practice. For example, in the field of anaesthesia, it has been proposed that an IRLS could improve patient safety (Mahajan, 2010). This potential would be contingent on front-end clinicians having access to a reliable reporting system, whereby reports are assessed in a non-punitive manner and used to enhance learning focused on future incident prevention (Mahajan, 2010). The author of this paper was a past head of the United Kingdom (UK) Royal College of Anaesthetists but remains active in promoting excellence in the field of anaesthesia, including the development of training, learning, and quality initiatives in the field. In an assessment of the core pillars of academic anaesthesia (education, training, testing, quality, and research), Mahajan notes that information sharing on an international level is crucial to advancement in anaesthetic practice (Van Zundert et al., 2016). One key initiative proposed by Mahajan and others is the need to develop an international repository of data to facilitate learning and development on an international level (Van Zundert et al., 2016). The potential for international data sharing is not unique to anaesthetic practice, however. It has been proposed more broadly that information sharing on an international level, through the development of partnerships across healthcare systems, plays a fundamental role in developing practice and learning (O'Donnell & O'Donnell, 2016; Issa et al., 2017). Hence, it is recognised that reporting data internationally can provide a basis for shared learning and analysis of events, which is of relevance to healthcare settings.

Pharmacovigilance networks and systems are a key example of how an international approach to data collection and analysis can work to meet the aim of promoting safe practice. The WHO (2014b) note that pharmacovigilance systems can provide a coordinated and collaborative approach to data gathering across nations, which meets a key goal of expanding the data set for identification and analysis of rare medication errors or adverse events. The WHO pharmacovigilance programme, World Alliance for Patient Safety and the International Medication Safety Network have aligned goals towards sharing information and promoting safer practice as a consequence. While the organisations vary according to their specific focus and purpose, the learning outcomes of pharmacovigilance tend to focus on how to prevent adverse events from occurring and to promote changes in resources, structure, accountability and curriculum design to prevent medication errors. It is important to note that pharmacovigilance national reporting systems are focused only on medication errors, not wider aspects of safety, and maintain a key goal of identifying rare events, which may be missed on a local or national level in smaller populations. Furthermore, learning resulting from these systems is highly heterogeneous in nature and can be challenging to implement across nations, depending on resources, local system design, and curricula for students and staff (van Eekeren et al., 2018). While pharmacovigilance systems may be an important example of international approaches to identifying safety issues and promoting learning from these events in healthcare, they may be more limited when considering more heterogeneous safety events outside of medication-related events.

2.1.2 Progress in healthcare and the facilitation of shared international learning

Data repositories that form the basis of learning valuable lessons to help prevent incidents being reported at the local and national levels are largely absent at the international level. Some agencies within healthcare, including collaborating centres working under the remit of the WHO (2018), collect information on a national level, which may then contribute to international learning through dissemination and sharing of findings. However, one international classification system for recording, reporting, interpreting, and comparing morbidity and mortality data is the International Classification of Disease and Related Health Problems (ICD) (WHO, 2022a). The ICD 11 (eleventh revision) is the result of collaboration between statisticians, clinicians, coders, epidemiologists, IT and classification experts from around the globe. This provides a mutual language for the classification of disease, injuries and the aetiology of death, and for the reporting and monitoring of health at an international level. It is revised periodically by the WHO, and it is presented to the

World Health Assembly for the implementation as well as adoption into the reporting systems as well as national data collection.

In order to introduce the WHO's efforts to promote international comparison of data on safety and incident reporting, further analysis of safety reporting and information sharing is needed. An extension of the human error and organisational accidents approach is illustrated by the work done by the World Alliance for Patient Safety to develop an international classification and a conceptual framework for patient safety. The classification of patient safety concepts and terms has seen numerous taxonomies proposed, but none has been broadly applied internationally (Runciman, 2006; Cohen & Hilligoss, 2010; Chang et al., 2005; McElroy et al., 2016; Donaldson, 2011). In this regard, WHO World Alliance for Patient Safety has identified the significance of this dilemma and encouraged the establishment of the "International Classification for Patient Safety (ICPS)" (Donaldson, 2009). The main aim of the classification is to avoid complexities in understanding definitions, selected terms and information in patient safety. For better implementation of safety procedures, the World Alliance for Patient Safety has involved not only developers and managers, but also had a keen desire to involve researchers, policymakers and patient groups in the establishment of strategies (Donaldson, 2009).

In this context, three associated papers have demonstrated different features of the work for the future development of the ICPS framework. The first paper by Sherman *et al.* provided an overview of the initiative, including the formation of a Drafting Group and the development of guiding principles. The second paper, by Thomson *et al.*, described how a web-based two-phase modified Delphi process ensured substantial input from interested parties throughout the world and informed the development of an agreed conceptual framework and related concepts. The third paper by Runciman *et al.* described in detail the resulting definitions and preferred terms for the 48 key concepts and how they relate to each other (Donaldson, 2009; Sherman et al., 2009; Thomson et al., 2009; Runciman et al., 2009).

Given the present scenario, significant issues and loopholes remain unaddressed in the practical development of IRLSs, as well as in defining the role of specific organisations or systems operating on a national level, which may have implications for international reporting and learning. Some of these include lack of awareness of how the reported incidents will be analysed, lack of understanding among clinicians about what should be reported, poor safety culture in an organisation, fear of punitive action, and how will these reports ultimately result in improvement of patient safety. Particularly, the lack of work in

terms of systematic analysis of incident reports and providing feedback directly to the clinicians are seen as major barriers to clinical engagement (Hoffmann et al., 2008). As noted in Chapter 1, the concept of knowledge mobilisation (i.e., generating robust knowledge and facilitating its impact in areas where it may be of greatest value) is crucial in facilitating learning from incident reporting (Haynes et al., 2020). Still, it remains largely under-explored in the context of international learning in healthcare organisations.

2.2 Gaps in the literature and a need for a review

The background analysis of the evidence base suggests that there are key gaps in the literature regarding the application of incident or safety reporting and learning systems in healthcare settings. Specifically, while evidence for the use of such systems is notable in safety-critical industries, such as aviation, the practical application of the principles of these systems to healthcare settings is uncertain. There is a need for the synthesis of evidence about these systems to consider options for optimising their application to improve safety in healthcare. Furthermore, to build on the need for international learning advocated by the WHO, identifying how other safety-critical industries learn from data, generate and share learning across their sector and multiple countries needs to be considered.

The overarching review question is: what can healthcare learn from the development and implementation of international reporting and learning systems used in safety-critical industries?

2.3 Aim

The aim of this systematic review is to describe the components of IRLS employed in various organisations at the international level across different safety-critical industries, identify reported barriers and facilitators for their effective implementation, and to consider the transferability of those findings to healthcare.

2.4 Objective(s)

1. To review existing literature from safety-critical industries and the healthcare industry, and to map out the constituent elements of a learning system and their ways of functioning and experiences.
2. To identify how existing organisations learn from safety incidents and transfer learning from one organisation to another, including multi-organisational sharing.
3. To explore and summarise the purpose and anticipated challenges and opportunities for an international patient safety learning system in healthcare, based on evidence from safety-critical and healthcare industries.
4. To assess the projected applicability/transferability of the key characteristics and functions of an international incident reporting and learning system in the healthcare context, with the framework of Benn et al. (2009) used as a reference standard.

2.5 Methods

2.5.1 Justification of the type of literature and evidence review

There are numerous strategies employed to synthesise literature on a topic within healthcare research, ranging from unstructured reviews to analytical or statistical methods (e.g., meta-analyses), suggesting multiple options for addressing the aim and objectives defined above (Grant & Booth, 2009). However, two main types are mostly used in healthcare research; systematic literature reviews and scoping reviews (Munn et al., 2018a; Munn et al., 2018b). The culture of developing systematic reviews in healthcare dates back to the 1970s and 1980s (Bastian et al., 2010) while conducting evidence synthesis through scoping review is much more recent. Both review methods follow a structured approach but differ in the reason for which they are performed as well as in their methodology.

2.5.2 Comparison of scoping reviews and systematic reviews

Fundamental differences in scoping reviews and systematic reviews favour the selection of one review type over another, depending on the topic and purpose of the review (Munn et al., 2018a; Munn et al., 2018b). Systematic reviews particularly seek to systematically search and then synthesise evidence. Scoping reviews provide scope or complete coverage of the literature available on a particular topic and, in the end, provide a clear indication of the volume of available literature (Anderson et al., 2008; Munn et al., 2018a; Munn et al., 2018b). The first and foremost reason to choose a systematic review is that

systematic reviews have a defined structure that includes quality assessment of included references, contrary to a scoping review. Contrary to scoping reviews, a systematic review uses explicit, systematic methods that are selected to minimise bias, and thus provide more reliable findings, from which conclusions can be drawn and decisions made (Munn et al., 2018a; Munn et al., 2018b).

Secondly, the scoping review performed by Wallace et al. (2009) has previously tried to cover the topic but did not include international learning elements. Therefore, this systematic review can be viewed as an extension of the previous work done by Wallace et al. and could add value and serve as an advancement by adding an international dimension to the scoping review (Wallace et al., 2009).

Another factor in making the decision to conduct a systematic review was the fact that PROSPERO, an international prospective register of systematic reviews, would not accept protocols for scoping reviews. Prospective registration of the systematic review was considered appropriate, as the step provides the advantage of gaining knowledge about anticipated methodological challenges that may emerge during the process, minimises the possibility of reporting bias, and ensures that all the pre-specified outcomes are reported. Thus, the decision to undertake a systematic review was taken after considering all the mentioned factors. The prospective registration of this systematic review in PROSPERO (Registration ID: CRD42019099507) facilitates optimal transparency, reproducibility, and usability of the published literature (Page, Shamseer & Tricco, 2018).

2.5.3 Systematic review method

Systematic reviews are considered a gold standard for evidence-based research with outcomes that support safe practice and have become a key to policymaking and informing practice guidelines (Garritty et al., 2010; Pearson et al., 2011). They aim to provide a comprehensive, unbiased synthesis of relevant studies of a subject using rigorous and transparent methods to ensure results that are reliable and meaningful to the profession and clinical practice (Aromataris & Munn, 2017). The justification for using a systematic review method in this research is that it provides a comprehensive method aligned with the aim defined above, which is to explore how safety-critical industries learn from safety incidents and how they share their learning at the international level, with the intention of applying these aspects to healthcare.

The remainder of this chapter will be based on the 27 steps mentioned in the PRISMA checklist (Moher et al., 2009). The completed PRISMA checklist is provided in Appendix

2.1. The systematic review and its protocol (see Appendix 2.2 for the protocol) employed steps and methods adapted from those used in Cochrane Reviews (Higgins et al., 2018).

2.5.4 Data sources and search strategy

The following databases were searched during the period of 02/07/2018 to 15/07/2018:

EMBASE, MEDLINE, ASSIA, PsycINFO, SCOPUS, Global Health, Web of Science, HMIC (Health Management Information Consortium), ICONDA (International Construction Database), and grey literature of websites belonging to accident investigation organisations for each safety-critical industry (e.g., healthcare, aviation, nuclear power, rail, chemical industries, ministry of defence, NASA; see Appendix 2.3 for the list of grey literature websites). These databases were chosen to identify a breadth of content from aeronautics, civil aviation, military aviation, railway, maritime operations, offshore oil/exploration, chemical process industry, and energy/nuclear power industries with input from a subject librarian at Cardiff University (Ms Mariann Hilliar) to ensure that they cover all safety-critical industries of interest to the review.

Two limits were set when searching the databases. The time period 1999-2018 was chosen because of the release of the seminal reports that catapulted patient safety to the attention of healthcare leaders and policymakers internationally from 1999 onwards (Institute of Medicine, 1999; Department of Health, 2000; Runciman, & Moller, 2001). The second limit was language, which is set to English only because of the language proficiency of the reviewers. This was a pragmatic decision to facilitate analysis of the literature more easily while avoiding the need for translations of research data, which can be costly and may introduce errors into the data. However, it is acknowledged that a focus on English language publications alone may limit the available dataset, potentially excluding more diverse international insights, which can limit the applicability of the review findings on a global level. The detailed search strategy is available in Appendix 2.4, which has been developed, piloted, and discussed with a subject librarian (Ms Mariann Hilliar) to enhance the sensitivity and specificity of the search strategy.

2.5.4.1 Searching other resources

Other potentially eligible articles or supplementary publications were identified by hand searching the reference lists of included and relevant journal articles, and key journals such as BMJ Quality & Safety, Safety Science, and Journal of Patient Safety and Risk Management for the same time period of 1999-2018.

2.5.5 Selection of studies

Records were imported into Endnote (ver. X8. 2, Jan 2018), and duplicates were removed. The process of selection was divided into two selection phases:

Phase one: Two review authors (JQ, KC; full names defined in the protocol in Appendix 2.2) independently scanned the title and abstract of each record retrieved to determine which studies should be assessed further based on the inclusion and exclusion criteria summarised in Table 2.1.

Phase two: All potentially relevant articles were reviewed (by JQ and KC) by retrieving the full text of each article and further assessed against the inclusion and exclusion criteria. Any discrepancies were resolved through consensus with third-person arbitration by ACS (full name defined in Appendix 2.2).

Table 2.1 Inclusion and exclusion criteria of studies

Criterion	Inclusion	Exclusion
Industry	Healthcare, Safety-Critical (e.g., aeronautics, civil aviation, military aviation, railway, maritime operations, offshore oil/exploration, chemical process industry, energy/nuclear power)	Any other organisations or industries (non-healthcare, non-safety-critical)
Operational level	Single or multi-organisation operating at local, regional, national, and international levels	None
Reporting systems	Learning system(s) such as: Incident reporting system(s), Safety learning system(s), Accident and incident investigation system(s), and Reporting system(s)	Analysis of incident reports rather than an explicit focus on the reporting system
Learning	How reporting and learning is achieved in those systems, including how learning is used, and transferred, in addition of barriers and enablers of learning	No mention of how reporting and learning is transferred or achieved. No mention of barriers and enablers of learning
Knowledge mobilisation	How knowledge is mobilised, transferred and shared within the organisation to improve service and outcomes	No mention of how knowledge is mobilised/transferred within the organisation
Design	Descriptive and Analytical designs such as: Empirical studies, Theoretical studies, Reports, Policy documents, Reviews (of reporting systems, relevant topics/concepts), and Descriptive papers	Opinion papers, Editorials, Reviews (of Books/reports), Protocols, and Conference Abstracts
Time period	1999 – Current (2018)	Any study outside these dates
Language	English	Non-English
Other	Full-text available	Full-text unavailable

2.5.6 Data extraction

For studies that fulfilled the inclusion criteria, data relevant to the aim and objectives of the review were extracted by one reviewer (JQ) and independently checked for accuracy by a second reviewer (KC). Study details were extracted using a modified data extraction form (Microsoft Word 2016, see Appendix 2.5 for the modified data extraction form) that was piloted and checked for relevance by three reviewers (JQ, KC, ACS), with disagreements resolved by discussion.

2.5.7 Quality assessment

Evaluation of quantitative and qualitative studies was done by using the appropriate Critical Appraisal Skills Programme (CASP) checklist (CASP, 2018) available at the time the review was carried out, while cross-sectional studies were evaluated using the Appraisal tool for Cross-Sectional Studies (AXIS) (Downes et al., 2016). These critical appraisal checklists were discussed with a subject librarian (Ms Mariann Hilliar) to ensure that relevant critical appraisal checklists are used appropriately (i.e., based on the study design/methods used). One reviewer (JQ) undertook quality appraisal of included literature and a second reviewer (KC) independently checked for consistency of the assessment. A third reviewer (ACS) was to be involved in cases of discrepancy. The outcomes of the CASP appraisals were used to inform the weighting of the discussion of the literature within the review, with preference given to higher-quality studies (i.e., a weighted discussion based on study quality). However, CASP scores are not recommended to guide the critical assessment of studies, as the descriptive components of the CASP findings are more valuable in guiding a critical discussion of the literature (CASP, 2018). Furthermore, insights from the appraisal process were used to inform a critical discussion of the findings using a narrative approach, aligned with the data synthesis method discussed in the following section. The AACODS checklist is designed to enable evaluation and critical appraisal of grey literature and was utilised to evaluate grey literature in this review (Tyndall, 2010).

2.5.8 Data analysis and synthesis

The results of the data extraction and quality assessment for each study were presented in structured tables and as a narrative summary. Identified learning systems were grouped and presented according to the following criteria:

- Author(s)
- Publication year
- Industry
- Level (local/national/international)
- Publication type
- Study design/type
- Quality Assessment

The process of data analysis focused on each study or dataset individually, with the extraction of key data (Barnett-Page & Thomas, 2009). This was facilitated using a structured data extraction table, with key criteria defined above, as well as through critical appraisal of individual studies, as recommended by King (2004). However, data synthesis involves an evaluation and comparison of the literature across studies (Thomas & Harden, 2008). Within the systematic literature review method, the use of a quantitative approach to data synthesis is often seen in the literature, typically comprising a meta-analysis of the data if sufficient homogeneity is demonstrated within the data (Snilstveit et al., 2012). While this may have value in combining numerical data sets with the intention of establishing the effectiveness of an intervention (or other defined clinical outcome) (Thomas & Harden, 2008), the suitability of this approach for the present review aim and objectives is questionable. Indeed, this review sought to evaluate a range of features of IRLSs across industries, and the use of meta-analysis would not be applicable or feasible, given the types of data anticipated, heterogeneity of the data, the combined use of journal articles and grey literature, and the nature of the review outcomes (e.g., barriers and facilitators etc.).

A widely used alternative to meta-analysis is a narrative approach to addressing the aim and objectives of a systematic review (Snilstveit et al., 2012). This approach involves presenting the results of an evidence synthesis in a narrative format, with discussions of similarities and differences between studies (Thomas & Harden, 2008). Different synthesis frameworks have been used to complete the narrative approach, each with relative

advantages and limitations. Thematic analysis remains one of the most common forms of evidence synthesis, and it is typically applied to qualitative study data, such as interview transcripts (Tuckett, 2005). The framework of Braun and Clarke (2006) is widely cited in relation to thematic analysis, illustrating the popularity of this method when applied to primary data. However, 'thematic synthesis' may be considered a broad term that reflects the process of synthesising literature according to identified commonalities and differences (Gale et al., 2013). One critique of the thematic analysis process, using frameworks such as that by Braun and Clarke (2006), is that this process can be highly subjective in nature (Guest et al., 2012). Indeed, thematic analysis of data can be challenging to reproduce and may be prone to influence from researcher/reviewer biases (Smith & Firth, 2011; Gale et al., 2013). Furthermore, thematic analysis is not always systematic in nature, and the generation of themes may lack a clear structure, particularly in relation to existing knowledge on a topic (Braun & Clarke, 2006).

One approach to increasing the systematicity of data analysis in a review is to apply a framework to the thematic method (Gale et al., 2013). The framework method was first developed in the UK by Ritchie and Spencer, part of the Qualitative Research Unit at the National Centre for Social Research (Ritchie & Spencer, 1994). This method was intended for use in large-scale policy research but has subsequently become common throughout health research literature (Smith & Firth, 2011). The essential feature of the framework method is that it applies an *a priori* framework to the thematic process, whereby data are analysed and then compared across studies, leading to the generation of distinct groups and structured outputs (Carroll et al., 2013). These outputs are related to a framework that provides a clear structure for the synthesis of the literature. Advantages of the framework method compared to other forms of qualitative synthesis include the systematic nature of the approach and the application of a theoretical framework (Brunton et al., 2020). This latter point is considered important by Damschroder et al. (2009), who note that frameworks enable a systematic approach to identifying and understanding findings and linking them to practice changes and implementation strategies. The result of applying a framework in this manner is that the outputs of the analytical process can be understood in terms of actionable consequences for the specific research setting (Brunton et al., 2020). This is important in the present review, as linking review findings to the potential application of features, processes, and other characteristics of an IRLS to healthcare systems inevitably requires more than a descriptive or abstract appreciation of these factors, but an appreciation that links theory to potential practice/implementation (Carroll et al., 2013).

Selecting a suitable framework to guide a framework analysis is crucial to the validity of the synthesis and subsequent interpretation of the review findings (Gale et al., 2013; Booth & Carroll, 2015). The framework of Benn et al. (2009) is used in the present review (Figure 2.1), as these authors provided insights into how local and national patient safety reporting and learning systems may operate and the relationship between local and national systems.

Benn et al. (2009) developed this framework from an analysis of the literature, using systematic methods, with a focus on national safety reporting systems. Consequently, the framework produced by Benn et al. (2009) provides a relevant basis for structuring key themes during the synthesis method, aligning the outcomes to the objectives of the study and framing them within a relevant conceptual framework. The framework illustrates key aspects of the foci of a feedback and IRLS on national levels (and local levels).

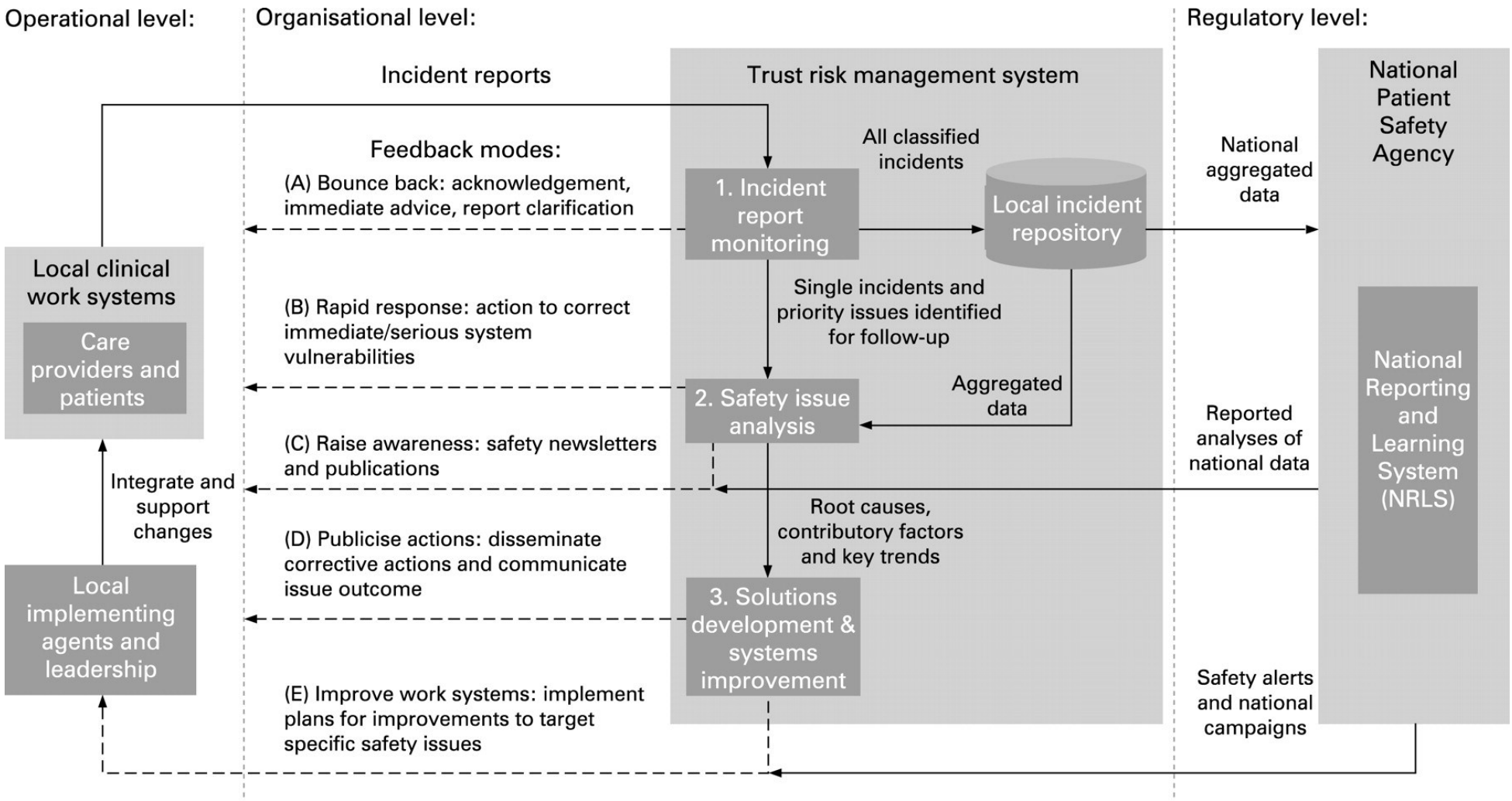

Figure 2.1 Framework for Safety Action and Information Feedback from Incident Reporting (SAIFIR) developed by Benn et al. (2009) [permission license number 5287131007159]

This framework illustrates multiple levels of a reporting and learning system and aspects of incident management/learning as key parts of a national reporting and learning system. The key features of this framework embody the stages of an effective safety feedback loop that aims to prevent adverse events through monitoring near misses and incidents at an organisational level. These features may be categorised as distinct stages in the feedback process, comprising incident reporting, safety issue analysis, solution development (system improvement), and feedback modes used to facilitate learning. Furthermore, the framework extends these organisational features to account for how learning and feedback may be linked at a regulatory level, which reflects the aggregation of organisational data at a national level (Benn et al., 2009).

It is important to acknowledge that the use of a framework method for data analysis may have limitations in a review context. Gale et al. (2013) note that the framework method may not be suitable for highly heterogeneous data, whereby data must be focused on similar topics or issues to enable categorisation. This method also relies on the nature of the framework employed to provide reliable and relevant findings in relation to the focus of the review. Importantly, deficiencies in the framework may limit the generation of novel findings and expansion of the knowledge base (Gale et al., 2013; Booth & Carroll, 2015). This is an important issue in the present review, as it is notable that Benn et al. (2009) have a clear framework for appreciating factors associated with a local or national IRLS, but this framework lacks appreciation of the international learning perspective. As the focus of the present review is on the international application of learning and safety outcomes related to IRLSs, this suggests that the framework of Benn et al. (2009) may need to be expanded or developed further to achieve the review aim and objectives. A pilot review may have been completed to determine heterogeneity in the sources and their relationship to the framework of Benn et al. (2009), but this was not considered necessary due to the lack of alternative existing frameworks for reporting and learning systems (national or international), suggesting that this framework may be the only feasible option to guide the review process.

Therefore, the synthesis method employed in this systematic review focused on the framework method defined by Ritchie and Spencer (1994) as the primary analytical strategy, while also incorporating a thematic synthesis process to offer further insights into the international perspective and novel outcomes that may not fit into the Benn et al. (2009) framework. This approach has been termed a ‘best fit’ framework synthesis (BFFS) and is described in detail by Booth and Carroll (2015). This is demonstrated in Figure 2.2.

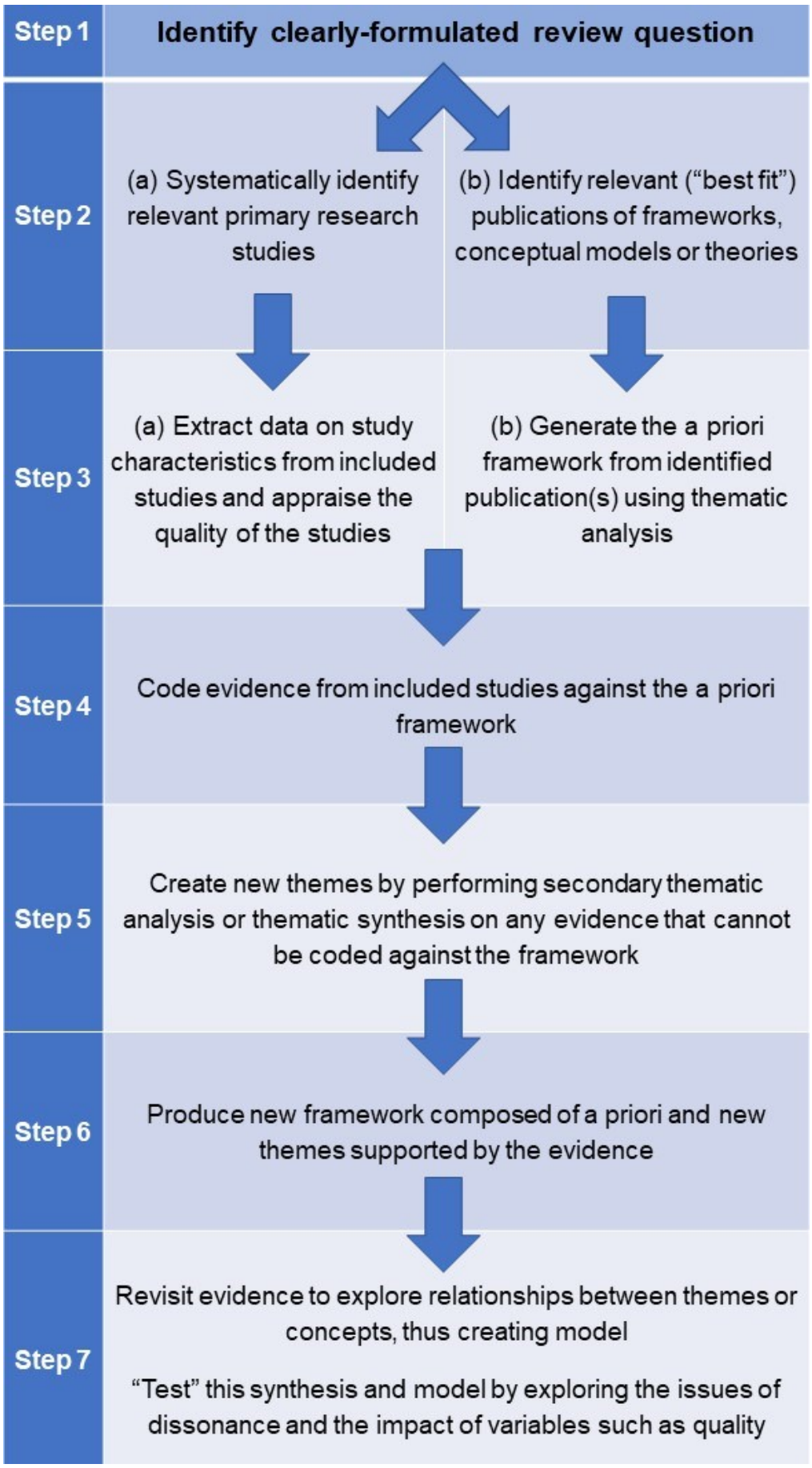

Figure 2.2 Best fit framework synthesis method (Booth & Carroll, 2015) [permission license number 5313750067693]

Seven steps are recognised in the use of this framework:

- Step one is the development of a clearly formulated review question.
- Step two involves systematic identification of studies and identification of a relevant framework or conceptual model (Benn et al. (2009), in this instance).
- Step three involves extraction of data, based on study characteristics and qualities (as noted in the data extraction description).
- Step four is the coding of evidence against the *a priori* framework. Up to this point, the steps are consistent with a framework method defined by Ritchie and Spencer (1994).
- Step five adds a secondary thematic analysis or thematic synthesis for evidence that is not coded against the framework, which leads to the generation of new themes (Carroll et al., 2013; Booth & Carroll, 2015).
- Step six is the subsequent development of a new framework (or modified framework) based on the new themes.
- Step 7 is to revisit the relationships between themes to finalise this framework (see Figure 2.2, Booth & Carroll, 2015).

The BFFS method was employed in this present review to provide a basis for systematically linking the evidence to an existing framework for local and national IRLSs, while offering an opportunity to expand this framework and develop further insights that may be applied to an international learning perspective. The relative limitations of the framework method (i.e., the potentially restrictive nature of the defined framework in generating new insights) and the thematic synthesis process (lack of systematicity) may be overcome using the BFFS (Carroll et al., 2013). The findings of this review are therefore structured according to the emerging themes related to the framework of Benn et al. (2009), as well as emergent themes that do not fit into this framework.

2.6 Results

2.6.1 Search Results

In this systematic review, a total of 3497 search articles from the scientific databases were identified starting from the year 1999 until July 2018 (time of first search) and eventually screened (see Figure 2.3 for PRISMA flow diagram) from the following databases: MEDLINE (n=728), EMBASE (n=1578), PsychINFO (n=163), Global Health (n=154), HMIC (n=139), ICONDA (n=126), Web of Science (n=342), SCOPUS (n=163), ASSIA (n=46), and IBSS (n=58). After removing duplicates, a total of 2679 studies remained. Further exclusion in phase one was based on title and abstract screening. Phase two of study screening included exclusion of the articles based on reasons such as being a review article (n=105), a conference abstract (n=36), a book/book section (n=16), not being related to incident reporting systems or learning (n=14), an editorial commentary, note or briefing (n=9), analysis or description of incident reports (n=8), performance evaluation of an incident reporting system (n=8), not from a safety-critical industry (n=3), a comparative study of two hospitals (n=2), a report on the use of reporting system (n=2) and non-English language content (n=1). The final step of phase two involved the inclusion of four studies identified based on the bibliography/references of the included studies.

Overall, the total number of included references (records) from searching electronic databases is nine, while hand searching (n=3) and grey literature search (n=10) added 13 more references, bringing the total to 22 (see Figure 2.3 PRISMA flow diagram). Hand searching the bibliography of included references and relevant studies identified three records (a grey literature report and two journal articles), while searching key journals did not identify any new records. A final search of electronic databases was performed on 10/06/2019 to update the results based on any publications that may have emerged following the first search, which resulted in the identification of 308 new records since the initial search, 70 of which were duplicated, leaving 238 unique records. No new records were identified after going through the selection process and applying the inclusion/exclusion criteria, the only exception is an updated version of an included grey literature reference (NASA, 2018), which was essentially the same document with dates changed to 2019.

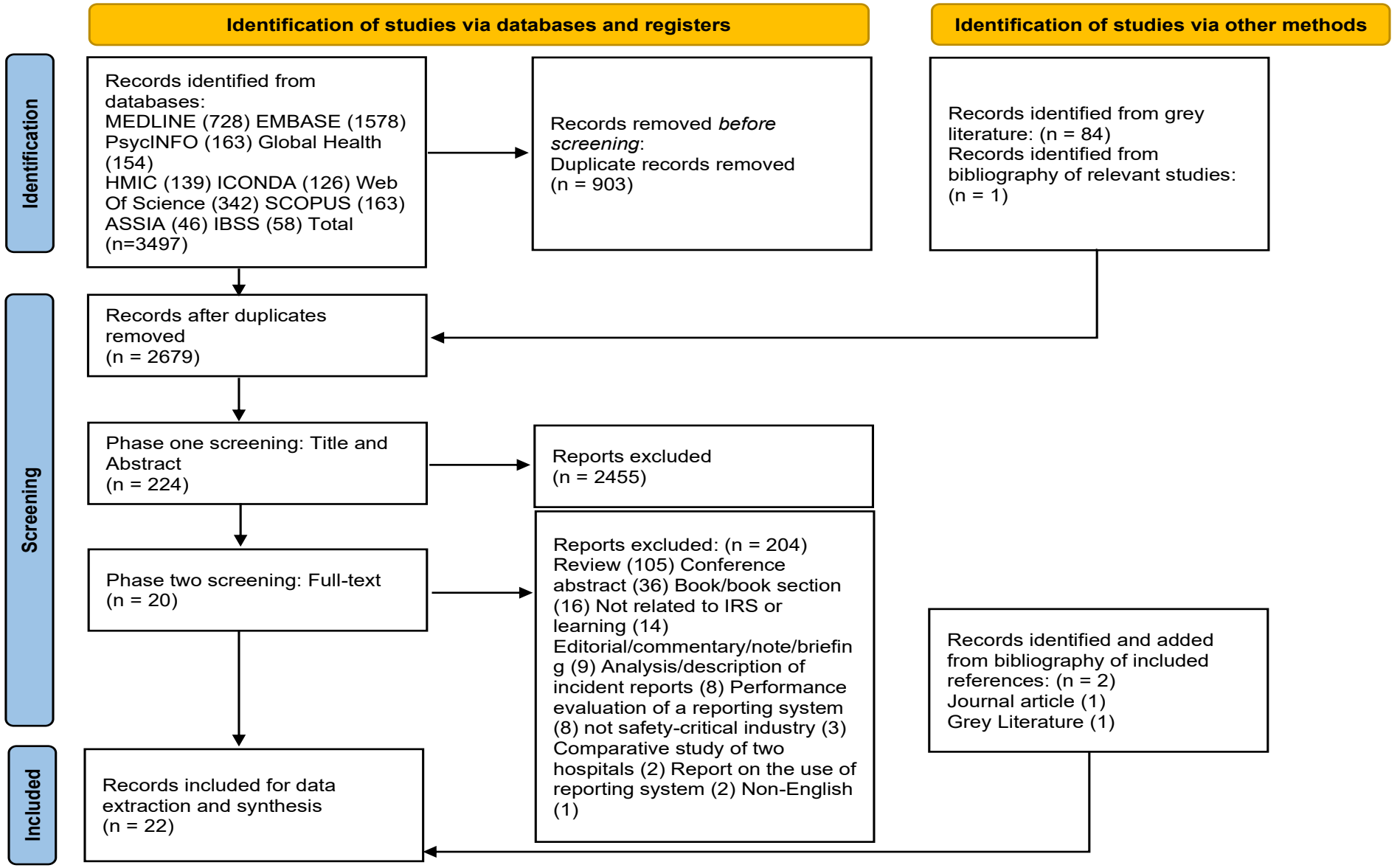

Figure 2.3 PRISMA flowchart of study selection process (Preferred Reporting Items for Systematic Reviews and Meta-Analyses; Page et al., 2021)

2.6.2 Study characteristics

Most of the studies (16 out of 22, 73%) were from the healthcare industry, two (12.5%) each from the civil aviation and oil and gas industries, while one (4.5%) each from the nuclear power and military aviation industries (refer to Figure 2.4). All the included studies were published in or after the year 2004. Nine (41%) discussed IRLSs at the international level, seven (32%) studies at the national level, and four (18%) at the local level; two (9%) studies discussed IRLS at all three levels. Of note, pharmacovigilance literature was not included in the review, as this was considered to be exclusively focused on suspected adverse drug reactions, rather than wider patient safety incidents at an organisational level.

The grey literature mostly constituted reports, guidelines, documents and user guides. Journal articles included cross-sectional studies, surveys, questionnaires, interviews, focus groups, Delphi consensus, and mixed methods (refer to Table 2.2 for characteristics of included studies). These included references which discussed and/or referred to at least nine IRLSs operating at multiple levels, including local, national, and international levels across healthcare and safety-critical industries (refer to Table 2.3 for a list of IRLSs represented in the included literature).

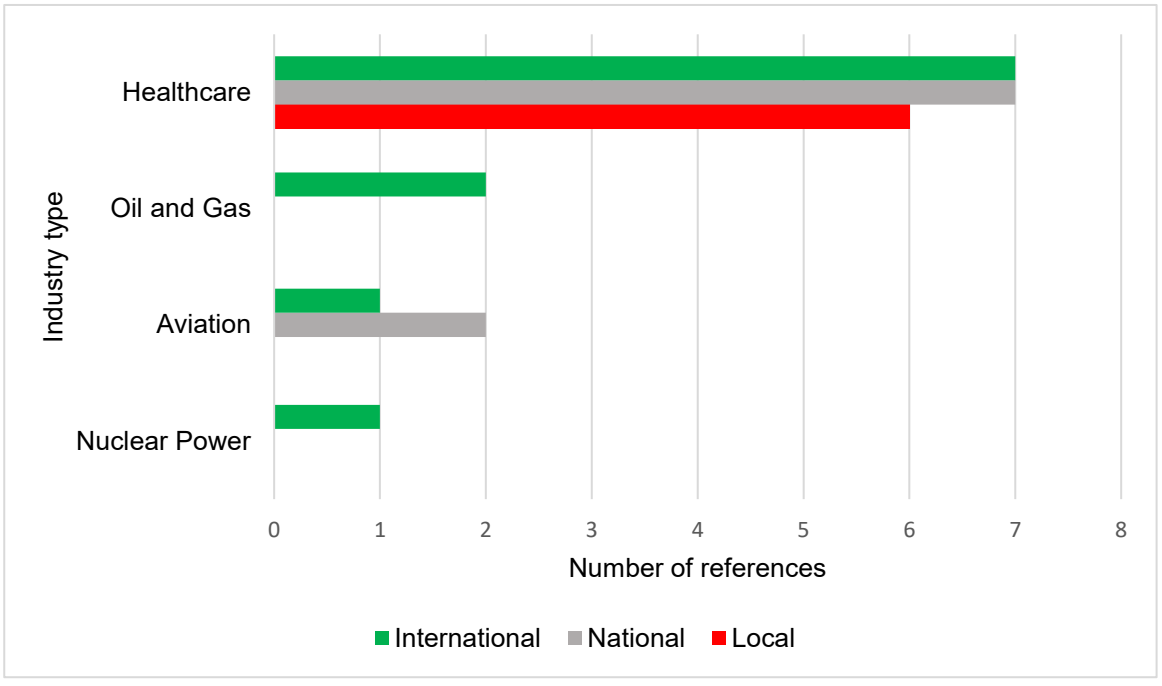

Figure 2.4 Breakdown of included references according to industry and operation level

Table 2.2 Characteristics of included studies

Author(s)	Year of publication	Industry	Level (local, national, international)	Publication type	Study design/ output/ methods	Quality assessment
National Aeronautics and Space Administration (NASA)	2018	Civil Aviation	National	Grey	Report	10/10 AACODS checklist
Howell et al.	2017	Healthcare	International	Peer-reviewed Journal Article	Scoping review, semi-structured interviews, and Delphi consensus	Moderate CASP checklist
Abu Bakar et al.	2017	Healthcare	National	Grey	Guideline	10/10 AACODS checklist
Mayer et al.	2016	Healthcare	National	Grey	Report	10/10 AACODS checklist
International Association of Oil & Gas Producers (IOGP)	2016	Oil and Gas	International	Grey	Document	10/10 AACODS checklist
International Civil Aviation Organization (ICAO)	2016	Civil Aviation	International	Grey	Document	10/10 AACODS checklist
Holmström et al.	2015	Healthcare	International	Peer-reviewed Journal Article	Descriptive cross-sectional study, online survey	High CASP checklist
Klemp et al.	2015	Healthcare	International	Peer-reviewed Journal Article	Systematic literature review and consensus procedure	High CASP checklist
Reed et al.	2014	Healthcare	International	Peer-reviewed Journal Article	Standardised questionnaire	Low CASP checklist

IOGP	2013	Oil and Gas	International	Grey	User's Guide	10/10 AACODS checklist
Vallejo-Gutiérrez et al.	2013	Healthcare	National	Peer-reviewed Journal Article	Multi-method, including literature review, expert group, Delphi consensus, focus groups, online questionnaire	Moderate CASP checklist
Holmström et al.	2012	Healthcare	International	Peer-reviewed Journal Article	Descriptive cross-sectional study, online survey	17/20 AXIS checklist
Datena et al.	2011	Military Aviation	National	Grey	Document	10/10 AACODS checklist
International Atomic Energy Agency (IAEA)	2010	Nuclear Power	International	Grey	Guideline	10/10 AACODS checklist
Wallace et al.	2009	Healthcare	National	Peer-reviewed Journal Article	Multi-method, including a scoping review using mixed method design	High CASP checklist
Benn et al.	2009	Healthcare	National	Peer-reviewed Journal Article	Mixed method review, and semi-structured interviews	High CASP checklist
Karsh et al.	2006	Healthcare	Local	Peer-reviewed Journal Article	Focus groups	High CASP checklist
Sharma et al.	2006	Healthcare	Local	Peer-reviewed Journal Article	Qualitative study using observations and interviews	Moderate CASP checklist
Cooke et al.	2006	Healthcare	Local	Grey	Reference guide	10/10 AACODS checklist

Expert Group on Safe Medication Practice (Expert Group)	2006	Healthcare	Local, National, International	Grey	Report	10/10 AACODS checklist
World Health Organization (WHO)	2005	Healthcare	Local, national, international	Grey	Guideline	10/10 AACODS checklist
Beasley et al.	2004	Healthcare	Local	Peer-reviewed Journal Article	Focus groups	Moderate CASP checklist

Table 2.3 IRLSs represented in the included studies

IRLS	Industry (country / continent)	Operating level	References
Patient Safety Events Reporting and Learning system (SiNASP)	Healthcare (Spain)	National, Local	Vallejo-Gutiérrez et al., 2013
Incident reporting system for European primary care	Healthcare (Europe)	International	Klemp et al., 2015
The International Reporting System for Operating Experience (IRS)	Nuclear energy	International	IAEA, 2010
ICAO Accident/Incident Data Reporting (ADREP) system	Civil Aviation	International	ICAO, 2016
The International Association of Oil & Gas Producers (IOGP) incident reporting system	Oil and Gas	International	IOGP, 2013
Incident Reporting & Learning System 2.0	Healthcare (Malaysia)	National, Local	Abu Bakar et al., 2017
(NASA) Aviation Safety Reporting System (ASRS)	Civil Aviation (USA)	National	NASA, 2018
Incident Learning System	Healthcare (Canada)	Local	Cooke et al., 2006
The Patient Safety Reporting System (PSR)	Military Healthcare (USA)	National	Datena et al., 2011

2.6.3 Quality assessment of included studies

The included references consisted of 11 grey literature publications, and these were critically appraised on the questions mentioned in AACODS checklist. The quality and reliability of included grey literature was considered good based on critical appraisal scoring (100% of articles achieved this rating). All other studies were assessed by the CASP tool, which consists of 10 questions to assess the quality of the included literature, except Holmström et al. (2012), which adopted a cross-sectional design which was not suitable for assessment using the CASP toolkit, and therefore, was appraised by the AXIS tool and was deemed to be of good quality (refer to Table 2.2). The quality of journal-based literature, contrary to that seen in grey literature, was not consistent, and methodological issues were noted across the studies. The quality grading for journal-based articles ranged from low to high (five were graded as high, four were graded as moderate, and one was graded as low; see Table 2.2), based on CASP scores ranging from 5 to 9 (out of a maximum of 10).

2.6.4 Themes derived from the framework method

Five main facets of the framework of Benn et al. (2009) were used to structure the findings of the review, according to the framework method discussed previously. For each facet, generated themes and sub-themes are considered across the literature. Furthermore, additional themes that reflect considerations outside of the framework of Benn et al. (2009) are presented at the level of international incident reporting and learning.

2.6.4.1 Purpose of an incident reporting and learning system

Multiple studies highlighted two main purposes of an IRLS (summarised in Table 2.4). The first theme is the improvement in patient or public safety informed by systematic detection and prevention processes serving dual purposes. The first purpose relates to the detection of improvements or systemic weaknesses by IRLSs, which are then highlighted by reporting patient safety incidents that may not be detected by other patient safety methods (e.g., safety audits). This should inform actions taken by the organisation to target identified systemic weaknesses in order to prevent the occurrence and/or recurrence of patient safety incidents. This broad purpose reflected the need to apply a systematic process to incident reporting that is aligned with improvement, which suggests the need to move beyond reporting of incidents and to facilitate a learning process (WHO, 2005b; ICAO, 2016; NASA, 2018).

The second purpose reflected that such a system should facilitate learning from safety incidents and sharing lessons learnt with stakeholders (Table 2.4). This theme builds on the previous theme and highlights how learning is generated from preventive actions taken in response to reported patient safety incidents. Lessons learnt are shared with relevant stakeholders (staff, management, national agency, international community) to raise awareness and sustain the effect of the actions taken and, thus, play a role in the improvement of organisational patient safety. However, there was inconsistency noted in who those stakeholders should be, particularly as few articles had a focus on international systems (WHO, 2005b; Holmström et al., 2015). For instance, Mayer et al. (2016) focused on national stakeholders, including frontline staff and members of the safety community (e.g., policymakers and safety specialists). Even wider studies that considered an international perspective failed to identify for whom learning should be targeted on an international level (WHO, 2005b). Therefore, while the key purpose of the IRLS was fairly consistent across studies, it should be noted that learning dissemination as a broad output, including shared learning with targeted stakeholders, was common across the literature.

Table 2.4 Themes related to defining the purpose of incident reporting and learning system

Framework facet	Descriptive theme(s)	Sub-themes	Supporting study/document
Purpose of an international safety reporting and learning system	Improvement in safety informed by systemic detection and prevention processes	– Improvement of organisational safety – Detection and prevention of potential systemic weaknesses.	NASA, 2018 Howell et al., 2017 Abu Baker et al., 2017 Mayer et al., 2016 ICAO, 2016 Holmstrom et al., 2015 Klemp et al., 2015 Vallejo-Gutiérrez et al., 2014 IOGP, 2013 Datena et al., 2011 IAEA, 2010 Karsh et al., 2006 Expert Group, 2006 WHO, 2005b
	Learning from safety incidents and sharing lessons learnt with stakeholders	– Sharing lessons learnt from reported incidents	Howell et al., 2017 Abu Baker et al., 2017 Mayer et al., 2016 Holmström et al., 2015 Klemp et al., 2015 Datena et al., 2011 IAEA, 2010 Expert Group, 2006 WHO, 2005b

Table 2.5 provides a summary of the key roles of IRLSs derived from a narrative evaluation of the literature, highlighting how these roles may span across local, national and international contexts.

Table 2.5 Functions of IRLS across different operating levels

Operating levels	Function(s) of IRLS
Local	- Patient safety incidents are reported, analysed, and targeted actions are taken - Support identification of patterns of patient safety incidents - Create an environment in which the entire organisation learns from reported incidents and where members of staff are encouraged to both proactively evaluate and reactively report risks - Local platforms for reporting patient safety incidents and sharing of lessons learnt should be developed - The objective of incident analysis is to uncover the causal system failures
National	- Creating a structure to encourage local incident reporting or connecting departments together to share lessons learnt - Support broader surveillance of problems, clusters of incident reports concerning particular problems identified, identifying rare but serious incidents where local action might be inadequate - Tackle generic and recurrent patient safety problems - Aggregation of data to have the highest value in revealing systemic failures, build-up of certain incidents or failures in new equipment that cannot be readily recognised at the local level - A national-level framework should be defined and applied to identify those incidents from local systems where national learning and action can prevent recurrence - Appropriate to capturing more serious incidents necessitating policy decisions at the national level
International	- Delivering timely and detailed information on lessons learned from operating and construction experience across nations - Events and operating and construction experience information reported should be of safety significance for the international community in terms of causes and lessons learned - Relies upon national operating experience systems and complements them by providing an international perspective

2.6.4.2 Incident reporting

The second facet of the framework by Benn et al. (2009) reflected the fundamental step of incident reporting within a learning system. According to included literature (WHO, 2005b; Cooke et al., 2006; Wallace et al., 2009; Vallejo-Gutiérrez et al., 2014; IOGP, 2016; Abu Baker et al., 2017), the first component in any incident reporting system is the process for reporting incidents within an organisation or at a national level. Four distinct themes were noted within this facet of Benn's framework (Table 2.6): the need for training in reporting incidents, variability in the types of severity of incidents that should be reported routinely, confidentiality and anonymity related to reporting practice, and access to the system.

Table 2.6 Themes related to incident reporting

Framework facet	Descriptive theme(s)	Sub-themes	Supporting study/document
Incident reporting	Incident reporting process within the organisation	– Identification and reporting of incidents – Variability in types of incidents and severity that should be routinely reported	Abu Baker et al., 2017 IOGP, 2016 Vallejo-Gutiérrez et al., 2014 Wallace et al., 2009 Cooke et al., 2006 WHO, 2005b
	Variability in types of incidents reported	– Urgency of reporting may be linked to severity of incidents – Different incidents may be routinely reported	Abu Baker et al., 2017 IOGP, 2016 Vallejo-Gutiérrez et al., 2014 Wallace et al., 2009 Cooke et al., 2006 WHO, 2005b
	Confidentiality and anonymity for staff reporting incidents	– Confidentiality is needed to ensure an open reporting culture	Klemp et al., 2015 Howell et al., 2017 NASA, 2018
	Access to the system	– Need for secure access – Variable criteria for who should have access to the system	Klemp et al., 2015 Howell et al., 2017 NASA, 2018

The first descriptive theme highlights how the concept of incident identification or detection assumes that the person that identified the incident has the training and knowledge in what is considered a 'reportable incident' and how to report it to the system (WHO, 2005b; Vallejo-Gutiérrez et al., 2014). While details of training were limited within the studies, there was a recognition that incident reporting needs to be based on a clear understanding of how an incident is conceptualised and that staff need to have a clear understanding of reporting processes. This may include training on local systems and clear lines of communication within the organisation (WHO, 2005b; Cooke et al., 2006), although these points were generally vague.

The second descriptive theme suggests that there is a threshold based on perceived urgency to reporting certain incidents, such as those that have resulted in death or severe harm to the patient, where prompt reporting is required for escalation and intervention when required, or near misses which may have led to severe outcomes (WHO, 2005b; IOGP, 2016). While the included studies all suggested that near misses or non-harm incidents should be included within an IRLS, some variability was noted in the emphasis

on the importance of near misses and no-harm events. For instance, Wallace et al. (2009) suggested that near misses are used in incident reporting but did not support this recommendation with evidence derived from stakeholder views within English and Welsh care settings. The IOGP (2016) only focused on fatal incident reports in their publication, which suggested that less severe incidents may not be routinely used for evaluation of safety; this is unlikely to be an applicable perspective in healthcare settings.

One of the most consistently noted sub-themes of this descriptive theme is confidentiality and anonymity (Benn et al., 2009; Klemp et al., 2015; Howell et al., 2017; NASA, 2018). When it comes to confidentiality and/or anonymity of reporters, the majority of the included references (11 out of 22, 50%) favoured a confidential incident reporting and learning system at the local level, some with anonymity as an option, while a minority of the included references (5 out of 22, 23%) favoured anonymity of reporters, particularly at the national level. The gap here is that there is no reference or indication as to what is desirable for an international IRLS when it comes to the confidentiality and/or anonymity of reporters. Table 2.7 outlines the preference for the confidentiality and anonymity of reporters in the included references.

The fourth theme related to incident reporting was the need to have accessibility to the system for incident reporting. This was variable across studies, with different perspectives on security needed to access systems and the users who may have input and reporting capacity (ranging from frontline staff to a select few leaders or senior staff). There was no general consensus as to whether access to the system should require a username and password. These cases are mainly relevant to local/national systems, whereas international systems, such as those in aviation and nuclear power (ICAO, 2016; IAEA, 2010), require secure access to the system. This is another identified gap where it is not known how and who should have access to an international IRLS operated in healthcare.

Table 2.7 Preference of confidentiality and/or anonymity in included references

Reference	Confidentiality	Anonymity
Benn et al., 2009	✓ (Initially at the local level)	-
Howell et al., 2017	-	✓
Karsh et al., 2006	-	✓ (Optional identification fields)
Vallejo-Gutiérrez et al., 2014	✓	✓ (Preferably)
Holmström et al., 2012	✓ (National/local level)	-
Reed et al., 2014	✓ (de-identification of reporters)	✓ (National level)
Wallace et al., 2009	✓	-
Klemp et al., 2015	✓ (With opportunity to report anonymously)	-
Mayer et al., 2016	✓ (Local level)	✓ (National level)
NASA 2018	✓	-
WHO 2005	✓ (Right to anonymity)	-
Datena et al., 2011	✓ (Supports anonymous reporting)	-
Expert Group 2006	✓ (Anonymity, where applicable)	-

2.6.4.3 Safety issue analysis

Once data are collected within an IRLS, there is a need for analysis of those data. This was observed consistently across the included sources (WHO, 2005b; Wallace et al., 2009; IOGP, 2016; Abu Baker et al., 2017). Two main themes emerged within this facet of the Benn et al. (2009) framework. The first theme was that analysis and/or investigation of reported incidents was fundamental in a coordinated response (Table 2.8). Across all studies, the degree to which analysis was required to facilitate a suitable response to the identified safety issue was consistent, although different analytical approaches were discussed. This included root cause analysis and other systematic approaches to identifying causes of incidents (WHO, 2005b; Cooke et al., 2006; Wallace et al., 2009).

The second theme suggested the need for a core platform and analytical abilities of the IRLS. The platform of the system should be simple, easy to use and report incidents, and complementary to other systems of reporting. Furthermore, the system should be online/web-based, particularly if it is operating at national or international levels (ICAO, 2016; IAEA, 2010; Klemp et al., 2015; Mayer et al., 2016). The interface of the system should be easy to use and clear, using human-centred design to create user-friendly incident reporting interfaces. This could be in the form of intuitive point and click, drop-down lists, and free text fields for reporters to use. With regards to language used, the nuclear power International Reporting System for Operating Experience (IRS) is operated in English (IAEA, 2010). In aviation, multiple languages are adopted, and contracting states may select one language to be adopted or translated into its own national language (ICAO, 2016), although having a coded taxonomy is desirable.

Table 2.8 Themes related to safety issue analysis

Framework facet	Descriptive theme(s)	Sub-themes	Supporting study/document
Safety issue analysis	Analysis and/or investigation of reported incidents	– Response, analysis and investigation to reported incidents	Abu Baker et al., 2017 IOGP, 2016 Vallejo-Gutiérrez et al., 2014 Wallace et al., 2009 Cooke et al., 2006 WHO, 2005b
	Common platforms for analysis of data	– Simple platform for input and analysis – User-friendly design – Consistency or selection of language input	ICAO, 2016 Mayer et al. 2016 Klemp et al., 2015 IAEA, 2010

2.6.4.4 Solution development and system improvement

The development of solutions and system improvement was the next facet of the framework by Benn et al. (2009) evaluated in this framework method. This theme provided an insight into when analysis and solution development may be justified, and the extent of solutions required (Table 2.9). For instance, developing targeted responses to identified weaknesses was considered a short feedback loop (IOGP, 2016), which was fundamental to correcting immediate safety concerns and risks or vulnerabilities within the system. This response can result in incident analysis or incident investigation, depending on the severity of the reported incident(s). Furthermore, the response at different operating levels (i.e.,

local, national, and international) might be initiated by the responsible member(s) of staff, risk manager(s), agency, or, possibly, an international organisation.

The approach to incident analysis varies depending on the operating level and the severity of the reported incident (IAEA, 2010, ICAO, 2016). Indeed, the framework of Benn et al. (2009) suggests that local clinical work systems feed into organisational systems and then regulatory level systems, reflecting a comparable hierarchy in local and national systems. However, a wider analysis of data was considered essential in most studies (WHO, 2005b; Vallejo-Gutiérrez et al., 2014; Abu Baker et al., 2017), even where the causes of underlying factors may be easily identified. Therefore, some discrepancy exists in the nature of the response and the need for extensive analysis of data to promote learning, particularly where immediate action may be needed to address vulnerabilities in a system.

It was acknowledged that some reported incidents might require immediate action, even before analysis or investigation are initiated (WHO, 2005b). However, to sustain the effect of any action taken, the organisation must also introduce long-term actions derived from the analysis of the incident (WHO, 2005b). The short-term actions aim to remedy any identified systemic weakness until the effect of the long-term actions takes over to make the systemic improvement sustainable in the future (WHO, 2005b; Abu Baker et al., 2017). Learning happens when an organisation acts in response to identified systemic weaknesses and when such actions are sustainable in the long term (IOGP, 2016). In order to ensure the sustainability of corrective actions, organisations should set short-term actions along with longer-term actions so that short-term corrective actions cover the gap that might be left before the effect of longer-term action is visible or measurable (IOGP, 2016).

Table 2.9 Themes related to solution development and system improvement

Framework facet	Descriptive theme(s)	Sub-themes	Supporting study/document
Solution development and system improvement	Targeted actions in response to identified systemic weaknesses	– Local implementation of changes with limited analysis – Wider analysis of data	Abu Baker et al., 2017 IOGP, 2016 Vallejo-Gutiérrez et al., 2014 WHO, 2005b

2.6.4.5 Feedback modes

The framework of Benn et al. (2009) recognised five feedback modes (bounce back, rapid response, raise risk awareness, inform staff of actions taken, and improve work systems safety). These modes were not exactly mirrored within the identified literature, but there was a clear recognition that different modes of feedback may be valuable for safety reporting (Table 2.10). It was viewed as a highly desirable feature of such a system by most of the included references (14 out of 20, i.e., 70%).

At the local level, feedback mechanisms include feedback on error analysis results, which can be in the shape of monthly e-mail newsletters, reports, alerts, and recommendations. At the national level, feedback can take the shape of patient safety alerts (Mayer et al., 2016) or periodic reports of lessons learnt from reported patient safety incidents, which might benefit local organisations as well. There is a paucity of information with regards to feedback at the international level.

One descriptive theme suggested that sharing of knowledge generated with stakeholders and users of the system is important. Both the importance of learning about system improvement and the dissemination of lessons learnt were noted. Different levels of feedback were acknowledged, depending on the need for improvement at a local, national, or wider level (WHO, 2005b), while targeting feedback to frontline staff, upper management or wider policymakers and leadership may require different strategies, although these were not explicitly defined (WHO, 2005b; IOGP, 2016).

The feedback mechanism was often considered one of the most important components of the system within the identified literature (WHO, 2005b; Cooke et al., 2006; Wallace et al., 2009). Feedback was considered at either local or national level, while no studies explored how international feedback may be used in practice. Feedback may be viewed as a closed-loop, where it starts from the identification and reporting of a patient safety incident, response in the shape of analysis and/or investigation, corrective actions taken, and ending with the lessons learned being shared. This process is where the feedback loop is said to be closed. However, it is critical to note that “closing the feedback loop” does not indicate the end of feedback (WHO, 2005b; Wallace et al., 2009). Thus, feedback should be viewed as a continuous cycle (Cooke et al., 2006). Feedback incorporates both action and information outputs that are aimed at improving patient safety through raising patient safety awareness (WHO, 2005b) and improving the delivery of care at all levels - local, national, and international (WHO, 2005b; Cooke et al., 2006).

Table 2.10 Themes related to feedback modes

Framework facet	Descriptive theme(s)	Sub-themes	Supporting study/document
Feedback modes	Sharing of generated knowledge with system users and stakeholders	– Learning levels for systemic improvement – Dissemination of lessons learnt	Abu Baker et al., 2017 IOGP, 2016 Vallejo-Gutiérrez et al., 2014 Wallace et al., 2009 Cooke et al., 2006 WHO, 2005b
	Feedback mechanisms throughout the system	– Local feedback mechanisms – National feedback mechanisms – International mechanisms (theoretical)	Wallace et al., 2009 Cooke et al., 2006 WHO, 2005b

Only three safety-critical industries' relevant references discussed feedback at the international level; civil aviation, nuclear power, and oil and gas (ICAO, 2016; IAEA, 2010; IOGP, 2013).

In the aviation industry, lessons learnt from particular incidents or accidents are shared between member states if it is relevant (NASA, 2018). The nuclear power industry allows for an efficient feedback process that takes many forms and is usually conducted through the IRS National Co-ordinators' meetings. Again, there are no specific criteria for what constitutes relevant feedback to the international community or what should be shared with the international community. In the oil and gas industry, feedback takes the form of an annual report that provides the information necessary to analyse incident trends within the industry, benchmark performance, and identify activities and subject areas where concentrated efforts can be made to have the greatest improvements. There was no mention of any alerts with regards to incidents that might require international attention or immediate action to prevent occurrence on an international scale, in contrast with the aviation and nuclear power industries, which would be expected within the conceptual framework adopted in this paper (Benn et al., 2009).

2.6.5 Additional themes outside of the framework of Benn et al. (2009)

This section highlights some of the themes that emerged from the literature that fell outside of the framework by Benn et al. (2009). Specifically, two themes emerged that have the potential to inform how international incident reporting and learning may occur in healthcare and other safety-critical industries: factors enabling the transfer of learning

between organisations at the international level, and organisational culture as a factor underlying reporting and learning. These themes are termed ‘novel themes’ as they go beyond the work of Benn et al. (2009) and represent themes with specific relevance to the international safety context.

2.6.5.1 Factors enabling the transfer of learning between organisations at the international level

The first novel theme related to enabling factors for the transfer of learning between organisations. While the Benn et al. (2009) framework acknowledges the aggregation of data and regulatory practice on a national level, there is a lack of clear appreciation of the transfer of learning at the international level. Hence, this was considered a novel insight, and the analytical theme was important in understanding how learning might be shared at an international level (objective 2).

Three descriptive themes were included within the framework facet ‘Key enabling factors for the transfer of learning between organisations at the international level’ (Table 2.11).

2.6.5.1.1 Methods that facilitate the sharing of lessons learnt from reported incidents with relevant stakeholders

The first descriptive theme includes two interrelated elements; feedback mechanisms, and dissemination of lessons learnt with relevant stakeholders. Throughout multiple included studies, feedback mechanisms have already been established as a critical component of IRLSs, and it plays a role in the transfer of learning from one organisation to another at multiple operating levels (NASA, 2018). Sharing of lessons learned at one organisation at local, national, or international levels is essential to the transfer of learning. This can be integrated within feedback loops or separately via a range of methods, including alerting messages, periodic newsletters, bi-monthly summaries, annual statistics, and more (WHO, 2005b; Expert Group, 2006; NASA, 2018). Wider dissemination of safety information and recommendations can be done anonymously, but the emphasis remains on sharing of lessons learned and experience gained at local, national, and international levels (Mayer et al., 2016).

Table 2.11 Themes linked to enabling factors for the transfer of learning between organisations

Framework facet	Descriptive theme(s)	Sub-themes	Supporting study/document
Key enabling factors for the transfer of learning between organisations at the international level	Methods that facilitate the sharing of lessons learnt from reported incidents with relevant stakeholders	– Sharing and communicating lessons learned with relevant stakeholders – Feedback mechanisms	NASA, 2018 Mayer et al., 2016 ICAO, 2016 Reed et al., 2014 IAEA, 2010 Benn et al., 2009 Cooke et al., 2006 Expert Group, 2006 WHO, 2005b
	Common communication networks and platforms	– Communication between organisations via networking channels – Shared online database of reported patient safety incidents	Abu Baker., 2017 ICAO, 2016 Klemp et al., 2015 Reed et al., 2014 IOGP, 2013 IAEA, 2010 Benn et a., 2009 Expert Group 2006
	Common reporting data formats and classification	– Standardised incident reporting formats – Common standardised classification system – Common language used in operating the system – Common defined terms used within the reporting system	Howell et al., 2017 ICAO, 2016

2.6.5.1.2 Common communication networks and platforms

The second descriptive theme includes two associated elements of an IRLS: a shared database, and common communication networks/platforms. At the heart of the system, one of the main features that facilitate the transfer of learning at all levels is having an online shared database. This could be a shared electronic online database of incidents or solutions/lessons learned (ICAO, 2016). Building on common features, novel features may include the potential for incidents in the database to be aggregated and analysed to see common themes that might be happening at a similar operating organisation at all levels. Alternatively, a database of solutions (e.g., corrective actions taken to prevent incidents from recurring [WHO, 2005b]) might benefit organisations at different operating levels, especially national and international levels. A common framework for the IRLS was emphasised as a key factor in the transfer of learning between organisations at various operating levels, and especially at the international level, where having a common framework for a shared IRLS means that the system's operation would be the same

regardless of the country or operating level (IOGP, 2013). This would mirror the national or local framework for the reporting of incidents, which may be helpful in shared learning for patient safety (IOGP, 2013).

2.6.5.1.3 Common reporting data formats and classification

The third descriptive theme highlights the importance of common reporting data formats and classification system. The important elements of reporting include standardised incident reporting formats, common taxonomy, definitions of terms used and language(s) of the system at national and local levels. The importance of standardisation is seen when it comes to reporting incidents, minimal information set that is standardised and consistent is required. Further, a common classification system that is coded facilitates the transfer of learning because the codes are universal and can be interpreted by organisations in different countries using different languages. This is especially applicable at the international level, as evident from the two main references that cited this key factor, which is used in civil aviation and nuclear power industries (ICAO, 2016, IAEA, 2010). This may be valuable in promoting consistency in reporting and a shared understanding of incidents.

A common taxonomy that is simple and effective is one of the top four desirable and/or essential features of IRLS (highlighted in 60% of included references). Having a coding taxonomy with fixed field codes combined with narrative text yields qualitative data for further secondary analysis. Moreover, the three international IRLSs in safety-critical industries (IAEA, 2010; ICAO, 2016; IOGP, 2013) along with the European IRLS in healthcare (Klemp et al., 2015) represented in the included references have a common taxonomy, two of which have a coded taxonomy, whereby incidents reported are assigned to specific codes based on a recognised codification system or scheme. This contrasts with a non-coded taxonomy, which may be based on descriptive terminology applied to safety reporting and various hierarchies used to classify errors (Dovey et al., 2005). Similarly, identified national IRLSs in the literature (Vallejo-Gutiérrez et al., 2014; Mayer et al., 2017; Abu Bakar et al., 2017; NASA, 2018) have a common taxonomy in their systems, and the WHO (2005) also emphasised the importance of having a common taxonomy.

Another relevant element that is related to classification systems is having common standardised key definitions (WHO, 2005b; ICAO, 2016). This would help reporters to know what to report, whether they are in the same organisation or at another national or international organisation. Finally, another element would be the operating official

language(s) of the system, because using the same language at different levels, especially at the international level, would make the transfer of learning easier.

Table 2.12 provides a summary of the three international IRLSs identified in the literature of safety-critical industries and aspects of the reportable events and taxonomies employed in these systems. Table 2.13 highlights multiple features of identified national IRLSs that could facilitate the transferability of the systems between nations, providing an international perspective on the use of these systems in practice.

Table 2.12 International IRLS from safety-critical industries and their criteria of reportable incidents/events

References	IRLS	Reportable events
ICAO, 2016	ICAO Accident/Incident Data Reporting (ADREP) system	Incidents/events that could affect aviation safety. A list of examples of reportable serious incidents is provided.
IOGP, 2013	The International Association of Oil & Gas Producers (IOGP) incident reporting system	Detailed categories for reportable events along with definitions are provided. These include work-relatedness, occupational injury, occupational illness, process safety event, and company/contractor activity
IAEA, 2010	The International Reporting System for Operating Experience (IRS)	Incidents/events and operating and construction experience information of safety significance for the international community in terms of causes and lessons learned. Reporting categories are supplied to highlight what should be reported.

Table 2.13 Transferability of IRLS across settings – potentially internationally applicable features

References	Transferability
NASA, 2018	– Model is utilised internationally in the aviation community – Being applied to other disciplines, e.g., healthcare, railroad, maritime, security, firefighting, law enforcement, and others
Holmström et al., 2015	– Findings can be valuable at the international level
Klemp et al., 2015	– Designed to be implemented across Europe, and trialled in Greece and Poland – Can be easily implemented and adapted to suit individual needs
Holmström et al., 2012	– Experiences and lessons learned are transferrable to other countries
Benn et al., 2009	– Grounded in practical experience across domains, not systematically evaluated in healthcare
Cooke et al., 2006	– Adaptable and generalisable to other programmes at other healthcare institutions – Can be modified and adapted to the requirements of other healthcare delivery processes

2.6.5.2 Organisational culture as a factor underlying reporting and learning

The second novel theme identified relates to whether the culture of the organisation is supportive of patient safety and reporting of incidents. The organisational culture has three interlinked elements, culture, fear, and training/education (Datena et al, 2011; Reed et al., 2014; Vallejo-Gutiérrez et al., 2014; Holmström et al., 2015; Mayer et al., 2016). As an enabling factor of incident reporting and implementation of an IRLS, having a blame-free, patient safety reporting culture is essential for the success of the IRLS and the improvement in patient safety as a whole. This was also noted by Benn et al. (2009) in their framework, whereby policies need to exist to reflect an organisational commitment to safety to promote transparency and minimise blame. One of the challenges in implementing a new IRLS is the existing reporting culture or having different cultures within the same organisation. Furthermore, fear of disciplinary, legal, or punitive actions was viewed as a hindering factor (Vallejo-Gutiérrez et al., 2014; Reed et al., 2014; Holmström et al., 2015; Mayer et al., 2016).

The final element of organisational culture is the training and education of staff and potential users of the IRLS (Holmström et al., 2015; Mayer et al., 2016). It might be argued that proper training and education on the importance of patient safety and incident reporting might change organisational culture into a blame-free, patient safety culture that encourages reporting for learning and improvement of the care delivery system. This could

also eliminate any fear element that is associated with blame or punitive cultures (Holmström et al., 2015; Mayer et al., 2016).

From a broader perspective, organisational culture may be influenced by legislative factors linked to incident reporting and safety, as noted by Karsh et al. (2006). Where support from legislators and professional bodies is presented, this may facilitate a top-down dissemination of culture supporting safety and incident reporting (Karsh et al., 2006; ICAO, 2016; Abu Baker et al., 2017). Furthermore, legislative support is needed to ensure that incidents reported are not negatively linked to organisational performance and linked to punitive measures (Vallejo-Gutiérrez et al., 2014). As with the need for staff confidentiality, similar assurances of a no-blame approach to incident reporting are needed on a wider level to facilitate openness in cultures (Holmström et al., 2012).

2.7 Discussion

2.7.1 Main findings

The findings of this review were that the framework of Benn et al. (2009), related to national learning for patient safety, is broadly consistent with the literature on patient safety from healthcare and other organisations. Key features of a reporting and learning system for patient safety include a system that facilitates incident reporting, which is accessible to staff, with the ability to report incidents in a confidential, anonymous and secure manner. These systems should be aligned with identifying safety incidents and then facilitating practice improvement to avoid these incidents in the future. In addition to Benn's framework elements, the review also identified two novel themes that may apply to the international learning perspective: transferability of learning across settings/nations, and the influence of a culture of safety on incident reporting. Specifically, a range of factors was associated with the transferability of learning across organisations. These factors included methods that facilitate the sharing of lessons learnt from reported incidents with relevant stakeholders, common communication networks and platforms, and common reporting data formats and classification systems. Indeed, the need for common platforms, inputs, and outputs was apparent, emphasising the value of a shared taxonomy for safety and incidents. The importance of organisational culture was also evident as this influenced safety and incident reporting at the level of the individual, organisation, and potentially at the wider levels, where national and organisational reporting systems may be influenced by legislation and professional oversight.

2.7.2 Comparison with the wider literature

The first objective of this review was to map out the constituent elements of a learning system, and their ways of functioning. The elements were closely aligned to the function/purpose of an IRLS. Importantly, the literature suggests that the purpose of an IRLS should broadly be aligned across local, national, and international settings, with the aim to report incidents accurately and to facilitate learning that promotes safety. The incident reporting process was considered an integral part of any system operating at the national or international level. While it was acknowledged that there was a need for a clear incident reporting process within the organisation, variability in types of incidents and severity that should be routinely reported and variability in types of incidents actually reported were observed.

For instance, a systematic review of incident reporting systems and processes in emergency departments highlighted that systems vary across settings based on their focus on determining aetiological factors, the adoption of systematic approaches to data analysis, and the focus on using data to improve individual performance or clinical processes/system improvements (Brunsveld-Reinders et al., 2016).

Variability in data analysis approaches may reflect variation in data sources and definitions used for incidents (Stavropoulou et al., 2015). The present review supports the importance of a shared taxonomy for data and consistency in definitions of incidents and the sources of data reported. The findings noted that common reporting data formats and classification were considered important features of an IRLS (Howell et al., 2017; ICAO, 2016). The main keywords identified were “common” and “shared”, which emphasised the importance of member states using the same systems which have their own taxonomy and definitions of reportable patient safety incidents. Another important factor in the literature is that the taxonomy should be coded and universal so that states with different languages can easily use it (Howell et al., 2017; ICAO, 2016). Such standardisation of terminology and data may be invaluable in promoting more consistent approaches to developing learning from the data, as this may facilitate the pooling of data and synthesis across settings (Health Quality Ontario, 2017; Gates et al., 2019). Furthermore, when incidents are reported, defining key criteria that should be included within the report should be encouraged to avoid incomplete data sets and variations in reporting practice, even within an established taxonomy. It has been observed in the literature that incident reports are not uniform and may contain different types of data categories, such as aetiological factors (Carson-Stevens et al., 2016), which may limit the value of reports.

The second objective of this review was to identify how existing organisations learn from safety incidents and transfer learning from one organisation to another, including multi-organisational sharing. The development of solutions to problems linked to incidents and dissemination of knowledge was also considered in the findings of this review, broadly aligning with the framework of Benn et al. (2009). These factors, as identified from included source studies, pertaining to all operational levels and supporting the findings of other studies, included methods that facilitate the sharing of lessons learnt from reported incidents with relevant stakeholders (NASA, 2018; Mayer et al., 2016; ICAO, 2016; Reed et al., 2014; IAEA, 2010; Benn et al., 2009; Cooke et al., 2006; Expert Group, 2006; WHO, 2005b), and common communication networks and platforms (Abu Baker., 2017; ICAO, 2016; Klemp et al., 2015; Reed et al., 2014; IOGP, 2013; IAEA, 2010; Benn et a., 2009; Expert Group 2006). Engaging stakeholders and promoting learning that can be shared across settings is a complex process of knowledge dissemination, which may be lacking in modern healthcare settings (Health Quality Ontario, 2017).

The third objective of this review was to explore the purpose and anticipated challenges and opportunities for an international patient safety learning system in healthcare, based on data from safety-critical and healthcare industries. As noted in the first objective, the purpose of an IRLS is to collate data and provide a basis for ensuring learning that can avoid future safety incidents, which is true for local, national and international systems. Challenges to an IRLS on an international level include those related to generating shared taxonomies of data, ensuring consistency in data reporting practice, and ensuring consistency in learning outputs. It has been noted that within IRLSs, feedback mechanisms are not consistently employed in practice, which may reduce the ability to learn from incidents and to target stakeholders appropriately (Ahluwalia & Marriott, 2005). Furthermore, a systematic review of IRLSs used in healthcare suggested that not only is feedback often limited, but this may not be considered the goal of an IRLS (Nicolini et al., 2011). Indeed, IRLS may be driven by an ‘audit culture’, which may reflect a surveillance approach rather than a learning approach to incident reporting (Nicolini et al., 2011; Stavropoulou et al., 2015). This would not be consistent with learning and knowledge dissemination and may reinforce challenges related to incident reporting, including the perception that incidents may be used to target individuals in a punitive manner (Waring et al., 2013; Freeman et al., 2016).

The final review objective was to assess the projected applicability/ transferability of the key characteristics and functions of an international IRLS in the healthcare context, which

also highlights some challenges and limitations to the use of an IRLS in current practice. The essential features of an international IRLS in the present review included established feedback mechanisms, anonymity and confidentiality of incident reporters, a clear data analysis process, and a clearly defined set of data to include in the system. These features are largely consistent with those outlined by Benn et al. (2009). However, importantly, there is a paucity of information with regards to feedback at the international level, the criteria for sharing feedback are not addressed, and there are no specific criteria for what constitutes relevant feedback to the international community, or what should be shared with the international community (Holmström et al., 2015; Holmström et al., 2012; Reed et al., 2014; Klemp et al., 2015; IAEA, 2010; Expert Group, 2006; WHO, 2005b).

Similarly, the anonymity and confidentiality of reporters were not clearly discussed in the included literature for an international IRLS. There were no clear definitions or details about how and who should have access to an international IRLS operated in healthcare. Avoidance of a culture of blame is imperative to encourage incident reporting (Reed et al., 2014; Cooper et al., 2017) and therefore protecting the identity of those reporting may be important, as well as aligning any incident analysis outputs with constructive system or process changes, and not punitive action against the individual (Weaver et al., 2021). On an international level, it is not certain who would be accessing information and how trans-national information sharing may maintain rigid standards of confidentiality and nationally variable standards of data protection. No clear information on legislative support of incident reporting by governing bodies was provided either (Holmström et al., 2015; Holmström et al., 2012; Reed et al., 2014; Klemp et al., 2015; IAEA, 2010; Expert Group, 2006; WHO, 2005b).

Gaps in the present review and in the wider literature are apparent, which highlight the need for further study in the field. For instance, there is no list of reportable patient safety events that would be deemed essential for learning at the international level in healthcare (ICAO, 2016; IOGP, 2013; IAEA, 2010). It is, therefore, not clear how this might be relevant on the international level, as the discussion in the included healthcare industry references was based on the local/national levels, with emphasis on the local level (Holmström et al., 2012; Reed et al., 2014; Klemp et al., 2015). At the international level, it is not clear about the type of database best suited for a reporting and learning system, and certainly, for an international IRLS operating in healthcare, this should be determined beforehand. For example, whether to have a database of safety solutions, a database of internationally relevant reported incidents, or both. There is also a dearth of information on

the method of analysis that should be adopted at the international level, especially in healthcare (Reed et al., 2014). Also, the mechanisms for setting priorities at the international level in healthcare with regards to what should be shared with the international community or what is relevant for international learning are not clearly defined (Holmström et al., 2015; Klemp et al., 2015; Reed et al., 2014; Holmström et al., 2012).

The lack of literature in the area of learning and knowledge mobilisation in the healthcare industry was notable. This was expected while designing the review, and it is one of the reasons why the review sought to cast a wider net to capture as much relevant literature as possible in this area of study. Nevertheless, the included references did answer the review questions with regards to constituents of IRLSs and their definitions, functions and features, enablers and barriers for an international level IRLS but the answer to the transferability of IRLS in the healthcare sector at the international level could not be sought.

2.7.3 Recommendations and future research

One of the main reasons for doing this review was a lack of literature in the field of learning regarding the potential role of an international IRLS in healthcare. Unfortunately, due to the lack of reliable literature, a clear answer regarding transferability and applicability for IRLS at the international level in healthcare could not be sought. Henceforth, in the future, the findings of the literature should be assessed for transferability and relevance to healthcare, especially by healthcare experts. In particular, patient safety incidents/risks that are relevant for international sharing and learning should be further explored with safety-critical and healthcare experts.

However, the review findings highlight some important areas where the key concepts included in existing models of incident reporting and learning could be advanced or adapted to apply to the international context. Specifically, international systems rely on appreciation of learning transfer across organisations, which extends to the nature of the outputs, how stakeholders are targeted, and the taxonomies employed to promote data sharing, analysis and learning. Although objective evaluation of such taxonomies is lacking in the current knowledge base, there is a clear need for validation and exploration of systems (e.g., WHO, 2009) on an international basis when attempting to transfer learning.

Another important insight from this review is that there remain a lot of gaps in the evidence base regarding how international systems of patient safety need to operate. This includes the need for clarity regarding key purposes of these systems, their features, and

identification of potential barriers and facilitators to their implementation. Specifically, the assessment of barriers and facilitators to learning across organisations will be an important point to explore in the future to fill the gaps in the knowledge base exposed in this review. These issues will be examined in Chapters 3 and 4 of this thesis.

2.7.4 Strengths and limitations

This review was based on a clear protocol and a defined scope, which is a strength of the review process, as noted in AMSTAR-2 criteria (Shea et al., 2017). The review used a range of databases and sources of information, which had the potential to maximise the data identified and thereby provide a comprehensive assessment of the evidence to date. Indeed, a strength of this review is the inclusion of a broad variety of data from both grey and journal-based literature. The inclusion of grey literature was considered appropriate to broaden the availability of literature and may have overcome publication bias to some extent, as the inclusion of unpublished literature and literature outside of academic journals may be less prone to bias that favours the presentation of 'positive' research findings (Booth et al., 2021). This was also particularly important, as journal articles tended to focus on local or national safety and learning perspectives, while grey literature had a broader and more relevant focus on international and national level IRLS and the relationship between levels.

The review also benefitted from the use of two reviewers to select and appraise the studies independently, which increases the reliability of the findings (Cooper et al., 2018). The studies identified and the critical appraisal of those studies was presented in detail to allow for transparency in the conclusions drawn within the review process, adding to the reliability of the review (Cooper et al., 2018). Furthermore, any risk of bias in the included studies was clearly presented and considered when interpreting the findings. The use of a framework synthesis method was justified in this review, given the heterogeneity of the dataset and the relevance of applying a model/framework to the review topic. Therefore, the underlying review methods, the registration of the review protocol with PROSPERO, the use of the PRISMA checklist and statement, and the adherence to clear frameworks and criteria guiding study selection, critical appraisal and evidence synthesis were strengths of the review.

Despite these strengths, the review has some important limitations. Firstly, there was a paucity of data specific to healthcare reporting and learning systems in patient safety contexts, facilitating the need for the inclusion of data from other safety-critical industries. While the inclusion of data from other industries was justifiable in promoting learning

relevant to healthcare, the diverse nature of these industries and their contrasting nature compared with healthcare organisations is an important point to note when interpreting the dataset.

The paucity of literature may also reflect limitations in the search strategy. One reason for the lack of literature might be that such terms/concepts are being used only recently within the scientific literature, as opposed to the time when the included references were published. Furthermore, variable taxonomies and nomenclature applied to safety incidents and associated factors may not have been captured in all search terms employed.

Another limitation pertains to the quality of the evidence identified. While the grey literature was considered to have a uniformly high level of quality, journal-based articles had a range from low to high-quality levels (five articles were graded as high, four were graded as moderate, and one was graded as low). This suggests some variability in the quality of the evidence, which may limit the validity of the review findings, or could be the result of the variability of the quality assessment tools used which might have affected the scoring as grey literature was assessed using a different tool than journal articles (Booth et al., 2021). The limitation here is that there is a paucity of available and reliable data at the international level to provide an answer to the most important question, which seeks an answer to the applicability of IRLSs at the international level in healthcare.

2.8 Conclusion

The systematic review thus provided some key evidence related to all of the defined objectives of the review, including purpose, components, barriers/enablers, functions and features of international IRLS. However, some gaps were noted in the knowledge base, particularly regarding the transferability/applicability of IRLS at the international level in the healthcare sector. This reflects a paucity of literature on this subject at the international level. Therefore, further research in this regard is warranted, particularly exploring and formulating a clearer context of patient safety IRLS in complex healthcare systems at the international stage. This could be further explored with safety-critical and healthcare industry experts.

Chapter 3 – Exploring the prospect of an international patient safety learning system with safety-critical industry experts: semi-structured key informant interviews

3.1 Introduction

This chapter presents a qualitative interview study to fill the gaps in the literature, focusing on the key purpose, functions, features, and practicalities of an international incident reporting and learning system (IRLS). The previous chapter identified components of a potential international IRLS, the transferability of concepts related to IRLS for individual countries, and factors affecting the functioning of an IRLS, including barriers and enablers. There were, however, several unanswered questions from the systematic literature review that relate to the applicability of some elements of an IRLS from other safety-critical industries into the healthcare sector (see section 3.2 for key questions). Expert insights have been shown to add value to the evidence base, providing unique perspectives and insights on topics that may be under-researched or novel in the field (Dewa et al., 2018). Conducting interviews with experts from different safety-critical industries was therefore considered to be an appropriate means to answer these issues. Indeed, the limitations of grey literature and published studies include the lack of data from a wide range of nations and a paucity of evidence on key areas. Obtaining expert opinions and insights can help to clarify any inconsistencies in the literature while providing an opportunity to meet gaps in the knowledge base. Furthermore, exploring expert opinions allows for a unique insight into their perceptions of an IRLS, which cannot be obtained from the literature.

The systematic literature review (SLR) identified several important gaps in the evidence base, which included a paucity of literature exploring how feedback (i.e., learning outcomes and strategies) on safety from the system to users is given at the international level, with most data emerging from three safety-critical industries (civil aviation, nuclear power, and oil and gas), rather than healthcare perspectives (International Civil Aviation Organization [ICAO], 2016). At the international level, it was not clear what characteristics of a database would be best suited for a reporting and learning system, particularly for an IRLS operating in healthcare.

The SLR also identified a number of other potential issues or relevance to likely IRLS-related processes, including:

- approaches to ensuring anonymity of reporters;
- the transparency of data and the purpose of data analysis in terms of the degree to which data are clearly linked to safety events and then used to derive learning outcomes;
- clarity regarding who can or should access such a system; and,
- standardisation of the reporting process, particularly the type of error, the clinical context, and the outcomes of that error.

Therefore, the empirical research described in this chapter aimed to explore international safety-critical industry experts' views and experiences of IRLSs. Figure 3.1 outlines where this interview study belongs in the exploratory sequential mixed methods design of the PhD.

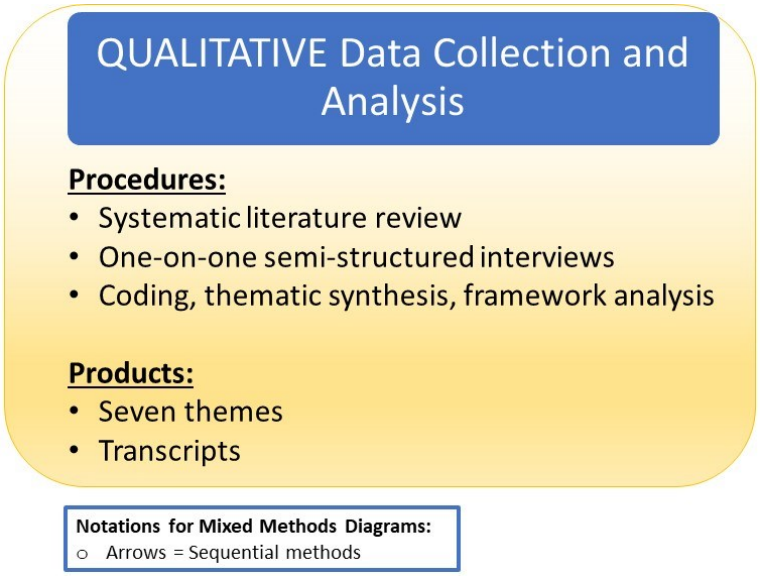

Figure 3.1 Outline of the current stage of exploratory sequential mixed-method design of the PhD (Creswell & Clark, 2018)

3.2 Key questions

From the systematic review, several questions remained unanswered or were unclear in the healthcare context and served as key starting points for discussion with experts. The following questions will assist in closing knowledge gaps identified by the systematic review, including:

- What can and should be the purpose of an international patient safety IRLS?
- What would be the key functions of an international patient safety IRLS?
- Related, what key features would the international patient safety IRLS serve, and to whom?
- What factors could enable the transfer of learning at the international level?
- What barriers and enablers are anticipated whilst setting up an international IRLS? And,
- What type of patient safety incidents are considered essential for sharing and learning at the international level?

3.3 Aim

The aim is to address the identified gaps in the literature. This will be done by developing an in-depth understanding of the purpose of and key requirements for an international patient safety IRLS from the perspective of experts from safety-critical industries.

3.4 Objectives

1. To develop an in-depth understanding of the purpose, key functions and features of an international patient safety learning system.
2. To identify the barriers and enablers to the set-up and transferability of an international patient safety IRLS.
3. To explore and identify patient safety incidents relevant to international sharing and learning.

3.5 Methods

3.5.1 Research design

To date, quantitative methods have primarily been used in patient safety research. Research designs have included case-control studies (Vetter et al., 2012; Kwon & Choi, 2017), randomised control trials (Hoffmann et al., 2014; Jha et al., 2015), and longitudinal studies (Lee et al., 2017; Gillespie et al., 2018), all of which focus on assessment of outcome variables to quantify the frequency of patient safety incidents and to determine the burden of patient safety incidents. These methods have also been employed specifically in the context of evaluating the use of IRLS to ensure patient safety, based on syntheses of such evidence (Baker et al., 2004).

Some researchers have found that qualitative methods are able to provide rich information to research questions relating to patient safety (Weaver et al., 2013). Hoff and Sutcliffe (2006) have also found that qualitative studies utilising methods of interviews, focus groups, and observation can capture the complexity of medical errors and lead to more person-centred, contextualised, and real-time study of medical errors and patient safety in day-to-day clinical settings.

The studies included in the SLR (presented in the previous chapter) reflected mixed methods, qualitative, and quantitative approaches to studying patient safety issues and the opportunities and challenges presented by IRLS in enhancing patient safety. Exploring these issues requires deeper insights into the practical issues facing individuals involved in patient safety processes in healthcare settings. A pragmatic paradigm is suited to this approach, as this focuses on establishing ‘what works best’ in the context of analysing a diverse range of data focused on solving a specific problem (Morgan, 2014; Morgan, 2007). Pragmatism is, therefore, the defined paradigm of this research, given the need to focus on solutions to implementing IRLS in practice.

Qualitative and quantitative research methods are ideally suited to the pragmatic paradigm, as both perspectives may offer insights into a phenomenon of interest (Morgan, 2014; Morgan, 2007). As quantitative data have been analysed as part of the SLR (Chapter 2), the use of qualitative data to build on the identified evidence gaps and to generate novel insights into end-user experiences and perspectives is justified. Therefore, the decision was taken to use a qualitative study approach to explore the perceptions of experts from the safety-critical industry regarding their experiences and attitudes towards IRLSs for improving patient safety.

Numerous qualitative research approaches may be employed in practice, each with relative advantages and disadvantages depending on the research question and context in which they are employed (Creswell & Creswell, 2017). Five key approaches have been defined by Creswell and Creswell (2017): narrative research, phenomenology, grounded theory, ethnography, and case studies. A phenomenological approach is best suited to the present study, as this provides a basis for exploring experiences and perspectives on a set phenomenon (i.e., IRLS for patient safety) and allows participant responses to shape the development of knowledge in this context (Silverman, 2020). Other approaches may be valuable in other contexts but would be limited in addressing this research aim. For instance, ethnography aims to describe group cultures, while narrative research is generally focused on telling the story of an individual's life. Similarly, grounded theory approaches seek to develop theories based on generated data, which may be abstract and not directly related to implementation on a pragmatic level. Finally, case studies provide an in-depth analysis of a specific case or episode but may lack generalisability (Creswell & Poth, 2016). Phenomenology has the potential to explore the values and experiences of a range of individuals exposed to the same phenomenon, allowing those experiences to be analysed in detail, with consideration also given to individual and group perspectives (Creswell & Poth, 2016).

Within the phenomenological approach, numerous methods for data collection and analysis may be used. Typically, data from individuals is required within this approach, highlighting the value of individual-level interviews or observations to address the research aim (Creswell & Creswell, 2017). This contrasts with focus groups which are commonly used data collection methods in qualitative research but typically have a limited depth of data collection from individuals (Carruthers, 1990). Consequently, focus groups do not allow for detailed exploration of individual views, which may be elicited by researcher-participant interactions during the interview process (Creswell & Poth, 2016). Furthermore, observations of participants may be a useful data collection method in practice but would be limited in this context. Observations would not provide a basis for understanding the perspectives and experiences of individuals included in the study. Rather, it would provide insights into individual behaviours and actions (Jamshed, 2014).

Interviews were therefore chosen as a means of collecting data in this qualitative study. Interviews have typically been categorised into three broad types: standardised open-ended interview, the guided semi-structured approach, and the informal, conversational style (unstructured) (Bearman, 2019). Unstructured interviews permit a large amount of

data to be collected, which is specific to the priorities and experiences of the participant but are hampered by the potential for a lack of focus on clear outcomes or agreed objectives, as used in a framework analysis approach (Whiting, 2008). In contrast, structured interviews may focus too heavily on pre-defined points of discussion, limiting the value of exploring opinions and experiences that may offer novel insights into a topic (DeJonckheere & Vaughn, 2019). Semi-structured interviews are commonly utilised in qualitative research and are the most frequent qualitative data source in health services research (Whiting, 2008). This method of qualitative research typically comprises of a scheduled dialogue session between the researcher or the interviewer and the participant. The conversation is guided by a flexible interview schedule as well as supplemented by comments, probes, and follow-up questions to explore the research questions. The researcher may explore participant beliefs, feelings, and thoughts on a particular topic (DeJonckheere & Vaughn, 2019).

3.5.2 Participants

In this qualitative interview study, the term ‘experts’ has been defined according to the definition of Skulmoski et al. (2007), as those with experience or knowledge of the issue under investigation, who are willing to participant, have the capacity to participate and can communicate sufficiently to participate. Knowledge and expertise are hard to define in this context (Trevelyan & Robinson, 2015), but research output, status, reputation, and professional characteristics reflective of an interest in the field of safety were used as markers of these key characteristics. Participants were therefore defined as experts based not purely on their length of time employed in the field, but using a multi-dimensional approach that encompasses interests, research outputs, and professional status. Table 3.1 outlines key knowledge areas and industrial domains that were expected to be represented in the semi-structured interviews during initial planning.

Table 3.1 Key knowledge areas associated with IRLS

Key knowledge area	**Industrial Domain**
Incident reporting/ learning systems	Civil Aviation Military aviation Rail Nuclear Power Maritime Chemical offshore & process Oil & Gas Production Healthcare
Other Safety-Specific Operations/ Research	

The expectation was to have a sample of 10-12 individuals and, based on an anticipated response rate of 50%, 21 experts were invited. The number of participants was deemed to be sufficient for data saturation, on the basis of previous studies based on semi-structured interview processes adopting similar protocols to the present study and within the theoretical literature (Walker, 2012; Nascimento et al., 2018). Data saturation provides a basis for ensuring that the data collected is sufficient to draw robust conclusions, where no new themes or information may be observed in the data (Fusch & Ness, 2015).

3.5.3 Recruitment and consent

Experts were identified through peer-reviewed publications that were relevant to the aims of the study. Although none of the experts were authors of the papers included in the systematic literature review chapter, most were published authors in a related field. Experts from safety-critical industries (e.g., healthcare, aviation, nuclear power, oil & gas) were invited, via e-mail, to participate in this study. The rationale behind this was to add further insight into and refine the themes that emerged through the SLR.

Every participant was provided with a participant information sheet to explain the purpose of the study and what was expected of them during their participation (see Appendix 3.1 for the sheet). The participant information sheet also covered topics such as their rights to withdraw and confidentiality. Participants were asked to give written informed consent, which was recorded on the consent form (see Appendix 3.2 for the consent form). Every participant was also informed of their right to withdraw from the study.

3.5.4 Ethics

Ethical approval was obtained from Cardiff University's School of Medicine Research Ethics Committee (SMREC Reference Number: 18/70). Ethical issues addressed in the design of the study include the requirement for experts to provide written informed consent, which was facilitated by an e-mail form. Experts were invited by e-mail to participate in the semi-structured interviews (see Appendix 3.3 for invitation e-mail). Potential participants were provided with a participant information sheet and a consent form (see appendices 3.1 - 3.2). Potential participants were given a deadline of up to 14 days to decide whether they wished to participate in the study and return the completed consent form to the research team. The data collected throughout this study were kept securely, in line with Cardiff University's Research Integrity and Governance Code of Practice, in password-protected computers using a secure Cardiff University server.

3.5.5 Reflexivity and power dynamics in the interview process

It is important to acknowledge the unique nature of the interviews undertaken in this study in relation to power dynamics and participant expertise. Typically, interview-based research is conducted with the researcher in the position of power or experience and the participants having a relative lack of power within the dynamic of the interview or research method undertaken (Haynes, 2012). The dynamics created during the interview may therefore reflect power imbalance and dynamics in multiple ways, potentially modifying the research outcomes as the interviewer has experience in completing interviews and guiding the data collection process (Dodgson, 2019). For instance, an experienced, expert interviewer will be able to guide the research process to obtain clear answers during an interview process, potentially aiding in exploring the specified aim or objectives of the study. This may be beneficial but, equally, the lack of power on the part of participants may limit exploration of more diverse issues or could potentially inhibit freedom of expression, unless steps are taken by the interviewer to promote sharing of ideas and freedom in this regard (Haynes, 2012).

The current interview-based study had different power dynamics, however, as the researcher was less experienced in the field of safety and in communicating complex ideas and knowledge mobilisation than the experts being interviewed. It has been noted in the literature that interviewing peers or experts may present additional challenges to the interview process and the need for reflection on the quality of the data set (Berger, 2015). For instance, the researcher may be less able (or confident) in directing the interview process or guiding exploration of prompts, deferring to experts and what they wish to discuss. This may reduce the quality of the data set and relevance to the study. Experts being interviewed may also exhibit defensive views of their profession or experiences, particularly if they feel scrutinised during the research process (Berger, 2015).

Reflexivity is a commonly used approach in qualitative research, which enables the researcher to appreciate their role and influence on data collection and analysis, as well as the role of the participant (Dodgson, 2019). By appreciating that the dynamics of power and interactions during the interview may guide discussions and information exchange, it is possible to avoid inhibiting opportunities for depth of analysis or freedom of exploration of topics (Dodgson, 2019). Therefore, a reflexive approach was adopted to ensure that a neutral researcher stance was possible, adhering to prompts to guide the interview process, while allowing the expert to express their views and opinions. Neutrality in this context was sought to counterbalance the potential for lively or detailed debates, which

may be the preference of elites in the field, whereby the researcher attempted to avoid expressing personal opinions excessively but aimed to provide a basis for discussion by engaging with topics and questions and seeking to explore issues further. Provided the researcher's role (and contributions) was considered in the analysis of the data set, this neutrality was critically explored and used to guide reasonable interpretation of the participant responses. Furthermore, the difference in power dynamics was considered throughout the analysis of the qualitative data to appreciate how knowledge may have been shared (from expert to novice) in this manner and how that may differ from other forms of interview information sharing. For instance, interviews may yield rich data where commonalities between researcher and participant are notable, including parity in experience, background, or knowledge; conversely, a lack of commonalities in this regard may impact the richness of data generated (Dodgson, 2019).

3.5.6 Data collection

An interview schedule was developed based on findings from the systematic literature review, as well as insights from the literature more generally, including Annexes 13 and 19 of the Safety Management Manual (ICAO, 2016; ICAO, 2013), research articles and relevant documents written by safety-critical industry experts. The interview schedule was piloted with a topic expert and was amended according to the feedback. This expert was someone working at the Division of Population Medicine at Cardiff University's School of Medicine and has a clinical and academic working experience in patient safety and learning systems. The interview schedule began with questions that first allowed the participant to introduce themselves and then focused on IRLS (e.g., purpose(s) of an IRLS, key functions and features of an IRLS). Questions then developed on topics of transfer of learning and feasibility (e.g., enabling factors and barriers to the setting up of an international IRLS). Due to the heterogeneity of the sample of interviewed experts, two versions of the interview topic guide were created (one for healthcare; one for other safety-critical industries), where the ordering of questions was changed based on industry (see Appendix 3.4 for interview schedule).

Interviews were conducted via phone/voice-to-voice interfaces/programmes (e.g., Skype). All interviews were recorded on a digital voice recorder and transcribed verbatim by a university-approved professional transcriber. The maximum interview time was 50 minutes, while the minimum was 31 minutes with an average of 35 minutes. Transcripts were proofread to ensure no errors were present in the transcripts, thereby ensuring the accuracy of the data set. Data collection was conducted between May and September

2019. The participants, when asked, agreed to be acknowledged in the write-up of this thesis and any future publication on the condition that their quotes are not directly linked to them (i.e., anonymised). Thus, all interview data were anonymised following the mapping and interpretation process of the data analysis phase, with randomly assigned non-specific identifiers used to refer to individual participants in the write-up.

3.5.7 Data analysis

Framework analysis was performed to identify descriptions, cases, and views that occurred and reoccurred in the interviews. Framework analysis is advantageous in qualitative studies, in that it allows specific questions to be answered, promoting a strong link between data interpretation and the aim and objectives of the research study (Ritchie & Spencer, 1994). The approach links with the pragmatic paradigm utilised in this study, which promotes specificity in addressing issues of IRLS implementation and potential challenges and barriers that need to be overcome.

The five stages of framework analysis were completed sequentially, according to the guidance of Ritchie and Spencer (1994). The first phase comprised a reading of all data (familiarisation), which provided a basis for subsequent analysis. A thematic framework was then constructed to guide the indexing and sorting of the data from individual studies in a manner similar to that seen in thematic analysis processes (stage 2). Key patterns of thought, expression, or ideas were coded and then compared across the transcripts using an indexing and sorting process and data summary and display process (stage 3). The qualitative data were imported into the computer package NVivo software (Ver 12.1.90) for indexing. This allowed for a simple comparison of the data set based on emerging findings within a thematic chart (stage 4). The context of the individual is maintained while adding to the thematic representation of data using this method (Ritchie & Spencer, 1994). The final stage involved mapping the data and interpreting the data, whereby the resulting material was reviewed for similarities, differences, definitions, and patterns of association (Ritchie & Spencer, 1994). This led to the generation of thematically linked topics for discussion, supported by individual data from participants.

In order to reduce the potential bias of subjectivity associated with coding and to facilitate the interpretation of findings, two transcripts (20%) were independently analysed and coded by one of the candidate's supervisors, Prof. Fiona Wood, who has an extensive experience in qualitative research. Discrepancies were resolved through discussion.

3.7 Results

Eleven experts were interviewed from a range of different industries. Table 3.2 outlines the industries, countries represented by the experts in this study in addition to their experience and expertise. The table is concise to prevent deductive disclosure of experts.

Table 3.2 Outline of Industries and Continents represented by the experts interviewed in this study

ID	Industry	Country	Experience/ expertise
P1	Healthcare	United Kingdom (UK)	National Health Service (NHS) management, worked for the National Audit Office and the Department of Health.
P2	Aviation/ Maritime/ Railway	Finland	Chief Safety Investigator.
P3	Aviation/ Healthcare	UK	Aviation: ex-Inspector of Air Accidents at a national aviation investigation organisation. Healthcare: Healthcare safety investigator at a healthcare safety investigating organisation.
P4	Healthcare	UK	Executive Medical Director and Deputy Chief Investigator at a safety investigating organisation.
P5	Healthcare	UK	Clinical Research Fellow in improvement science including health services, medical education, and patient safety.
P6	Healthcare	Australia	Programme Manager with an Institute of Health Innovation. Formerly Associate Director of Patient Safety at the National Patient Safety Agency (NPSA), London, UK. Former member of the WHO's development committee for the ICPS and a member of the Patient Safety Committee for a WHO Regional Office.
P7	Healthcare	UK	A Fellow of a professional society for ergonomists and human factors. Contributor for 'Policy and Practice in Health and Safety'.
P8	Healthcare	UK	Director of a Patient Safety Translational Research Centre in the UK.
P9	Healthcare	Canada	Focused research on quality improvement and patient safety. Professor and former Programme Lead of a Master of Science degree in Quality Improvement and Patient Safety.
P10	Healthcare	UK	Provides patients' perspectives to the study and was a member of an expert advisory group that helped pioneer a safety investigation organisation.
P11	Healthcare	Norway	Professor of Quality and Safety in Healthcare. Involved with a large research centre in Norway investigating quality and safety in healthcare.

Taken together, the collective characteristics and experience of the participants highlight the breadth of expertise in the sample.

The results are presented according to the main themes/topics derived from the collective data set, according to the framework analysis process (Ritchie & Spencer, 1994). A

thematic framework was devised and then used to index and sort data, summarise and display the data, and then map and interpret the findings. The mapping and interpretation process that proceeded from the charting of the data is visualised in Appendix 3.5. These stages yielded a total of seven topics (or thematically linked findings), which are critically discussed in this chapter. The seven identified topics are presented with quotations to support the interpretation of the analytical findings.

3.7.1 Purpose of an International Patient Safety IRLS

3.7.1.1 Facilitate learning

One of the major purposes of IRLS reported by participants was to facilitate learning. As most of the participants were from the healthcare sector, their views regarding the purpose of establishing an international platform for patient safety were aligned; the very purpose of such a system would be to learn from such incidents.

Some of the participants gave more detailed responses. Learning was viewed as a way of not only appreciating what is going on (raising awareness) but also in facilitating learning from errors specifically and using that knowledge to avoid errors for personal practice. The concept of learning from reported incidents was also noted consistently across responses. Participants expressed a desire to identify errors and use an understanding of how and why those errors occurred to avoid future events. Furthermore, participants recognised the value of the international learning process.

"I suppose, big picture-wise, it's learning from other people's mistakes before you make them yourself… and it's an awareness of what else is going on." (P3, Healthcare/ Aviation Expert)

"…but it's more of an overview to learn across countries…." (P11, Healthcare Exprt)

One participant reported that the main focus for the government in the context of safety and IRLS establishment was to use this learning for (re)designing processes, systems, rules, regulations, guidelines, or interventions.

"it would facilitate learning from events, patterns of error, learning from events, which could be fed back to redesign. So, learning can mean setting up bodies to deal with safety, it can also mean new procedures, new rules, new regulations, new Government guidelines" (P7, Healthcare Expert)

There appeared to be support for an approach centred on learning from events and patterns of events from another expert from the healthcare industry, who tried to explain the kind of learnings that comes from healthcare sector scenarios. The expert described a surgical error, for which, if details had been recorded, there may be some situation-based solutions that could be developed from this error. However, there was some recognition from this participant that the complexity of the healthcare system will inevitably lead to errors that are complex or multifactorial in nature.

> *"if it's a surgical incident, and how would we go about improving, fixing things, and I think there's also something about the fact that when things go wrong and they're sufficiently worrying or serious, they need to be looked at in more detail." (P1, Healthcare Expert)*

Learning in this context may therefore be viewed as a means of appreciating complexity in practice and unpacking the key elements that can lead to practical solutions. Furthermore, learning to avoid errors and to inform others was considered vital in transferring learning to a practical reality. Learning was therefore viewed as a process whereby issues were logged or identified and then used to prevent future episodes following analysis of those incidents. Learning reflected the ability to analyse and identify incidents but also to communicate them effectively to staff and then to devise strategies to prevent incidents in the future.

> *"...to establish and log what has happened... but also as a ... means to an end, in order to be able to explain to those involved, what's happened, and then if necessary, go on and identify learning that may be needed, in order to stop a repeat of whatever it is that's happened in, you know, in the future, or in other places." (P10, Healthcare Expert and Patient representative)*

Therefore, learning was conceptualised as a key purpose of an IRLS and was viewed as the strategies and processes that could be derived from reported incidents to drive the prevention of future occurrences in a practical manner.

3.7.1.2 Awareness and sharing of knowledge

The second identified sub-theme was "awareness and sharing of the knowledge". Many of the participants acknowledged that an IRLS would serve to generate awareness in safety-critical industries about clinical issues or areas of greatest risk. While raising awareness and sharing knowledge may be linked to the first sub-theme (facilitating learning), this is a

distinct sub-theme related to how information is shared and how raising awareness is a distinct purpose of an IRLS. One of the experts who had experience in both aviation and the healthcare industry felt that the basic purpose of any safety-critical industry is to make the stakeholders aware that such incidents do take place. The expert's insights here are useful due to their knowledge that an international IRLS in the aviation sector has already helped in developing awareness of the frequency of safety-related incidents internationally and also provided information about the frequency of similar events and consequently in establishing solutions.

> *"I suppose, big picture-wise, it's learning from other people's mistakes before you make them yourself. It is that sharing of information, and it's an awareness of what else is going on." (P3, Healthcare/ Aviation Expert)*

P11 felt that the use of an IRLS would be of immense benefit in documenting risk areas across the globe. Specifically, the value of an IRLS, according to this participant, is not to have a detailed insight into all types of safety incidents but to provide an overview of those seen across countries, suggesting that less detailed incidents may be prioritised in this learning context, to focus efforts to maximise learning.

> *"Yeah, I would say it is to get an overview of the most important, risk areas and be able to learn across countries I would say, it's not necessary to go into all kind of incidents…" (P11, Healthcare Expert)*

3.7.1.3 Improvement of the existing system

Participants felt that one of the important purposes of IRLS is to facilitate the improvement of the existing system of safety and incident reporting; the purpose is therefore to overcome gaps in existing systems and to overcome existing limitations. As mentioned previously, most of the experts believed that incident reporting in healthcare is at the nascent level at present and suffers from negligence. This belief stems from personal insights into inefficiencies in incident reporting and a lack of supportive cultures for reporting. Flaws in existing systems were commonly cited as reasons underlying negligence in this area, including a lack of consistency in reporting, fear of reporting (related to culture), and poor standardisation of error reporting terminology and practices. Therefore, any new system should provide an opportunity to not only appreciate areas for

improvement (i.e., flaws in existing systems noted above) but also provide a basis for improvement.

> *"And the analysis function has to be able to understand what's getting reported, understand what the common themes are in that, understand where the system has broken down. And then link to something that will improve that." (P4, Healthcare Expert)*

3.7.1.4 Detection of errors

Participants noted that an IRLS could help in identifying clinical errors and identifying the severity and types of harm. An IRLS would serve as an important step in examining safety incidents and eventually making corrective actions, allowing healthcare organisations and patients to benefit from the resulting actions. As mentioned previously, the healthcare industry is complex and diverse across nations. A strategic approach to incident or error detection was recognised to account for this complexity:

> *"One [approach] would be to identify levels and types of harm, how it might be different for different types of healthcare systems and what are the events that are occurring most frequently internationally. You could look at factors like how health services are delivered and whether types of adverse events or levels of adverse events differ" (P8, Healthcare Expert)*

This reflects the need for detailed analytical methods noted in the previous sub-theme. Similarly, the need for higher-level detection of errors to detect patterns was noted by the participants. This suggests that not only is the detection of errors important, but specific approaches to error detection may also be justified, including pattern recognition and how errors relate to the health service.

> *"it would facilitate learning from events, patterns of error…" (P7, Healthcare Expert)*

Furthermore, participants felt that IRLSs were most valuable in the detection of rare or uncommon events than common events. This is important as rare events may be associated with more significant consequences (due to the unanticipated nature of their occurrence) and may pose challenges for management due to their rarity. Indeed, in the automobile industry, rare event analysis is valued as a means of identifying factors

underlying such events, which may not be easily discerned at a local level due to the low incidence of these events (Theofilatos et al., 2019). Furthermore, the focus on rare events reflects a way of understanding events that are not widely known, maximising the value of an IRLS inclusive of a large population for learning.

> *"for the international level the main purpose is I think to detect, rare and emerging incidents so the purpose of the system is to be less focused on the really big problems that we know exist, but more on rare or emerging incidents" (P6, Healthcare Expert)*

3.7.1.5 Standardisation of IRLS

The safety-critical industry experts interviewed also felt that an IRLS could serve to standardise processes of how the incidents should be reported and the essential steps needed to tackle those incidents. Their views reflect their reported beliefs that an IRLS still needs to be established for the healthcare sector and that, as yet, not much is known about how such a platform would operate. Standardisation could reduce confusion between nations and thus was considered to be important by many participants:

> *"I think the standardisation. So, the way we see things reported is very non-standard. And that makes any sort of analysis difficult. So standardisation of the way things are reported." (P4, Healthcare Expert)*

> *"So in my view, you know again it comes back to this issue of trying to standardise how reporting is done to enable people to get the most benefit." (P9, Healthcare Expert)*

3.7.2 Key functions of an International IRLS

3.7.2.1 Relevant feedback

Of all the identified desirable functions of an international patient safety learning system, participants felt that the most important was a feedback mechanism. This reflected the experiences of all the experts with national systems, whereby national priorities and experiences influenced their perceptions and conceptualisations of the functions and outputs of an international system. The industry experts emphasised the necessity of establishing a feedback loop that would keep the frontline staff/stakeholders from the safety-critical industries, including the healthcare sector, informed about the progress of the reported incident and about the steps that were being taken to avoid further critical

situations. While this would operate on a national basis, it is important to consider that the international system has to provide outputs consistent with the establishment of feedback loops and local applications.

The necessity of a feedback loop was justified by one participant who mentioned that a feedback mechanism would ensure that the reporters realise what they have learnt from the incident is important and of value.

> *"And the other one being feedback to those that were involved, I think both are important, because the feedback to those that were involved in the original incident, is the moment where it can all be tested and um, the assurance that what has been learnt is correct and relevant is important too." (P10, Healthcare Expert and Patient representative)*

In addition to this, one participant stated that feedback mechanisms could prevent similar errors from occurring if frontline workers are kept informed about the incidents and their management. They explained the process with an example from the orthopaedic surgery department, in which reminding the surgeons about the previous errors just before entering the operation theatre could prevent their further recurrence.

> *"...you know to get information back to the front line whether it's an electronic board in theatres that says to the orthopaedic surgeons who are about to start their afternoon list you know guys these are the last five things that happened in your operating theatres you know when you've been doing your orthopaedic list, you know just mind out". (P1, Healthcare Expert)*

P8 (Healthcare Expert) reiterated the importance of feedback mechanisms but was not sure if feedback was consistently implemented. Other participants also felt that the reporters are not always kept informed of the progress of incidents under investigation, which is also a challenge in the reporting system.

> *"I think feedback mechanisms are critical in kind of local, reporting systems, but they don't work very effectively-currently I don't think and often that's, as you'll know from the literature, that's a complaint that reporters of incidents have that they report, they spend time, they make the effort to do it and they never hear anything about it again." (P8, Healthcare Expert)*

Relevant feedback would therefore be considered a crucial function of an IRLS and should be available to all stakeholders involved in patient safety reporting.

3.7.2.2 Investigative and Analytical function

It was noted that for any reporting and learning system to function properly, it requires investigative and analytical components. Participants considered that this would be equally applicable to an IRLS. This is inferred from the statement of P1, who reported this component as a top priority for the aviation industry. The aviation industry follows the routine of deeply understanding what actually went wrong in the process and then formulating the solutions and eventually disseminating the information internationally.

> *"You know one of the things that [company name] was always very good at was you know the safety data that they had, I mean they had some telemetry and the like from every flight you know, they would review and they would look at it in a searching way and they would talk through with, you know pilots. Now, I don't think we're, you know it's not the same in healthcare" (P1, Healthcare Expert)*

It was also noted that analysis relies not only on the use of specific systems to collect and collate data, but also on the way in which analysis of data can be facilitated. This observation is further supported by P6, who discussed the importance of a diverse range of experts to analyse data.

> *"It's really important in that mechanism, that risk surveillance and review and response mechanism, you need clinicians, subject matter experts and human factor experts to interrogate and understand the data." (P6, Healthcare Expert)*

It was perceived that individuals from different fields would think differently about a situation, and in the end, a holistic solution can be derived, which includes a range of possible factors which led to the error. This may be an important strategy for analysing data, but the practicalities of combining expertise from multiple organisations and organisational contexts were not considered by the respondents.

3.7.2.3 Generation of Safety Recommendations

Another important identified desirable function was the generation of safety recommendations in response to reported incidents. This reflects the translation of incident reporting into a process of learning and practice improvement, providing a crucial insight into the perceived utility of the IRLS approach. Indeed, an outcome-driven perspective was

favoured in the responses, reflecting the importance of learning and recommendations rather than overly detailed incident characteristics:

> *"It might be too much to include incident details. The most important substance would be the recommendations, short reasoning and the information where you can get more detailed information." (P2, Aviation/ Maritime/ Railway Expert)*

The need for recommendations to be generated from reported incidents was also noted as a means of preventing harm and reducing future similar incidents, further supporting the outcome-driven focus of the IRLS process:

> *"...learning system ideally comes up with recommendations around what to, how to reduce the incidents or reduce the harm associated with those incidents"(P6, Healthcare Expert)*

P9 (Healthcare Expert) mentioned the importance of having recommendations but, at the same time, commented on the importance of having quality standards maintained across the process.

> *"Well, the priority should be to establish some sort of you know quality standard around the reporting of incidents and the types of recommendations, the analysis process that leads to the recommendations" (P9, Healthcare Expert)*

It was also suggested that the use of an IRLS should be customised according to the country in which the error occurred. This approach seems reasonable, as the culture and handling processes across countries will differ.

> *"The recommendation that you might make or the expectations that you might have for one country and one healthcare system might be quite different from another" (P8, Healthcare Expert)*

3.7.3 Key features of an international IRLS

3.7.3.1 Broad database

Participants emphasised the necessity of utilising a database which is expansive in nature, encompassing multiple variables for incident classification, context, and details of the

incident and outcomes of that incident. The use of a broad set of variables or inputs for the databases would serve as a foundation for including the incidents that took place and learning from those incidents. They believed that this would help the healthcare industry to retrieve essential data to improve or mitigate safety risks. All participants believed that the database is one of the key features of learning systems, as documentation is critical for any system to work properly and to keep the process and improvements in check.

Furthermore, one of the participants suggested that the established database should include both the incidents that occurred at the organisation and the details of the solution to that incident.

> *"It [database] should include both ways [reported incidents and safety solutions]." (P5, Healthcare Expert)*

Likewise, one of the experts, P2, emphasised the importance of adding recommendations in the database which would be openly available to anyone. They further added that the interface and database should be simple enough for people from safety-critical industries to understand. The expert also mentioned that databases for national and international levels should be different, and only relevant data should be transferred to the international database. Their approach was that the platform should be as simple as possible with quality information being added to it.

> *"Well maintained database in which the recommendations are openly available for anyone. Recommendations should have a national follow-up in the country in which the recommendation was issued. Other countries should have a process to keep itself up to date of new recommendations. Interface and the database itself should be simple enough. National databases should be separate and only the relevant information should be transferred to the international database." (P2, Aviation/ Maritime/ Railway Expert)*

3.7.3.2 Easy Access

Another key feature on which most of the experts agreed upon was "easy access" to the established international database. A number of participants made it clear that if the reporter is not given easy access to the interface, with or without the password to the platform, the reporter would not bother to register the safety incident. They expanded on this by explaining that processes which are complicated are least likely to be perceived as

useful or accessible, as people are intimidated to use them, and they are often time-consuming. As a consequence, potential reporting events are lost to the system.

> *"Something that's easy for people to access, something that's intuitive for clinicians, other people, to understand. Something that's designed to make it, to make it easy to report in a standardised way." (P4, Healthcare Expert)*

P2 added that the interface for IRLS should be easily accessible and simple to use, but ideally operated by only a single responsible organisation in each country to facilitate the process. This suggests that each nation has some oversight regarding its reporting processes into a single system. The idea expressed here was to keep the responsibility in the hands of a single national organisation so that it operates in a much more managed way, while adhering to the principles of one system that has additional international oversight.

> *"Access should be open for everyone to read the information that helps organisations and individuals learn. Maybe there should be only one named responsible organisation in each country." (P2, Aviation/ Maritime/ Railway Expert)*

3.7.3.3 Universal guidelines and definition

The majority of participants were clear in their beliefs that there has to be an established, international, independent organisation which would set universal guidelines, which should be followed by all safety-critical industries, including the healthcare sector. These guidelines exist for other safety-critical industries, such as nuclear power and aviation, and their applicability to healthcare safety systems may be considered relevant. This view arose from a belief that a single organisation would bring more uniformity to the content of the system and more compliance with universal guidelines, making it easier for frontline workers across different countries to understand the reported incidents and effective ways to handle them. However, it was recognised that multiple organisations across nations would be needed and should work in concert to achieve a universal approach, while considering national variations in incidents and reporting.

The key principle was that a shared understanding of guidelines and definitions is needed to align these organisations:

"A responsible organisation should be found in each nation, the commitment of participants national processes to investigate and collect information, guidelines and definition which kind of information is wanted into the database." (P2, Aviation/ Maritime/ Railway Expert).

3.7.3.4 Simplicity of Reporting

Most participants agreed about the importance of having a sound mechanism of reporting. The first requirement of the reporting system is to make it as easy as possible. P1 mentioned a situation where one healthcare worker refrained from entering a safety incident in the national RLS because they found the mechanisms of reporting highly complicated and time-consuming. Similar views were discussed by participants in other safety-critical industries.

"She just come off shift and said, you know I'd sit down at the end of the day, and I spent ages you know messing around with DATIX reporting something. So, I think, if we want people to report readily, we have to make reporting straightforward and easy to do." (P1, Healthcare Expert)

Another participant mentioned that the details of the reporting document should be kept to a minimum. This would also mean limited sub-options, and opportunities for free text entry. Data entry could be further facilitated by ensuring that the system was accessible across numerous platforms, such as in the form of mobile applications, software designed for computers and laptops, and chatbots. One participant emphasised that the medium should be electronic to further simplify the reporting process and make the reporter feel more confident about its security. As discussed previously, the participants knew that any system would only be practised if people find it user-friendly.

"You want it to be fairly user friendly from that front with minimal pages, a minimum number of pages, minimum number of options, free text entries". (P5, Healthcare Expert)

3.7.3.5 Anonymity

Another desirable feature identified was the preference for reporter confidentiality and anonymity. All participants felt that anonymity builds the confidence of the reporting individuals, lowers the barriers in the reporting process, and aids the development of a

blame-free culture. However, some of the participants felt that being explicit about the location of the incident would be of value.

> *"I think they should be anonymous, or I think people should have the option to make them anonymous. I think the names, and the location, apart from maybe the country where it happened, isn't particularly relevant". (P3, Healthcare/ Aviation Expert)*

Similarly, P2 (Aviation/ Maritime/ Railway Expert) stated

> *"I'd prefer anonymity. Anonymity lowers the barriers in reporting. This way all information is better handled, available and easier to share when there are not restricting confidentiality issues."*

3.7.3.6 Database updates, sharing and standardisation

Most of the participants talked about the need to keep the database updated. This practice would ensure that contemporaneous data would be readily available for reference. However, one of the participants could not decide if the established database should include only the incidents that occurred at the organisation, the solution(s) for reported incidents, or both. The characteristics of a good database require that the development and updating of the database should be based on multiple user inputs, which is user-friendly and shared.

> *"Good database that does not drive users away. Regular/continuous information exchange and development of the process" (P2, Aviation/ Maritime/ Railway Expert)*

The need for a standardised classification system was felt to be equally important as this would make the system user-friendly.

> *"An agreed high level, classification system, not too detailed, it needs to be useable so that they, you know it doesn't take too long to, make a report." (P6, Healthcare Expert)*

3.7.4 Transferability of learning between organisations/countries

3.7.4.1 Common taxonomy and reporting mechanism

The first identified sub-theme for transferability of IRLS from other safety-critical industries to healthcare at an international level was having a common taxonomy. This would help the stakeholders to be aligned with the reporting process and recommendation.

> *"Yeah, I fully agree so common language would be a facilitator, a taxonomy of important words would be a facilitator, a common you know like taxonomy that would make things easier, so you understand cos you're using the same terms". (P5, Healthcare Expert)*

One finding that was noted in the response of a single participant is that common reporting mechanisms are crucial for the use of an international system of safety recording and reporting. Indeed, standardisation was considered vital to ensure that things were reported consistently, which was not considered to be the case in routine practice.

> *"I think the standardisation. So, the way we see things reported is very non-standard. And that makes any sort of analysis difficult so standardisation of the way things are reported." (P4, Healthcare Expert)*

Standardisation could also be facilitated using forums for learning and conventions that provide scope for international panels to agree on such terminology. Most experts agreed that conducting regular conventions, conferences, or seminars to discuss the progress and updates would also facilitate in transferability of IRLS from other safety-critical industries to the healthcare sector. Such conventions would also help to validate the included recommendations, as such meetings provide scope for debate and eventually lead to improvement of the outcome.

> *"So you know, having an international conference or, getting the people around the table, they all feel that their voice is being heard, in terms of the preparation. I don't know, five or six years, having to expense of it eventually, but every word would be debated, you know, and that's why you've got such a great document, that the wording is accepted in 190 states around the world." (P3, Healthcare/ Aviation Expert)*

3.7.5 Enabling Factors for International IRLS

3.7.5.1 Sharing learning and developing recommendations from patient safety incidents

There was consensus between the interviewed experts that sharing of information on patient safety incidents was one of the most important enabling factors of an international IRLS. This was because in order to identify solutions, you need to make stakeholders aware of safety incidents and errors.

> *"If you were to have adoption of learning across systems and countries what you need is those boundary spanners. So, your knowledge mobilisers, you need people who have a stake-hold (sic) in those different healthcare systems, so they've got buy-in in different healthcare systems." (P5, Healthcare Expert)*

The sharing of learning should also encompass the development of clear recommendations. P1 provides scope for understanding the relevance of an investigation, stating:

> *"So, you need enough information in there to see is it relevant to your particular scenario, your particular situation. Whether that's at local, national or international level." (P3, Healthcare/ Aviation Expert)*

Some participants emphasised the importance of maintaining quality and keeping a check on the quantity, as they felt that too much information fails to gain the attention of stakeholders.

> *"...we'd need to have a look at the quality of the recommendations and, the number of recommendations, if you're producing a recommendation every week, at a global level then I think that could be problematic." (P8, Healthcare Expert)*

P9 (Healthcare Expert) felt that incidents needed to be described along with the essential recommendations to deal with them. P5 also highlighted that just providing the information about the incident does not serve the purpose, and that recommendations to deal with the situation are equally important.

"So that's kind of, again it runs from a description of the incidents, the description of the recommendations to a description of the implementation that comes from those recommendations". (P9, Healthcare Expert)

3.7.5.2 Quality and regulation

Both quality of the investigation and regulation of the organisational aspects of reporting and learning were also seen as potential facilitators for an international IRLS. The experts mentioned that the quality of content derived from the reporting and the analysis of safety data are of crucial importance. They felt the quality of investigation will directly impact the understanding of an incident.

"I think everything should start with a good quality investigation". (P3, Healthcare/ Aviation Expert)

Having a regulatory body to oversee the process of transferring the knowledge generated in the incident reporting and analysis process was recommended by numerous participants. This is justifiable, as having a governing body is essential for proper working.

"Probably the other thing that's missing there is the governance of it. So, you have to have overarching governance, around that database and you need representation from the countries who are submitting data". (P6, Healthcare Expert)

3.7.6 Barriers to the set-up of an international IRLS

3.7.6.1 Blame and organisational culture

The concept of blame as a barrier to reporting of safety incidents was noted across the responses of participants. Blame was viewed as reflecting organisational culture and legislative processes and potentially interfering with the set-up of an international IRLS. Within this theme, the most significant barrier identified by many of the safety-critical industry experts was organisational culture. One of the industry experts reflected that they felt that poor maintenance of databases often occurred due to a culture that was not aligned with optimal safety practices, while this type of culture also reflected a culture inconsistent with reporting practices due to the risk of blame.

"Or if operators are afraid to report. So people won't report if it's too much work, difficult to do, they're afraid" (P4, Healthcare Expert)

Furthermore, P6 added that the culture of the organisation and support from within the safety-critical industry is important. Organisational support was perceived to be essential in reassuring the reporter about subsequent blame. Legislative principles and policies were also seen to constrain the freedom of reporting safety incidents. Experts felt there has to be a legislative power that decides who can have access to the database and ensures that reporters are not punished and do not hide the real information due to fear of damaging the reputation of the healthcare system.

"legislation, again if you have legislation that ensures that reporters are not punished then that can be an enabling factor" (P5, Healthcare Expert)

Trust and transparency were also identified as crucial barriers in disclosing information of a specific nature due to the consequences and implications of the action. Most of the experts, irrespective of the safety-critical industry in which they work, expressed that making the system transparent builds the trust of the stakeholders. Trust can relate to a number of issues, including the reliability of IT software and the support of governance processes.

"and it needs to be trusted you know, from that community and that governance process needs to have good representation from people." (P6, Healthcare Expert)

As P11 (Healthcare Expert) noted, the barriers proposed can also be altered:

"it's an enabler depending on if you succeed or not."

3.7.6.2 Involvement and Engagement

The theme of involvement and engagement reflects the degree to which organisations, as well as individuals, feel prepared or are suitably supported to engage with an international IRLS reporting process. The lack of a clear organisational approach within any given organisation (at a local, national, or international level) was one of the key factors identified as a barrier in IRLSs. The experts felt the requirement of an established organisation with

strong leadership skills was necessary for an IRLS to operate successfully. It was highlighted by experts that the working system needs committed countries to come along so that the reported incidents are not just reported but worked upon to provide meaningful recommendations which have utility in safety-critical industries.

> *"Main priority should be to develop simple enough system and get as many possible countries to be committed. Important question is, which organisation can be responsible for the system? Maybe within the EU or the UN." Someone should take strong leadership and invite organisations from each country to collaborate. It should be accepted that many countries will not attend, and the quality of shared information will be variable. Maybe there should be requirements from the EU." (P2, Aviation/ Maritime/ Railway Expert)*

Study participants noted that frontline staff might find it cumbersome to get involved in the process of reporting. The lack of understanding or involvement in reporting at a local level may potentially have an impact on the prospective of international reporting and learning. A lack of appreciation that locally reported safety data may be used on an international basis may have implications for the success of an IRLS. The process requires them to find additional time to do this work, time that has not been allocated for patient care. Consequently, some incidents are not reported. It may also be the case that frontline staff would not consider engagement with IRLS a key part of their role.

> *"The fact that it may be too cumbersome to just report things because I mean it is a problem we face in the UK so it's not user friendly at times and there are too many different drop-down menus. If you have to report something alongside looking after your patients and it takes you away from the frontline so you end up doing it in your own time" (P5, Healthcare Expert)*

> *"And then nothing comes back, I think people if they report something, they're entitled to know how it's been dealt with, and how, has it been dealt with, has it been investigated?". (P7, Healthcare Expert)*

Difficulties in mobilising clinical staff to take an interest in the data, either due to time constraints or by being overwhelmed by the amount of data, were also noted by one participant.

> *"I think one of the big cultural challenges over the next you know ten to twenty years is getting people more interested in the data". (P1, Healthcare Expert)*

Taken together, the combination of poor organisational approaches to safety reporting and the difficulty in mobilising staff at a local level suggests that organisations (including healthcare organisations) need to do more to empower and support staff and increase engagement with safety reporting processes. This has implications for an international IRLS, as each component within the international system needs to be aligned in order to contribute to the ultimate goals (defined in this interview study) of facilitating sharing of information and subsequent learning. While the focus of this study was on international perspectives, and not local issues, in this instance, it is apparent that local support, involvement, and engagement may influence the operational success of an international IRLS, both from the perspective of data reporting and subsequent learning.

3.7.6.3 Transferability and context of incidents

One final sub-theme in this theme emerged as a point of particular importance when considering the sharing of information at an international level. The interview data suggested that context relevancy is another important factor essential for the transfer of IRLS to healthcare at the international level. This means that lessons learned from a particular patient safety incident may not be relevant to a particular country but may be important to others.

> *"Even then I think it may need to be contextualised according to different regions, so for instance if you were to have learning and reporting system for Western Europe the priorities of that particular area would be completely different to learning and reporting system" (P5, Healthcare Expert)*

Appreciation of the differences between nations and the context in which an incident occurred may therefore be crucial to interpreting the learning from that incident at a local level. Where such issues are not considered, the lack of contextualisation of reported data may be a barrier to the implementation of an international IRLS, particularly if relevance to the local context is lacking. This presents an interesting contrast to the need for standardisation in reporting of data (3.6.4.1), as standardisation of outcomes and reporting variables may be valuable for data integrity and comparability. However, interpretation of outcomes based on local context may need to be non-standardised or individualised to the local setting to avoid inappropriate generalisation of recommendations for learning. Therefore, the standardisation of a system should not come at the cost of failing to take into account local and national variations in learning outputs.

3.7.7 Patient Safety Incidents relevant to International Sharing and Learning

3.7.7.1 Serious incidents and those with the greatest potential to improve safety

The safety-critical industry experts agreed that serious incidents should be treated as a priority within the reporting system so that the necessary steps would be taken to reduce their intensity, as well as to prevent their reoccurrence. One of the experts (P7) felt that, in healthcare, most of the serious events are associated with medication errors, blood transfusion errors, or the events which fall in the list of "never events" (i.e., wholly preventable safety incidents).

"In my opinion at the international level there should be learning at three categories, all most serious incidents (resulting in the death of several persons), clear technical problems (they can be solved worldwide), learning from statistics (incidents resulting in serious consequences)." (P2, Aviation/ Maritime/ Railway Expert)

"Well never events, I guess, things which are the most commonly occurring serious events, so retained instruments, medication errors, blood transfusion errors, those sorts of things and even accounts, I think whatever the definition somewhere is of a never event in the NHS, that's probably the starting point, because they're the most severe risks, and then, unfortunately, they're the ones that reoccur all the time.". (P7, Healthcare Expert)

Similarly, experts felt that serious adverse events relating to high-risk medications (i.e., chemotherapy drugs) should be a key focus of the IRLS reporting process. Experts all felt that it is of supreme importance to report the critical situations that were the outcome of the administration of high-risk medications to the patients. The reporting of rare and emerging events was also discussed, such as events that occur in a small number of cases or which are associated with new medications. One expert reflected that reporting such events at the international level would serve to inform other frontline staff about their occurrence and steps to rectify them.

"For the international level, the main purpose is I think to detect, rare and emerging incidents and you don't know until you see it, so, but thinking about categories, erm, it's rare or emerging incidents". (P6, Healthcare Expert)

Finally, incidents with the most potential to improve the international patient safety learning were also viewed as important variables. There was consensus that reporting patient safety incidents in which no individual was harmed but that had a high potential to end up

in severe consequences is of high importance. Such incidents serve as a learning source to prevent future lethality.

"Well I don't think it needs to have resulted in harm, but it just has to have the potential for it". (P3, Healthcare/ Aviation Expert)

"I think we need to be very clear about addressing, reporting the things that have either the most actual or potential for harm." (P4, Healthcare Expert)

3.8 Discussion

This semi-structured interview chapter reports on the experiences and perceptions of eleven safety-critical industry experts with extensive experience in the healthcare and aviation sector. The transcripts of the interviewed experts were coded to the seven topics using the framework analysis method. This chapter was conducted to seek answers relating to the value of an IRLS for healthcare systems and the potential barriers and facilitators to the implementation of IRLS. The focus of the interviews was on patient safety in comparison to the SLR chapter, which focused on IRLS in all safety-critical industries.

The topics identified and explored were largely consistent with the background literature noted in the SLR and served to guide the exploration of expert views and experiences. However, the content of the study also expanded and added to the background literature findings. Table 3.3 outlines the key difference between the findings of the SLR and semi-structured interviews. These similarities and differences are considered in further detail throughout this section.

Table 3.3 Key differences between SLR and Semi-structured interview chapter

Topics	SLR chapter (Deals with IRLS)	Semi-structured interviews (Deals with PSLS)	Differences
Purpose of an international IRLS	• Improvement in patient safety informed by systemic detection and prevention processes • Learning from patient safety incidents and sharing lessons learnt with stakeholders	• PSLS can facilitate learning • Awareness and sharing of knowledge should be a key part of learning • Improvement of the existing system is necessary to overcome limitations on a national basis • Detecting errors is a key aspect of the system • Standardisation of PSLS will be crucial to facilitating the above	No difference. The purpose of any RLS was found to be the same in both studies.
Key functions of an international IRLS	• Established feedback mechanisms • The process of reporting an incident at an organisation • Methods that facilitate the sharing of lessons learnt from reported incidents with relevant stakeholders • Core platform and analytical abilities of the IRLS • Established key roles of IRLS at various operational levels	• Investigative and analytical functions should be present within the system • Recommendations should be generated to guide practice • Relevant feedback is needed on national and international levels	The experts talked about only the general approach to features in any safety learning system, contrasting with a focus on specific international issues seen in the SLR.
Key features of an international IRLS	• Incident reporting process within the organisation • Analysis and/or investigation of reported incidents • Targeted actions in response to identified systemic weaknesses • Sharing of generated knowledge with system users and stakeholders	• Broad database inclusive of multiple factors and events (large data set) • Easy Access to the system is needed to promote reporting • Mechanism of Reporting should be clear and standardised • Responsible Organisations and universal guidelines should be considered to oversee PSLS operations and updates	All of the sub-themes derived in the semi-structured interview chapter are different to the themes from the SLR; resolving differences in key components between the literature and expert insights will be important in future research.

	• Feedback mechanisms	• Anonymity should be prioritised to optimise reporting practice • Ease of classification of events and incidents is necessary to increase used acceptability • Updating of database should be routine to ensure relevance of the database to contemporary practice	
Transferability of learning between organisations/countries	• Methods that facilitate the sharing of lessons learnt from reported incidents with relevant stakeholders • Common communication networks and platforms	• Common reporting mechanisms will improve information sharing and learning transfer from one setting to another • Shared learning will necessitate a common taxonomy • Context relevance is important in transferring results to local contexts and across national borders • A forum for learning should also be established to facilitate expert input into learning outcomes	The views on this question were similar in both studies
Enabling factors for an international IRLS	• Methods that facilitate the sharing of lessons learnt from reported incidents with relevant stakeholders • Common communication networks and platforms • Common reporting data formats and classification • The culture of the organisation is supportive of patient safety and reporting of incidents • Legislative support of incident reporting by governing and international bodies	• Details and relevance of recommendations will be crucial in enabling implementation • Utility will rely on the quality of the investigation • Regulation of organisations will be important to maintain standards • Sharing of patient safety incidents and learning is fundamental in promoting learning and improvements in practice	Enabling factors remain the same in both studies

Barriers to the set-up of an international IRLS	• Lack of established feedback mechanisms • The process of reporting an incident at an organisation may be inefficient or barriers may be present • The culture of the organisation is obstructive to patient safety and reporting of incidents • Legislative support of incident reporting by governing bodies is lacking	• The culture of an organisation, trust and transparency can influence reporting and blame associated with poor reporting. • Lack of involvement and engagement at an organisational or individual level may impair the utility of a system • Lack of an organisational approach to incident reporting will impair involvement in an international system • Privacy legislation should be considered to ensure anonymity and freedom of information sharing	Privacy legislation and organisational culture were considered from national perspectives in the SLR, and not international perspectives, as seen in the semi-structured interviews.
Patient Safety Incidents relevant to an International IRLS	N/A	• Serious incidents should be prioritised, including those with the greatest impact on wellbeing and outcomes • Rare or emerging events should also be captured, not only common events, to maximise the value of the international data set from a large population • Incidents related to high-risk medications should be included to promote enhanced safety and quality improvement with those medications	This question was only considered in the semi-structured interview chapter

The intended use of IRLS was consistent with observations in the wider literature focusing on national systems (WHO, 2020; Hewitt et al., 2017; ICAO, 2016; Klemp et al., 2015; Stavropoulou et al., 2015). Published literature is broadly in agreement with the findings from this chapter regarding the overall purpose of an IRLS at an international level, which is to improve patient safety and share learning from safety incidents/risks. This suggests a common understanding of the importance of safety reporting purposes across industries and across the experts included in this study.

Similarly, the features of an IRLS suggested by the experts were broadly consistent with the literature (Harsoor, 2010; Wallace et al., 2009; Donaldson et al., 2011; Donaldson et al., 2009). However, the interview study supplements this by adding that key priorities are needed to optimise an IRLS, including the need for organisational accountability/ responsibility, clarity in mechanisms of reporting, and access to the databases, all of which are key practical considerations for implementation. Additionally, the experts agree that shared incident reports should be anonymous at the international level while some added that having a way to get further detail might also be beneficial (i.e., similar to medico-legal databases where cases are held securely in confidence). This is also true when reflecting on the functions and features of an international system, and the challenges linked to the utility of this system in practice. Most of the experts were in support of having a feedback mechanism embedded in the IRLS, as this makes the task of reporting feel of value and gives some reassurance that solutions would help to prevent future incidents. Similar reasoning has been provided in the published literature (Hewitt et al., 2017; ICAO, 2016; Klemp et al., 2015; Stavropoulou et al., 2015). It is important to note that this study adds that participants value specific functions and features which could be present in an international IRLS. In this instance, it is important to note that a function is a goal that may be accomplished using the IRLS, while a feature is a tool that can assist in accomplishing a function. For instance, a feature of an IRLS may be a broad database or easily accessible user interface, which would facilitate the functions of investigation and analysis and the potential for recommendations to be generated and feedback, all of which highlight a focus on practical and focused applications of the system.

The experts agreed that some recommendations are region-specific, and this needs to be explored while updating national IRLSs and when developing an IRLS, suggesting the potential for variations in the national implementation or use of an IRLS. Most importantly, the whole process needs to be regulated by an established organisation in each country or region. Specifically, enablers reflecting the potential to share information, strong clinical

relevance of the IRLS process, and regulatory standards and frameworks were perceived to have an impact on how IRLSs are used in practice by participants in this study.

The fifth topic revolved around the transferability of the IRLS from other safety industries to the healthcare sector. Most of the experts agreed that it was important to have a reporting and learning system that focuses specifically on healthcare, as this industry is considered to be more complex than other safety-critical industries. The views of the experts build on reports in the literature that suggest specific functions and features of a proposed international IRLS are needed to ensure relevance to the healthcare industry (Hewitt et al., 2017; ICAO, 2016; Klemp et al., 2015; Stavropoulou et al., 2015). Indeed, the findings suggest that there is a need for a learning forum and clarity in taxonomy to share information, while it is acknowledged that this may be particularly complex for healthcare compared to other industries. Therefore, this study adds to the theoretical knowledge base regarding the needs and priorities of an international IRLS within the context of healthcare settings, a perspective not seen in previously published data.

The barriers and enablers identified in the expert interviews were similar to those identified in the SLR chapter and are supported by the published literature (Hewitt et al., 2017; ICAO, 2016; Klemp et al., 2015; Stavropoulou et al., 2015). However, it is a unique finding to note that organisational culture, trust, and engagement are closely linked in the minds of participants and may reflect patient and professional attitudes towards data management and safety reporting. A balance between safety reporting and maintaining ethical control over confidential information emerges and is supported by the final topic, where most of the experts considered serious events, rare and emerging events, incidents related to high-risk medications, and incidents with the most potential to improve safety and most relevant to be shared at the international level (Mahajan, 2010; Health Quality Ontario, 2017). This suggests that targeting the most severe incidents only should be prioritised, potentially reflecting the drive to maintain a manageable (and confidential) dataset, while maximising the utility of the system.

3.9 Strengths and Limitations

The strength of this chapter lies in developing a thorough set of questions/prompts after a critical review of the safety manuals, research, and review publications from the industry experts. Further strengths include the opportunity to engage in-depth with safety experts and probe answers to questions that were left unanswered by the SLR. The participants came from a broad range of countries. Although efforts were made to invite people from a variety of different safety-critical industries, most of the experts who made themselves available for the interviews were from the healthcare industry; hence transferability of the findings could not be fully explored.

A total of 21 experts were approached for the study, which was deemed sufficient for robust data collection. Of these 21, 18 experts replied to the e-mail and 11 took part in an interview (Table 3.2), while the remaining seven did not follow through with correspondence to set up an interview in the dedicated time frame. The conversion rate (interviewed/response) was calculated to be 61% (11/18). Whilst a qualitative study of 11 participants is acknowledged to be relatively small, other authors in the field have published qualitative research using similar sample sizes (Howell et al., 2017; Benn et al., 2009). Whilst it might have been possible to increase the sample to include other healthcare experts, a decision was made to reserve these potential participants for the Delphi study (chapter 4).

Positionality (what we know and believe, or as Flick, 2018, defines it, our assumptions, in relation to people and how they exist in the world, and how we generate knowledge) and reflexivity (what we do with that knowledge, i.e., questioning assumptions etc) should also be considered, particularly given the nature of the semi-structured interviews and previously noted issues relating to the use of elites as participants in the study. As a student interested in this topic, my views tended to favour the development and use of an IRLS, which may have influenced my perceptions and interpretation of responses, as well as prompting in the interview. As a student and a relatively inexperienced practitioner in the field of safety, the position of the researcher was that of a relative novice, which shaped an understanding of the key issues explored in this study. Consequently, data interpretation may have been influenced by this perspective. In addition, my professional background in medicine may have emphasised the healthcare implications of the findings of the study; this final point allows for a useful process of focusing the findings on the healthcare context, as specified in the review objectives. However, the position of the participants as elites raised challenges in guiding the discussion of key topics, as lively

debates may be anticipated, including discussions of more nuanced issues that may be beyond my knowledge. The use of a structured guide to ensure all interview prompts were covered was valuable in ensuring clarity during interviews. However, it is apparent that I played a key role in generating data by serving as a partner in debate within the interview pair for each participant. Therefore, the use of quotations from the interviews was carefully considered within the context in which those data were obtained, including the contextualisation of the researcher-participant dynamic at that moment. Indeed, this provided a means of contextualising the findings and reflecting on my role in generating that discussion point, lending transparency to the interpretation of the findings.

3.10 Conclusions

To conclude, the semi-structured interview study with safety-critical industries experts provides a new perspective to the findings from the SLR chapter regarding a potential international patient safety reporting and learning system, including a healthcare-focused perspective on IRLS, as well as unique insights into how trust, culture, and organisational approaches to data sharing may influence IRLS implementation and perceived utility. While the SLR chapter explored safety reporting and learning systems in safety-critical industries at local, national, and international levels, this chapter narrowed the focus to international safety reporting and learning systems. Moreover, this chapter explored potential patient safety incident types that the safety-critical industry experts deemed essential to international sharing and learning, which the SLR could not identify. This newly generated knowledge could be further explored and expanded with healthcare experts, including policymakers at a national and international level. Furthermore, this chapter also raises some new questions relating to the applicability of these findings to healthcare and the potential feasibility of an international patient safety reporting and learning system (PSRLS).

Additionally, the findings from the SLR chapter and this chapter have highlighted the need to expand the focus of a potential international PSRLS to include any patient safety data relevant to international sharing and learning and not just reported incidents. Therefore, the following chapters will further explore a potential framework for an international patient safety learning system (PSLS), with or without an incident reporting function.

Chapter 4 – International healthcare experts' recommendations for a potential international patient safety learning system: A Modified Online Delphi Study

4.1 Introduction

The synthesis of findings from Chapter 2 (Systematic Literature Review) and Chapter 3 (interviews) have resulted in the identification of four key themes that should be considered when exploring the applicability of an international patient safety learning system. These themes are:

- The purpose of an international patient safety learning system (PSLS);
- How the purpose of an international PSLS is operationalised through unique functions and features;
- Identification and sharing of learning from internationally relevant patient safety incidents; and,
- Enablers and challenges to setting up an international patient safety learning system.

The findings from Chapters 2 and 3 illustrated that there are unresolved issues and challenges remaining in relation to these four key themes. The thematic synthesis of the available literature served a clear purpose in understanding what is presently available at a national level within healthcare systems, or used in safety-critical industries (non-healthcare) at the international level, and illustrated how unanswered questions remain in four key areas, relating to the purpose of international PSLS, operationalisation of this purpose, ways to share information and learning, and challenges and enablers to establishing an international PSLS.

Figure 4.1 shows a proposed framework for the design and operationalisation of an international PSLS, based on findings from Chapter 2 and Chapter 3, including questions that need to be answered to finalise the framework.

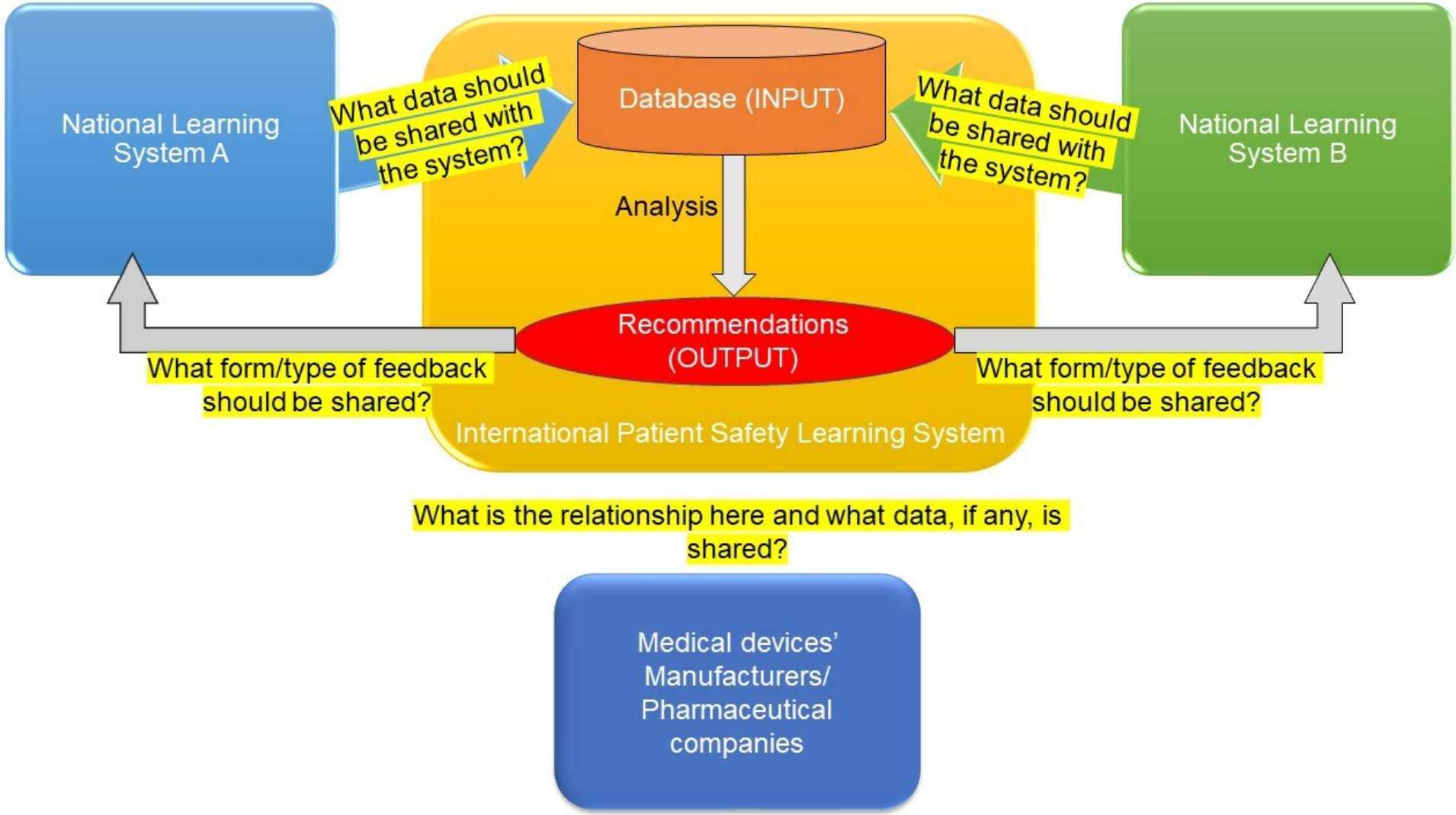

Figure 4.1 Framework for an international patient safety learning system

The figure illustrates how the basic design of an international PSLS may be structured, based on a simplistic view of two nations sharing information and recommendations generated to share knowledge with other nations and wider stakeholders (e.g., pharmaceutical companies). The figure highlights the missing elements that need to be addressed to arrive at a final draft of the framework, where the unanswered questions from the previous chapters are highlighted.

These questions are as follows:

- What data can national learning systems contribute to international PSLS?
- What are the optimal characteristics and format of these data?
- What form/type of feedback is to be shared with national learning systems?

Certainly, from chapters 2 and 3, there was some uncertainty over the type of information that should be shared and the ways in which that information can be consistently and reliably added to the system. This is identified in previous chapters by the lack of consistency noted in data collected from national safety systems and the potential for incompatibility between national systems, which justifies the need for a homogenised approach to collating data within this model. Indeed, even the implementation of a multi-site PSLS in the United Kingdom (UK) found that this system was better suited to within and not between hospital safety reporting and learning due to variations in surveillance factors and population characteristics (Forster et al., 2020), highlighting how heterogeneity in system implementation, use and applicability may impede information sharing across settings. Furthermore, the type and format of safety recommendations that are to be shared at the international level with other countries or stakeholders (and if available, their own national learning systems) need to be clarified. The nature of safety recommendations and their ultimate implementation is a challenging area, as safety events may be diverse in nature and application to specific health systems, and the degree to which outputs are prescriptive or advisory was an issue of contention.

Additionally, the proposed framework requires consensus from a broad panel of international healthcare policymakers, managers, and academics (i.e., healthcare experts), in order to provide a platform from which to evaluate its applicability to healthcare, due to the derivation of data from safety-critical industries, such as aviation. Hence, the gaps noted in the proposed model illustrate the fundamental outcomes of the thematic synthesis of the literature (Chapter 2) and prior expert interviews (Chapter 3), while highlighting the value of a consensus-based approach to building on these findings and answering areas

where the evidence base is unclear or lacking, and experts have identified as important in developing an international PSLS.

Finally, it should be noted that a crowded market exists in how PSLSs are designed and software used, without any clear coordination or inter-communication between systems. The nature of safety data collection and subsequent generation of learning is prone to variation across nations, while the systems in place are often not designed to facilitate information sharing easily (Health Quality Ontario, 2017). Consequently, governance of these systems can be variable across nations, precluding clear opportunities to integrate systems on an international basis (Hegarty et al., 2021). Furthermore, applying an international system requires an appreciation of enablers and barriers to their use in practice, including potential barriers to uptake among physicians and other healthcare professionals (Health Quality Ontario, 2017). These issues require specific insights and careful design of the international PSLS to ensure the utility of such a system across diverse nations, particularly acknowledging the likely differences in resources and expertise (Forster et al., 2020).

As previous chapters have explored these themes through the literature of, and interviews with experts from, safety-critical industries, the next step of the thesis (see Figure 4.2) is to explore these findings with international *healthcare* experts (Objectives 3 and 4). This step is necessary to ensure that the findings are applicable and potentially transferable to healthcare, and to also achieve international expert consensus regarding the purpose(s), key functions and features, and feasibility of a potential international PSLS. Additionally, as evident from the interviews, criteria for deciding what patient safety risks would be of international concern need to be explored with international healthcare experts. The term expert is defined in the methods section of this chapter (section 4.4.3.1); however, it should be noted that the term includes healthcare policymakers, managers and academics.

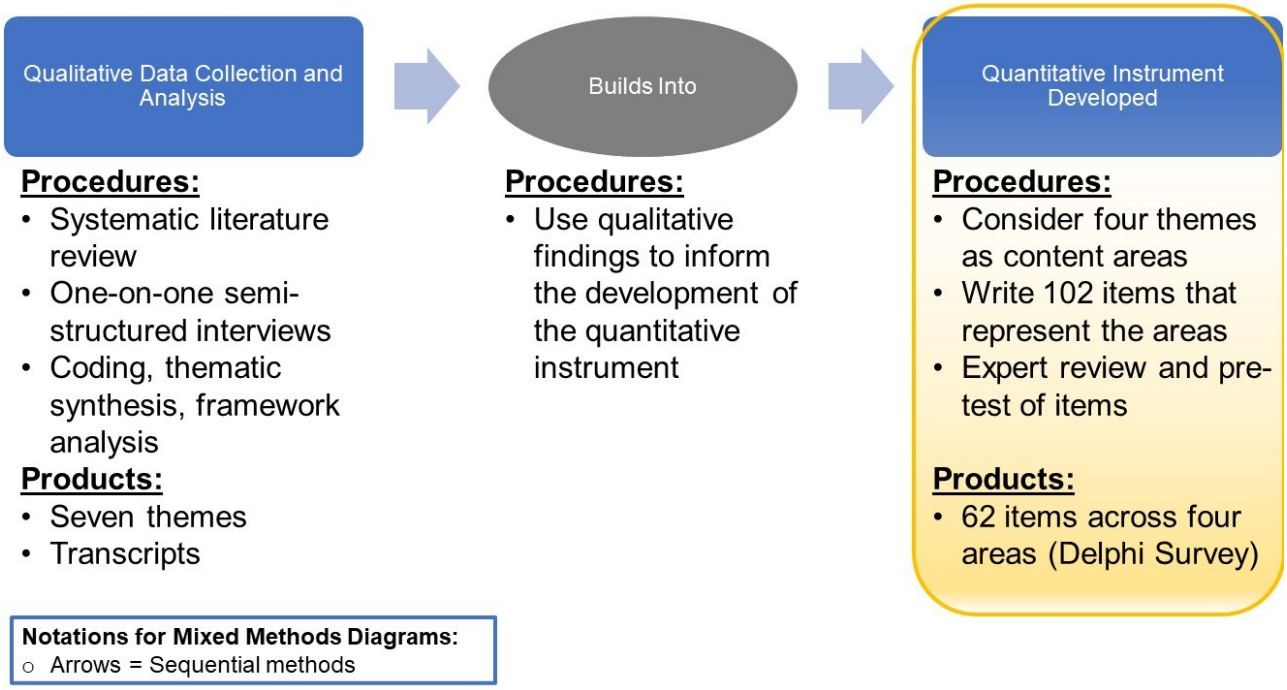

Figure 4.2 Quantitative stage of the sequential exploratory mixed methods design (Creswell & Clark, 2018)

This chapter provides a description of the approach used to integrate the findings described in Chapters 2 and 3. Integration of the systematic literature review findings and the interview findings was performed in order to generate a list of statements related to the above themes and to achieve international expert consensus regarding the purpose(s), key functions and features, and feasibility of a potential international patient safety learning system. The themes noted here represent an integrated analysis of the findings of Chapters 2 and 3, combining previous themes and findings from each chapter individually into an integrated set of four themes. It then describes the testing of the statements using a Modified Online Delphi approach, the outcomes of the consensus process, and the evaluation of the significance of these outcomes for an international PSLS.

4.2 Aim

To gain consensus agreement from a broad panel of international healthcare experts regarding the key elements that would be required for a potential international patient safety learning system, with or without an incident reporting function.

4.3 Objectives

The objectives of this study are to:

- Gain international healthcare expert consensus agreement regarding the purpose(s) and key requirements of an international patient safety learning system;
- Gain international healthcare expert consensus agreement regarding the feasibility of an international patient safety learning system, in terms of opportunities and challenges of its functioning;
- Develop a list of patient safety incidents deemed relevant for international sharing and learning; and,
- Develop a list of criteria that are essential for deciding whether a patient safety risk is of international concern.

4.4 Methods

To achieve the aim and objectives of this study, two consensus-building methods were considered, which are widely used in healthcare. These methods were: the Delphi technique (Keeney et al., 2011; Iqbal & Pipon-Young, 2009; Okli & Pawlowski, 2004; Linstone & Turoff, 2002; Powell, 2003; Keeney et al., 2000; Hasson et al., 2000; Selfe, 1996), and the nominal group technique (NGT; Olsen, 2019; Peña et al., 2011), although Campbell and Cantrill (2001) argued that the NGT is not a consensus-building method but part of a consensus process. Other consensus methods, such as the National Institutes of Health (NIH) consensus development method and Glaser's approach to consensus, were considered (Glaser, 1980; Fink et al., 1984). However, these techniques have not been standardised, and lack validation as research methods for achieving consensus, unlike the Delphi and nominal group techniques (Fink et al., 1984). Additionally, Campbell and Cantrill (2001) argued that the RAND Appropriateness Method (RAM) is considered a consensus-building method; however, Fitch et al. (2001) argued that it does not belong in that category because its objective is not to obtain consensus among experts but to detect when experts agree. Despite this initial reservation, the RAM approach has been successfully applied to consensus recommendation development for clinical practice, with a high level of reproducibility of the findings (Silverman et al., 2008) and acceptable validity

based on randomised controlled trial findings (Yazdany et al., 2009). However, this method is limited by the need for physical person-to-person interactions, which is costly and lacks convenience when gaining consensus from an international panel of experts (Nair et al., 2011; Waggoner et al., 2016). Furthermore, the process is based on presenting a large number of scenarios (e.g., cases, examples), which is time-consuming and may be challenging to construct, given the need for a third-party group of experts to develop these cases.

4.4.1 The Nominal Group Technique (NGT)

The NGT is a highly structured face-to-face group discussion, typically involving five to 12 participants, led by a moderator, to gain consensus from target groups who are associated with the area of inquiry (Olsen, 2019; Humphrey-Murto et al., 2017; Peña et al., 2011; Jones & Hunter, 1995). The possibility to debate and discuss issues lacking consensus, and the opportunity for more robust concept development are the principal advantages of the NGT (Humphrey-Murto et al., 2017; Waggoner et al., 2016). In contrast, the smaller number of participants and the possibility of dominant participants unduly influencing the group were flagged disadvantages (Humphrey-Murto et al., 2017; Waggoner et al., 2016).

4.4.2 Selection of the Delphi Method

Since the aim and objectives of this study were to gain consensus agreement from a broad panel of international healthcare experts, the NGT was excluded because it would have required arranging for international healthcare experts to be present at the same time, which was challenging during the COVID-19 pandemic, in addition to the difference in time zones and potential cost. The NGT process may also be based more on discussions rather than quantifiable processes of measuring consensus, which can be a limitation in providing clear objective outcomes, highlighting the use of the NGT method in exploring consumers' views rather than in healthcare guideline formulation (Mukherjee et al., 2018). Thus, the Delphi technique was selected, and the rationale behind the selection is supported by the fact that the Delphi technique can be modified into an online version, making access to international healthcare experts (i.e., geographically dispersed) easy and affordable, particularly during the COVID-19 pandemic. Furthermore, the Delphi technique is widely validated for use in obtaining consensus agreement and is supported by a range of literature.

4.4.2.1 The Delphi technique

The Delphi technique is a commonly used method to gain consensus from a group of experts on a certain topic (Diamon et al., 2013; Keeney et al., 2011; Hsu & Sandford,

2007; Linstone & Turoff, 2002; Black et al., 1999; Duffield, 1993). The technique has been used across various fields, such as healthcare, as a method to combine expert opinion into group consensus in an iterative, structured manner (Keeney et al., 2011; Lynn et al., 1998). Anonymity between panellist experts (participants) with controlled feedback provided are some of the Delphi method's key features. In a number of subsequent iterations (rounds), the panellists then may adjust their initial ratings or scores based on feedback from the group derived from formal notes and comments associated with the Delphi process (Hsu & Sandford, 2007; Keeney et al., 2005). The Delphi method is appropriate for exploring areas of research where empirical evidence is lacking, contradictory, or limited (Humphrey-Murto et al., 2017).

Within health, social care, and intervention research, the Delphi Technique has been used extensively (Ensaldo-Carrasco et al., 2018; Webber et al., 2016; Efstathiou et al., 2008; Buetow & Coster, 2000; Walker & Selfe, 1996). Experts are invited to provide their opinions on specific themes where there is a scarcity of knowledge or general consensus. Any generated consensus may be considered to be a valid expert opinion, because it is assumed that the opinions of many outweigh those of the individual (Habibi et al., 2014; Hasson et al., 2000). The Delphi study method is not universally agreed upon, however, with variations in a range of factors used to define and quantify consensus in a field (Hasson et al., 2000). This is problematic in terms of comparing Delphi study outcomes between studies (especially if consensus definitions are not consistent across studies) but is considered less problematic in the design of one study, as the variability in guidance reflects the need to adapt the Delphi technique to a specific context or topic to some extent. Therefore, decisions made in this project reflect the use of Delphi recommendations or examples from the wider literature, with justification for the choices made, rather than adhering to one overarching guideline, which is non-existent in the field.

4.4.2.2 Types of Delphi

The Delphi technique has evolved into many modifications since its development (Table 4.1), and these adaptations might be based on the fact that there are no ***formal*** or ***universally agreed*** guidelines for the use of the Delphi, as Keeney et al. have argued (2011). Some of these variants reflect strategies that can be useful in assessing outcomes other than consensus (e.g., dissensus, or the degree to which opinions differed) or in promoting Delphi consensus at a pace unique to each expert participant, which may be time-consuming in nature. As the focus of the Delphi in this instance was intended to provide a timely approach to acquiring feedback and consensus from an international

expert panel, many approaches would be excluded as they have been used previously for different purposes and are inefficient from a time perspective. Hasson et al. (2000) have provided a research guideline for the Delphi technique, which was helpful in the development of the Delphi study discussed in this chapter.

Table 4.1 Variants of the Delphi technique (Referencing information derived from Niederberger & Spranger, 2020)

Variant of Delphi technique	Main differentiating feature from the standard Delphi approach
Argumentative Delphi	Focus on qualitative justification for the standardised judgments made by the expert panel
Group Delphi	Experts are invited to a joint workshop and provide contextual justifications where judgments diverge
Modified Delphi	The first postal round is typically replaced with focus groups or face-to-face interviews.
Online Delphi	The Delphi process (rounds of consensus and feedback) is exclusively performed online
Policy Delphi	To determine dissensus (the range of judgments)

The original form of the Delphi technique, known as the Classical Delphi, comprised of two or more rounds of surveys administered by post to a panel of experts (Keeney et al., 2011). The first survey round generated qualitative data by asking open-ended questions to the panel for their expert opinion on a specific topic or issue. The research team then analysed the generated qualitative data and sent it back to the panel in the form of questions, statements, or a combination of both. The panel would then rank or rate the questions or statements within the second survey based on their expert opinion on the subject matter. Further survey rounds would continue until consensus was achieved on some or all of the statements or questions as required.

In a Modified Delphi, the first qualitative survey round is replaced with interviews, a focus group(s) or a literature review, while a Policy Delphi utilises the opinions of experts to gain consensus and approve future policy on a given issue (Keeney et al., 2011). The Online Delphi has a similar process to the Classical Delphi or Modified Delphi but is completed and submitted online. These adaptations could be due to natural developments over time, such as using online platforms for disseminating materials and collecting data from panellists, while also facilitating expert opinions on an international basis in a more convenient manner than traditional face-to-face approaches, particularly during the travel restrictions of the COVID-19 pandemic.

4.4.2.3 Selected Delphi modification

The adopted Delphi technique in this chapter is a Modified Online Delphi, where the first idea-generating qualitative round is replaced with a literature review (Chapter 2) and semi-structured key informant interviews (Chapter 3). The survey is administered online (Hasson et al., 2000).

A multimethod, multiphase approach was adopted to gain consensus from academic/ industry healthcare experts about the purpose, key functions and features, and feasibility of an international PSLS.

This approach has three phases:

4.4.2.3.1 Phase one: systematic literature review

A systematic literature review (Chapter 2) was conducted to outline the potentially relevant themes that form the basis of a framework (key functions and outputs) for an international PSLS. This review yielded information from a breadth of literature relating to the functions and services viewed as potentially helpful or valuable in an international PSLS, the possibilities of these systems in terms of enabling identification of risk and improving patient safety, the degree to which features of these systems exist at a national level, and an understanding of how these may work between countries.

4.4.2.3.2 Phase two: semi-structured key informant interviews with international safety-critical industry experts

Next, eleven experts from safety-critical industries (e.g., aviation, railway, healthcare) were interviewed (Chapter 3). The interview schedule was structured around key themes and identified gaps from the systematic literature review (Chapter 2), including the optimal features of an international PSLS, the value of such a system, the barriers and facilitators of introducing and using the system, and the outputs of the system required to facilitate international learning and safety. The themes that emerged from the interviews, combined with those of the systematic literature review informed the development of the Delphi survey.

4.4.2.3.3 Phase three: the Delphi study design

Due to the fact that there is no existing international PSLS, and the lack of consensus on the purpose, key functions and features, and feasibility of such a system, a Delphi study was considered to be a suitable research tool to achieve consensus (Powell, 2003). The Delphi technique has distinctive characteristics such as (a) anonymity, (b) controlled feedback, (c) iteration, and (d) statistical “group response” (Rowe & Wright, 2001). There

is considerable variation in how consensus should be measured (the level of agreement, mode, mean/median ratings and rankings, standard deviation); however, achieving consensus is the primary aim of the Delphi study (von der Gracht, 2012). The list of statements was developed using an iterative process, whereby the list of items and statements were discussed between the researcher and his supervision team, the meanings of statements were challenged or questioned, and the statements were then refined accordingly. The Delphi study was conducted to determine if experts agree with the results of the systematic review (Chapter 2) and interviews (chapter 3), i.e., whether they feel the suggested purpose, functions and features of an international IRLS are applicable to healthcare or transferable to healthcare settings.

The survey was administered electronically via Qualtrics survey platform. Experts were required to state their level of agreement with statements using 9-point Likert-like scales. The 9-point scale was adopted, as it contains an odd number of options (allowing for a central 'neutral' option), while having a sufficient number of options to facilitate not only assessment of agreement or disagreement (as in a 5-point scale) but a more nuanced appreciation of the strength of agreement or disagreement. Because rigid Delphi study designs have been criticized for their inability to allow their experts to elaborate on their opinions (Habibi et al., 2014; Walker & Selfe, 1996; Beretta, 1996), this Delphi design, as stated earlier, is a modified one. In order to provide experts with the opportunity to elaborate on their opinions, free text response options accompanied each set of statements put to the panel (Keeney et al., 2001). Furthermore, since there is no consistent definition as to what may be considered a level of consensus within a Delphi study, rounds were to continue until the panel reached ≥80% agreement on all statements (i.e., ranked 7-9 on a 9-point Likert-like scale) or the response rate of fell under 70% in the second or further rounds. This is aligned with the recommended quality indicators for a Delphi study: reproducible participant criteria, consensus generated over a number of rounds, clear criteria for excluding/dropping items and other stopping criteria (Diamond et al., 2014). Importantly, the number of rounds was not pre-determined in the present study, as the process was intended to reflect the responses of panellists until the pre-determined cut-off point of consensus agreement for ≥80% statements was achieved. See Figure 4.3 for a summary of the Delphi study process outlined in this chapter.

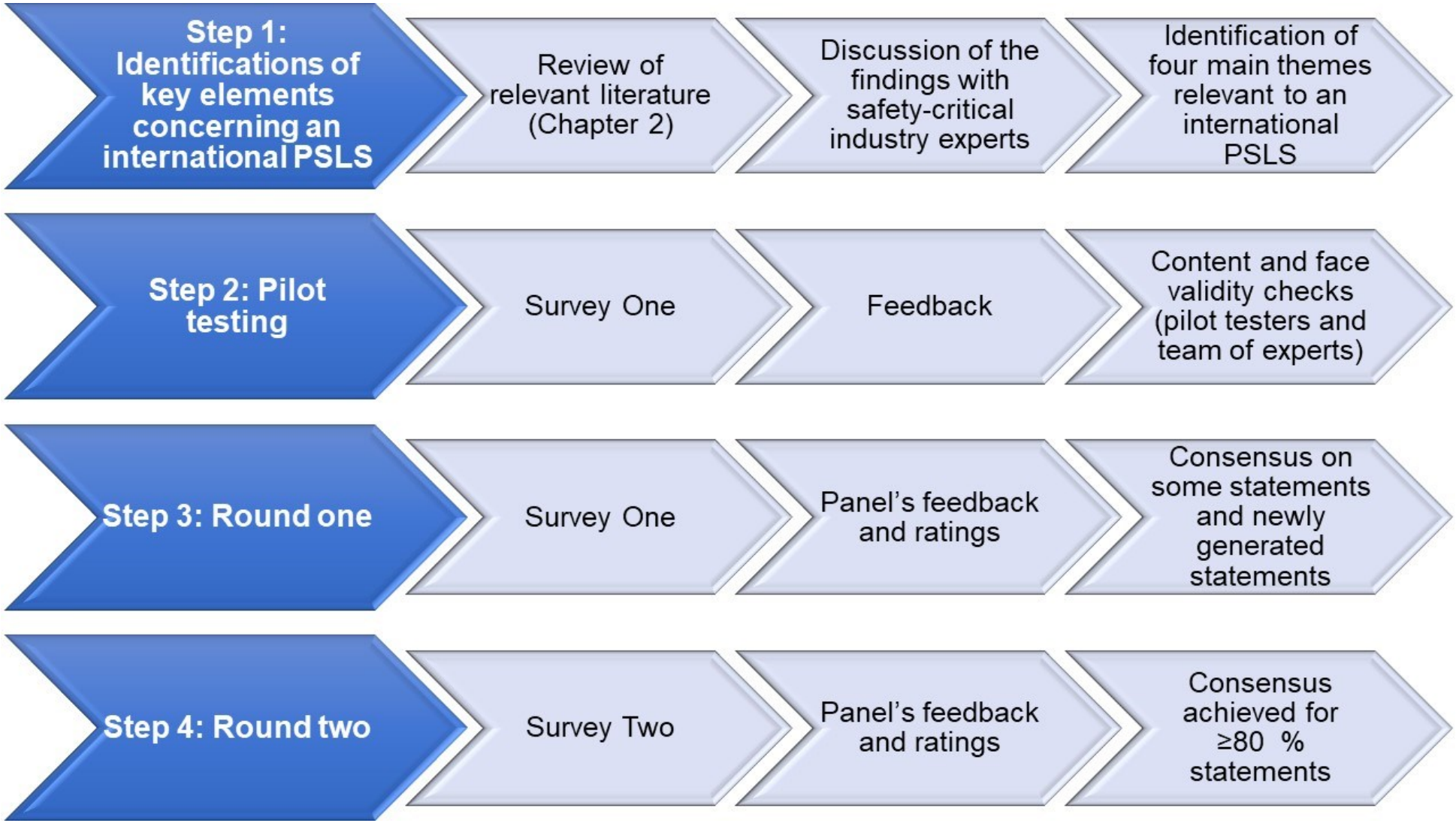

Figure 4.3 Summary of the Delphi Study process

4.4.3 Selection of international experts (participants and recruitment)

As indicated by Green et al. (1999), the first stage of a Delphi technique is the formation of a 'panel of experts'. A critical review of the Delphi technique by Keeney et al. (2001) cites a range of definitions of 'expert', including 'informed individual', 'specialist in the field' or 'someone who has knowledge about a specific subject', though it is generally acknowledged that there is little agreement on what an 'expert' is (Baker et al., 2006).

4.4.3.1 Definition of 'expert'

The definition of an expert in this context is closely aligned with the definition proposed by Skulmoski et al. (2007), where experts are defined as having experience and knowledge of the issue under investigation, willingness to participate, capacity to participate, and adequate communication skills. Knowledge and experience in this context are difficult to define, as years spent within a profession or possessing a professional qualification may serve as markers of these features, but they do not ensure expertise in a subject (Trevelyan & Robinson, 2015). However, it is generally thought that assessment of expert knowledge and experience can be evaluated on the basis of research output, status and reputation, among other factors; hence, experts were defined according to a range of characteristics that reflected an interest in patient safety and incident reporting or learning systems and expertise in this field. The participants in this study were selected and considered as 'experts' based on their knowledge and experience in patient safety, incident reporting/ learning systems, organisational learning/ knowledge mobilisation, and healthcare services. This included participants being invitees to World Health Organization (WHO) safety meetings, suggesting their high likelihood of being international experts in the field, as well as details found on public-facing web pages, publications and participation in guidance development. The rationale behind excluding experts from other safety-critical industries outside of healthcare is that the panel would be asked about the purpose and feasibility of an international PSLS, generated from the systematic literature review and semi-structured interviews, and it was agreed by the candidate and his supervisory team that an expert outside of healthcare industry might not be able to answer such questions.

4.4.3.2 Identification of experts

Experts were identified either on the basis of their authorship of studies included in the systematic literature review (Chapter 2; n=18), or additionally had been previously included in the interview study (chapter 3) (especially those that were not interviewed, n=9). Furthermore, in order to gain a comprehensive set of views, patient group

representatives (n=2) from WHO patient safety meetings were asked to participate as well as representatives of front-line healthcare staff (n=6). Additionally, international experts that participated in relevant WHO consultative meetings were also identified (n=44).

4.4.3.3 Inclusion criteria of experts

Experts were invited to participate in the first round of the Delphi if they met the inclusion criteria outlined in Table 4.2.

Table 4.2 Inclusion criteria for the panel of experts

Expert Panel Inclusion Criteria
Either: A listed author in a peer-reviewed publication (date: 1999-2020, Language: English) relevant to - Patient Safety - Incident reporting and learning systems - Organisational learning/knowledge mobilisation or: - Expertise in the development, management or evaluation of a reporting system Incident reporting and learning systems - Role at a local/national/international level for patient safety/incident reporting and learning systems

Additionally, having an active e-mail address to be able to participate in the online Delphi study was considered essential since invitations were sent via e-mail. Thus, experts that did not have a valid, publicly available e-mail address were excluded in the final step of the identification process. This process included searching for online profiles that the identified experts had in order to find contact details. Furthermore, participants were able to recommend other experts for participation in the study; these experts (n=3) were included only where they met the inclusion criteria for all participants to minimise the risk of bias and to maintain the integrity of the study. Figure 4.4 outlines a summary of the expert identification process.

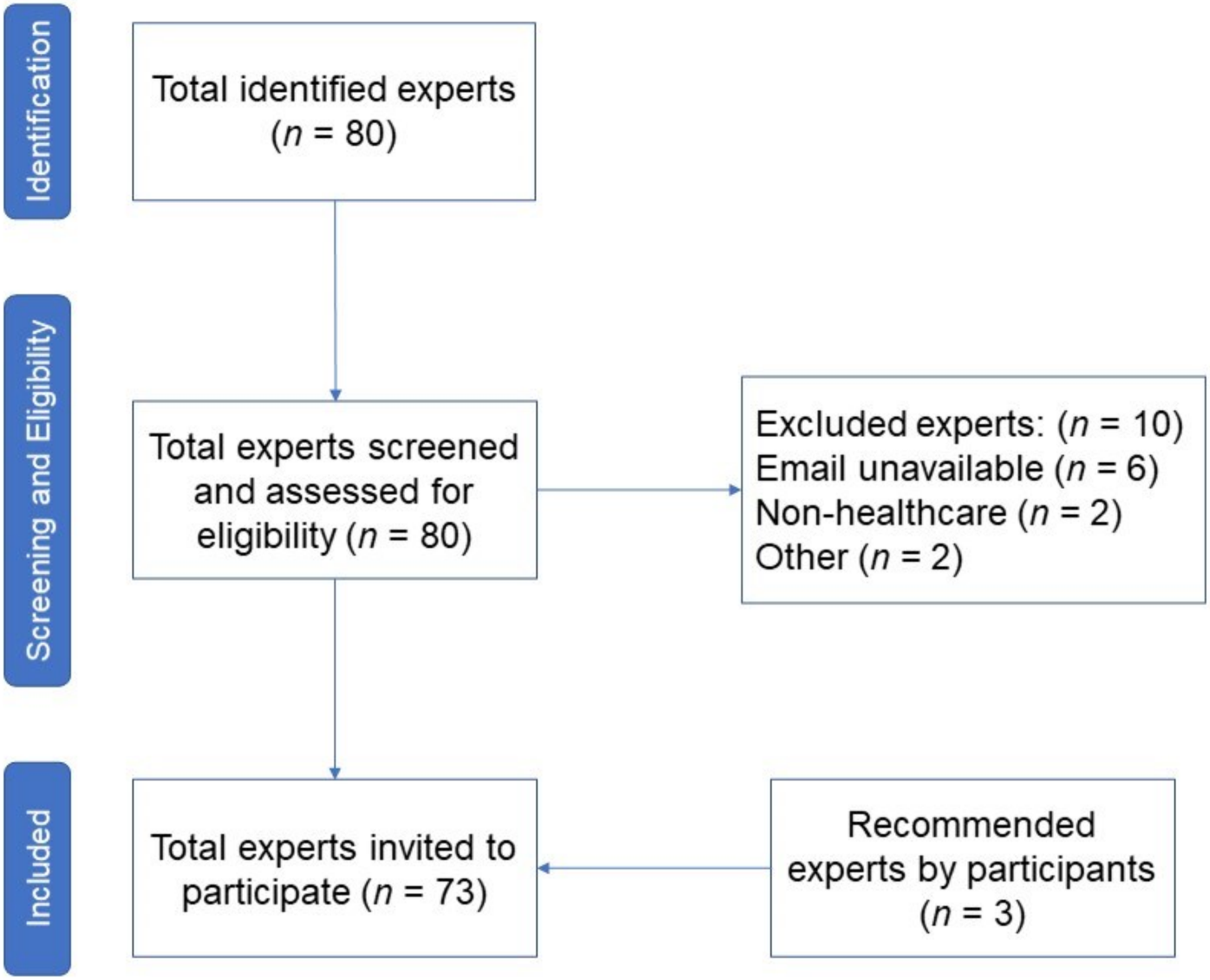

Figure 4.4 The Process of identification of experts

4.4.3.4 Size of the panel of experts

Another area of consideration among researchers is the number of participants in Delphi studies. According to Hasson et al. (2000), the scope of the problem and the resources available typically dictate the number of participants needed. In addition, a heterogeneous sample can help to ensure that the entire spectrum of opinions on a topic is included (Keeney et al., 2001), and Linstone and Turoff (2002) advise a panel size of anywhere from 10 to 50 participants. For this Delphi study, a minimum of 20 experts were estimated to be recruited. It is anticipated that a minimum of 20 participants would provide a wide spectrum of opinions for this study as the identified international experts were purposively selected to represent broad knowledge and experience in the field (e.g., academics, healthcare manager, policymakers, clinicians, patient representative). This is in keeping with other studies with similar objectives (Howell et al., 2017; Dewa et al., 2018).

4.4.3.5 Invitation process of the Delphi

Experts, once identified, were directed toward information about the aim and purpose of the Delphi study, and a formal invitation, along with a participant information sheet and consent form were also provided (see Appendices 4.1 - 4.3 for invitation e-mail, information sheet, and consent form). Potential and recruited panel members were also asked to refer other suitable individuals (i.e., snowball sampling). This was used in order to increase the heterogeneity of the sample, which it did, especially with less represented countries in South America, Africa, and Southeast Asia. By way of best practice in the Delphi study design, solicitation of nominations of appropriate field experts is typically recommended (Ludwig, 1994).

Before the first round of questioning began online, informed consent was obtained from all participants, which includes an agreement to publish anonymised data and non-identifiable data results (see Appendices 4.1 – 4.3 for invitation e-mail, information sheet, and consent form). Participants were offered to receive copies of any publications that may result from the study and a summary of outcomes.

4.4.4 Ethics

Ethical approval was obtained from Cardiff University's School of Medicine Research Ethics Committee (SMREC Reference Number: 18/70). Ethical issues addressed in the design of the study include the requirement for experts to provide electronic informed consent. Following the invitation of experts by e-mail, potential participants were provided with a link to view and download the participant information sheet, while the electronic consent form was included as a mandatory first part of the survey. Potential participants

had a deadline of up to 14 days to decide whether they wished to participate in the study and inform the researcher, with a set date for when the survey link would expire.

All data and feedback presented in the questionnaires and reports were anonymised. The data collected throughout this study were to be kept securely in line with Cardiff University's Research Integrity and Governance Code of Practice (see Appendix 4.2 for further detail). Specifically, all data were stored with minimal identifiable information in secure, encrypted Cardiff University servers, with limited access to only the researchers of the study. Once the study was concluded (November 2020), all data were anonymised and will be kept for a further two years (minimum) before being deleted. Anonymisation of the data was to ensure confidentiality and data protection was further maintained through encryption and careful information sharing practices, where only researchers working on the study had access.

4.4.5 Definition of Consensus

For this study, consensus agreement was defined and considered to be achieved for statements with an Inter-Quartile Range (IQR) ≤ 2.00 when rated on the 9-point Likert-like scales and ≥ 70% level of agreement. Ratings of 1-3 were considered as *disagreement* (i.e., participants did not consider the statement of importance), while ratings of 4-6 were considered *neutral*, and ratings of 7-9 were considered as *agreement* (participants considered the statement of importance/agreed with the premise of the statement). Table 4.3 shows an example of the 9-point Likert-like scale used and two statements that the participants were asked to rate their agreement with using the scale points.

Table 4.3 An example of the 9-point Likert-like scale used in the survey

1. Please rate the extent to which you agree that the purpose of an international patient safety learning system (PSLS) is:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
1.01 Identification of patient safety risks relevant internationally.									
1.02 Surveillance of patient safety incidents to detect potential risks relevant internationally.									

Consensus agreement for the example statements in Table 4.3 was measured according to the two specified criteria above, IQR and percentage level of agreement. Thus, consensus is said to have been achieved for the statements if the IQR is ≤ 2.00 and 70% or more of the experts rated them 7 or higher on the 9-point Likert-like scale.

4.4.6 Delphi procedure

The online survey was developed by using Qualtrics online platform (https://www.qualtrics.com/uk/), and potential participants were invited via e-mail, sent via the platform. An explanatory statement about the project was included in the e-mail (See Appendix 4.1 for the invitation e-mail).

4.4.6.1 Round one

Participants in the first round were asked to rate their agreement with the presented statements on a 9-point Likert-like rating scale from 1: Strongly disagree to 9: Strongly agree. Participants were asked for justification for rating a statement 6 or below, in addition to optional free text to provide their comments/suggestion regarding the included statements and any additional statements they felt were applicable. With the ability to complete the survey over several sessions, and to allow participants to review their answers before final submission of their responses, the survey was estimated by the Qualtrics software to take around 30 minutes to complete. A pilot survey was completed to test the validity and reliability of the survey process; this is described further in 4.4.7.1.

4.4.6.2 Round two

Invitations to participate in round two were sent to only those who completed the first round of the survey. Each member of the panel was sent, after the first round, de-identified results comprising overall scores for each statement, which included the group median, agreement percentage and IQR for each statement. Driven by feedback and suggestions of the first round, newly generated statements were included in the second round along with statements that did not reach consensus agreement (i.e., less than 70% of participants agreed with the statement or felt the statement was important). This process involved an iterative series of discussions between the researcher and his primary supervisor, based on feedback from participants in the first round. Decisions to update or amend statements were based on feedback suggesting a lack of clarity or a need for refinement of wording, while new statements were considered where more extensive changes to the meaning or further clarification of a point was necessary. Furthermore, statements that were updated or amended were added along with original statements that did not reach consensus agreement. Statements that reached consensus in the first round were not included in the second round.

4.4.6.3 Possibility of a further round and terminating the Delphi

When it comes to a decision about conducting further rounds of the survey or terminating it, there is some debate over the optimal cut-off value used in Delphi surveys to determine

agreement levels. Agreement level values from 51 to 80% agreement with the importance of the variable have been reported, with no specific rule that specifies a clear cut-off value for consensus (Hasson et al., 2000; Veugelers et al., 2020). However, an agreement rate/consensus baseline of at least 70% has been suggested in order to maintain rigour in defining consensus (Hasson et al., 2000; Keeney et al., 2011) and is a commonly used benchmark based on an analysis of 98 Delphi studies published between 2000 and 2009 (Diamond et al., 2014). This cut-off value is also consistent with recent Delphi reports and was therefore considered appropriate (Dewa et al., 2018; Veugelers et al., 2020). It was decided by the researcher that if the response rate for the second round fell below 70%, then the survey would be terminated. Additionally, it was decided that if the panel reached consensus agreement on 80% of the statements of the first and second rounds (total statements achieved consensus/total statements in both rounds), then the survey would also be terminated regardless of the response rate. It was anticipated that there would be a total of three rounds of the survey. This is in line with the Delphi quality indicators proposed by Diamond et al. (2014), which would give this Delphi study a quality score of 4 out of 4.

4.4.7 Survey development

The development of the survey questions and statements was a product of three distinctive phases:

- Triangulation of the results of the systematic literature review (Chapter 2) and the results of the semi-structure key informant interviews (Chapter 3).
- Pilot testing with subject matter experts.
- Feedback from WHO affiliated group leading the WHO Collaborating Centre in Human Factors and Communication for the Delivery of Safe and Quality care in Florence, Italy. This group has led international consultation meetings on the subject of international sharing and learning and are therefore considered experts and reliable informants for shaping the content of the survey. This expert group provided a key role in validating earlier triangulation of results from previous chapters, based on this experience and knowledge.

Additionally, the candidate's supervisory team provided feedback that helped refine the wording of the questions and statements. Furthermore, the candidate's primary supervisor, Prof. Andrew Carson-Stevens, a health services researcher with a special interest in patient safety, was consulted during the entire process to provide his valuable feedback.

This feedback was based on reviewing the results of the study, particularly the qualitative feedback, and synthesising the feedback into statements. Moreover, a safety-critical industry expert that was interviewed (Chapter 3) was contacted to help answer three questions about how decisions are made on what safety incident is considered of international concern for sharing and learning in safety-critical industries. This communication has influenced the development of section 4B of round two's survey (see Appendix 4.4 for the e-mail).

4.4.7.1 Pilot

Polit and Beck (2008) suggest that any survey-based research methods should undergo pilot testing, a small-scale version of the major study, where the research process may be a concern or reliability or validity need to be established. Delphi surveys do not necessarily require pilot testing, according to Powell (2003), but it is recognised that pre-testing allows for the identification of ambiguities and can improve the quality of the research process. There is variability in the use of pilot studies for Delphi surveys in the literature, but Clibbens et al. (2012) found that common features of a pilot study in 25 published Delphi studies included an initial first-round whereby a small sample of participants undergo the survey to provide feedback not only on the content of the survey but also on a range of factors related to comprehension, time taken to complete the survey and survey structure. The survey was tested with two subject matter experts (see Appendix 4.5 for Pilot invitation e-mail).

The pilot testers were asked to provide feedback on the following, based on broad guidance provided by Clibbens et al. (2012):

- Survey layout (e.g., was it easy to follow and read?).
- Comprehension of the questions and statements (e.g., were they easy to understand?).
- Suggested changes to the survey.
- Duration of the survey (e.g., the time it took to complete the survey).
- Feedback on the instructions provided in the proposed invitation e-mail.
- Suggested changes to the invitation e-mail.

The aim of pilot testing the survey was to ensure content and face validity (Keeney et al., 2011), while the questions asked of the pilot testers were intended to assess flow, content, comprehension and clarity of the survey questions and statements.

4.4.7.2 Results of the pilot

The pilot testers provided extensive feedback in the form of written comments. A Microsoft Word document (Microsoft 365, version 2101; Redmond, Washington, US) was used to organise the feedback and track changes made to the survey based on the feedback. Changes included:

- Removal of duplicated texts (e.g., texts included in the information sheet and the online survey).
- Changes to the online survey layout (e.g., text size).
- Integrating two sections of the survey to reduce responder fatigue.
- Definitions of key terms used in the survey were integrated within the text as a hover-over text (i.e., hovering over a key term would display its definition).
- Rewording of certain text to clarify what is asked of the participants.
- Free text questions asking for feedback/ suggestions were made optional.
- The consent form was embedded within the survey in an electronic form.
- Editing of the invitation e-mail and participant information sheet to reduce duplicate texts.

These changes helped to reduce the estimated time (calculated by Qualtrics) to complete the survey from 40 to 30 minutes.

4.4.7.3 Further feedback from experts

The approved draft of the first round of the survey was shared with a team of experts, working at a WHO Collaborating Centre in Human Factors and Communication for the Delivery of Safe and Quality care, Florence, Italy, for further feedback. The experts evaluated the survey and made suggestions for further statements or areas of investigation, based on perceived value, as well as suggesting changes to the structure of the survey. This resulted in the addition of four new statements and the reorganisation of the order of statements in some sections (see Appendix 4.6 for the final version of the first round survey). The results of the pilot were submitted to the Chair of School of Medicine Research Ethics Committee for approval of the changes.

4.4.8 Data analysis

4.4.8.1 Qualitative data

Microsoft Word documents (Microsoft 365, version 2101; Redmond, Washington, US) were used to:

- Aggregate text-based data relating to participants' justifications for giving a statement a score of 6 or below.
- Aggregate text-based data concerning suggestions for new statements or feedback relevant to survey statements.

Panellists' justifications for giving a score of six or lower for statements were reviewed and used to generate new statements. Furthermore, feedback and suggestions from the panel were reviewed and used to generate new statements that were not covered in the first round. This included the introduction of a section about the criteria used to decide what patient safety risk(s) are of international concern for sharing and learning.

4.4.8.2 Quantitative analysis

A Microsoft Excel spreadsheet (Microsoft 365, version 2101; Redmond, Washington, US) was used to calculate percentage agreement, median, and IQR for each statement.

As described earlier with justification (section 4.4.5), the following consensus measurements were used:

- Certain level of agreement: ≥ 70% agreement with a statement on a 9-point Likert-like scale.
- IQR: ≤ 2.00 when rated on the 9-point Likert-like scale.

4.4.8.3 Ranking

Statements that have reached consensus agreement were ranked from highest to lowest based on:

- Percentage agreement,
- IQR, and
- the median, as Likert scales used comprised ordinal data, amenable to descriptive statistical analysis

4.5 Results

4.5.1 Demographics of the panellists

The first round of the survey included a section to collect demographic data to ensure that the participants met the inclusion criteria of the study (see Table 4.4 for a summary of participants' demographics). Figure 4.5 outlines the represented countries in the first round of the survey, respectively. Countries from all six continents were represented in the first round, which is in alignment with the international aspect of this study.

Table 4.4 Summary of the Demographics of Delphi Survey Participants

Profession	Total Number	Average number of years' experience in patient safety/quality improvement (range: 32 years)	Example of experience in patient safety at a national/international level	Example of experience in leadership roles within healthcare or patient safety organisations
Medical Doctor*	8	12 years	Contributor to various WHO medication safety initiatives	Chief quality and safety office at university hospital
Researcher	5	15 years	Consulted to the WHO	Senior executive in a national patient safety agency
Academic	3	28 years	Government committees, international meetings, advisory work	Former Chief Medical Adviser for a Health Agency
Leadership/ Management	3	15 years	Director of a national patient safety centre	Executive leader of national agency
Patient representative	1	12 years	Advisor to numerous national and international patient safety research initiatives	Patient safety teaching responsibility in medical and nursing programs
Medical coder	1	3 years	Works for a national patient safety centre	N/A

*Including physician, medical specialist (e.g., cardiologist)

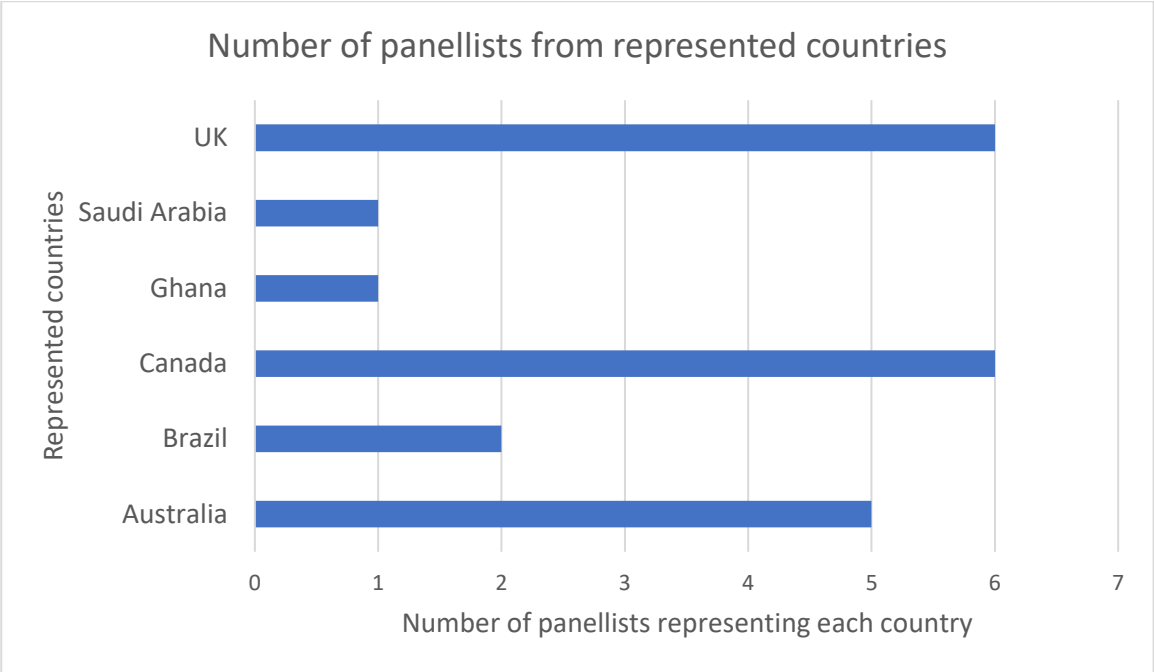

Figure 4.5 Countries represented in round one and the respective number of panellists

4.5.2 Results of the first round

A total of 73 potential participants were contacted to take part in the first round of the online Delphi study, three of whom were recommended by a participant. This resulted in 21 completed survey responses which equate to a response rate of 29%. The rationale behind inviting a large number of potential participants was to ensure that the recruitment target of 20 experts would be achieved.

The first round of the online Delphi survey consisted of four main sections (see Appendix 4.6):

- Section one: purpose(s) of a potential international patient safety learning system.
- Section two: key features and functions of a potential international patient safety learning system (PSLS).
- Section three: patient safety Incidents relevant to international sharing and learning.
- Section four: enablers and challenges to setting up an international patient safety learning system (PSLS).

Each section had a rating question with listed statements, and optional free text questions for further feedback/suggestions, producing quantitative and qualitative data.

4.5.2.1 Purpose of an international patient safety learning system (PSLS)

The panel was presented with 12 statements to rate the importance of the statements on what could be viewed as a purpose of a potential international PSLS. Consensus (as defined in 4.4.5) was achieved for nine of the statements (9/12=75%), as shown in Figure 4.6. For the remaining three statements, no consensus agreement was achieved regarding importance or unimportance. Table 4.5 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median. Statements that the panel did not reach consensus agreement on are written in dark red text.

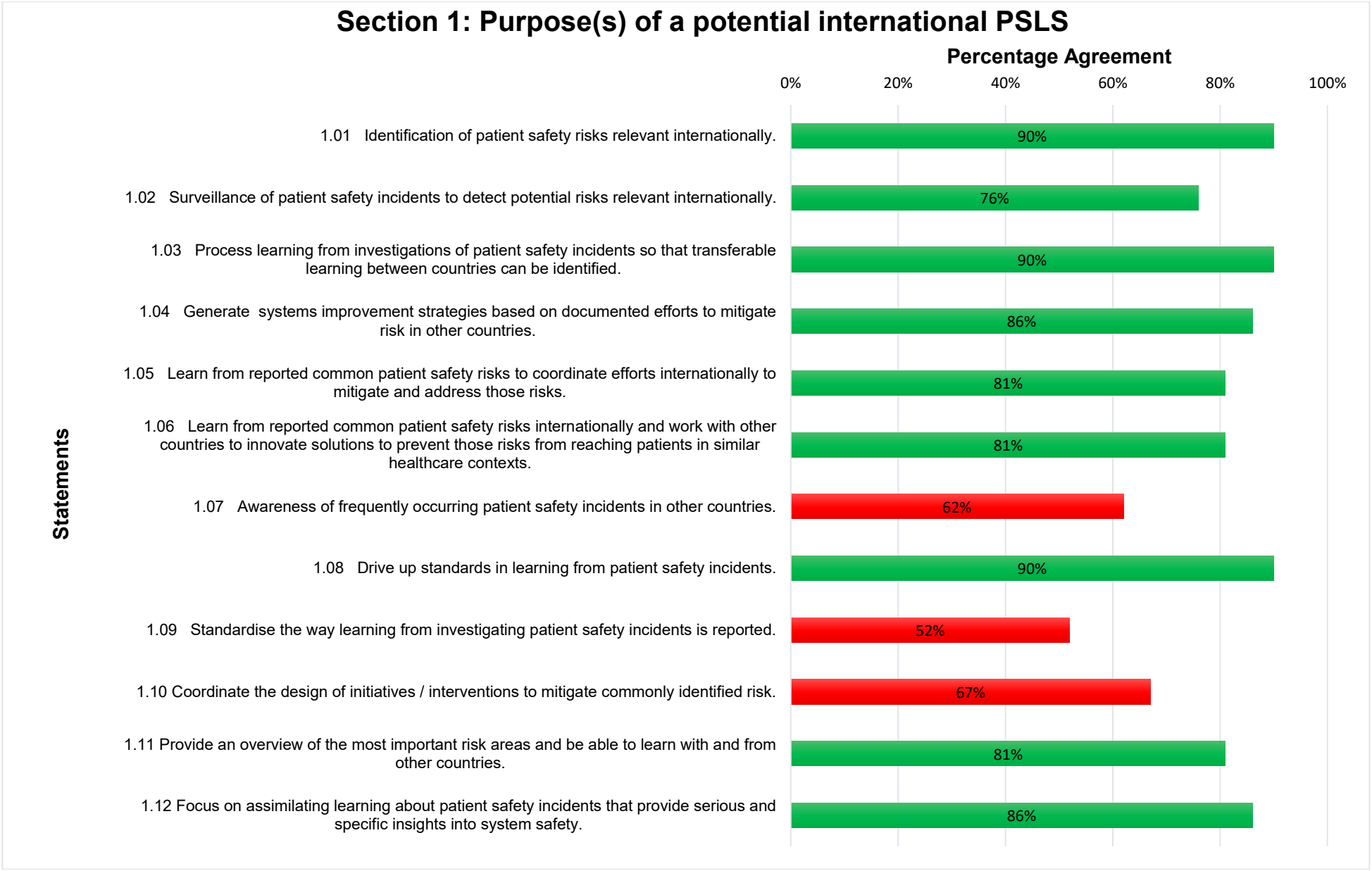

Figure 4.6 Percentage agreement of statements in section 1 (round one)

Table 4.5 Statistical breakdown for statements in section 1 (round one)

Section 1: Purpose(s) of a potential international patient safety learning system (PSLS)					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
1.01 Identification of patient safety risks relevant internationally.	90%	10%	0%	2	8
1.02 Surveillance of patient safety incidents to detect potential risks relevant internationally.	76%	19%	5%	2	8
1.03 Process learning from investigations of patient safety incidents so that transferable learning between countries can be identified.	90%	10%	0%	1	9
1.04 Generate systems improvement strategies based on documented efforts to mitigate risk in other countries.	86%	14%	0%	2	8
1.05 Learn from reported common patient safety risks to coordinate efforts internationally to mitigate and address those risks.	81%	14%	5%	1	8
1.06 Learn from reported common patient safety risks internationally and work with other countries to innovate solutions to prevent those risks from reaching patients in similar healthcare contexts.	81%	14%	5%	2	8
1.07 Awareness of frequently occurring patient safety incidents in other countries.	**62%**	33%	5%	**2**	8
1.08 Drive up standards in learning from patient safety incidents	90%	5%	5%	1	9
1.09 Standardise the way learning from investigating patient safety incidents is reported.	**52%**	33%	14%	**2**	7
1.10 Coordinate the design of initiatives / interventions to mitigate commonly identified risk.	**67%**	33%	0%	**2**	8
1.11 Provide an overview of the most important risk areas and be able to learn with and from other countries.	81%	19%	0%	1	8
1.12 Focus on assimilating learning about patient safety incidents that provide serious and specific insights into system safety.	86%	14%	0%	2	8

4.5.2.2 Key features and functions of an international PSLS

The panel was presented with 17 statements to rate the importance of key variables of key features and functions of a potential international PSLS. Consensus was achieved for 14 of the statements (14/17=82%), as shown in Figure 4.7. For the remaining three statements, no consensus was achieved either on the importance or unimportance of the variables for an international PSLS. Table 4.6 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median. Statements that the panel did not reach a consensus agreement on are written in dark red text.

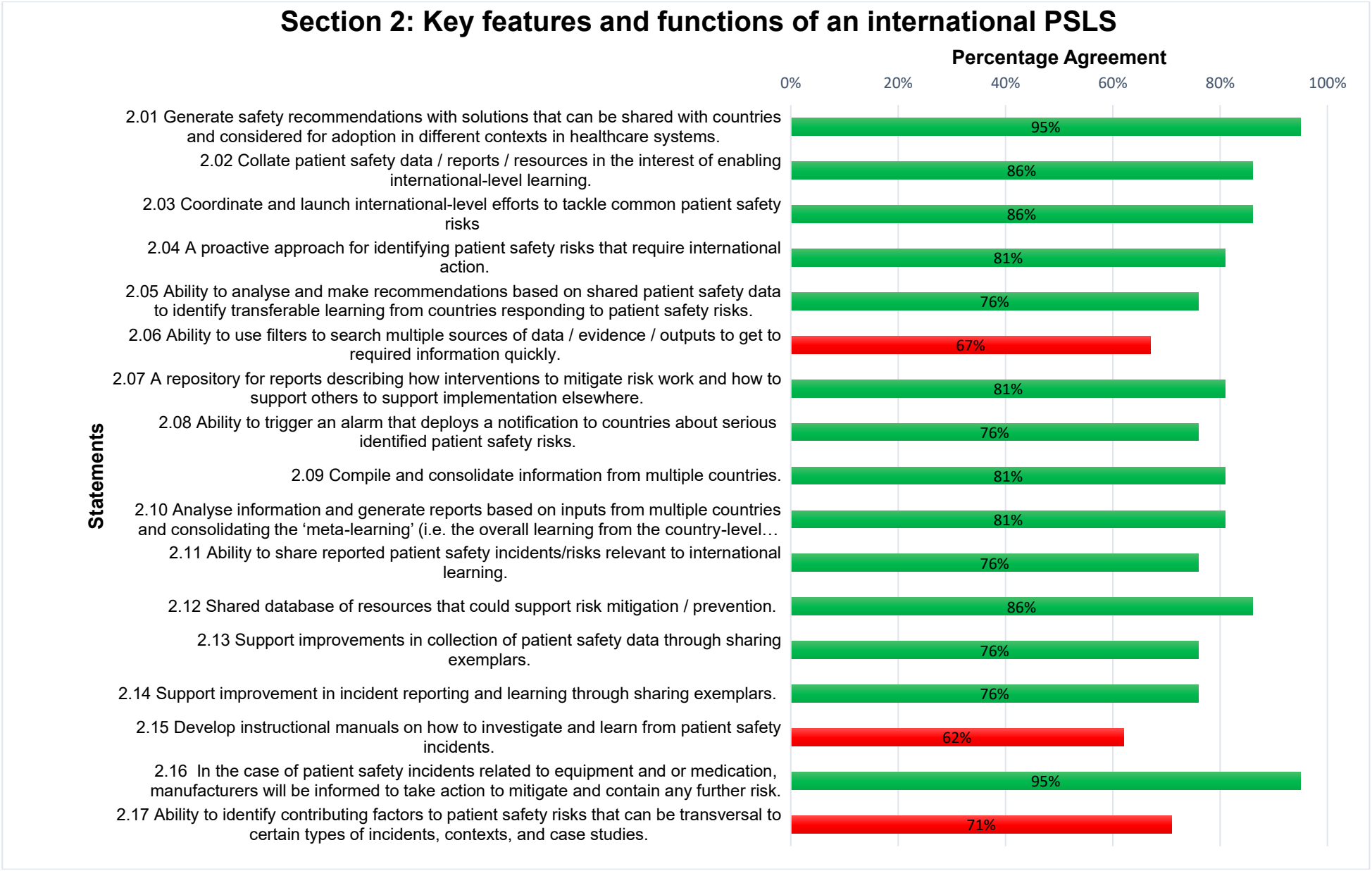

Figure 4.7 Percentage agreement of statements in section 2 (round one)

Table 4.6 Statistical breakdown for statements in section 2 (round one)

Section 2: Key features and functions of a potential international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
2.01 Generate safety recommendations with solutions that can be shared with countries and considered for adoption in different contexts in healthcare systems.	95%	5%	0%	2	8
2.02 Collate patient safety data / reports / resources in the interest of enabling international-level learning.	86%	14%	0%	2	8
2.03 Coordinate and launch international-level efforts to tackle common patient safety risks	86%	14%	0%	2	8
2.04 A proactive approach for identifying patient safety risks that require international action.	81%	19%	0%	2	8
2.05 Ability to analyse and make recommendations based on shared patient safety data to identify transferable learning from countries responding to patient safety risks.	76%	24%	0%	2	8
2.06 Ability to use filters to search multiple sources of data / evidence / outputs to get to required information quickly.	**67%**	24%	10%	**2**	8
2.07 A repository for reports describing how interventions to mitigate risk work and how to support others to support implementation elsewhere.	81%	19%	0%	2	8
2.08 Ability to trigger an alarm that deploys a notification to countries about serious identified patient safety risks.	76%	19%	5%	2	8
2.09 Compile and consolidate information from multiple countries.	81%	19%	0%	2	8
2.10 Analyse information and generate reports based on inputs from multiple countries and consolidating the 'meta-learning' (i.e. the overall learning from the country-level learning).	81%	14%	5%	2	8
2.11 Ability to share reported patient safety incidents/risks relevant to international learning.	76%	19%	5%	2	9
2.12 Shared database of resources that could support risk mitigation / prevention.	86%	10%	5%	2	8
2.13 Support improvements in collection of patient safety data through sharing exemplars.	76%	19%	5%	2	8

2.14 Support improvement in incident reporting and learning through sharing exemplars.	76%	19%	5%	1	8
2.15 Develop instructional manuals on how to investigate and learn from patient safety incidents.	**62%**	33%	5%	**2**	7
2.16 In the case of patient safety incidents related to equipment and or medication, manufacturers will be informed to take action to mitigate and contain any further risk.	95%	5%	0%	1	9
2.17 Ability to identify contributing factors to patient safety risks that can be transversal to certain types of incidents, contexts, and case studies.	**71%**	24%	5%	**3**	8

4.5.2.3 Patient safety incidents relevant to international sharing and learning

The panel was presented with nine statements to rate the importance of the variables of proposed patient safety incidents that are deemed relevant to international sharing and learning, as part of the proposed PSLS. Consensus was achieved for seven of the statements (7/9=78%), as shown in Figure 4.8. Table 4.7 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median. Statements that the panel did not reach a consensus agreement on are written in dark red text.

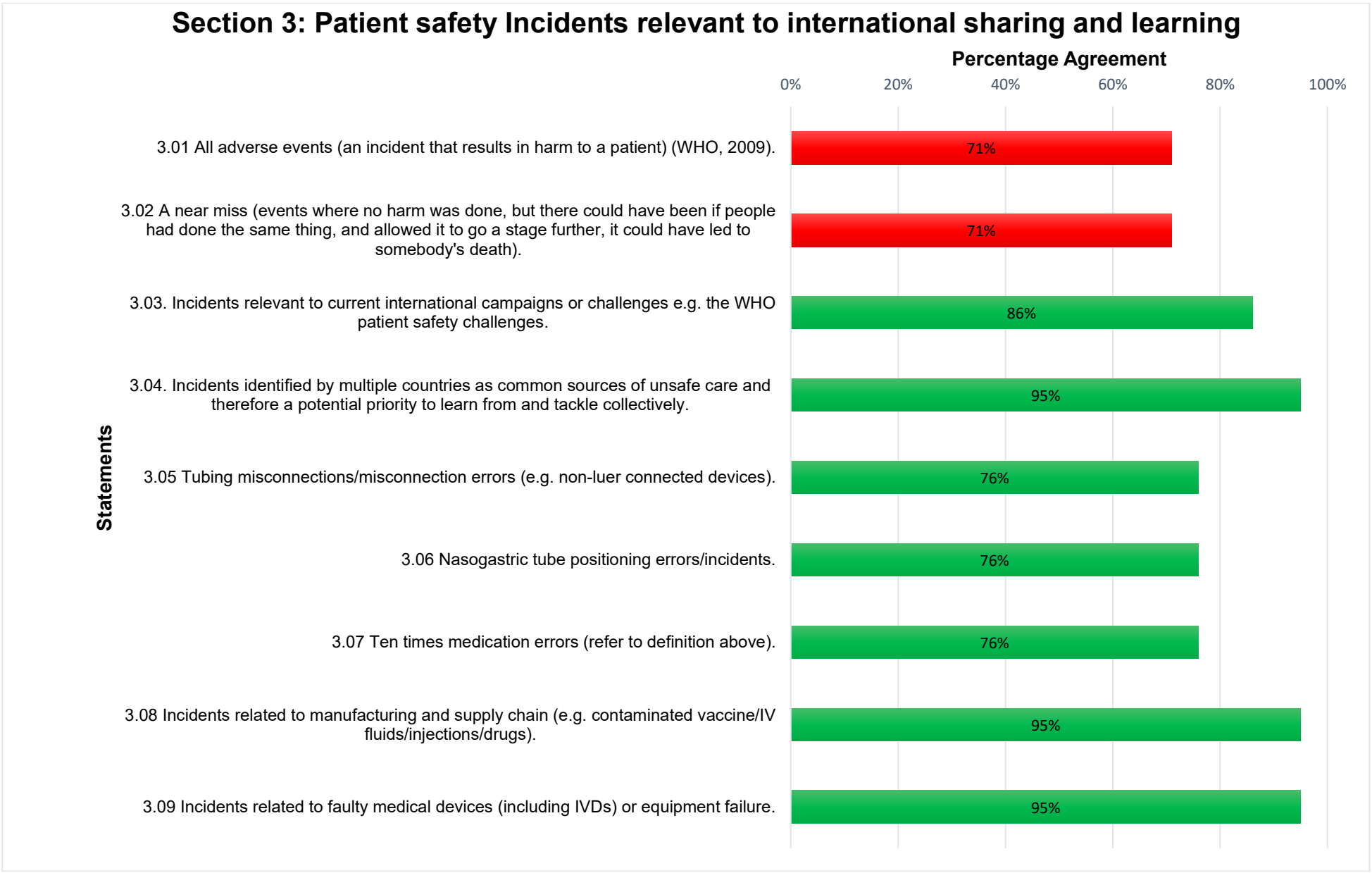

Figure 4.8 Percentage agreement of statements in section 3 (round one)

Table 4.7 Statistical breakdown for statements in section 3 (round one)

Section 3: Patient safety Incidents relevant to international sharing and learning					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
3.01 All adverse events (an incident that results in harm to a patient) (WHO, 2009)	**71%**	14%	14%	**3**	8
3.02 A near miss (events where no harm was done, but there could have been if people had done the same thing, and allowed it to go a stage further, it could have led to somebody's death).	**71%**	14%	14%	**3**	7
3.03. Incidents relevant to current international campaigns or challenges e.g. the WHO patient safety challenges	86%	14%	0%	2	8
3.04. Incidents identified by multiple countries as common sources of unsafe care and therefore a potential priority to learn from and tackle collectively.	95%	5%	0%	2	8
3.05 Tubing misconnections/misconnection errors (e.g. non-luer connected devices).	76%	19%	5%	2	7
3.06 Nasogastric tube positioning errors/incidents.	76%	19%	5%	2	7
3.07 Ten times medication errors (refer to definition above)	76%	19%	5%	2	8
3.08 Incidents related to manufacturing and supply chain (e.g. contaminated vaccine/IV fluids/injections/drugs)	95%	5%	0%	1	8
3.09 Incidents related to faulty medical devices (including IVDs) or equipment failure.	95%	5%	0%	1	8

4.5.2.4 Criteria used to decide what patient safety incident is of international concern for sharing and learning

The panel was asked an open-ended question about the criteria used when deciding what patient safety incident is of international concern, particularly for sharing and learning. Review and thematic analysis of the free-text feedback and comments from the panel resulted in the generation of the following statements, to be included in the second round of the survey as a new sub-section:

- Morbidity and mortality from patient safety risks/events (i.e. impact and severity).
- Stakeholders' interest on specific patient safety incidents/risks.
- Ease of measurement of the identified patient safety risk(s) in multiple countries.
- The availability of evidence to support unequivocal preventability.
- Identified patient safety risk(s) is/are relevant to more than one country e.g. supply of material/medicine/raw materials/devices originating in another country.
- Risk of harming a large number of individuals in multiple countries if no intervention is taken.
- Identified patient safety risk(s) is/are relevant to more than one country facing similar clinical challenges e.g. prevention and control of infectious disease.
- The proposed patient safety solution needs international action, e.g. action from major pharmaceutical companies.

4.5.2.5 Enablers and challenges to setting up an international PSLS

The panel was presented with 24 statements to rate the importance of statements of potential enablers and challenges to the setting up of an international PSLS. These statements were divided into 16 statements that addressed enablers and eight statements that addressed challenges/ barriers.

4.5.2.5.1 Key enablers to the setup of an international PSLS

Consensus that the statements were important was achieved for 14 of the statements (14/16=88%), as shown in Figure 4.9. There was no clear consensus for the other two statements for either importance or unimportance in relation to an international PSLS. Table 4.8 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median. Statements that the panel did not reach a consensus agreement on are written in dark red text.

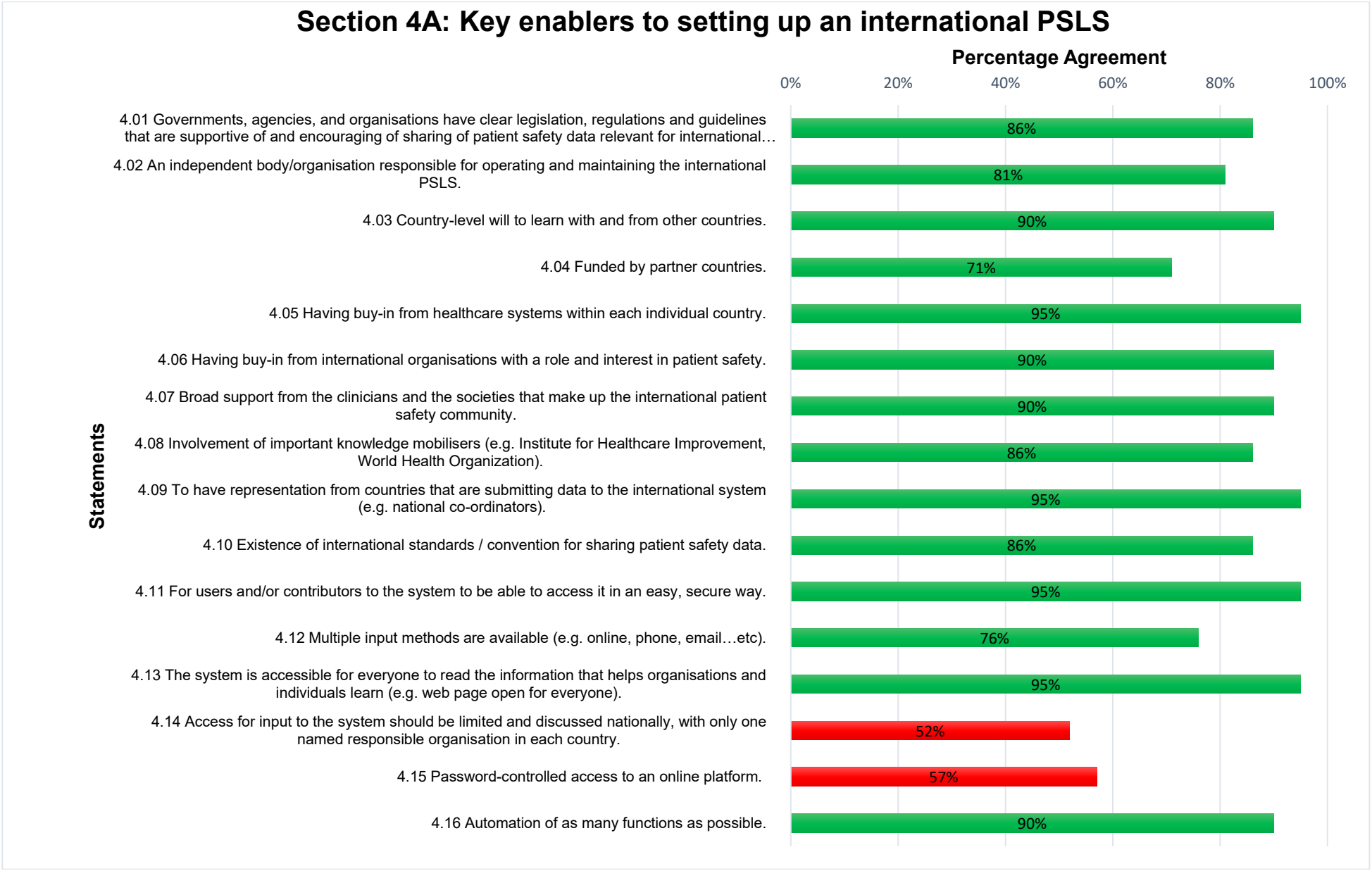

Figure 4.9 Percentage agreement of statements in section 4A (round one)

Table 4.8 Statistical breakdown for statements in section 4A (round one)

Section 4A: Key enablers to setting up an international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
4.01 Governments, agencies, and organisations have clear legislation, regulations and guidelines that are supportive of and encouraging of sharing of patient safety data relevant for international learning.	86%	5%	10%	2	8
4.02 An independent body/organisation responsible for operating and maintaining the international PSLS.	81%	19%	0%	1	7
4.03 Country-level will to learn with and from other countries.	90%	10%	0%	1	8
4.04 Funded by partner countries.	71%	29%	0%	2	8
4.05 Having buy-in from healthcare systems within each individual country.	95%	5%	0%	1	8
4.06 Having buy-in from international organisations with a role and interest in patient safety.	90%	10%	0%	2	9
4.07 Broad support from the clinicians and the societies that make up the international patient safety community.	90%	10%	0%	1	9
4.08 Involvement of important knowledge mobilisers (e.g. Institute for Healthcare Improvement, World Health Organization).	86%	14%	0%	2	8
4.09 To have representation from countries that are submitting data to the international system (e.g. national co-ordinators).	95%	5%	0%	2	8
4.10 Existence of international standards / convention for sharing patient safety data.	86%	14%	0%	2	8
4.11 For users and/or contributors to the system to be able to access it in an easy, secure way.	95%	0%	5%	1	9
4.12 Multiple input methods are available (e.g. online, phone, e-mail…etc).	76%	14%	10%	2	8

4.13 The system is accessible for everyone to read the information that helps organisations and individuals learn (e.g. web page open for everyone).	95%	0%	5%	1	8
4.14 Access for input to the system should be limited and discussed nationally, with only one named responsible organisation in each country.	**52%**	24%	24%	**4**	7
4.15 Password-controlled access to an online platform.	**57%**	24%	19%	**3**	7
4.16 Automation of as many functions as possible.	90%	5%	5%	2	9

4.5.2.5.2 Key challenges/ barriers to the setup of an international PSLS

Consensus that the statements were important was achieved for all eight statements (8/8=100%), as shown in Figure 4.10. Table 4.9 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median.

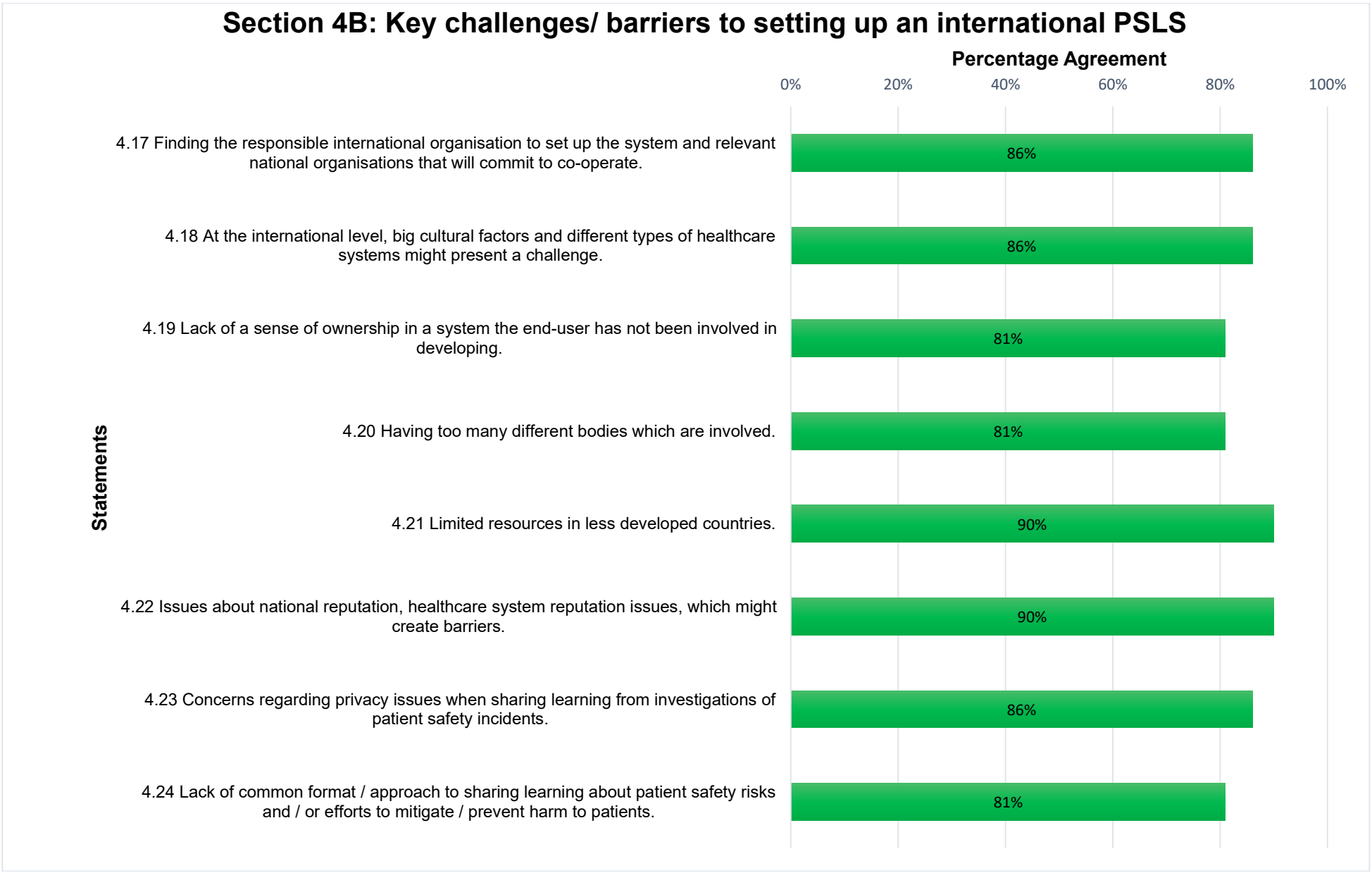

Figure 4.10 Percentage agreement of statements in section 4B (round one)

Table 4.9 Statistical breakdown for statements in section 4B (round one)

Section 4B: Key challenges/ barriers to setting up an international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
4.17 Finding the responsible international organisation to set up the system and relevant national organisations that will commit to co-operate.	86%	10%	5%	2	8
4.18 At the international level, big cultural factors and different types of healthcare systems might present a challenge.	86%	10%	5%	2	8
4.19 Lack of a sense of ownership in a system the end-user has not been involved in developing.	81%	14%	5%	2	8
4.20 Having too many different bodies which are involved.	81%	19%	0%	1	7
4.21 Limited resources in less developed countries.	90%	5%	5%	1	9
4.22 Issues about national reputation, healthcare system reputation issues, which might create barriers.	90%	10%	0%	2	8
4.23 Concerns regarding privacy issues when sharing learning from investigations of patient safety incidents.	86%	10%	5%	2	8
4.24 Lack of common format / approach to sharing learning about patient safety risks and / or efforts to mitigate / prevent harm to patients.	81%	14%	5%	2	8

4.5.2.6 Newly generated statements to be included in round two of the Delphi study

The qualitative data from the panel have resulted in the generation of 33 statements, in addition to the eight statements outlined in section 4.5.2.4. These 33 statements are outlined below, organized by their relevant section of the survey (Table 4.10).

Table 4.10 Delphi statements according to their main categories

Category	Associated statements
Purpose(s) of an international PSLS	Identify evidence-practice gaps that are occurring in similar contexts in other countries in order to develop interventions together.
	Learn from patients and families about risk, harm, response, and remediation.
	Bolster capability of those seeking to improve safety by benefitting from the shared learnings of those that have achieved improvements in safety in similar care contexts.
	Learn with and from countries about efforts to improve patient safety in terms of what works and how.
	Identify priorities for research and development to focus international efforts and resources where they are needed most.
	Co-ordinate efforts of national patient safety organisations in collaboration with WHO.
	Sharing affordable design-based interventions.
Key features and functions of an international PSLS	Facilitate learning and support through a range of formats (e.g. instructional manuals, train-the-trainer workshops, webinars, onsite learning)
	Develop a structured process for investigating patient safety risks identified by the international learning system.
	Develop methodologies to evaluate practices to learn from patients and family members in all facets of patient safety, including prevention, response, recovery, and remediation.
	Support the progression of countries towards a proactive and personalised clinical risk management approach i.e. moving from a reactive to a proactive mindset.
	To develop methodological approaches for assimilating a range of descriptive patient safety data to build a more complete understanding of safety within countries.
Patient safety incidents relevant to international sharing and learning	Incidents where risk of severe harm or death is likely, should the same incident reoccur.
	Incidents that result from relatively novel contributory factors e.g. pandemics, electricity outage, internet outage, civil unrest, war, funding issues, natural disasters, deliberate sabotage, criminal activity.
	Patient safety risks that are new and/or have not been reported before in your country.
	Patient safety risks related to diagnostic errors.

	Incidents related to drug and equipment safety.
	Any incident type that impacts paediatric patients.
	Incident involves a product or device that might be a major contributing factor to the incident.
Key enabling factors for the setup of an international PSLS	Having political will to generate and co-ordinate patient safety interventions of international concern.
	Having internationally comparative patient safety data.
	Encouraging and funding cross-jurisdictional studies of strategies designed and evaluated to understand better system functioning and implementation impact.
	Having a standardised international patient safety taxonomy.
	Having the patient experience as a facilitator around which common definitions of harm and their priority for mitigation are set.
	The benefits for those who are supposed to feed the information to the system are very clear.
	Deploying resources/learning where they are needed most.
Key challenges/ barriers to the setup of an international PSLS	Many countries have multiple reporting and learning organisations.
	Many countries are at very different maturity levels with respect to just/safety culture.
	Difficulty with funding this learning system even from participating countries.
	The "what's in it for me" problem, i.e. to find the value proposition/business case in the various and varied jurisdictions.
	Potential cost of establishing and maintaining the system.
	The information collected by this system will have limited utility if it is relying on system centric versions of patient harm without explicitly including the patient perspective of harm.
	Lack of a data / information governance strategy.

4.5.3 Results of the second round

Experts who participated in the first round were invited to participate in the second round of the Delphi. A total of 21 invitation e-mails were sent. This resulted in **15** completed survey responses which equates to a response rate of **71%** (15/21). This is also in line with the required 70% response rate to maintain rigour (Keeney et al., 2011; see also section 4.4.2.3.3).

The second round of the online Delphi survey consisted of the same four main sections (see Appendix 4.7) as the first round, with the addition of a new subsection to section three that explored the criteria that are used when deciding about what constitutes an

internationally relevant patient safety risk(s) for sharing and learning. Furthermore, statements that did not achieve consensus in the first round were forwarded to the second round. Each of these forwarded statements gave individual panellists the chance to change their scoring and were provided with their scoring from the first round as well as the group median score.

4.5.2.7 Purpose of an international patient safety learning system (PSLS)

The panel was presented with ten statements to rate their level of agreement with statements on what could be viewed as a purpose of a potential international PSLS. These statements included three statements from the first round that did not achieve consensus and seven new statements based on feedback/ suggestions from the panel. Consensus was achieved for nine of the statements (9/10=90%), as shown in Figure 4.11. Table 4.11 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median. Statements that the panel did not reach a consensus agreement on are written in dark red text.

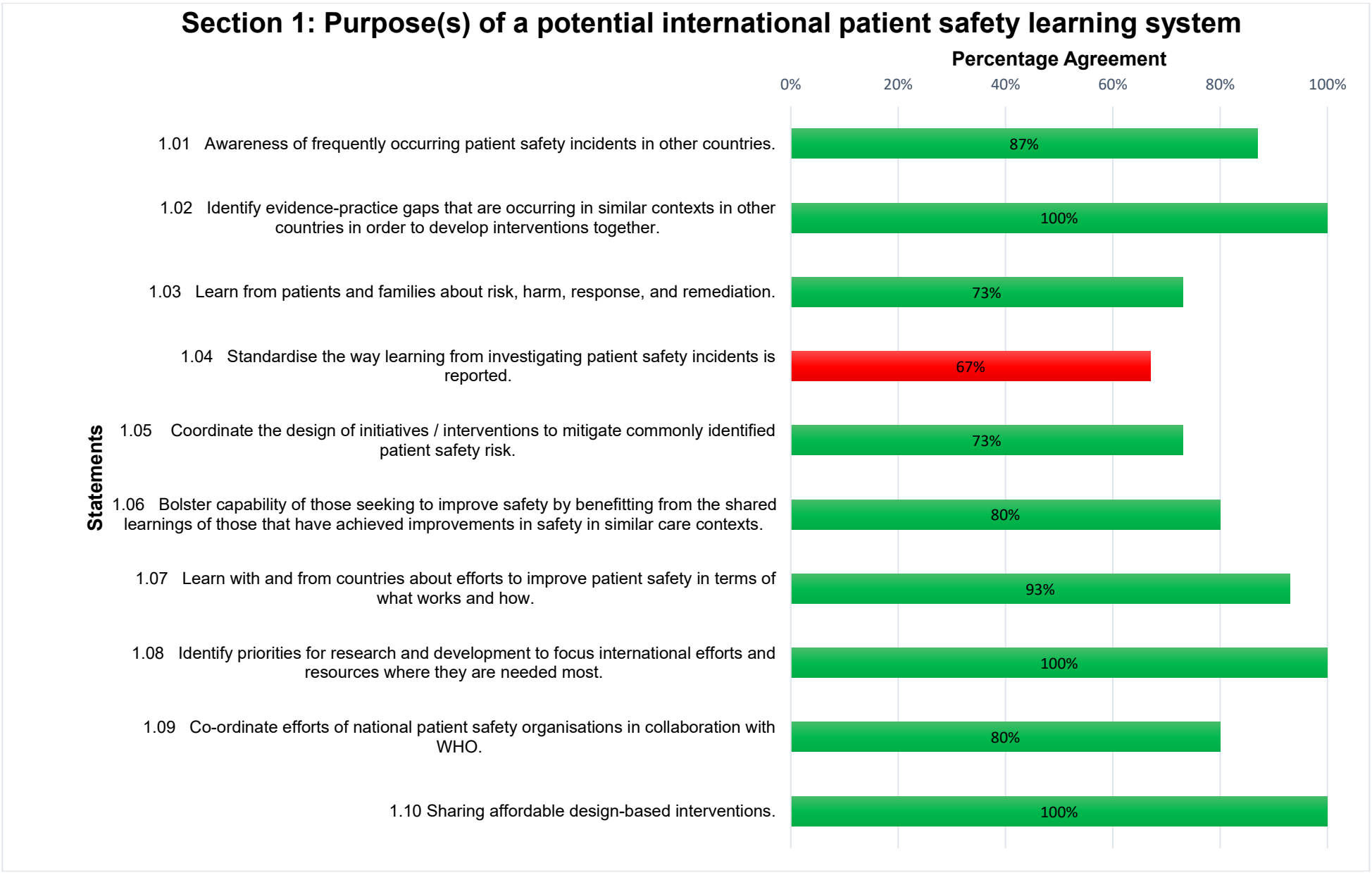

Figure 4.11 Percentage agreement of statements in section 1 (second round)

Table 4.11 Statistical breakdown for statements in section 1 (second round)

Section 1: Purpose(s) of a potential international patient safety learning system (PSLS)					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
1.01 Awareness of frequently occurring patient safety incidents in other countries. [1st round % agreement = 62% ; IQR = 2 ; group median = 8]	87%	7%	7%	2	8
1.02 Identify evidence-practice gaps that are occurring in similar contexts in other countries in order to develop interventions together.	100%	0%	0%	1	7
1.03 Learn from patients and families about risk, harm, response, and remediation.	73%	27%	0%	1.5	8
1.04 Standardise the way learning from investigating patient safety incidents is reported. [1st round % agreement = 52% ; IQR = 2 ; group median = 7]	**67%**	27%	7%	**2**	7
1.05 Coordinate the design of initiatives / interventions to mitigate commonly identified patient safety risk. [1st round % agreement = 67% ; IQR = 2 ; group median = 8]	73%	27%	0%	1.5	7
1.06 Bolster capability of those seeking to improve safety by benefitting from the shared learnings of those that have achieved improvements in safety in similar care contexts.	80%	20%	0%	2	8
1.07 Learn with and from countries about efforts to improve patient safety in terms of what works and how.	93%	7%	0%	1.5	8
1.08 Identify priorities for research and development to focus international efforts and resources where they are needed most.	100%	0%	0%	1	8
1.09 Co-ordinate efforts of national patient safety organisations in collaboration with WHO.	80%	20%	0%	1	8
1.10 Sharing affordable design-based interventions.	100%	0%	0%	1.5	8

4.5.2.8 Key features and functions of an international PSLS

A total of eight statements were presented to the panel, three of which were forwarded from the first round, and five new statements that were generated based on the panel's feedback and suggestions. Consensus was achieved for all statements (8/8=100%), as shown in Figure 4.12. Table 4.12 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median.

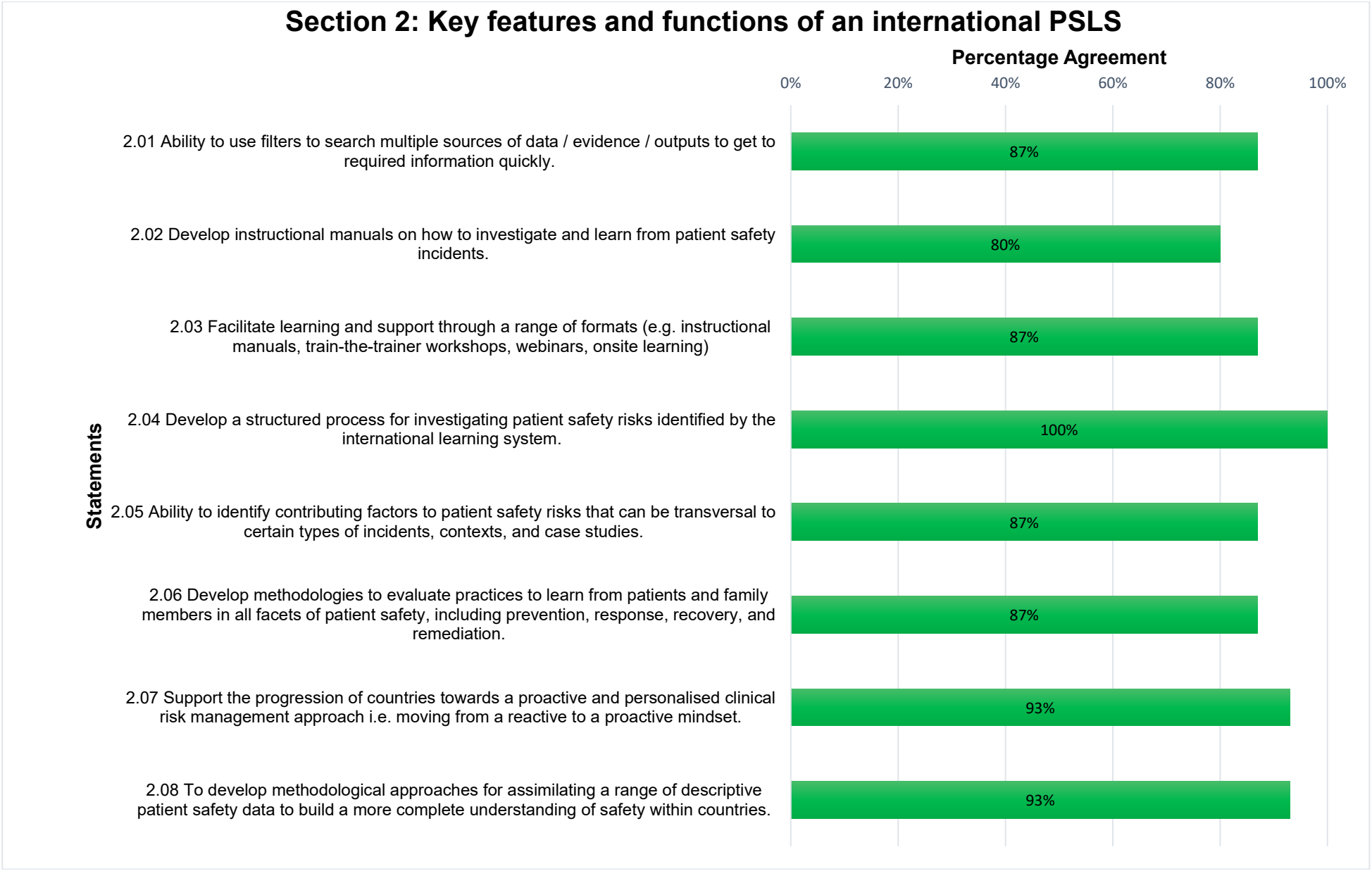

Figure 4.12 Percentage agreement of statements in section 2 (second round)

Table 4.12 Statistical breakdown for statements in section 2 (second round)

Section 2: Key features and functions of a potential international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
2.01 Ability to use filters to search multiple sources of data / evidence / outputs to get to required information quickly. [1st round % agreement = 67% ; IQR = 2 ; group median = 8]	87%	7%	7%	0.5	8
2.02 Develop instructional manuals on how to investigate and learn from patient safety incidents. [1st round % agreement = 62% ; IQR = 2 ; group median = 7]	80%	20%	0%	1	8
2.03 Facilitate learning and support through a range of formats (e.g. instructional manuals, train-the-trainer workshops, webinars, onsite learning)	87%	13%	0%	1	7
2.04 Develop a structured process for investigating patient safety risks identified by the international learning system.	100%	0%	0%	2	7
2.05 Ability to identify contributing factors to patient safety risks that can be transversal to certain types of incidents, contexts, and case studies. [1st round % agreement = 71% ; IQR = 3 ; group median = 8]	87%	7%	7%	1	8
2.06 Develop methodologies to evaluate practices to learn from patients and family members in all facets of patient safety, including prevention, response, recovery, and remediation.	87%	13%	0%	1.5	7
2.07 Support the progression of countries towards a proactive and personalised clinical risk management approach i.e. moving from a reactive to a proactive mindset.	93%	7%	0%	1.5	8
2.08 To develop methodological approaches for assimilating a range of descriptive patient safety data to build a more complete understanding of safety within countries.	93%	7%	0%	1	8

4.5.2.9 Patient safety incidents relevant to international sharing and learning

A total of nine statements were presented to the panel, two of which were forwarded from the first round, and six new statements that were generated from the panel's suggestions and feedback. Consensus was achieved for all statements (9/9=100%), as shown in Figure 4.13. Table 4.13 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral as, explained in 4.4.5, in addition to IQR and group median.

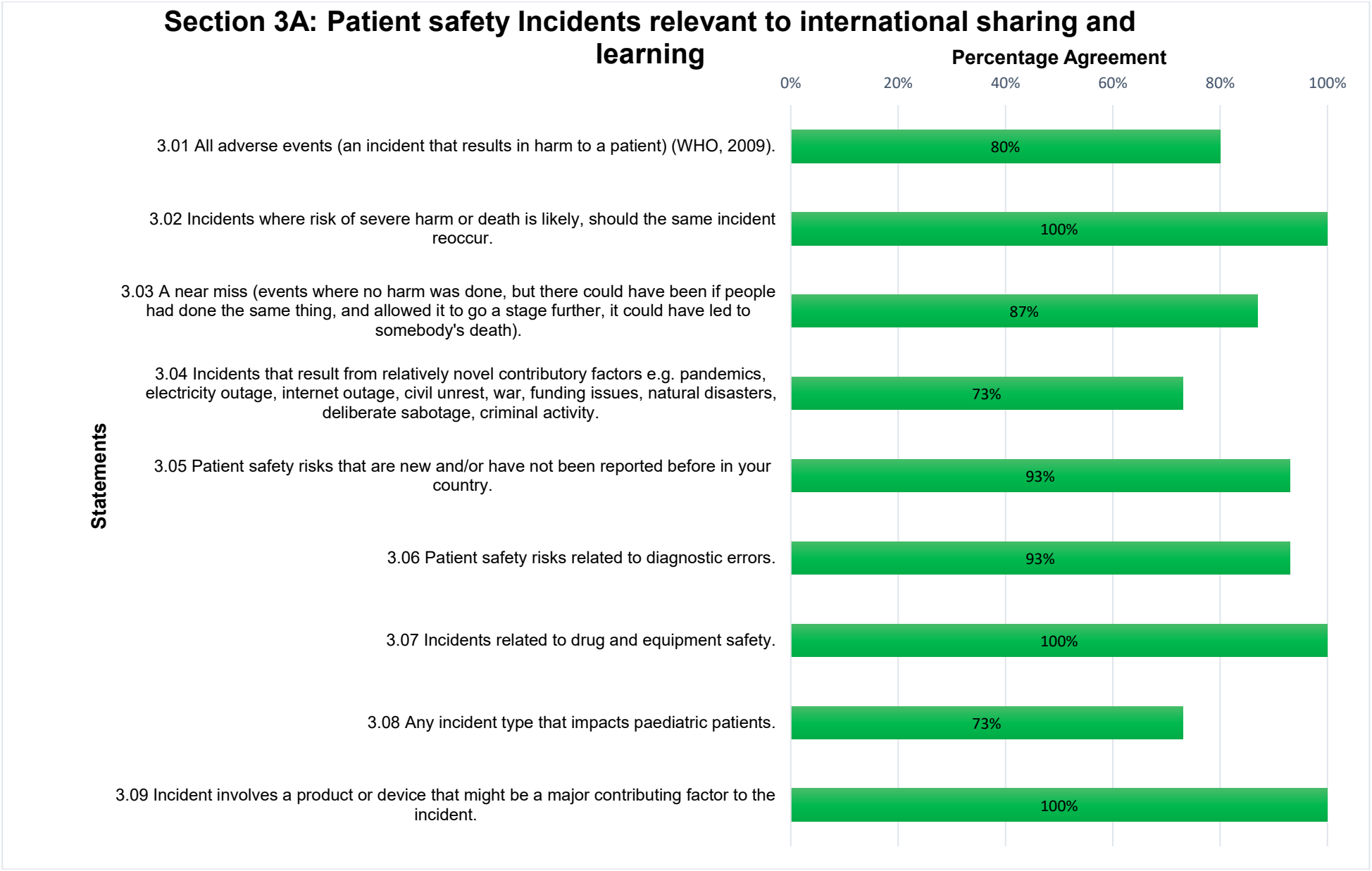

Figure 4.13 Percentage agreement of statements in section 3A (second round)

Table 4.13 Statistical breakdown for statements in section 3A (second round)

Section 3A: Patient safety Incidents relevant to international sharing and learning					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
3.01 All adverse events (an incident that results in harm to a patient) (WHO, 2009). [1st round % agreement = 71% ; IQR = 3 ; group median = 8]	80%	20%	0%	3	8
3.02 Incidents where risk of severe harm or death is likely, should the same incident reoccur.	100%	0%	0%	3	7
3.03 A near miss (events where no harm was done, but there could have been if people had done the same thing, and allowed it to go a stage further, it could have led to somebody's death). [1st round % agreement = 71% ; IQR = 3 ; group median = 7]	87%	7%	7%	2	8
3.04 Incidents that result from relatively novel contributory factors e.g. pandemics, electricity outage, internet outage, civil unrest, war, funding issues, natural disasters, deliberate sabotage, criminal activity.	73%	27%	0%	2	8
3.05 Patient safety risks that are new and/or have not been reported before in your country.	93%	7%	0%	2	7
3.06 Patient safety risks related to diagnostic errors.	93%	7%	0%	2	7
3.07 Incidents related to drug and equipment safety.	100%	0%	0%	2	8
3.08 Any incident type that impacts paediatric patients.	73%	27%	0%	1	8
3.09 Incident involves a product or device that might be a major contributing factor to the incident.	100%	0%	0%	1	8

4.5.2.10 Criteria used to decide what patient safety incident is of international concern for sharing and learning

Suggestions and feedback from the panel in the first round resulted in the generation of eight new statements, which were presented to the panel as a subsection (Section 3B). Consensus was achieved for all statements (8/8=100%), as shown in Figure 4.14. Table 4.14 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median.

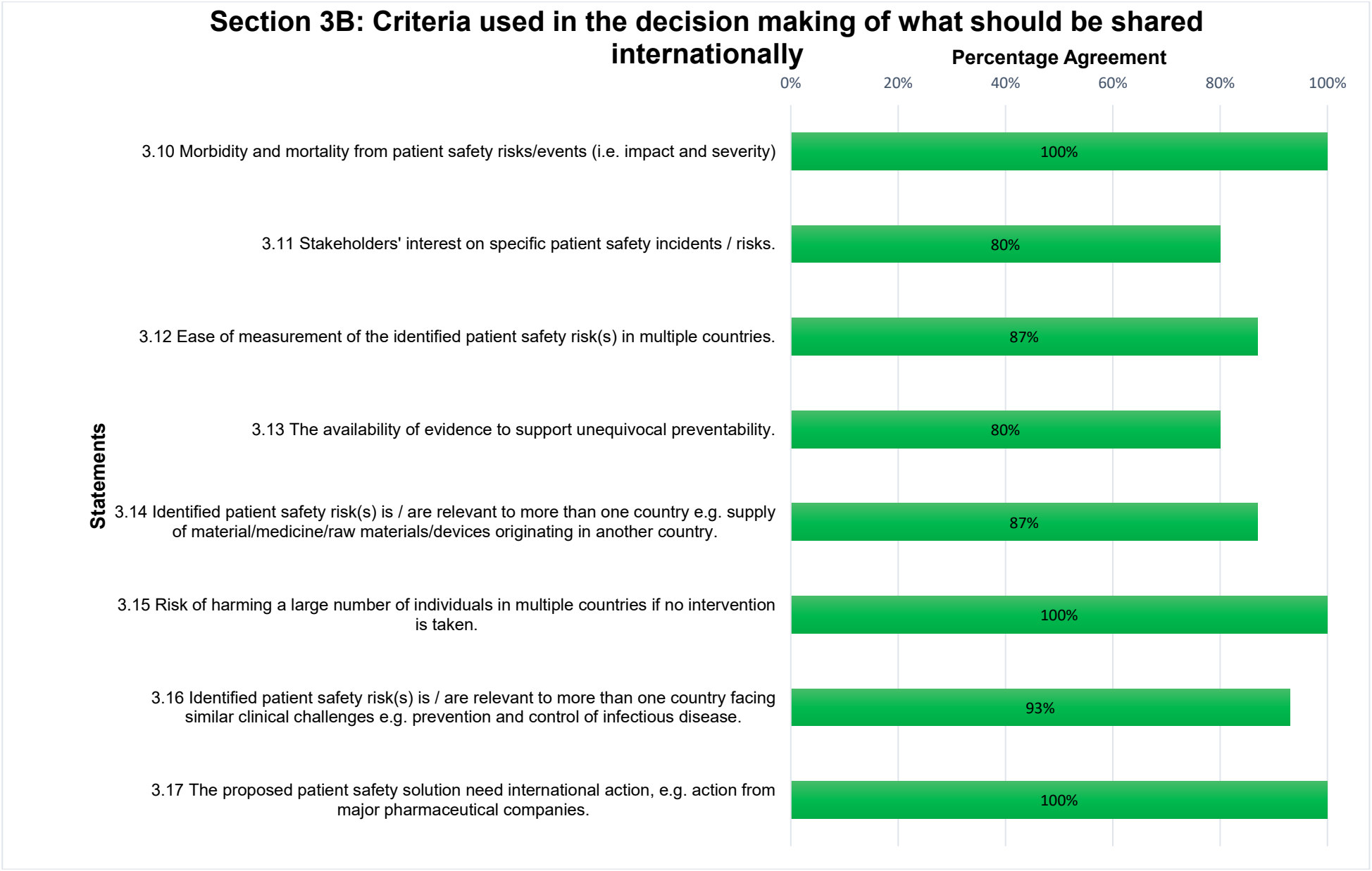

Figure 4.14 Percentage agreement of statements in section 3B (second round)

Table 4.14 Statistical breakdown for statements in section 3B (second round)

Section 3B: Criteria used in the decision making of what should be shared internationally					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
3.10 Morbidity and mortality from patient safety risks/events (i.e. impact and severity)	100%	0%	0%	1	8
3.11 Stakeholders' interest on specific patient safety incidents / risks.	80%	20%	0%	1	7
3.12 Ease of measurement of the identified patient safety risk(s) in multiple countries.	87%	7%	7%	1.5	8
3.13 The availability of evidence to support unequivocal preventability.	80%	13%	7%	2	8
3.14 Identified patient safety risk(s) is / are relevant to more than one country e.g. supply of material/medicine/raw materials/devices originating in another country.	87%	7%	7%	1	8
3.15 Risk of harming a large number of individuals in multiple countries if no intervention is taken.	100%	0%	0%	0.5	9
3.16 Identified patient safety risk(s) is / are relevant to more than one country facing similar clinical challenges e.g. prevention and control of infectious disease.	93%	0%	7%	0	8
3.17 The proposed patient safety solution need international action, e.g. action from major pharmaceutical companies.	100%	0%	0%	1	8

4.5.2.11 Key enablers to the setup of an international PSLS

Nine statements were presented to the panel, two forwarded from the first round and seven new statements that were generated from the panel's feedback and suggestions. Consensus was achieved for eight of the statements (8/9=89%), as shown in Figure 4.15. Table 4.15 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median. Statements that the panel did not reach consensus agreement on are written in dark red text.

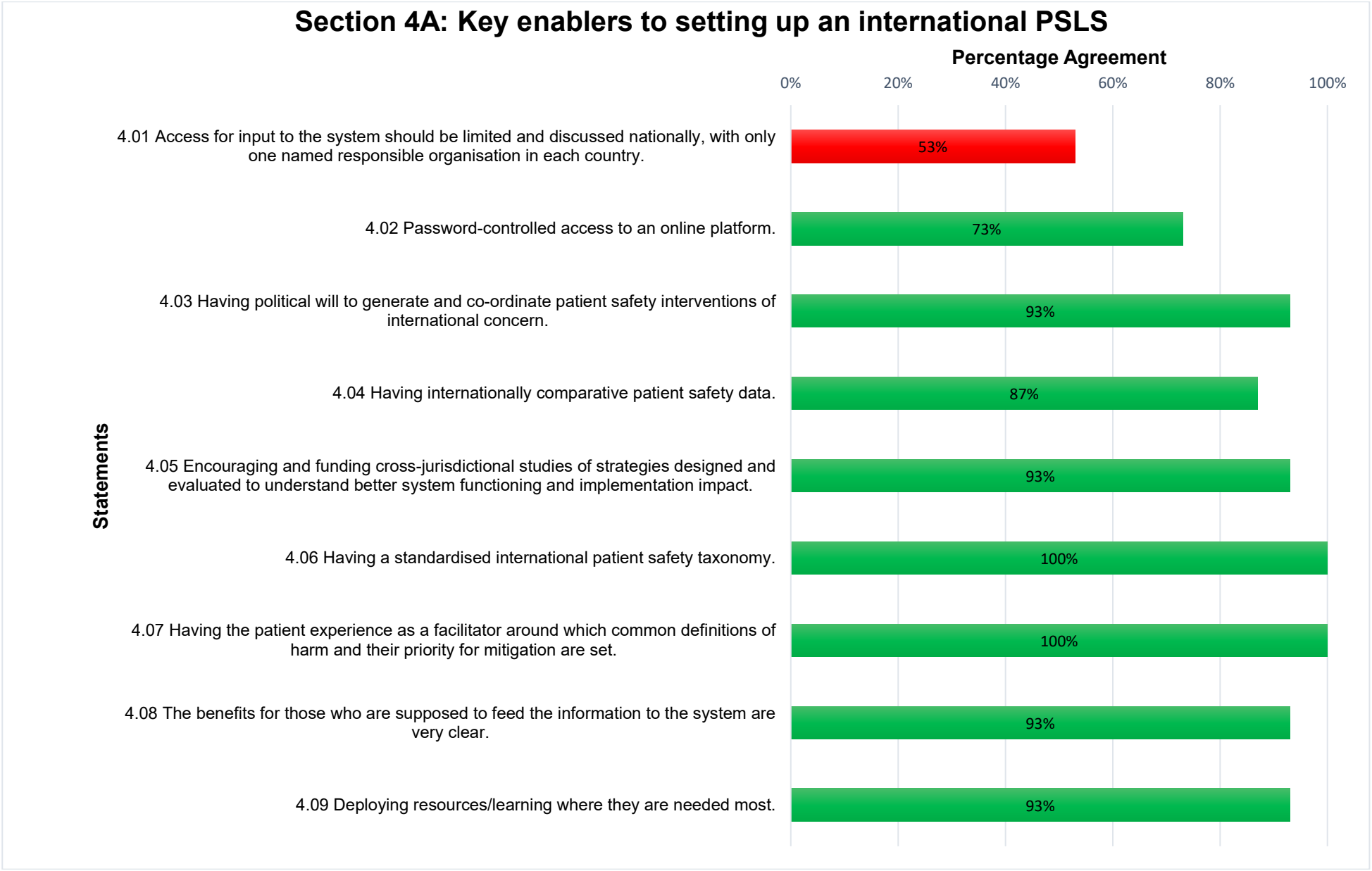

Figure 4.15 Percentage agreement of statements in section 4A (second round)

Table 4.15 Statistical breakdown for statements in section 4A (second round)

Section 4A: Key enablers to setting up an international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
4.01 Access for input to the system should be limited and discussed nationally, with only one named responsible organisation in each country. [1st round % agreement = 52% ; IQR = 4 ; group median = 7]	**53%**	27%	20%	**2.5**	**7**
4.02 Password-controlled access to an online platform. [1st round % agreement = 57% ; IQR = 3 ; group median = 7]	73%	13%	13%	1.5	7
4.03 Having political will to generate and co-ordinate patient safety interventions of international concern.	93%	7%	0%	1	8
4.04 Having internationally comparative patient safety data.	87%	7%	7%	2	8
4.05 Encouraging and funding cross-jurisdictional studies of strategies designed and evaluated to understand better system functioning and implementation impact.	93%	7%	0%	1	7
4.06 Having a standardised international patient safety taxonomy.	100%	0%	0%	1	9
4.07 Having the patient experience as a facilitator around which common definitions of harm and their priority for mitigation are set.	100%	0%	0%	1.5	7
4.08 The benefits for those who are supposed to feed the information to the system are very clear.	93%	0%	7%	1.5	7
4.09 Deploying resources/learning where they are needed most.	93%	7%	0%	1	8

4.5.2.12 Key challenges/barriers to the setup of an international PSLS

Feedback and suggestions from the panel generated seven new statements for this subsection for the second round. Consensus was achieved for all statements (7/7=100%), as shown in Figure 4.16. Table 4.16 outlines a detailed breakdown of the scores for each statement with regards to agreement, disagreement, and neutral, as explained in 4.4.5, in addition to IQR and group median.

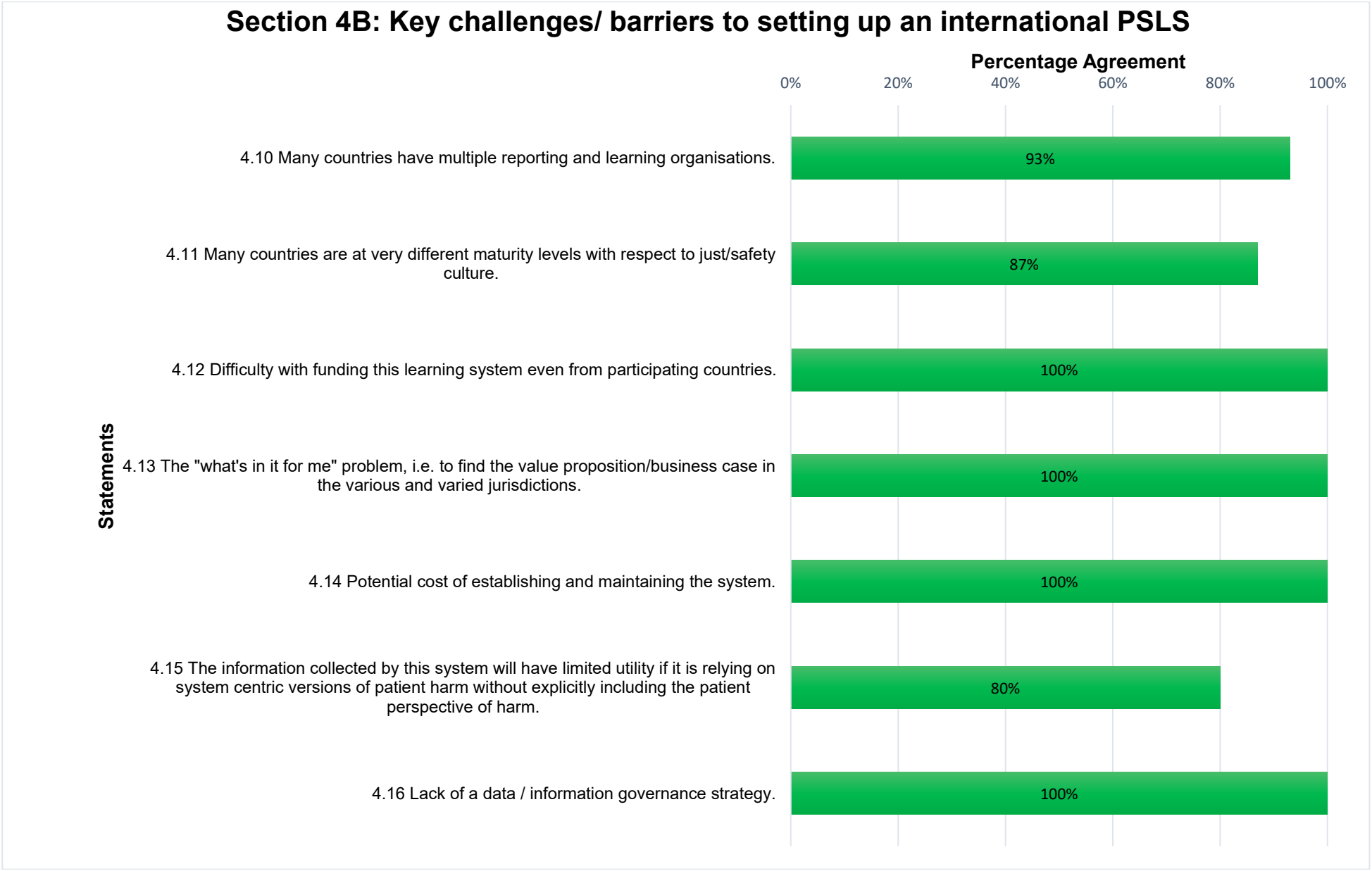

Figure 4.16 Percentage agreement of statements in section 4B (second round)

Table 4.16 Statistical breakdown for statements in section 4B (second round)

Section 4B: Key challenges/ barriers to setting up an international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
4.10 Many countries have multiple reporting and learning organisations.	93%	0%	7%	2.5	7
4.11 Many countries are at very different maturity levels with respect to just/safety culture.	87%	7%	7%	1.5	7
4.12 Difficulty with funding this learning system even from participating countries.	100%	0%	0%	1	8
4.13 The "what's in it for me" problem, i.e. to find the value proposition/business case in the various and varied jurisdictions.	100%	0%	0%	2	8
4.14 Potential cost of establishing and maintaining the system.	100%	0%	0%	1	7
4.15 The information collected by this system will have limited utility if it is relying on system centric versions of patient harm without explicitly including the patient perspective of harm.	80%	20%	0%	1	9
4.16 Lack of a data / information governance strategy.	100%	0%	0%	1.5	7

4.5.3 Termination of the Delphi

As stated in section 4.4.4.4, the Delphi study was terminated after the second round as the panel reached consensus on ≥ 80% of statements, which was the set termination criteria at the beginning of the Delphi study.

4.5.4 Final results of the Delphi

Table 4.17 outlines the final result of the Delphi study, where statements are ranked in each section based on the median, percentage agreement and IQR. Statements that did not achieve consensus are written in red font. It should be noted that due to the large number of statements that reached consensus over the two rounds of the Delphi, the threshold for consensus was raised from 70% to 80% after the conclusion of the Delphi. The rationale behind this move was to further reduce the number of statements that reached consensus to a reasonable size. This change was taken while considering the next phase of the PhD, which involves validating the results of the Delphi study with potential end-users. While the change in threshold for achieving consensus may have altered the results of the study, it can be argued that raising the threshold in this way allows for the identification of areas with the greatest level of consensus, increasing the validity of the method (Keeney et al., 2011).

Table 4.17 Ranking of Delphi statements

Section 1: Purpose(s) of a potential international patient safety learning system (PSLS)					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
1.01 Identify priorities for research and development to focus international efforts and resources where they are needed most.	100%	0%	0%	1	8
1.02 Identify evidence-practice gaps that are occurring in similar contexts in other countries in order to develop interventions together.	100%	0%	0%	1	7
1.03 Sharing affordable design-based interventions.	100%	0%	0%	1.5	8
1.04 Learn with and from countries about efforts to improve patient safety in terms of what works and how.	93%	7%	0%	1.5	8
1.05 Process learning from investigations of patient safety incidents so that transferable learning between countries can be identified.	90%	10%	0%	1	9
1.06 Drive up standards in learning from patient safety incidents	90%	5%	5%	1	9
1.07 Identification of patient safety risks relevant internationally.	90%	10%	0%	2	8
1.08 Awareness of frequently occurring patient safety incidents in other countries.	87%	7%	7%	2	8
1.09 Generate systems improvement strategies based on documented efforts to mitigate risk in other countries.	86%	14%	0%	2	8
1.10 Focus on assimilating learning about patient safety incidents that provide serious and specific insights into system safety.	86%	14%	0%	2	8
1.11 Learn from reported common patient safety risks to coordinate efforts internationally to mitigate and address those risks.	81%	14%	5%	1	8
1.12 Provide an overview of the most important risk areas and be able to learn with and from other countries.	81%	19%	0%	1	8

1.13 Learn from reported common patient safety risks internationally and work with other countries to innovate solutions to prevent those risks from reaching patients in similar healthcare contexts.	81%	14%	5%	2	8
1.14 Co-ordinate efforts of national patient safety organisations in collaboration with WHO.	80%	20%	0%	1	8
1.15 Bolster capability of those seeking to improve safety by benefitting from the shared learnings of those that have achieved improvements in safety in similar care contexts.	80%	20%	0%	2	8
1.16 Surveillance of patient safety incidents to detect potential risks relevant internationally.	**76%**	19%	5%	**2**	8
1.17 Learn from patients and families about risk, harm, response, and remediation.	**73%**	27%	0%	**1.5**	8
1.18 Coordinate the design of initiatives / interventions to mitigate commonly identified patient safety risk.	**73%**	27%	0%	**1.5**	7
1.19 Standardise the way learning from investigating patient safety incidents is reported.	**67%**	27%	7%	**2**	7
Section 2: Key features and functions of a potential international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
2.01 Develop a structured process for investigating patient safety risks identified by the international learning system.	100%	0%	0%	2	7
2.02 In the case of patient safety incidents related to equipment and or medication, manufacturers will be informed to take action to mitigate and contain any further risk.	95%	5%	0%	1	9
2.03 Generate safety recommendations with solutions that can be shared with countries and considered for adoption in different contexts in healthcare systems.	95%	5%	0%	2	8
2.04 To develop methodological approaches for assimilating a range of descriptive patient safety data to build a more complete understanding of safety within countries.	93%	7%	0%	1	8
2.05 Support the progression of countries towards a proactive and personalised clinical risk management approach i.e. moving from a reactive to a proactive mindset.	93%	7%	0%	1.5	8

2.06 Ability to use filters to search multiple sources of data / evidence / outputs to get to required information quickly.	87%	7%	7%	0.5	8
2.07 Ability to identify contributing factors to patient safety risks that can be transversal to certain types of incidents, contexts, and case studies.	87%	7%	7%	1	8
2.08 Facilitate learning and support through a range of formats (e.g. instructional manuals, train-the-trainer workshops, webinars, onsite learning)	87%	13%	0%	1	7
2.09 Develop methodologies to evaluate practices to learn from patients and family members in all facets of patient safety, including prevention, response, recovery, and remediation.	87%	13%	0%	1.5	7
2.10 Collate patient safety data / reports / resources in the interest of enabling international-level learning.	86%	14%	0%	2	8
2.11 Coordinate and launch international-level efforts to tackle common patient safety risks	86%	14%	0%	2	8
2.12 Shared database of resources that could support risk mitigation / prevention.	86%	10%	5%	2	8
2.13 A proactive approach for identifying patient safety risks that require international action.	81%	19%	0%	2	8
2.14 Compile and consolidate information from multiple countries.	81%	19%	0%	2	8
2.15 A repository for reports describing how interventions to mitigate risk work and how to support others to support implementation elsewhere.	81%	19%	0%	2	8
2.16 Analyse information and generate reports based on inputs from multiple countries and consolidating the ‘meta-learning’ (i.e. the overall learning from the country-level learning).	81%	14%	5%	2	8
2.17 Develop instructional manuals on how to investigate and learn from patient safety incidents.	80%			1	8
2.18 Support improvement in incident reporting and learning through sharing exemplars.	**76%**	19%	5%	**1**	8
2.19 Ability to share reported patient safety incidents/risks relevant to international learning.	**76%**	19%	5%	**2**	9
2.20 Ability to analyse and make recommendations based on shared patient safety data to identify transferable learning from countries responding to patient safety risks.	**76%**	24%	0%	**2**	8

2.21 Ability to trigger an alarm that deploys a notification to countries about serious identified patient safety risks.	**76%**	19%	5%	**2**	8
2.22 Support improvements in collection of patient safety data through sharing exemplars.	**76%**	19%	5%	**2**	8
Section 3A: Patient safety Incidents relevant to international sharing and learning					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
3.01 Incident involves a product or device that might be a major contributing factor to the incident.	100%	0%	0%	1	7
3.02 Incidents where risk of severe harm or death is likely, should the same incident reoccur.	100%	0%	0%	1.5	8
3.03 Incidents related to drug and equipment safety.	100%	0%	0%	1.5	8
3.04 Incidents related to manufacturing and supply chain (e.g. contaminated vaccine/IV fluids/injections/drugs)	95%	5%	0%	1	8
3.05 Incidents related to faulty medical devices (including IVDs) or equipment failure.	95%	5%	0%	1	8
3.06 Incidents identified by multiple countries as common sources of unsafe care and therefore a potential priority to learn from and tackle collectively.	95%	5%	0%	2	8
3.07 Patient safety risks that are new and/or have not been reported before in your country.	93%	7%	0%	1.5	8
3.08 Patient safety risks related to diagnostic errors.	93%	7%	0%	1.5	7
3.09 A near miss (events where no harm was done, but there could have been if people had done the same thing and, if allowed to go a stage further, it could have led to a death).	87%	7%	7%	1	7
3.10 Incidents relevant to current international campaigns or challenges e.g. the WHO patient safety challenges	86%	14%	0%	2	8
3.11 All adverse events (an incident that results in harm to a patient) (WHO, 2009).	80%			2	8
3.12 Ten times medication errors	**76%**	19%	5%	**2**	8

3.13 Tubing misconnections/misconnection errors (e.g. non-luer connected devices).	**76%**	19%	5%	**2**	7
3.14 Nasogastric tube positioning errors/incidents.	**76%**	19%	5%	**2**	7
3.15 Incidents that result from relatively novel contributory factors e.g. pandemics, electricity outage, internet outage, civil unrest, war, funding issues, natural disasters, deliberate sabotage, criminal activity.	**73%**	27%	0%	**1.5**	8
3.16 Any incident type that impacts paediatric patients.	**73%**	27%	0%	**1.5**	7
Section 3B: Criteria used in the decision making of what should be shared internationally					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
3.17 Risk of harming a large number of individuals in multiple countries if no intervention is taken.	100%	0%	0%	0.5	9
3.18 Morbidity and mortality from patient safety risks/events (i.e. impact and severity)	100%	0%	0%	1	8
3.19 The proposed patient safety solution needs international action, e.g. action from major pharmaceutical companies.	100%	0%	0%	1.15	8
3.20 Identified patient safety risk(s) is / are relevant to more than one country facing similar clinical challenges e.g. prevention and control of infectious disease.	93%	0%	7%	0	8
3.21 Identified patient safety risk(s) is / are relevant to more than one country e.g. supply of material/medicine/raw materials/devices originating in another country.	87%	7%	7%	1	8
3.22 Ease of measurement of the identified patient safety risk(s) in multiple countries.	87%	7%	7%	1.5	8
3.23 Stakeholders' interest on specific patient safety incidents / risks.	80%	20%	0%	1	7
3.24 The availability of evidence to support unequivocal preventability.	80%	13%	7%	2	8

Section 4A: Key enablers to setting up an international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
4.01 Having a standardised international patient safety taxonomy.	100%	0%	0%	1	9
4.02 Having the patient experience as a facilitator around which common definitions of harm and their priority for mitigation are set.	100%	0%	0%	1.5	7
4.03 For users and/or contributors to the system to be able to access it in an easy, secure way.	95%	0%	5%	1	9
4.04 Having buy-in from healthcare systems within each individual country.	95%	5%	0%	1	8
4.05 The system is accessible for everyone to read the information that helps organisations and individuals learn (e.g. web page open for everyone).	95%	0%	5%	1	8
4.06 To have representation from countries that are submitting data to the international system (e.g. national co-ordinators).	95%	5%	0%	2	8
4.07 Having political will to generate and co-ordinate patient safety interventions of international concern.	93%	7%	0%	1	8
4.08 Deploying resources/learning where they are needed most.	93%	7%	0%	1	8
4.09 Encouraging and funding cross-jurisdictional studies of strategies designed and evaluated to understand better system functioning and implementation impact.	93%	7%	0%	1	7
4.10 The benefits for those who are supposed to feed the information to the system are very clear.	93%	0%	7%	1.5	7
4.11 Broad support from the clinicians and the societies that make up the international patient safety community.	90%	10%	0%	1	9
4.12 Country-level will to learn with and from other countries.	90%	10%	0%	1	8
4.13 Having buy-in from international organisations with a role and interest in patient safety.	90%	10%	0%	2	9
4.14 Automation of as many functions as possible.	90%	5%	5%	2	9

4.15 Having internationally comparative patient safety data.	87%	7%	7%	2	8
4.16 Governments, agencies, and organisations have clear legislation, regulations and guidelines that are supportive of and encouraging of sharing of patient safety data relevant for international learning.	86%	5%	10%	2	8
4.17 Involvement of important knowledge mobilisers (e.g. Institute for Healthcare Improvement, World Health Organization).	86%	14%	0%	2	8
4.18 Existence of international standards / convention for sharing patient safety data.	86%	14%	0%	2	8
4.19 An independent body/organisation responsible for operating and maintaining the international PSLS.	81%	19%	0%	1	7
4.20 Multiple input methods are available (e.g. online, phone, e-mail…etc).	**76%**	14%	10%	**2**	8
4.21 Password-controlled access to an online platform.	**73%**	13%	13%	**1.5**	7
4.22 Funded by partner countries.	**71%**	29%	0%	**2**	8
4.23 Access for input to the system should be limited and discussed nationally, with only one named responsible organisation in each country.	**53%**	27%	20%	**2.5**	7
Section 4B: Key challenges/barriers to setting up an international PSLS					
Statements	**%Agreement**	**%Neutral**	**%Disagreement**	**IQR**	**Group median**
4.24 Difficulty with funding this learning system even from participating countries.	100%	0%	0%	1	9
4.25 Potential cost of establishing and maintaining the system.	100%	0%	0%	1	9
4.26 Lack of a data / information governance strategy.	100%	0%	0%	1.5	8
4.27 The "what's in it for me" problem, i.e. to find the value proposition/business case in the various and varied jurisdictions.	100%	0%	0%	2	8
4.28 Many countries have multiple reporting and learning organisations.	93%	0%	7%	1.5	9

4.29 Limited resources in less developed countries.	90%	5%	5%	1	9
4.30 Issues about national reputation, healthcare system reputation issues, which might create barriers.	90%	10%	0%	2	8
4.31 Many countries are at very different maturity levels with respect to just/safety culture.	87%	7%	7%	2	8
4.32 Finding the responsible international organisation to set up the system and relevant national organisations that will commit to co-operate.	86%	10%	5%	2	8
4.33 At the international level, big cultural factors and different types of healthcare systems might present a challenge.	86%	10%	5%	2	8
4.34 Concerns regarding privacy issues when sharing learning from investigations of patient safety incidents.	86%	10%	5%	2	8
4.35 Having too many different bodies which are involved.	81%	19%	0%	1	7
4.36 Lack of a sense of ownership in a system the end-user has not been involved in developing.	81%	14%	5%	2	8
4.37 Lack of common format / approach to sharing learning about patient safety risks and / or efforts to mitigate / prevent harm to patients.	81%	14%	5%	2	8
4.38 The information collected by this system will have limited utility if it is relying on system centric versions of patient harm without explicitly including the patient perspective of harm.	80%	20%	0%	1	7

4.6 Discussion

4.6.1 Main findings

The main aim of this Delphi study was to gain consensus agreement from international healthcare experts regarding the elements that would be required for a potential international PSLS, with or without an incident reporting function.

The panel of experts has reached consensus agreement on the majority of the presented statements, which further supports the findings from Chapters 2 and 3. Furthermore, the panel helped in developing a novel list of patient safety incidents/risks that are relevant for international sharing and learning, as well as a novel list of criteria that should be used when deciding what learning should be shared internationally.

4.6.2 Links to the existing literature

4.6.2.1 Framework for an international PSLS

As discussed in Chapter 1, this Delphi study builds on work done by Benn et al. (2009) regarding shared learning at the national/local level, where this Delphi adds an international dimension to the Framework for Safety Action and Information Feedback from Incident Reporting (SAIFIR) developed by Benn et al. (2009). Figure 4.17 shows an annotated framework for an international PSLS, developed from the findings of Chapters 2, 3, and 4, that could complement the SAIFIR framework.

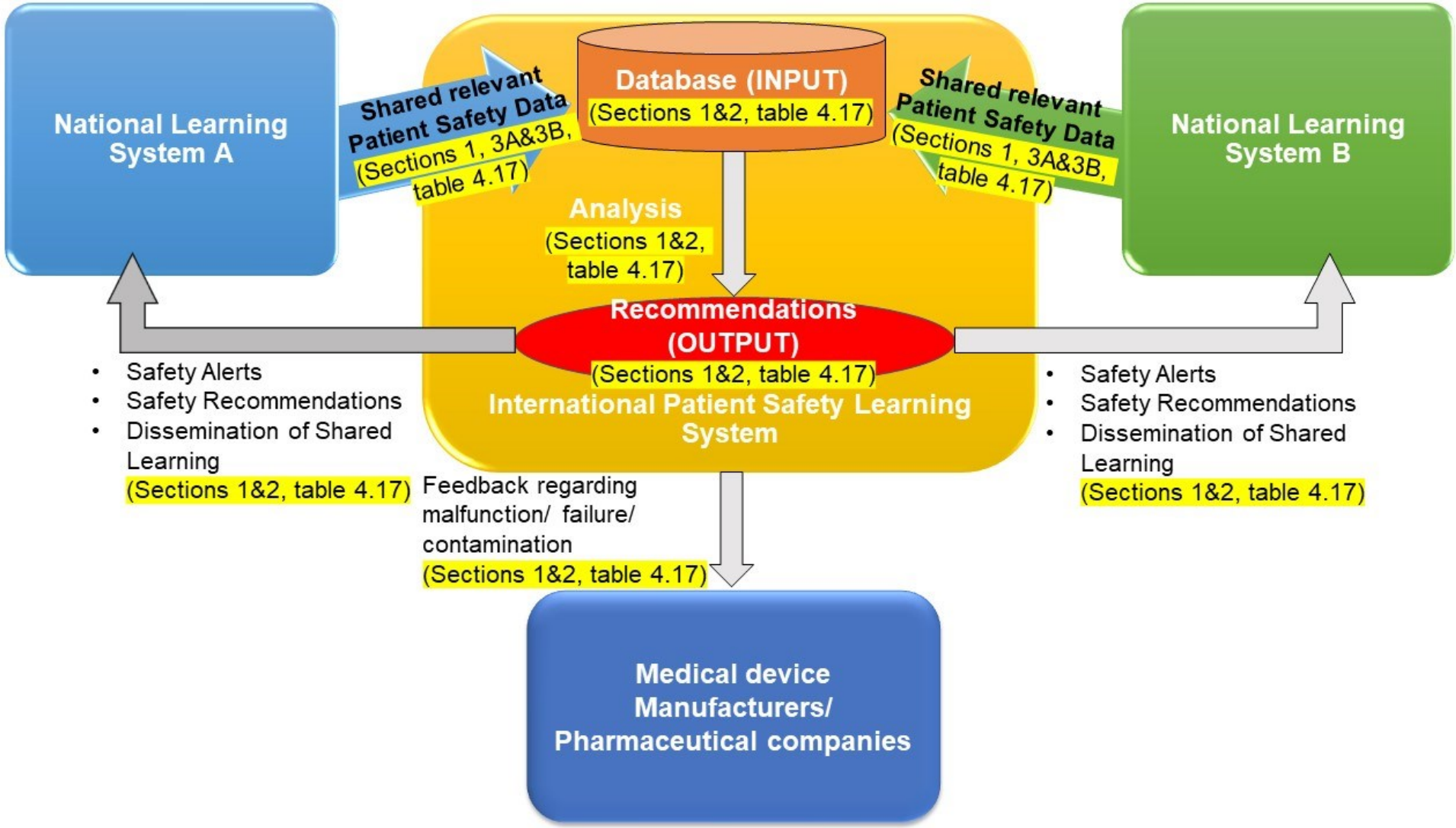

Figure 4.17 Proposed framework for an international PSLS

The framework in Figure 4.17 conceptualises how the international PSLS would operate in the event of a recognised safety incident/ risk. For instance, identification of a contamination event in a batch of medicine or a malfunction in medical devices may be identified through patient safety data analysis within any national learning system. This would then feed into the database, leading to analysis that generates recommendations for that incident. The international PSLS would then permit safety recommendations and alerts to be generated (i.e., informing healthcare professionals and managers about the specific items or batches affected and advising they are not used in practice), as well as providing medical device manufacturers or pharmaceutical companies with feedback on the issues identified to enact safety recommendations, warnings and changes in protocols, as demanded by the specific nature of the incident. For instance, patient safety incidents related to a medication could be an issue flagged in any national system and which would raise a suitable alarm to the European Medicines Agency (EMA) or the UK Medicine and Healthcare products Regulatory Agency (MHRA) to prompt changes in practice, generate new guidance and patient monitoring recommendations, while also permitting feedback to the drug manufacturer to determine risks of batch contamination and to explore this safety issue further in trials.

4.6.2.2 Key purposes and features of an international PSLS

This is the first Delphi study to explore the purposes, key functions and features, and feasibility of a potential international PSLS (as of March 2021). Howell et al. (2017) conducted a Delphi study to establish an international expert consensus on the purpose of patient safety incident reporting systems regarding monitoring and learning from incidents and developing recommendations for their future role. Their Delphi study was one of the included studies in the systematic literature review (Chapter 2), which helped inform the development of this Delphi study. However, a direct comparison between the two Delphi studies is not feasible as Howell et al. (2017) focused on *national* and *local* patient safety **incident reporting systems**, while this Delphi study focused on a potential *international* patient safety **learning system**. To further explain the difference between the two systems, and as discussed in Chapters 1 and 2, an incident reporting system relies on reported patient safety incidents while a learning system can use different patient safety data (e.g., safety audits, case studies, safety investigation reports, etc.) to generate learning. Thus, this study would be a helpful reference point for further feasibility research and potential piloting of an international PSLS.

The key findings of the Delphi survey suggest broad agreement regarding the purpose and features of an international PSLS, generally consistent with other safety reporting systems used across safety-critical industries. The purpose of the PSLS is not only to reduce harm to patients, but to encourage learning, recommendations and changes to practice across a range of stakeholders, while facilitating learning and preventative strategies across nations. The ability to generate recommendations and learning points of relevance to local and international contexts is important in any patient safety system. Pysyk et al. (2020) evaluated the introduction of a PSLS at a local level as part of a quality and safety initiative in the peri-operative care context. During the implementation of the system, the authors noted that variation in reporting of incidents was evident and that this led to challenges in defining clear learning and recommendations from the accumulated events. Over time, quantification of events relating to a specific area of practice was sufficient to lead to the automation of alerts that were then reviewed by a committee, formulating recommendations for practice and introducing those changes locally (Pysyk et al., 2020). This study, therefore, highlighted how reporting standards and the ability to develop recommendations required time to stabilise, while recommendations and learning remained largely the responsibilities of local committee members, rather than through an automated learning system. While local committees may be invaluable in reviewing safety system output data and developing locally acceptable and relevant interventions, the capacity to make these decisions and the resources available across different nations may preclude this practice (Sparrow, 2020).

4.6.2.3 Enablers and barriers to the use of an international PSLS

Enablers and barriers to the use or implementation of an international PSLS were also noted in the Delphi survey. Importantly, support from national bodies, governments and other stakeholders was vital, as well as international oversight. Equally, the difficulty in obtaining a reliable and coordinated body to oversee PSLS on an international basis is a challenge. As in the aviation industry, international oversight of safety can be considered crucial to coordinating data across nations and then implementing recommendations consistently across those nations (Cusick et al., 2017). Standardisation of reporting practices and standards on an international basis has assisted in the development of international learning and safety systems in aviation and other safety-critical industries (Cusick et al., 2017), although such standardisation is still considered challenging in healthcare, according to the findings of the present study. Therefore, the formation of international oversight committees/bodies, as well as standardisation of healthcare data

and compatibility of information shared across nations, will be needed in the future to facilitate coordination of data sharing and learning in an international PSLS.

The use of electronic medication prescribing and monitoring systems has been recommended as a strategy to prevent patient safety incidents (Urquhart et al., 2021) and reflects an important drive towards automation and the use of electronic systems to guide safety incident reporting. Indeed, automation of reporting practices in safety-critical industries is widespread and a topic of constant evolution based on emerging learning systems (Cummings & Britton, 2020). Automation of medical interventions has emerged gradually over time, and while it is met with acceptance in many regards, physicians may be distrustful of automated systems, including those related to patient safety (Ruskin et al., 2020). Interestingly, it is argued that this distrust often stems from a lack of training in such systems or errors in use/interpretation (Ruskin et al., 2020). However, machine learning from safety incidents, particularly involving reports with a large amount of free-text (i.e., non-coded variables), remains an important challenge in the automation of incident reports, which is an acknowledged challenge in such systems (Evans et al., 2020). Therefore, improvement not only in the use of such systems, but also in their capacity to reliably analyse data in an autonomous manner, may be needed to meet the needs of an automated approach to PSLS.

Other challenges may relate to the detail of outcomes/reports generated by the international PSLS and their use in practice. Reporting of core incidents within a PSLS is a key aspect of the function of that system, and examples from the wider literature may be used to illustrate how reporting may be used to improve patient safety. Improvement in outputs from a PSLS may be needed, based on sufficient detail to guide interventions, identify safety incidents that are rare in nature, or to adequately evaluate patient protection. One example of how improvements in systematic reporting of incidents may be needed relates to vincristine use. Vincristine, a vinca alkaloid chemotherapy drug, has been associated with deaths following inappropriate administration (via the incorrect route) since the 1960s in the UK and fatal incidents persisted over time until 2001 (Noble & Donaldson, 2010). Incidents in vincristine use are related to systematic failures, involving vulnerability due to manufacturing errors, ambiguous labelling, procedures, and lack of standardisation of units (Franklin et al., 2014). While changes to policy and guidance have reduced the incidence of adverse administration of vincristine (and associated deaths), the success of current policies has led to further challenges in identifying any remaining vulnerabilities, due to their infrequency (Franklin et al., 2014).

The National Reporting and Learning System (NRLS) is a large database of patient safety incidents in England and Wales and has been used to examine hazards linked to the administration of vincristine and associated vinca alkaloids (Vincent & Amalberti, 2016). The findings of 38 patient safety incident reports indicated that there are challenges to the use of NRLS and associated systems for identifying rare events and near misses. Indeed, the low volume of reports and their scattering across a system may escape the attention of regulators, manufacturers and safety experts. Furthermore, many reports lacked sufficient detail on the nature of the hazard, suggesting that more comprehensive narratives are needed to strengthen the outputs of PSLS reports related to patient safety incidents (Franklin et al., 2014). The authors of this study also suggested that no-harm incidents need to be reported more frequently to increase reporting of potentially relevant issues and to identify how patients may be protected, adding to the data set against which harmful events may be compared (Franklin et al., 2014). Indeed, this is echoed within the aviation industry, where identifying safety protective behaviours is considered as valuable as safety-threatening behaviours when collecting and analysing data for safety (Holbrook, 2021).

The outputs of the reporting process are not the only important features of a PSLS, as the degree to which professionals report incidents may also be a potential limitation. Anonymity in reporting processes has been suggested as one method to improve the use of such systems, as fear of blame and professional consequences may preclude complete adherence to reporting system use (Macrae, 2016). Furthermore, the ease with which a system may be used by staff across health settings and nations needs to be considered to optimise the use of PSLS reporting procedures (Macrae, 2016). It has also been noted that when physicians identify a potential safety incident, there is a divergence in the drive to report such incidents based on the perception of that problem as having been ‘fixed’ (Hewitt & Chreim, 2015). Where physicians adopt an attitude of fixing a problem and forgetting that problem, this may lead to instant resolution of a safety event or near miss but preclude opportunities for wider learning on a systems level. Therefore, changing the culture of an organisation to promote reporting, even where solutions have been proposed for a local challenge, should be prioritised to maximise the use and therefore, the value of PSLS (Hewitt & Chreim, 2015). Forming a habit of reporting practices is considered an important feature of a highly reliable healthcare system (Vogus & Hilligoss, 2016).

4.6.3 Strengths and limitations

As discussed in section 4.4 (Methods), the Delphi technique has some limitations (Keeney et al., 2011; Hsu & Sandford, 2007). These limitations are outlined in table 4.18, along with the action taken to address these limitations; however, this does not mean that these limitations were eliminated entirely.

Table 4.18 Limitations of the Delphi technique and corresponding mitigating actions

Limitation of the Delphi technique	Action taken
There is a lack of universal guidelines.	Exemplars of relevant published studies in the field were followed (Zhai et al., 2020; Ensaldo-Carrasco et al., 2018; Howell et al., 2016; Schneider et al., 2016; Pezaro & Clyne, 2015; Slade et al., 2014; Creamer et al., 2012; Efstathiou et al., 2008; Buetow & Coster, 2000; Green et al., 1999), in addition to academic research on the Delphi technique (Fackrell et al., 2017; Habibi et al., 2014; Diamond et al., 2014; von der Gracht, 2012; Keeney et a., 2011; Hsu & Sandford, 2007; Keeney et al., 2006; Landeta, 2006; Okoli & Pawlowski, 2004; Powell, 2003; Linstone & Turoff, 2002; Keeney et al., 2001).
There is lack of agreement on the size of the expert panel.	The recruited expert panel was heterogenous with representatives from all six continents, including non-English speaking countries. This gave the study a true international perspective and the size of the panel is in line with the average recommended panel size.
There is a potential of low response rate.	In order to recruit the targeted panel size, keeping the COVID-19 pandemic in mind, the initial response rate was expected to be between 25%-30% and thus, invitations were sent to a larger number of experts. Additionally, potential panellists were informed about the entire survey process, including time commitment, and expected automated e-mails that were generated under the name of the candidate's primary supervisor by the Qualtrics platform. The use of an online platform to conduct the survey is also a contributing factor to reaching the target panel size. For the second round of the survey, the panellists were sent a brief report of the results of the first round to keep them engaged and invested, and the second round of the survey was conducted after two weeks from the end of the first round.
The Delphi process is time-consuming.	Pilot testing the survey helped in making the process as easy as possible. Changes included the shift to an electronic consent form, significant reduction in time taken to complete the survey, and providing digital copies of all required documents. Furthermore, the panellists were given ample time to complete their responses, and time between rounds was kept as short as possible to keep the panellists engaged. The second round was also significantly shorter than the first round, with optional questions clearly labelled.
Divergence in interpretation of consensus findings may result from the process	While a high percentage agreement of consensus may be viewed as a high degree of validation of knowledge in the field, it may be argued that this reflects a flawed methodology, as universal agreement suggests the issues explored did not require the use of a Delphi process. Transparency in presenting the findings and clarity in the derivation and justification for the questions asked were strategies used to improve the validity and reliability of the method.

The vast experience (314 years of experience in the subject matter) and heterogeneity of the expert panel is one of the main strengths of this international Delphi study. However, the study could have benefited from having more panellists from non-English speaking countries, including participants from low-resource countries, as specific perspectives may have been obtained that are of value when considering an international system. The use of participants who have the knowledge and an interest in the topic of the study has helped in increasing the content validity of the Delphi, and the use of successive rounds of the survey has helped in increasing the concurrent validity (Hasson et al., 2000).

Another limitation of the study was the way in which the Delphi's statements were phrased and the wording used to guide the consensus process. Rating statements according to the level of agreement with that statement is a key aspect of the Delphi process, but it is notable there may have been ambiguity in how the importance of statements may have been perceived. This may also apply to instances where consensus was achieved regarding the lack of perceived importance or value of a statement in relation to the functions or purpose of an international PSLS. In the future, clarity in wording and within the Delphi process to ensure participants could rate the importance of a statement accurately should be considered.

While consensus was achieved for the majority of the statements in the two rounds of this Delphi study, this has presented a new challenge. This was mainly concerning the large number of statements within each section. While one might argue that exploring a potential international PSLS might merit such a large number of statements, others might argue that the Delphi could have benefited from a further round where the panellists are asked to rank these statements based on their priority. However, this would not have been possible because the initial response rate for the second round was below the 70% cut-off point to maintain rigour, and a decision was made to extend the second round for a further week and inform participants that it would be the final round of the Delphi. Furthermore, the survey termination criteria (see section 4.4.5.4) were set prior to conducting the survey, and by the end of the second round, those criteria were met.

Furthermore, conducting the survey online has allowed access to experts from all over the world, particularly during the initial period of the COVID-19 pandemic. This allowed for greater representation of experts from low- or middle-income countries, which increases the generalisability of the findings and their specific application to these settings. However, it is appreciated that countries with established infrastructures in healthcare safety were selected for the study as these were the most likely to immediately benefit from an

international system. The online survey has also enabled the collection of consensus expert opinions on an anonymous basis, thus reducing bias while also increasing the validity and reliability of the results (Keeney et a., 2011; Bowling, 2002). In contrast, the survey design and the invited panellists might play a part in unintentional researcher bias (Linstone & Turoff, 2002). As discussed in the methods section, these two factors were mitigated by pilot testing the survey, receiving further feedback from the WHO Collaborating Centre in Human Factors and Communication for the Delivery of Safe and Quality care, and by asking invited panellists to recommend potential participants. It should be noted that achieving consensus in a Delphi does not mean that all of the findings are necessary or applicable in real-life (Keeney et al., 2001). This is one of the main reasons why engaging potential end-users and assessing the acceptability of what the international healthcare experts agreed on was an essential next and final step for this PhD.

4.6.4 Recommendations and future research

The results of this Delphi study outline that healthcare experts (e.g., policymakers, academics, safety/risk managers) agree on the purpose and key requirements of an international PSLS. However, this does not take into account what potential end-users think of such a system, in terms of the usability and acceptability of the system in practice. Therefore, the next logical step in this research would be to engage with potential end-users to determine the acceptability of the proposed international PSLS. This would focus mainly on the key functions and features that end-users might deem acceptable for their line of work in improving patient safety. Additionally, the acceptability of the novel list of patient safety risk(s) that might be of international concern for sharing and learning will also be explored with potential end-users.

4.7 Conclusion

The aim and objectives of this Delphi study were achieved by gaining international healthcare expert consensus on the purpose(s), key functions and features, and feasibility of a potential international PSLS. This expert consensus also included a novel list of potential patient safety incidents/risks that might be of international concern for sharing and learning, in addition to another novel list of the criteria that should be used when deciding what learning should be shared internationally. The next step in the process of this PhD is the exploration of the acceptability of the proposed international PSLS with potential end-users.

Chapter 5 – Assessing the acceptability of an international patient safety learning system with potential end-users: An Online Survey

5.1 Introduction

The previous chapter (Chapter 4) reported the findings of a Delphi study, which aimed to clarify the purpose and core functions and features of an international patient safety learning system (PSLS), the feasibility (in terms of facilitators and barriers) of an international PSLS, and the outputs and learning that would be of greatest value within such a system. The findings of Chapter 4 suggested that the experts involved in the Delphi study showed a broad level of agreement regarding the purpose of an international PSLS (reducing harm, encouraging learning, and facilitating changes in practice), while identifying many key functions and features of an international PSLS that would be needed to achieve these outcomes.

Importantly, the findings suggested that there are anticipated barriers or challenges to the use of an international PSLS. Local challenges at a national level include the reliability of data, infrastructure to support data collection and analysis, and leadership. Internationally, challenges related to concerns about the compatibility of the system across different nations and the potential difficulties in standardising the process of safety incident reporting and learning. Further challenges may be apparent in implementing an international PSLS in practice, given the differences in resources, infrastructure, leadership, and oversight between nations.

Figure 5.1 presents a proposed framework of an international PSLS and how this would operate, incorporating findings from the expert consensus panel, which built upon findings from Chapters 2 (systematic literature review) and 3 (semi-structured key informant interviews).

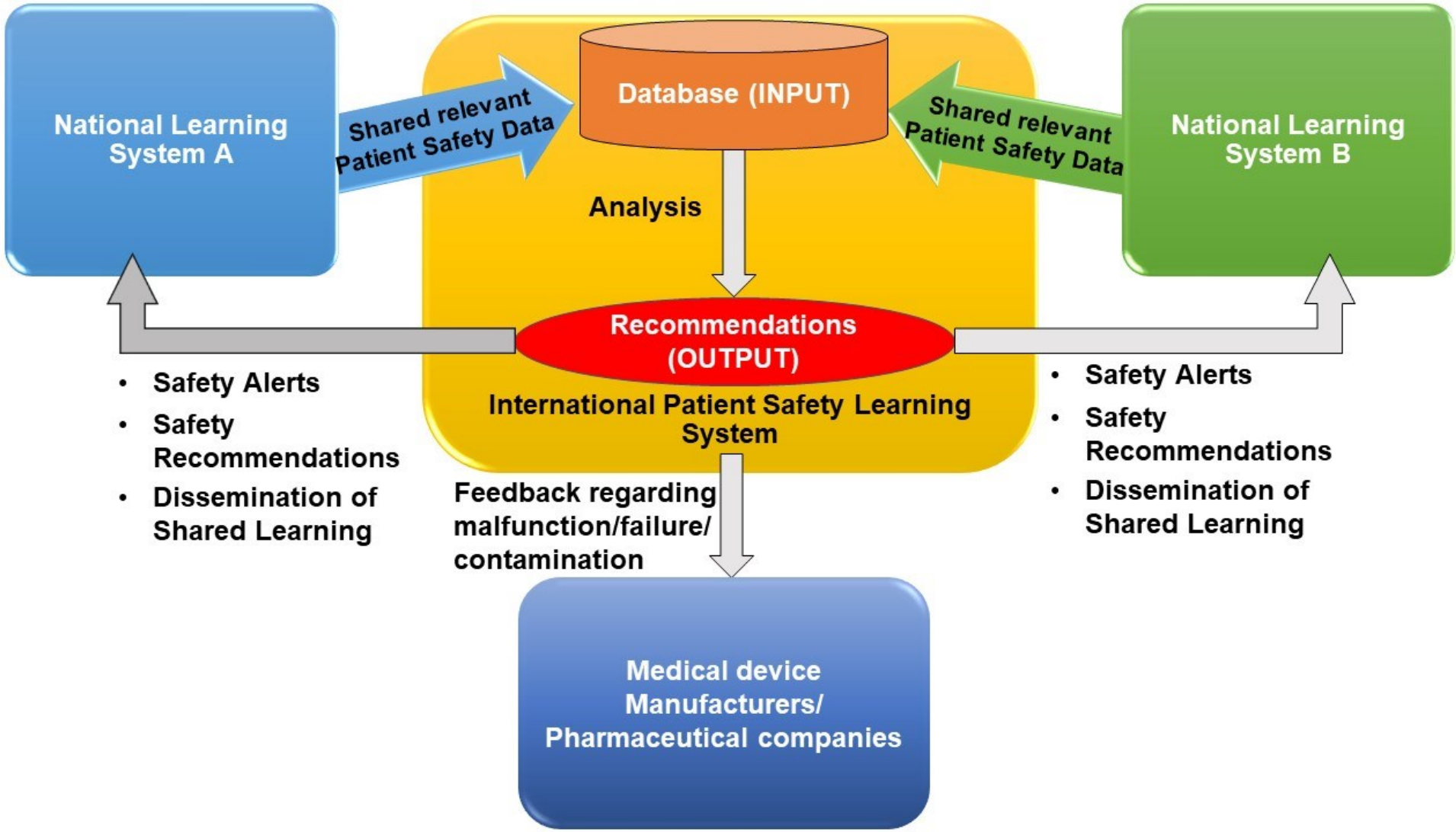

Figure 5.1 Proposed framework for an international PSLS

Although the Delphi provided a means to identify the core purpose, functions and features, outputs, and facilitators and barriers to an international PSLS, it is important to consider how the implementation of such a system may be achieved in practice. While the framework may be supported by the available literature and the consensus achieved, a crucial factor determining the actual value of the design of an international PSLS will be its acceptability amongst potential end-users of such a system.

Indeed, given the barriers noted in the previous chapter, the implementation of an international PSLS may be challenging in practical terms. For example, funding contributions and actively participating in this learning system might be challenging for participating countries, especially less developed countries with limited resources.

Therefore, this chapter considers the need for implementation research in the field, with a specific hypothetical focus on the prospective acceptability of the international PSLS as a driver for implementation and successful deployment of such a system (i.e., pre-implementation). This chapter will focus on Kuwait as a single-nation case study to explore the potential implications of a country participating in the PSLS. The acceptability of the proposed framework in Kuwait may provide a basis for issues and challenges of relevance in other nations, while providing an initial case to determine areas that may require further exploration in an international context. This was an enforced decision due to the COVID-19 pandemic where National Health Service (NHS) Wales ethical approvals were granted to COVID-19-related research only, thus limiting the target population for this study (original targets were Wales and Kuwait).

Figure 5.2 outlines the exploratory sequential mixed methods design followed for this PhD and highlights where this final study fits within this design.

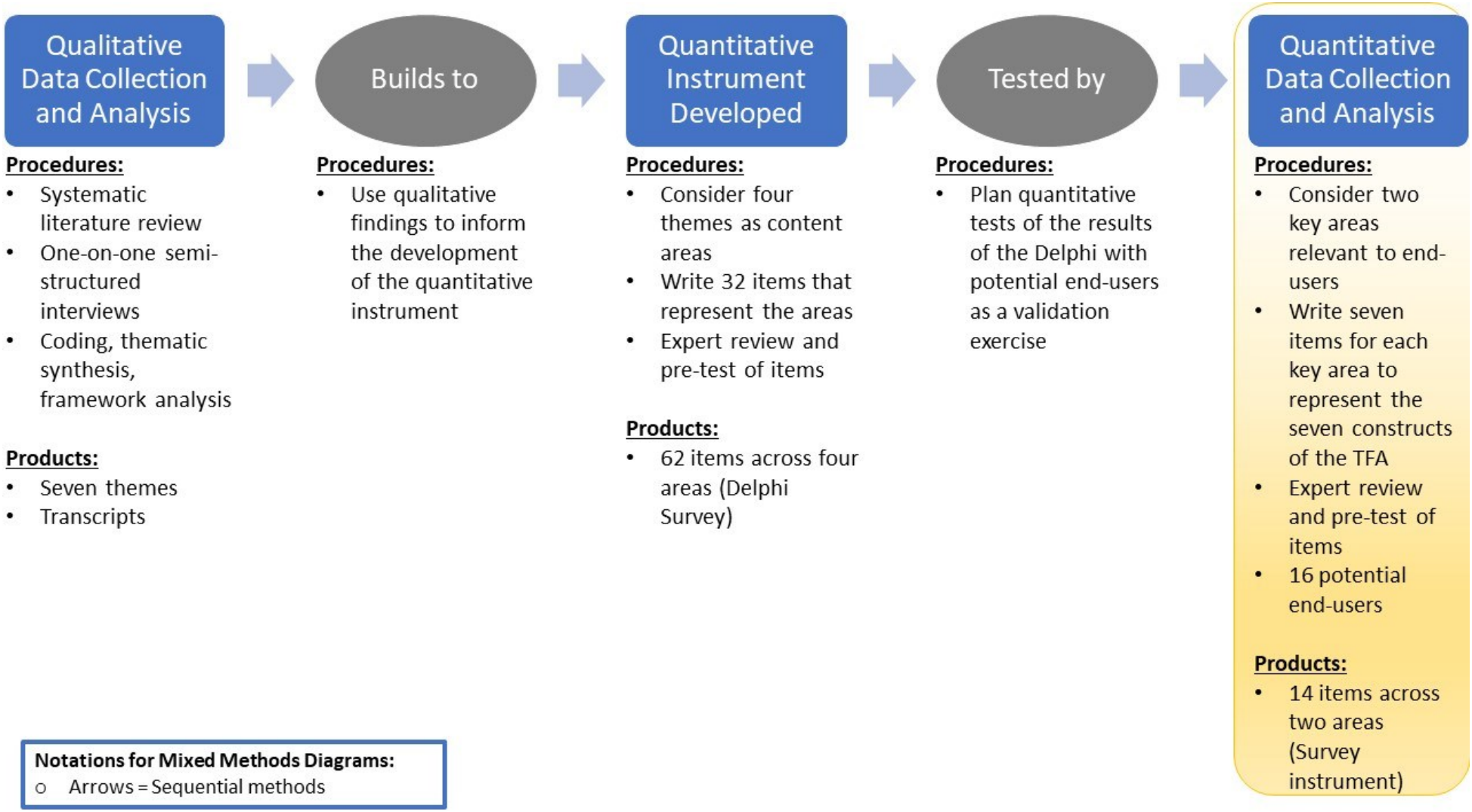

Figure 5.2 The second quantitative stage of the sequential exploratory mixed method design (Creswell & Clark, 2018)

5.2 Aim

This final study seeks to assess the acceptability of a proposed international patient safety learning system (PSLS) with potential end-users working in the Governmental healthcare sector in the State of Kuwait.

5.3 Objectives

This study sought to determine the acceptability of:

- A proposed international PSLS among potential end-users in the Governmental healthcare sector in the State of Kuwait, specifically; and,
- The anticipated requirements for contributing and sharing national data with an international community.

5.4 Methods

This study is a cross-sectional survey and analysis of the acceptability of an international PSLS among end-users in Kuwait. The intention is to use Kuwait as a case study for the implementation of an international PSLS, with a view to evaluating the acceptability of the proposed system. The remainder of this section considers how implementation research is conducted and its purpose in healthcare, with a focus on justifying the need to explore the acceptability of a complex intervention in this context. The specific methodological approach and design is then detailed and justified prior to presenting the results of the study.

5.4.1 Implementation research

The implementation of change in practice is a challenging process, which is dependent on multiple variables and influences (Pinnock et al., 2015). Implementation research is broadly defined as research that focuses on implementation of change, including the introduction of any intervention in a healthcare context (Pinnock et al., 2015). Despite a growing awareness of the need for implementation research to guide the implementation process and identify potential facilitators and barriers to successful implementation, the concept of implementation research has been noted to be poorly understood and inconsistently defined in the wider literature (Peters et al., 2013; Theobald et al., 2018).

Within health services, the importance of incident reporting has been recognised, with notable examples including the incident reporting process as part of the Confidential Reporting System for Surgery (CORESS) and Central Line Associated Blood Stream Infection (CLABSI) rate reporting, which are now widely used and considered key

measures of health quality (Woodward & Umberger, 2016). Implementation of these incident reporting systems and their effective use is one example of how implementation research may be applied to healthcare settings for the purpose of facilitating safety improvement in this context.

Within healthcare, the introduction of new technology or interventions is typically based on a formal change strategy (Pinnock et al., 2015). While changes in healthcare practice may be prompted by a range of events, including needs assessments, consultations, health body mandates and inquiries, the process of quality improvement is considered an ongoing and cyclical means of introducing change in practice and which should be at the centre of improvement in care quality on a routine basis (Pinnock et al., 2015; Hayes, 2022).

The first stage of quality improvement involves planning for the change, which should involve a clear justification for the change and its impact on practice stemming from the research (Hayes, 2022). The present study aims to provide a basis for justifying the implementation of an international PSLS, forming a key aspect of the planning phase of a quality improvement initiative.

The following sections consider how implementation research (a pre-implementation phase) may be completed, the methods suited to this research, and consideration of a suitable framework to explore implementation, with a focus on the healthcare context.

5.4.2 Defining implementation research

According to Peters et al. (2013), implementation research aims to solve problems associated with the implementation of any change or intention, with origins in multiple disciplines and research traditions. In health research, implementation often focuses on policies, programmes, or individual practices, collectively known as interventions (Peters et al., 2013; Theobald et al., 2018). While there may be differences in what constitutes implementation among different stakeholders, a focus on the scientific inquiry regarding implementation of health practices, policies, or programmes is considered a core aspect of implementation research as it relates to healthcare (Peters et al., 2013). This form of research has the potential to evaluate factors related to successful implementation, the result of implementation, and the potential to broaden or diversify implementation processes within a given context (Curran et al., 2012; Damschroder, 2020).

Importantly, implementation research is grounded in a pragmatic paradigm, where the focus is to identify how to navigate implementation successfully in practice, based on

identifying what works (Tabak et al., 2012). This research can therefore be considered a bridge between research and practice at the level of introducing change or implementing novel processes or practices (Tabak et al., 2012). Therefore, the perspectives of individuals who are affected by the proposed change (i.e., that which is being implemented) can be considered essential in implementation research, as these perspectives are vital in appreciating the contextual factors that influence change and implementation success (Nilsen & Bernhardsson, 2019).

While implementation research is typically contemporaneous or retrospective in nature (based on the evaluation of change that is being or has been implemented), it has been noted in the literature that hypothetical implementation research (i.e., pre-implementation) may be valuable (Berry et al., 2016). The hypothetical introduction of a change in practice can be evaluated by measuring the hypothetical (i.e., prospective) acceptability of a proposed intervention (Allan et al., 2019). In this thesis, implementation of a change process was not completed, but perspectives were sought regarding the hypothetical use of an international PSLS (i.e., pre-implementation).

Therefore, while the current approach may not reflect a standard approach to implementation research, the hypothetical approach may be considered a valid strategy for exploring prospective acceptability and providing the hypothetical basis of those claims are considered in data analysis (Allan et al., 2019). Further studies to confirm acceptability and other evaluation outcomes based on the practical implementation of an international PSLS would still be required in the future.

Identification of key stakeholders to whom implementation research may be targeted is a fundamental process in successfully engaging in this form of research (Peters et al., 2013). The wider context of the healthcare system, local infrastructure, environmental conditions, and socioeconomic conditions can all impact the experiences of stakeholders when engaging in change (Tabak et al., 2012; Boaz et al., 2018). By focusing on key stakeholders that are involved in the implementation process, the actual effects of these conditions and contextual factors can be understood to not only generate knowledge but also provide a basis for understanding how stakeholders are affected and may influence implementation. These stakeholders commonly include policymakers, decision-makers, and frontline practitioners, all of whom may directly or indirectly be impacted by change (Peters et al., 2013). The focus on these individuals is so important that it has been proposed that these stakeholders should be involved in identifying, designing, and conducting research phases for the dissemination of study results, rather than serving as

targets for dissemination (Peters et al., 2013). Therefore, a user-centred research process that attempts to understand implementation is often valuable when conducting implementation research. Another principal element in defining implementation research is a focus on the outcome variables that are linked to this form of research (Proctor et al., 2011). Eight outcome variables have been recognised that describe intentional actions to deliver services, serving as indicators of the success of implementation: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, coverage, and sustainability (Proctor et al., 2011). A summary of these variables is presented in Table 5.1. These outcome variables are not mutually exclusive and may be inter-dependent; for example, perceived feasibility and appropriateness of the intervention or change may influence the acceptability among stakeholders. Furthermore, these outcomes capture different elements of the implementation process, based on stages prior to implementation (e.g., acceptability, feasibility) and those that assess the implementation when in process (e.g., coverage, sustainability).

Table 5.1 Implementation research outcome variables. Adapted from Proctor et al. (2011)

Outcome variable	Working definition	Associated or related terms
Acceptability	The perception among stakeholders that an intervention is agreeable; applies to any stakeholder within a given context (e.g., healthcare policy makers)	Factors related to acceptability: comfort, advantage, credibility, perceived utility
Adoption	The intention or action to attempt to introduce and utilise a new practice or process	Uptake, utilisation, intention to change
Appropriateness	The relevance of perceived suitability of an intervention relative to a context or population	Relevance, perceived fit, compatibility, perceived suitability
Feasibility	The practical potential for an intervention or change to be introduced in a specific context	Practicality, fit
Fidelity	The extent to which an intervention or change was implemented in the manner described in the protocol or literature	Adherence, dosage, intensity, validity
Implementation cost	The incremental or total cost of the implementation process and associated changes in practice	Marginal cost, total cost
Coverage	The extent to which the target population is effectively reached by the implementation process, or degree to which the intervention is adopted across the defined context/setting	Access, reach, suitability, equity
Sustainability	The degree to which the intervention can be integrated into practice effectively and can form a long-term change	Maintenance, continuation, durability, integration, incorporation

Measuring all these implementation outcomes is not possible with the limited time and resources for this PhD, nor feasible given the focus will be on the prospective acceptability of an intervention (in this case, the pre-implementation of an international PSLS), and it will therefore not be possible to explore coverage, sustainability and cost until implementation has been completed in practice.

Acceptability was the focus of this study as it can be considered a key barrier or facilitator to the adoption of change and the success of implementation among a diverse group of stakeholders. Indeed, given the existence of national safety systems and reporting systems, which may be perceived to be flawed based on fear of blame, lack of feedback and the absence of positive reporting cultures (Archer et al., 2017; Health Quality Ontario, 2017), the acceptability of an international PSLS may be questioned. This may reflect the perceived lack of value of an international system, particularly in resource-constrained settings where the perceived advantages of the system may be limited compared to the anticipated costs.

Acceptability underlies the initial stage of any change process, prior to more practical considerations, as noted in Table 5.1. The decision to focus on this variable is considered in the following section, followed by an analysis of the ways to assess acceptability within the defined research methods comprising implementation research.

5.4.3 Acceptability as a core feature of implementation

Acceptability is recognised as a necessary, but not sufficient, condition for the realisation of an effective intervention in healthcare (Nilsen, 2020). Many interventions in healthcare are complex in nature, involve multiple stakeholders, and require coordination of change across professional groups and between different care environments. These features of healthcare interventions require that all stakeholders accept the intervention (i.e., perceive it as an agreeable change) to ensure it is implemented successfully. Acceptability, therefore, applies to a wide range of groups in the healthcare context, including patients and research and healthcare professionals, who may deliver interventions, as well as the recipients of the interventions (typically patients) (Tabak et al., 2012). Many factors can influence the acceptability of an intervention, based on the context, content, and quality of care perceived by patients, in addition to the perceived value and required change to established practice needed to implement change among healthcare professionals (Vuong et al., 2012).

The decision to focus on acceptability, out of all implementation outcomes, can be considered to reflect not only the general importance of acceptability as a key outcome, but also as a key aspect of the perspective of service users. Indeed, as an international PSLS does not exist, the acceptability of a theoretical system is an important consideration that may determine the acceptance and perceived value of this system. Furthermore, acceptability may be more easily conceptualised on a theoretical level, compared with costs, feasibility, and other factors, which require a more concrete appreciation of the practical aspects of implementation (which are lacking in this instance).

Over time, the importance of assessing patient and professional acceptability of interventions has emerged in policy documents in the United Kingdom (UK), such as those published by the Medical Research Council (MRC; Craig et al., 2008; Moore et al., 2015; Skivington et a., 2021). Such documents define, provide guidance on developing, evaluating and implementing complex interventions to improve healthcare and have gone through multiple updates (e.g., Craig et al [2008], Moore et al [2015], and Skivington et al [2021] are updated versions of the MRC guidance). However, such guidance tends to focus on how to measure or assess acceptability without providing a clear definition of the term. While the value of quantitative methods (i.e., satisfaction scales) and qualitative methods (in-depth interviews and questioning of interactions and experiences) to assess acceptability are noted in such guidance, failure to clearly define acceptability limits the degree to which this may be operationalised in practice.

The definition of acceptability as a concept in implementation research has been attempted in the wider literature (Diepeveen et al., 2013; Sekhon et al., 2017). Defining acceptability is complex, however, as there is variability in the published literature. For instance, acceptability may be broadly conceptualised as the perceptions and reactions of deliverers and recipients to an intervention (Bowen et al., 2009) or may be viewed as synonymous with ‘tolerability’, often from the perspective of patients (Perski & Short, 2021). However, other components may be needed to enhance these definitions of acceptability, including perceived ease of use or uptake of an intervention, perceived value, and social, cognitive, and emotional attitudes towards the intervention (Perski & Short, 2021).

The disparity in the conceptualisation of acceptability is problematic in that it limits the degree to which instruments or tools to measure acceptability can be validated and compared in practice. Importantly, measuring acceptability is considered an important strategy not only in assessing the willingness to engage with an intervention, and hence

contributory to behaviours and associated outcomes, but also to act in the interests of stakeholders, including patients, to maintain an ethical and responsive approach to healthcare interventions (Dievepeen et al., 2013). However, unless there is clarity in how acceptability is defined, such measurement remains challenging.

5.4.4 Defining and assessing acceptability

The focus of this study was on the acceptability of an international PSLS; therefore, consideration of how to assess acceptability, including the research methods and framework for this assessment process, is discussed here.

Sekhon et al. (2017) devised a Theoretical Framework of Acceptability (TFA; see Figure 5.3) within healthcare settings in order to overcome limitations related to poor definition and assessment of acceptability in the wider literature.

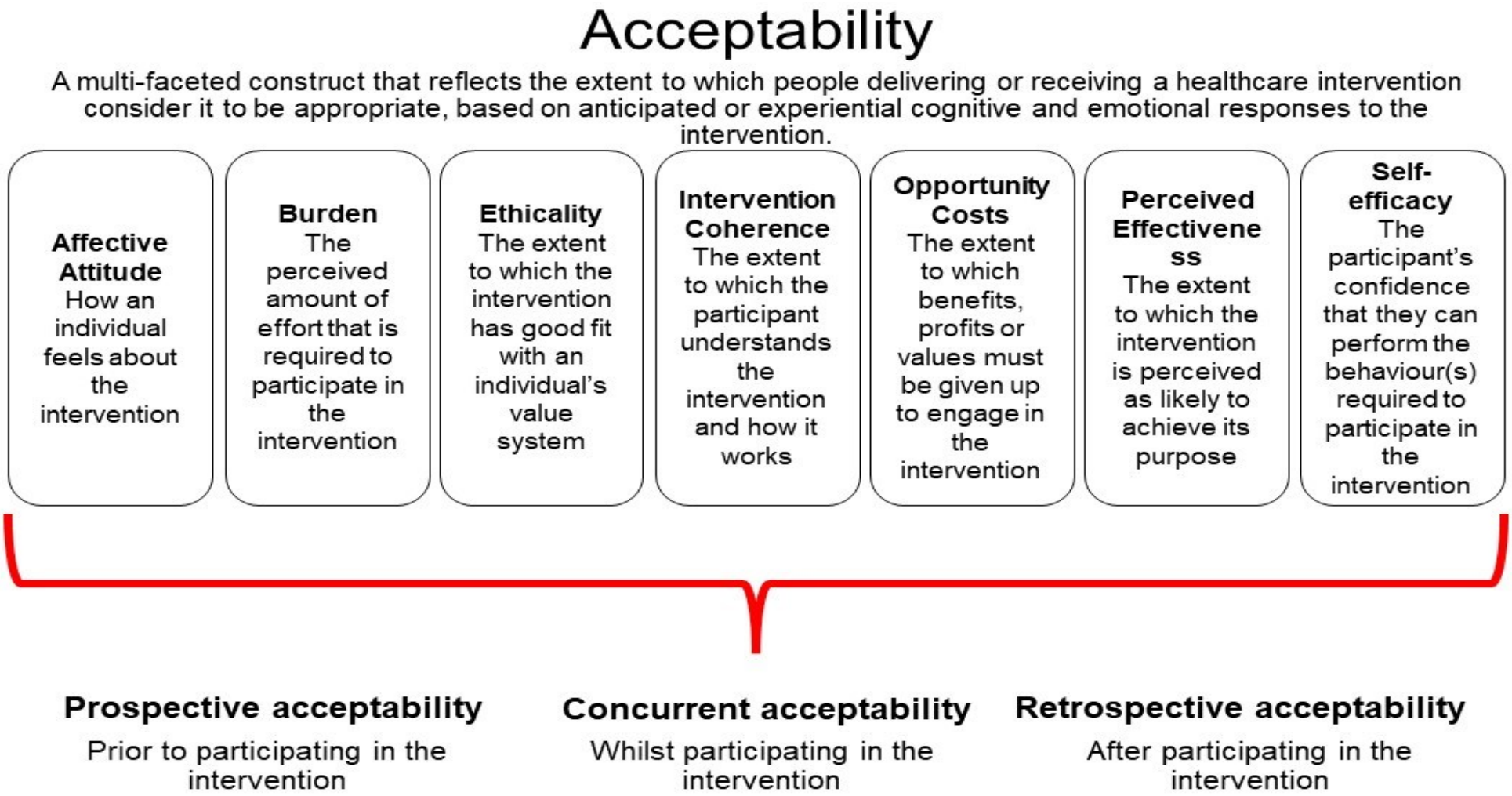

Figure 5.3 The multi-faceted construct of acceptability (Sekhon et al., 2017) adapted and used under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/)

The TFA was developed based on a review of systematic reviews (n=43) focusing on theorising acceptability in healthcare intervention, as well as both inductive and deductive reasoning applied to theoretical concepts (Sekhon et al., 2017). The resulting definition of acceptability emphasised the multi-faceted nature of the construct, with consideration of both cognitive and emotional responses to the intervention from the perspective of defined stakeholders. Seven component constructs were identified within the TFA: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy (Figure 5.3; Sekhon et al., 2017). Within these component constructs, there is also a hypothesis: cognitive and emotional responses to an intervention influence behavioural engagement with that intervention (Sekhon et al., 2017). Of particular importance, the TFA can be used for the operationalisation of measuring acceptability, providing a basis for evaluating this outcome variable of implementation research.

For the present study, it is proposed that the TFA may be utilised to guide the assessment of the acceptability of an international PSLS, adding nuance to the MRC guidance on developing and evaluating complex interventions (Craig et al., 2008; Moore et al., 2015; Skivington et a., 2021). During the development phase of a complex intervention, such as an international PSLS, researchers are advised to identify a theory of change and model processes and outcomes; consideration and use of the TFA at this specific stage can facilitate informed decision-making regarding the content, form, and mode of delivery of the intervention components. This prospective approach is important, as it provides a basis for examining perceived acceptability and identifying any barriers to implementation that may stem from acceptability.

Based on the component constructs of acceptability, such as the feelings of an individual towards an intervention (affective attitude), the perceived effort to engage (burden), and the agreement with the value system of the individual (ethicality), changes can be made to the intervention to facilitate optimal acceptability, overcoming any identified barriers or challenges. Furthermore, the TFA may be applied beyond the initial development phase, encompassing implementation and retrospective evaluation phases, guiding further adjustments and changes to the intervention (Sekhon et al., 2017).

The TFA has been used in health services research, encompassing a wide range of interventions and safety initiatives. This includes using the model as a means of evaluating the perceived effectiveness of insulin prescribing safety interventions (Bain et al., 2020) and in the assessment of perceived effectiveness, acceptability, and satisfaction with

health services (Dalinjong et al., 2019). Therefore, this model provides a reasonable theoretical basis for assessing acceptability as a multi-faceted construct, and its use is supported in the present context.

5.4.5 Methodological approach and design

Utilising the TFA as a guide for the research process, wider consideration of the methodological approach to implementation research is needed to contextualise the use of the TFA. Implementation research is based on a pragmatic standpoint, and hence the ability to address a research question relies on using the best available data to appreciate 'what works?' to solve the defined problem (Hall, 2013). Consequently, pragmatism allows for a combination of qualitative and quantitative data to address a focused issue, with a mixed methods approach utilised to combine both forms of data in a complementary manner toward realising practical solutions to the problem (Shannon-Baker, 2016). Indeed, the definition of acceptability has evolved to incorporate both objective and subjective elements, which may be addressed through quantitative and qualitative methods (Sekhon et al., 2017). Therefore, the philosophical stance of pragmatism is aligned with the purpose and objectives of implementation research and the mixed methods approach that is compatible with acceptability measurement.

Mixed methods research has been described in detail in the wider literature, highlighting how this form of research may be linked to pragmatism (Johnson & Onwuegbuzie, 2004; Allmark & Machaczek, 2018). The value of the mixed methods approach lies in combining qualitative and quantitative data to address the research question and specified aims and objectives. Both the qualitative and quantitative elements of the research process must be clearly defined to facilitate an effective design, while consideration of the synthesis of these data sets and the analytical processes required to ensure reliability and validity in mixed methods research is also needed (Johnson & Onwuegbuzie, 2004). This thesis has been working within the hypothetical phase to inform any physical development of an actual international PSLS; the final study adds value to prior chapters by exploring acceptability for end-users, meeting the thesis aims and objectives (aim 3, objectives 4-5).

The remainder of this chapter provides an analysis of the completed quantitative study, which forms part of the sequential exploratory mixed methods design for this PhD, providing justification for the decisions made regarding the core elements of the research process noted above.

5.4.6 Identification of end-user participants

The healthcare system in Kuwait is decentralised, with an established network of primary care centres that cover residential areas (World Health Organization [WHO], 2018b). This is further covered by six secondary healthcare facilities, which are supplemented by 16 tertiary healthcare facilities. Accreditation of the healthcare centres and facilities is undertaken by the Quality and Accreditation Directorate (QAD) of the Ministry of Health of Kuwait. The QAD has four departments that deal with accreditation, standards and indicators, safety, and research and technical support. The QAD has offices at all secondary and tertiary healthcare facilities to collect data, train staff, and maintain safety and national standards. These offices are supported by technical support teams from the QAD as well as having dedicated quality and safety-trained clinicians working at those healthcare facilities.

5.4.6.1 Sampling method and size

The population size (n=19) represented all staff at the safety and research and technical support departments at the Kuwaiti QAD to serve as a case study for the present study, which was necessary for logistical reasons. All eligible professionals (n=19) working within the QAD of the Ministry of Health were invited to participate in the survey. Therefore, bias due to selection within the designated target population was avoided, although limitations associated with the small total sample size should be considered, along with potential limitations on the generalisability of the findings of the Kuwaiti perspective to the international context. The survey was administered to potential end-users and/or contributors to an international PSLS, specifically patient safety/risk/healthcare managers working in the government healthcare sector in the State of Kuwait.

5.4.6.2 Identification of Participants

A full list of potential participants was obtained from the head of research and technical support department at the QAD at the Ministry of Health of Kuwait. The QAD is responsible for overseeing all initiatives and matters related to healthcare quality improvement and patient safety, including the collection and analysis of reported patient safety incidents at the national level. Participants (n=19) were invited to participate in the survey if they met any of the first three inclusion criteria presented in Table 5.2, along with the final inclusion criterion (working in Kuwait, i.e., 1 OR 2 OR 3, AND 4).

Table 5.2 Participant Inclusion criteria

Participant Inclusion Criteria
1. Expertise in the development, management, or evaluation of a patient safety learning/reporting system. 2. Role at a local/national level for patient safety/incident reporting and learning systems 3. Experience in patient safety/quality improvement/risk management/healthcare management 4. Working experience in Kuwaiti government healthcare systems.

Identified participants were directed toward information about the purpose of the survey, and a formal invitation, along with a link to view and download the participant information sheet, were also given (see Appendices 5.1-5.3 for invitation e-mail, consent form, and participant information sheet). The consent form was in electronic format and was part of the online survey. No names or signatures were collected; thus, the survey was anonymous (see Appendix 5.4 for the initial survey flow).

5.4.6.3 Participant characteristics

The end-users (n=19) included in this study are medical doctors that were trained in healthcare quality improvement, accreditation, and patient safety. Furthermore, some of these end-users are holders of graduate degrees (MSc/PhD) in public health and healthcare management, in addition to working experience as heads of departments in multiple healthcare organisations. Most of these end-users work (or have worked in the past) in teams that cover all 22 governmental healthcare organisations in Kuwait, where they lead and train local teams regarding quality improvement, accreditation, and patient safety. Another section of these end-users works at the Patient Safety Department at the QAD at the Ministry of Health of Kuwait. These end-users oversee national patient safety initiatives as well as collect and aggregate national patient safety data to analyse and generate learning and share that learning with the local governmental healthcare organisations to improve patient safety.

5.4.7 Data collection platform

The survey was administered electronically via Online surveys (formerly Bristol Online Surveys) software. Participants were required to state their level of agreement, using a 5-point Likert-like scale, with 14 statements, divided into two sections, that reflected the seven constructs of the TFA (see Table 5.3 for an example). In order to provide participants with the opportunity to elaborate on their opinions, free text boxes were added after each section.

Table 5.3 An example of the 5-point Likert-like scale used in the survey

1. Please rate the extent to which you agree with the following statements, based on your experience and as a potential user of the proposed system:	1 (strongly disagree)	2	3 (neutral)	4	5 (Strongly agree)
I think that an international system with such features and functions would be acceptable for my use.					
Using such a system would not require too much effort from me.					

5.4.8 Survey design

The design and development of the online survey went through three stages.

5.4.8.1 Stage one: development of survey questions

The development of survey questions was based on the findings from the Delphi Study (Chapter 4), as well as targeting the seven constructs of the TFA to assess the prospective acceptability of an international PSLS with potential end-users, specifically key functions and features of a potential international PSLS, as well as the potential sharing of patient safety data. The main author of the TFA (Sekhon et al., 2017) was contacted to confirm that the seven constructs are equally weighted and to obtain exemplar questions that address the seven constructs of the TFA. The author confirmed that the seven constructs are equally weighted and provided a conference poster of a study with questionnaire examples (Sekhon et al., 2022).

5.4.8.2 Stage two: pilot testing

A small sample of three potential end-users was invited to pilot test the survey to ensure face and content validity. These end-users had working experience in Patient Safety and Quality Improvement in the UK to keep potential participants in Kuwait available for the main survey. An e-mail with a link to the survey was sent, with the following questions asked of participants:

- Is the layout of the survey easy to follow and read?
- Are the questions/statements easy to understand?
- Are there any changes you would make to the survey?
- How do you feel about the time it took to complete the survey?
- Does the following e-mail invitation give explicit instructions about what is required of the participants?

- Are there any changes you would make to the invitation e-mail and participant information sheet?

5.4.8.3 Stage three: finalising the design and conducting the survey

One pilot tester completed the survey (response rate: 1/3 = 33%) and provided minor edits (suggestion to delete a couple of words and to add a couple of words) to the invitation e-mails. The pilot tester commented that the survey *'flowed well'*.

Feedback from the pilot test was used to finalise the design and content of the survey before inviting potential participants. The final drafts of relevant survey documents were shared with the ethics committees (Cardiff University School of Medicine Research Ethics Committee and the Standing Committee for Coordination of Health and Medical Research at the Ministry of Health of Kuwait) before conducting the survey (see Appendix 5.5 for final survey flow). The invitation e-mail that was sent to participants included information about the study, an anonymous link to the study, which included the consent form as part of the survey, and the participant information sheet. Due to possible delays in responding due to work demands related to the COVID-19 pandemic, participants were given a period of six weeks to provide consent and submit their answers (April – May 2021). For those that had not responded to the initial invitation e-mail, a reminder e-mail was sent approximately two weeks after the initial invitation.

5.4.8.4 Stage four: respondent validation

The final results of the analysis were shared with the participants to validate the conclusions made by analysing the survey data. Participants were asked to provide feedback on data interpretation, offering the chance for further insights and clarifications.

5.4.9 Data Analysis

The survey data were extracted from the online platform as an SPSS (Statistical Package for the Social Sciences) Statistics Data Document (.sav), and IBM SPSS Statistics (Ver. 27.0) software was used to perform statistical analysis and generate charts.

5.4.10 Ethics

Ethical approvals were obtained from Cardiff University School of Medicine Research Ethics Committee (SRES reference: SMREC 20/85) and from the Standing Committee for Coordination of Health and Medical Research at the Ministry of Health of Kuwait (reference: 1630/2021).

Ethical issues addressed in the design of the study include the requirement for participants to provide informed consent electronically. Participants were invited by e-mail to participate in the online survey administered electronically via Online surveys. Potential participants had up to six weeks to decide whether they wished to participate in the study and complete the consent form and survey.

All data and feedback presented in the questionnaires and reports were anonymous, as the names and signatures of participants were not collected. The data collected throughout this study were kept securely in line with Cardiff University Research Integrity and Governance Code of Practice (see Appendix 5.3 for participant information sheet).

All data were processed on the basis that doing so is necessary for public task scientific and historical research purposes in accordance with the necessary safeguards and is in the public interest.

5.5 Results

5.5.1 Results of the survey

The response rate to the survey was high (16/19 = 84%).

5.5.2 Demographics of the participants

The participants represented two distinct groups: those working at the safety department at the QAD (n=7) and those who mainly worked at government healthcare organisations (e.g., primary, secondary, tertiary care; n=9). The participants covered 22 (100%) of such healthcare organisations (some covering more than one organisation), with 10 participants having ≥ 10 years of working experience, and six participants having < 10 years of working experience (range = 15 years).

5.5.3 Acceptability of key functions and features of a proposed international PSLS

Table 5.4 outlines basic descriptive statistics for each construct of the TFA for the first section (see Appendix 5.5 for the final survey flow), based on survey results. See Appendix 5.6 for individual histograms of each construct.

Table 5.4 Descriptive statistics for each construct of the TFA for section one of the survey

	Affective attitude	Burden	Ethicality	Intervention Coherence	Opportunity costs	Perceived effectiveness	Self-efficacy
Mean	4.44	3.50	4.56	4.50	3.81	4.00	4.06
Median	5.00	**3.50**	5.00	4.50	4.00	4.00	4.00
Minimum	3	2	4	4	2	3	3
Maximum	5	5	5	5	5	5	5
n	16	16	16	16	16	16	16

5.5.4 Acceptability of patient safety data to be shared for international learning

Table 5.5 outlines basic descriptive statistics for each construct of the TFA for the second section (see Appendix 5.5), based on survey results. See Appendix 5.7 for individual histograms of each construct.

Table 5.5 Descriptive statistics for each construct of the TFA for section two of the survey

	Affective attitude	Burden	Ethicality	Intervention Coherence	Opportunity costs	Perceived effectiveness	Self-efficacy
Mean	4.31	3.44	3.94	4.50	3.75	4.25	4.25
Median	4.50	**3.00**	4.00	5.00	4.00	4.00	4.00
Minimum	3	2	2	3	2	2	3
Maximum	5	5	5	5	5	5	5
n	16	16	16	16	16	16	16

5.5.5 Inferential statistics

The descriptive statistics highlighted an expected lower median for the Burden construct of the TFA. This was further explored by dividing the participants into two groups: those working directly at healthcare organisations (labelled on-site end-users; n=9) and those working at the safety department at the QAD (labelled off-site end-users; n=7). Discussions with a statistician at the Data Clinic at Cardiff University led to the decision to perform nonparametric statistical tests, particularly the Mann-Whitney U. This decision was made based on the available survey data (ordinal data), sample size, and the distribution of the data. According to the appropriate table of critical values for the Mann-Whitney U test (Corder & Foreman, 2014), the critical value for this case was 12. The significance level was set to 0.05.

The following are the null and alternative hypotheses:

H_0: the two groups have no significant difference in scoring the TFA's constructs.

H_a: the two groups have significant difference in scoring the TFA's constructs.

If the test statistic (the U) is ≤ 12, then the null hypothesis is rejected, while if the test statistic is > 12, then the null hypothesis is retained.

Tables 5.6 and 5.7 outline the results of inferential nonparametric statistical tests (Mann-Whitney U) for the first section of the survey.

Table 5.6 Mann-Whitney Test Ranks for each construct of the TFA for section one of the survey

Mann-Whitney Test

Ranks

	Role	N	Mean Rank	Sum of Ranks
Affective attitude	Off-site end-user	7	8.00	56.00
	On-site end-user	9	8.89	80.00
	Total	16		
Burden	Off-site end-user	7	8.00	56.00
	On-site end-user	9	8.89	80.00
	Total	16		
Ethicality	Off-site end-user	7	8.57	60.00
	On-site end-user	9	8.44	76.00
	Total	16		
Intervention Coherence	Off-site end-user	7	9.07	63.50
	On-site end-user	9	8.06	72.50
	Total	16		
Opportunity costs	Off-site end-user	7	7.21	50.50
	On-site end-user	9	9.50	85.50
	Total	16		
Perceived effectiveness	Off-site end-user	7	8.50	59.50
	On-site end-user	9	8.50	76.50
	Total	16		
Self-efficacy	Off-site end-user	7	7.43	52.00
	On-site end-user	9	9.33	84.00
	Total	16		

Table 5.7 Mann-Whitney test statistics for each construct of the TFA for section one of the survey

Test Statistics[a]

	Affective attitude	Burden	Ethicality	Intervention Coherence	Opportunity costs	Perceived effectiveness	Self-efficacy
Mann-Whitney U	28.000	28.000	31.000	27.500	22.500	31.500	24.000
Wilcoxon W	56.000	56.000	76.000	72.500	50.500	76.500	52.000
Z	-.416	-.405	-.061	-.488	-1.055	.000	-.842
Asymp. Sig. (2-tailed)	.677	.685	.951	.626	.291	1.000	.400
Exact Sig. [2*(1-tailed Sig.)]	.758[b]	.758[b]	1.000[b]	.681[b]	.351[b]	1.000[b]	.470[b]

a. Grouping Variable: Role

b. Not corrected for ties.

Table 5.7 shows that the null hypothesis is retained for all seven constructs of the TFA, as there is no significant difference between the two groups (test statistics for all constructs > 12, and significant levels for all constructs > 0.05) when it comes to the first section of the survey, which is related to key functions and features of an international PSLS.

Tables 5.8 and 5.9 outline the results of inferential nonparametric statistical tests for the second section of the survey.

Table 5.8 Mann-Whitney Test Ranks for each construct of the TFA for section two of the survey

Mann-Whitney Test

Ranks

	Role	N	Mean Rank	Sum of Ranks
Affective attitude	Off-site end-user	7	7.29	51.00
	On-site end-user	9	9.44	85.00
	Total	16		
Burden	Off-site end-user	7	7.14	50.00
	On-site end-user	9	9.56	86.00
	Total	16		
Ethicality	Off-site end-user	7	7.57	53.00
	On-site end-user	9	9.22	83.00
	Total	16		
Intervention Coherence	Off-site end-user	7	6.14	43.00
	On-site end-user	9	10.33	93.00
	Total	16		
Opportunity costs	Off-site end-user	7	6.86	48.00
	On-site end-user	9	9.78	88.00
	Total	16		
Perceived effectiveness	Off-site end-user	7	5.71	40.00
	On-site end-user	9	10.67	96.00
	Total	16		
Self-efficacy	Off-site end-user	7	6.79	47.50
	On-site end-user	9	9.83	88.50
	Total	16		

Table 5.9 Mann-Whitney test statistics for each construct of the TFA for section two of the survey

Test Statistics[a]

	Affective attitude	Burden	Ethicality	Intervention Coherence	Opportunity costs	Perceived effectiveness	Self-efficacy
Mann-Whitney U	23.000	22.000	25.000	15.000	20.000	**12.000**	19.500
Wilcoxon W	51.000	50.000	53.000	43.000	48.000	40.000	47.500
Z	-.981	-1.047	-.744	-1.988	-1.296	-2.258	-1.400
Asymp. Sig. (2-tailed)	.327	.295	.457	.047	.195	.024	.162
Exact Sig. [2*(1-tailed Sig.)]	.408[b]	.351[b]	.536[b]	.091[b]	.252[b]	**.042[b]**	.210[b]

a. Grouping Variable: Role

b. Not corrected for ties.

Table 5.9 shows that the null hypothesis is retained for six out of the seven constructs of the TFA, while rejecting it for the Perceived effectiveness. This is because the test statistic is 12 and the significance level is < 0.05 (p = 0.042). The interpretation of this statistically significant difference between the two groups, as well as the lower median scores for the Burden construct, was shared with the participants as a respondent validation exercise to validate the interpretation of the survey analysis results with the participants.

5.5.6 Comments or feedback from participants

Some feedback or comments from participants were included in the free-text form. These comments included the need for follow-up and monitoring of an international PSLS and

uncertainties over how these processes could be achieved in practice. Only four comments were included within these qualitative data, precluding formal analysis of the content. However, these comments are presented with respect to the section of the survey to which they related.

5.5.6.1 Comments related to section one of the survey

- Comment one: “Follow up and monitoring of such a system”
- Comment two: “One of the largest barriers not mentioned above and that affects the potential for such a system is local regulations and the government sector bureaucracy’s willingness to share this information”
- Comment three: “At this point, I think what we need most is reaching out and working hand in hand with front line healthcare providers through their everyday struggles to provide patient care the safest way possible...less talking and more doing”

5.5.6.2 Comment related to section two of the survey

- Comment one: “Sharing such data is feasible [sic] and of great importance. At the level of QAD, we can share these data using the info from the statistics we are receiving from healthcare facilities. But Unfortunately, healthcare facilities might be hesitant to share such data directly due to their blaming culture.”

5.5.7 Results of the respondent validation exercise

The main findings of the survey were shared with all participants (n=16), and they were asked to provide their feedback/suggestions regarding the interpretations of the survey results (see Appendix 5.8 for the survey). The participants were asked whether they agreed or disagreed with the interpretations of the survey results and were asked to provide comments whenever they disagreed with the interpretations.

The participants were given seven days to complete the survey. Within the seven-day period, only three responses were recorded (3/16 = 19%), a low response rate which might be attributed to the time gap between the original survey (conducted in April 2021) and the respondent validation survey (conducted in July 2021), changes in COVID-19 situation in Kuwait, and the summer holiday season. There were no disagreements with the presented interpretations of the survey results, and, therefore, no further feedback/comments were provided.

5.6 Discussion

5.6.1 Main findings

The main findings of this study were that the respondents of the survey showed a moderate-to-high level of acceptability of the proposed international PSLS, based on the TFA construct components. Most domains of acceptability were rated agree or strongly agree, with the only exception being the domain of burden, which had a mean value consistent with a neutral response. This suggests that acceptability was generally high among healthcare staff and safety directorate employees in Kuwait, although the perceived amount of effort in implementing the international PSLS may present a possible barrier to successful implementation. However, none of the responses to the survey were negative, suggesting no significant attitudes toward the unacceptability of the proposed intervention.

When analysing the responses from either frontline (on-site) or safety directorate (off-site) staff, there was general agreement on the acceptability of the international PSLS among both groups, with only one statistically significant difference related to the perceived effectiveness of the intervention, which was ranked higher by on-site staff ($p = 0.042$). The finding that only one element of acceptability was statistically different, whereas the others were not, may have limited practical significance, given small sample size.

Several comments were noted from participants, based on comments and suggestions from participants in the original survey. One insight was the need for follow-up and monitoring of such an international PSLS. This was recognised as an important part of the implementation process, as the sustainability of the system is crucial following its initial introduction into practice.

5.6.2 Context of existing literature

Other studies that have used the TFA to evaluate the acceptability of interventions in practice lack a clear focus on patient safety and the Kuwait healthcare context (e.g., Murphy & Gardner, 2019; Chakrapani et al., 2020; Pavolva et al., 2020). However, published studies have demonstrated the value of the TFA in assessing acceptability and highlighting potential areas for refinement of the implementation process for small or local interventions (e.g., Murphy & Gardner, 2019; Pavola et al., 2020). Damush et al. (2021) have also used the TFA to assess the acceptability of a complex quality improvement programme at a local and national level. In that study, the authors noted that acceptability for complex interventions was

high among stakeholders but varied according to time, the experience of the quality improvement team, self-efficacy of the team, and perceived effectiveness of the potential to improve care quality.

Concerns over the follow-up and monitoring of an international PSLS were communicated in the present study. Specific concerns as to how follow-up or monitoring could be completed were expressed among the participants of the study. Barriers to follow-up and monitoring may reflect those linked to the culture of the organisation and other factors that constrain the ability of staff to report safety outcomes. An important barrier was also noted in the qualitative dataset, which is that local regulations and bureaucracy within the government health sector could reduce the willingness of healthcare professionals/organisations to share information on safety and learning. Healthcare facilities may also be reluctant to share data based on a culture of blame within the organisation (Brborovic et al., 2019), which can impact the quality of the data shared as part of the QAD, a body that can facilitate data sharing on a national basis based on data received from individual healthcare facilities. A culture of blame has been recognised as a barrier to information sharing and openness regarding safety issues in healthcare in the wider literature (Mahajan, 2010). Therefore, barriers to information sharing at the local level, including those related to organisational culture, bureaucracy, and blame, may impact the acceptability of the proposed international PSLS.

Indeed, a culture of blame and excessive bureaucracy has been noted within the specific context of the Kuwaiti healthcare system, which suggests that this culture may be specific to Kuwait, potentially reducing the generalisability of the findings on an international level. Negative culture features were identified in this study, including excessive bureaucracy and a culture of blame within healthcare settings, which may limit data sharing and quality of data, as noted above. Both factors have been noted in the wider literature as contributing to poor patient safety and challenges in adequate safety incident reporting (Cooper et al., 2017). A recent systematic review found that within Arab countries, there remains a challenge in establishing a culture of patient safety due to the persistence of punitive responses to incidents and the lack of communication of errors and incidents (Elmontsri et al., 2018). While not specific to Kuwait, these findings suggest that a culture of blame is persistent in many nations and may influence behaviours and safety reporting among physicians. Ali et al. (2018) have recently suggested that further improvement is needed in establishing a safety culture in hospitals in Kuwait, including the need to support staff in reporting incidents, learning from

incidents, and communicating effectively across teams. Therefore, addressing this issue may be of particular importance in facilitating the effective use of a PSLS within Kuwait, as attitudes towards incident reporting and information sharing can influence reporting processes and the value of this system (Mahajan, 2010).

While the cultural aspects of healthcare in Kuwait may be relevant for the international application of these findings, variations in acceptability of an international PSLS according to staff backgrounds and professions may also be relevant within an organisation, potentially with implications across nations. Generally, the findings of this study suggested that there was minor variation between frontline staff and directorate (non-frontline) staff regarding the acceptability of an international PSLS. Only one domain showed any significant difference between these groups (perceived effectiveness). This could be due to the lack of clarity as to what those working in healthcare facilities might consider as essential patient safety learning data, which is an interpretation that respondents agreed to in the respondent validation survey (see Appendix 5.8). Additionally, this finding may reflect differences in perceived workload associated with safety reporting processes as part of an international PSLS between frontline and safety directorate staff. However, there is no clear evidence suggesting that different staff perceive such interventions in contrasting ways. It remains to be seen if factors other than the presence of staff on-site or off-site can influence the acceptability of the international PSLS.

5.6.3 Strengths and limitations

The findings of this study are novel, in that they are based on insights from an understudied target population (healthcare professionals in Kuwait) in relation to a newly developed framework of an international PSLS, based on feedback from a panel of experts in patient safety. Consideration of the wider acceptability of patient safety systems in practice and the potential challenge associated with an anticipated burden for physicians and safety directorate staff may prove valuable in this context. Therefore, it is an important limitation to note that the lack of actual implementation of an international PSLS makes this a theoretical examination of perspectives, which may not reflect experiences following implementation.

One of the strengths of the present study was the use of a pragmatic approach, which offers an opportunity to link the data to practical implementation of the findings (Palinkas & Cooper, 2017). The potential to use quantitative assessments of the international PSLS implementation process afforded insights that may apply to the practical use of such a

system. However, it is important to note that limited numbers of questionnaires, and especially qualitative data, were obtained as part of the research process, with qualitative insights limited to comments from a small number of participants who added free-text responses during data collection. This limits the depth of insight into experiences and perceptions/perspectives of the stakeholders, limiting a full evaluation of acceptability, which is recognised as a multi-faceted construct of qualitative and quantitative data describing the constructs of acceptability (Sekhon et al., 2017).

Another limitation is that the sample size used in the study was small, which may have reduced the reliability of the study findings when validating the survey, as well as the wider generalisability to other healthcare systems, outside of Kuwait, that may be involved in an international PSLS. A more expansive investigation of the acceptability of the proposed international PSLS is suggested for future research: taking into account the perspectives of healthcare staff, managers, and government employees may be valuable in Kuwait and other nations, informing the development process of this complex intervention. This may be considered a complex intervention due to the interacting components and organisational levels targeted by the international PSLS, as well as the variable outcomes and focus on changes in practice (i.e., reporting practice) that can constitute an intervention. Similarly, only three participants completed the respondent validation survey process, which limited the degree to which validation of responses could be achieved. Adjustment of the timing of the respondent validation process (i.e., a shorter time between survey completion and validation feedback), changes to the timing of the survey outside of the summer holiday period and using face-to-face interviews may have facilitated a greater number of responses and a more detailed level of feedback at this stage. However, this was not feasible during the COVID-19 pandemic.

Another point to consider is that the present study did not evaluate acceptability over different time points, or with respect to a variety of factors, such as experience or self-efficacy, which may limit the depth of the analysis. These insights may have been valuable in capturing the dynamic nature of acceptability and factors that can influence acceptability. However, the small sample rendered this form of evaluation void, due to the low response rate of the respondent validation survey and limited data available from the sample.

5.6.4 Recommendations and future research

This study provided an insight into the prospective acceptability of a proposed international PSLS developed through a Delphi consensus process and a systematic appraisal of the literature. Based on the findings, it can be recommended that the international PSLS is likely to be broadly acceptable to staff in the Kuwaiti healthcare system, as well as within the QAD, although the findings should be interpreted cautiously given the high response rate but low total number of responses (small sample size). Consequently, implementation of the system may be further evaluated, including feasibility and pilot testing, as appropriate. It is recommended that further evaluation of this proposed system is performed according to the MRC guidance on developing and evaluating complex interventions in practice, to explore further the acceptability findings (MRC, 2008; Skivington et al., 2021).

Prior to these further stages of developing and implementing this complex intervention, further research to clarify acceptability across stakeholders may be advisable. Such research should build on the present study by including a more diverse range of professionals and government or industry professionals (across settings and nations), such as policymakers, pharmaceutical staff and other stakeholders involved in patient safety data collection and analysis. A wider range of insights may be valuable in appraising the acceptability of the intervention for all relevant stakeholders. Furthermore, a larger sample size based on multiple nations or nations other than Kuwait, and a deeper exploration of qualitative insights related to the use of an international PSLS may be valuable in future research. Sample size limitations in the present study were associated with low statistical power of the findings and limited generalisability, emphasising the need to overcome this barrier in future studies.

Further research may be valuable in exploring the level of agreement between directorate and frontline staff with regards to the acceptability of an international PSLS. While the present study indicated a high level of agreement between these groups, divergence in acceptability may be possible based on the different perspectives and roles of these groups in healthcare provision and safety. Therefore, further validation and exploration of inter-group differences using qualitative methods (e.g., interviews), as well as demographic or occupational features that may influence acceptability, should be considered.

Finally, particular insights into the Kuwaiti cultural and social aspects of this change (and resistance to change) may be valuable in providing a basis for assessing national barriers and

facilitators that may impact acceptability. Analysis of the Kuwaiti healthcare system in contrast with another system may be valuable in contrasting these systems and acceptability. A wider range of national evaluations may also be important in increasing the generalisability of the findings and in supporting future evaluations and implementation processes.

5.6.5 Implications for research, practice and policy

The main findings suggested that survey respondents were broadly accepting of the proposed international PSLS intervention. Acceptability was consistently high across the seven domains of acceptability defined by the TFA. These findings may be interpreted in a number of ways.

Firstly, it can be assumed that the proposed intervention was considered acceptable across participants, reflecting a broadly agreeable approach (for this sample) to enhancing patient safety and affording opportunities to learn in a systematic manner.

Secondly, the acceptability noted may reflect positive attitudes towards the concept of an international PSLS, rather than a true willingness and commitment to implementing this system. The reasons underlying the acceptability seen among participants in this study may be hard to determine due to the lack of actual implementation and the resulting lack of experience of participants with such a system. Indeed, the proposed international PSLS is complex, and full appreciation of the implications of the system and the repercussions to staff and patients may not have been realised by the participants. Acceptability also needs to be considered an incomplete marker of potential implementation success, as acceptability alone does not guarantee success (Shaw et al., 2014). As initial implementation processes are completed, changes in acceptability may be apparent, reflecting the bidirectional relationship between context and acceptability (Shaw et al., 2014); therefore, it is not clear if acceptability of the concept was favoured in an abstract manner, rather than acceptability as a true practical concern. Further exploration of these attitudes and perspectives may be facilitated by using qualitative research methods to investigate this in more detail in the future.

From a practice perspective, the adoption of an international PSLS relies on engaging both frontline staff and those working in directorates, policy or other non-frontline contexts. The lack of divergence in acceptability among frontline and directorate staff, with the exception of the perceived efficacy domain, suggests that the international PSLS may be broadly accepted in settings with similar circumstances. These circumstances include factors that may be important in adopting an international PSLS, including sufficient resources and reporting

infrastructures, a clear patient safety policy agenda, and organisational cultures that promote positive reporting and blame-free approaches to safety (Health Quality Ontario, 2017; Naome et al., 2020; Hegarty et al., 2021). The limitation of the small sample size needs to be taken into account here when applying the findings to other populations or healthcare contexts in other nations. This is an important observation, as the perspectives of frontline staff may differ from those who are more removed from the clinical activities of safety reporting (Parand et al., 2011). Indeed, the value of implementation research lies not only in evaluating multiple aspects of implementation but also in exploring perspectives across different groups of stakeholders. In this instance, general agreement between directorate and frontline staff indicates that the international PSLS may have similar implications for both groups, which limits divergence in acceptability.

From a policy perspective, further validation of this finding would be valuable when exploring the views of healthcare staff in other nations, including low- and middle-income nations. Adoption and acceptance of the international learning approach by the WHO, or a similar international body, would also be a prerequisite before expanding this approach to other nations. The finding that perceived efficacy of the approach is a more important factor in frontline staff does emphasise the need for clear value in improving patient safety and achieving clear clinical outcomes for physicians who interact with patients daily, which may increase motivation and acceptability of the approach. This perspective is important and illustrates how the international PSLS should have clear goals and anticipated outcomes, which are related to clinical outcomes and benefits (Phipps et al., 2017). Communicating these potential benefits and exploring expectations and desired outcomes among frontline staff may provide a basis for improving the acceptability of the intervention.

5.7 Conclusion

In summary, this chapter presented the findings of a quantitative study evaluating the prospective acceptability of a proposed international PSLS among Kuwaiti staff in frontline and safety directorate positions within the government healthcare sector. The assessment of prospective acceptability was based on a conceptual framework that provided a robust insight into various dimensions of acceptability. The TFA guided the development of the survey instrument and allowed for clarity in determining that the acceptability of the proposed international PSLS was broadly positive across domains. One area that may require further attention is the potential for the international PSLS to be seen as a burden for staff. Further research will be needed before proceeding further to allow for a larger sample size and improved level of qualitative data to provide further insights into perceived acceptability. Further clarification of the potential burden of an international PSLS using qualitative data and potential factors to reduce the burden for staff should be considered prior to further development, implementation and evaluation of this complex intervention in practice.

Chapter 6 – Discussion

6.1 Principal findings

The preceding chapters have provided a sequential assessment of how international learning may be conceptualised and implemented as part of an international patient safety learning system (PSLS). The stages of this thesis were designed to structure an approach to establish the key requirements of an international PSLS and to explore the prospective acceptability of implementing such a system in practice. These stages are outlined in Figure 6.1, which presents an overview of the steps undertaken to meet the aims and objectives of this thesis.

Initially, a systematic review of the existing literature (Chapter 2) was used to identify key gaps in the knowledge base regarding safety learning approaches and international learning. It was identified that, while learning has been explored in detail within national approaches to safety and quality improvement, there remains a lack of knowledge and practical strategies regarding international safety learning processes and mechanisms in healthcare settings. Literature from safety-critical industries was evaluated to determine potential applications to the healthcare setting. It was noted that profound shifts in how safety can be approached are needed to ensure that an organisational approach to learning is seen in healthcare, matching approaches seen in other industries. For example, a shift from reacting to harmful incidents towards utilising data to promote wider development of safer practices is a fundamental move toward a proactive and systematic approach to safety in practice. A focused review of the literature was intended to highlight how healthcare organisations may develop safety and associated learning within an international PSLS.

The results of the systematic literature review, alongside expert interviews (Chapter 3), led to the development of a conceptual framework for an international PSLS. However, three unanswered questions remained relating to the establishment of a final framework for international safety learning, including: what data are needed from national learning systems to contribute to an international PSLS; what the optimal characteristics and format of these data are; and what form or type of feedback can be shared with national learning systems? The proposed framework was therefore limited by gaps in the literature and through identified challenges from expert interviews across safety-critical industries.

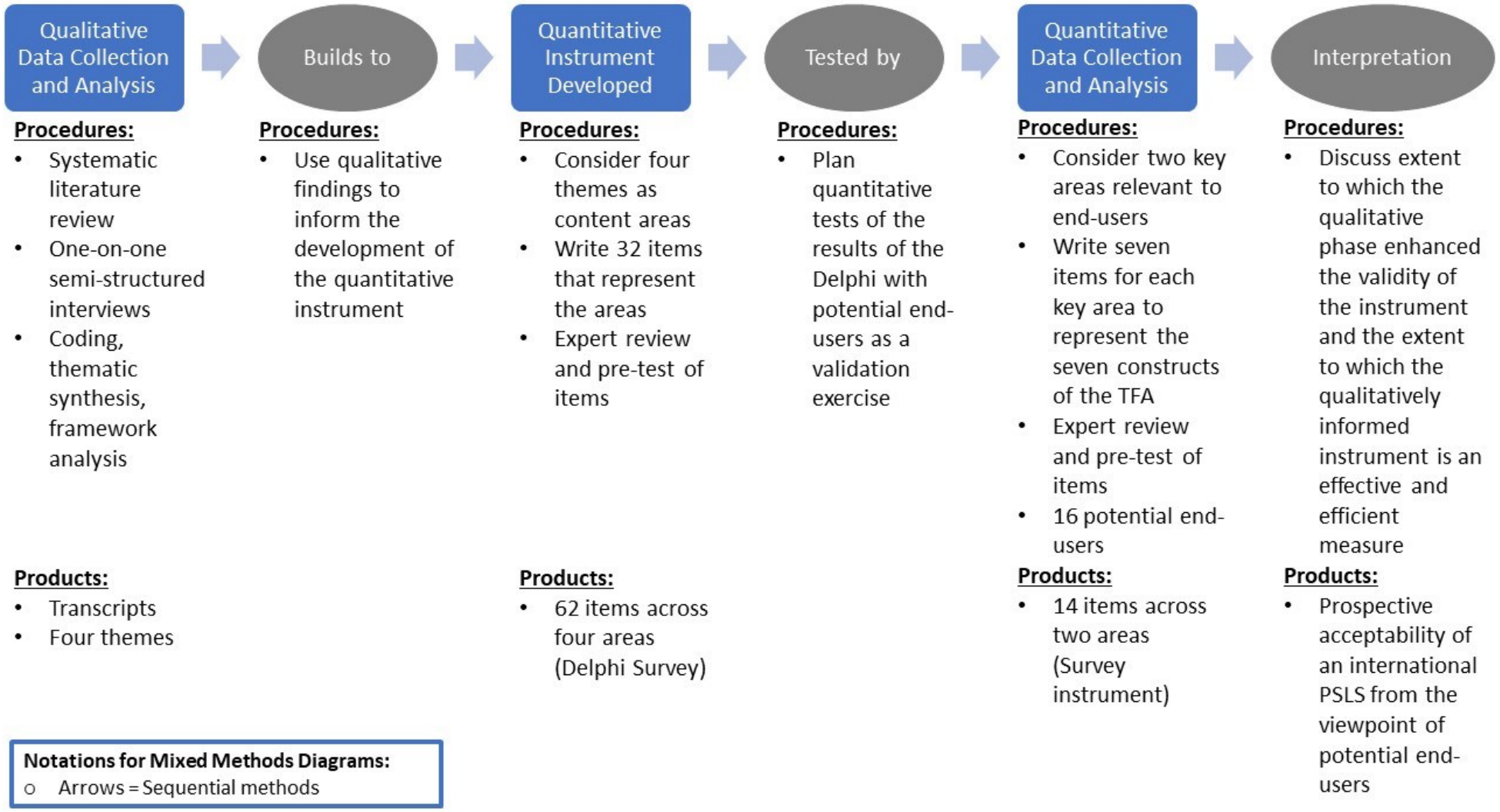

Figure 6.1 Structure of the thesis (Creswell & Clark, 2018)

Next, a modified online Delphi study (Chapter 4) was completed to develop this proposed framework further and to provide a basis for meeting the gaps mentioned earlier. International healthcare expert consensus was obtained regarding the purpose of an international PSLS, the key features and functions of this system, and the feasibility, in terms of enablers and barriers, of such a system. Furthermore, this process informed a deeper understanding of the learning features linked to such a system, with specific reference to the data inputs and outputs that facilitate learning on an international basis. It was agreed among experts that the proposed core features of an international PSLS were consistent and aligned with the principles of reducing patient harm, promoting learning, and developing recommendations and changes to facilitate learning and preventative steps for promoting safe care. An international PSLS should therefore have the potential to generate recommendations and learning points which are relevant to local and international contexts. Enablers for an international PSLS included support from national bodies, standardisation of practices and data reporting, and facilitation of a learning culture that is consistent with safety improvement.

Finally, the prospective acceptability of the developed framework was evaluated using an assessment of healthcare staff (frontline) and safety directorate staff in the Kuwaiti healthcare system, with selection of Kuwait as a single country example. This process highlighted that the prospective acceptability of the proposed framework was high and that there was general agreement between safety directorate and frontline staff in the Kuwaiti healthcare system. One caution evident in this prospective acceptability assessment is the risk for an international PSLS to place a high burden on staff, while staff also expressed a need for monitoring and support when utilising an international learning framework. These findings, overall, suggest that a framework developed to guide international learning as part of a PSLS was acceptable to staff in one nation (Figure 6.2). The development of this framework encompasses novel perspectives on international learning and patient safety from healthcare staff and staff in safety-critical industries, where the development of international learning is at advanced stages.

The remainder of this chapter considers the implications of the findings of this thesis for international learning in healthcare and for the implementation of an international PSLS, with reference to the wider literature and contemporary practice and policy. The limitations, strengths and future perspectives related to this topic are discussed to provide a basis for recommendations for research, practice, and policy.

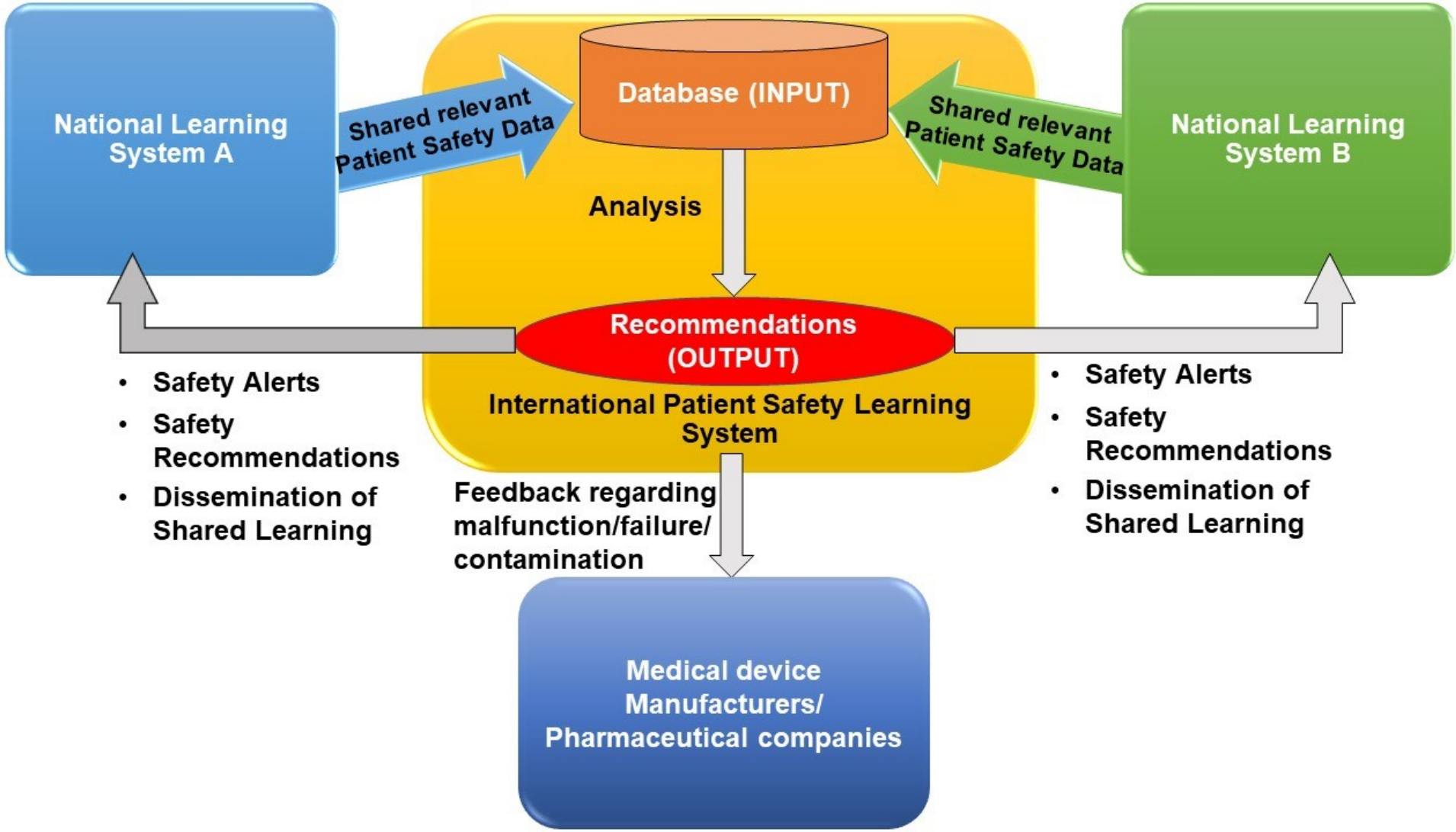

Figure 6.2 Proposed framework for an international PSLS

6.1.1 Update on Systematic Literature Review (Chapter 2)

In preparation for the writing of this chapter, a final search was conducted on 8/6/2022 to make sure that any breakthrough journal articles that might change the conclusions of the thesis were addressed. Two new peer-reviewed journal articles were identified (Archer et al., 2020; Mohamed et al., 2021). The articles mainly address barriers and enablers to the reporting of patient safety incidents at the local level; however, they lend more credibility to the findings from chapter 2 and will be included for re-analysis prior to the publication of the systematic review.

6.2 Gaps in the evidence base addressed by this thesis

6.2.1 Overview of gaps in the evidence base

The previous chapters identified a number of gaps in the evidence base that focused the collection of primary data for the research described in chapters 3, 4 and 5. Specific gaps were identified that related to the various components, design features and implementation-related factors of an international PSLS, as well as a wider understanding of international learning based on the use of an international PSLS. To address the main aim of this thesis, concepts of patient safety and learning in healthcare settings and across wider safety-critical industries were explored, with a specific focus on how those industries learn from safety incidents and learning can be shared internationally. This is discussed in chapter 1 and highlights How the wider literature on safety learning suggests that healthcare systems have specific challenges in achieving effective system-wide learning and that international approaches to learning are valued but often not achieved in practice (World Health Organization [WHO], 2021).

In terms of promoting a deeper understanding of learning in the context of safety, the findings from chapter 3 add an important perspective from international experts, as well as from those with experience working in safety-critical industries, other than the healthcare industry, where learning has been established practice on an international level for some time. Exploring these perspectives is an important step towards promoting the application of established practices and knowledge to the healthcare setting, facilitating a critical insight into how these practices may be applied to international learning in healthcare and specifically to patient safety contexts.

6.2.2 Organisational learning and patient safety

The findings of this thesis support claims that organisational learning is a key aspect of patient safety and that an international PSLS should have clear purposes, such as

enabling country-level organisational learning. This is broadly consistent with the theoretical literature on the topic of safety and learning systems, though often within a national context. Learning in relation to safety is vital in understanding where and how the system can be improved to mitigate similar future incidents from recurring and affecting the quality of care and outcomes for future patients (Goh et al., 2013). The provision of safe care in healthcare settings has been viewed as a balance between human and organisational factors within a 'risk society' (Beck, 1992; Perrow, 2011), a concept that remains valued in contemporary safety literature (Kodate et al., 2021). Since the COVID-19 pandemic, papers on risk and safety in healthcare have highlighted how risk management is complex in nature and can be a delicate balance in preventing ill health in an acute context, while preventing unintentional consequences in the long term (Alauddin et al., 2020; Alaszewski, 2021). The challenges of the COVID-19 pandemic have been wide-ranging, including cancellations of medical procedures, changes to the way practice is completed (including remote consultations and the use of virtual wards), increasing workload, discontinuations of treatments and follow-ups, and redeployment of the workforce, all of which may impact the safety of patients (Fassarella, 2021). It has also been argued that maintaining a culture of safety within an organisation, one consistent with organisational learning, has been of paramount importance in promoting patient safety in these challenging circumstances (Fassarella, 2021; Lyman et al., 2022). Thus, the ways in which organisations learn is of vital importance in modern society, to provide a basis for learning that supports interventions and their implementation, leading to improvements in patient safety.

Despite the importance placed on organisational learning to facilitate safety as a consequence of reporting and monitoring of safety incidents, there is evidence that this is not often seen in practice. Organisational learning is challenging to complete in practice, and it has been shown that healthcare organisations have traditionally not been effective at engaging with organisational learning to promote patient safety. For instance, Claridge et al. (2008) evaluated the responses of a health organisation to a coroner's report (Rule 43) that relays the findings of an inquest with important lessons to prevent future safety incidents. The resulting evaluation found that the role of the coroner was not clear to senior staff involved in patient safety and that there was little evidence of an organisational approach to information sharing from that report, learning, or development of recommendations.

As patient safety is enhanced by utilising multiple sources of data, the finding that the coroner and coroner's report were not well understood by those in a patient safety role illustrates how data that should inform learning may not be appropriate or identified effectively. Secondly, this study illustrates how lapses in data dissemination and use in practice may limit approaches to learning and subsequent organisational outputs that promote safety. These findings are closely aligned with the key gaps in the literature and issues identified through expert interviews regarding safety learning, notably: clarity regarding the type and format of data used to inform learning, and the need for feedback mechanisms to promote learning on a national level (Claridge et al., 2008).

A more recent systematic review of 11 patient safety culture dimensions (e.g., teamwork across units, communication openness, and handoffs and transitions) within hospitals, encompassing 33 articles published across 21 countries, found that weaknesses persist in approaches to learning (Reis et al., 2018). Specifically, organisational cultures were not strongly aligned with safe practice, with a lack of non-punitive responses to error, poor teamwork, and a failure to effectively coordinate improvements based on incident reporting (Reis et al., 2018). It has also been noted in contemporary practice that staff may be undermotivated to engage in organisational learning and that learning environments and opportunities may be limited in the hospital setting (Farokhzadian et al., 2018). Therefore, challenges to organisational learning appear to be as relevant in current healthcare contexts as was the case over a decade ago.

Safety within an organisation has been described by Gherardi and Nicolini (2000) as a form of organisational expertise. This definition recognises that safe practice emerges as the consequence of organisational reliability in collective actors interacting successfully within an organisation and by interactions among organisations within the wider industry. Rather than knowledge being seen in terms of mental and individual thought, knowledge and learning are cultural in nature and exist through the practices of that organisation (Gherardi & Nicolini, 2000). This is an important divergence from learning at an individual level, as the emphasis is placed on recognising the organisation as a socio-technical environment, where a culture of safety is needed among staff in the organisation in combination with technologies and textual and symbolic forms assembled into a system of relationships (Gherardi & Nicolini, 2000; Foy et al., 2011; Adriaensen et al., 2022). Organisational learning may therefore be defined as a system of representation that enables a discourse on social processes involved in the construction of knowledge, with knowledge situated in work practices (Waterson, 2018). A recent review by Foster et al.

(2019) suggests that adaptation is a core feature of patient safety within an organisational learning system, whereby changes in processes and work routines underscore the potential to generate safe practice. This has also been recognised in the healthcare setting (Dekker-van Doorn et al., 2020). Therefore, how adaptations occur within this context reflects the learning process from safety incidents, as part of a dynamic process (Dekker-van Doorn et al., 2020). How organisational learning occurs in this context and its relevance to the healthcare setting is considered further in the following section.

6.2.3 Learning in organisations: relevance to healthcare

Healthcare organisations have been slow to adopt an approach to organisational learning that is seen in construction and safety-critical industries. Safety, and learning around safety, is embedded within those organisations as a form of practice and not based on placing the burden of safe care on an individual practitioner (Cook & Yanow, 1993; Nicolini & Meznar, 1995; Morello et al., 2013). Evolution of safety from an unstructured and reactive approach to intervening for issues considered most harmful towards an approach that uses data to drive improvement efforts underpins how learning is shaping modern approaches to patient safety. Theoretically, if the organisation is efficient and effective in supporting practices aligned with safety, and all members of the organisation form teams that engage in specific routines, safety may be optimised (Gherardi, 2018). Furthermore, learning can be facilitated through the construction of communities of practice, which emphasises that staff engage in relationships that are centred on practice and activities, with social relationships and experiences of those performing activities combining to form an individual identity within a community (Gherardi, 2018). The existence of a community in this manner facilitates learning by allowing practical knowledge and routines to be perpetuated among staff, including new staff in the workplace (Monaro et al., 2015). Therefore, a change in focus from individual responsibility and accountability for safety towards a collective approach to optimising processes and practices and embedding safety within the social, technical, and cultural domains of healthcare is necessary to appreciate the foundations of an international PSLS.

While there are attempts to appreciate how learning is developed through healthcare organisations, there remains a challenging barrier to overcome relating to the emphasis of safety as a concept in the mind of the individual member of staff (Gherardi, 2018). Healthcare literature contains numerous examples of areas where safety education remains focused on individuals, while learning processes are largely directed through targeting staff behaviours and actions (Aveling et al., 2016; Lark et al., 2018). Where wider

approaches to safety learning are recognised as valuable, there is a lack of empirical data supporting their impact on patient safety outcomes. This challenges the drive towards promoting safety as an outcome of key learning processes combined with changes in practice, as empirical support is crucial in justifying dynamic shifts in healthcare practice and policy (Larson et al., 2015). While the present thesis does not provide empirical support for learning on an organisational basis, the findings suggest that this approach aligns with expert views, the existing literature, and views of safety-critical industry professionals. Therefore, it can be suggested that more needs to be done to evaluate the impact of organisational approaches to safety learning to further support this area of enquiry in the future.

Safety culture is defined as the product of individual and group values, beliefs, attitudes, and behaviours that reflect how an approach to health and safety management occurs at an organisational level (Health and Safety Executive, 1998). Safety culture is, therefore, a local issue but may also be captured within national systems; it has been argued that a culture of safety needs to start at the national level to be effectively translated into a wider context (European Observatory on Health Systems and Policies; Busse et al., 2019). Benchmarking national assessment of safety efforts and learning is crucial to providing a basis for comparing organisations and national strategies, which may inform international learning (Busse et al., 2019). Indeed, as well as the focus on organisational learning on a local or national level, there is a need for an appreciation of how organisational learning may be achieved on an international basis.

One of the main issues to arise from this thesis is that healthcare organisations may struggle to adopt a culture that is consistent with safe practice, as noted by experts in safety across organisations (Chapter 3) and the published literature (Chapter 2). A safety culture in healthcare settings is often considered within the context of staff being supported in ‘driving safety’, transparency in safe practices, incident reporting, a no-blame approach to incident recognition and reporting, and alignment of core values within the organisation towards the safety of patients (Daker-White et al., 2015). Indeed, establishing a culture consistent with these values is crucial to ensuring that any form of safety surveillance or reporting network can operate effectively (De Bienassis & Klazinga, 2022).

A recent Organisation for Economic Cooperation and Development (OECD) health working paper (De Bienassis & Klazinga, 2022) presented the findings of a patient safety culture pilot data collection process in relation to developing international benchmarks for patient safety culture in hospitals. Findings of the OECD patient safety culture report

suggest that there are important challenges remaining in promoting a safety-oriented culture in practice (De Bienassis & Klazinga, 2022). In this report of 16 OECD countries, only 50% of staff surveyed felt that safety was a top priority of managers, with 50% of staff believing that management provides a culture that is consistent with patient safety. The ability to speak freely about safety issues is fundamental in promoting a culture that is transparent and consistent with patient safety culture (Pascoe, 2017). However, there is evidence to suggest that such openness is not achieved in current healthcare practice, with De Bienassis and Klazinga (2022) noting that only 52% of staff felt that they were able to speak freely to colleagues or authority figures regarding safety issues in their work setting. Therefore, these findings are consistent with the findings of this thesis that safety cultures and support are a necessary, but often absent, elements of promoting safety learning in healthcare. Local safety cultures are vital in supporting national approaches to learning, which are in turn important in informing an international approach to learning. Hence, safety cultures at local levels may contribute to the potential for an international PSLS to operate effectively and facilitate learning.

Wider reading about safety-critical industries has emphasised the importance of moving away from a safety perspective that is focused on the individual to an organisational approach to learning. While safety incidents may occur as a result of human error, incidents can always be understood as the convergence of multiple factors or failings that are individual, organisational, or cultural in nature. Therefore, placing the burden of safety on the individual and expecting all safety learning to focus on individual behaviours do not allow for learning that is truly oriented towards addressing the multitude of factors linked to safety (Edwards, 2017). In contrast, the development of a systems approach to managing safety has been widely advocated in practice and is reflected in the development of strategies that take into account organisational learning and wider learning across settings to promote structured, multi-level practices that are aligned with safety (Edwards, 2017).

The findings of this thesis suggest that experts from safety-critical industries (Chapters 3 and 4) agree with the notion that safety learning should be delivered using a system that takes into account organisational learning strategies. Insights from experts support the development of an international learning system for patient safety that has core functions, features, and outputs that are aligned with organisational learning linked to safety. This is an important finding that confirms the widely accepted view in safety-critical industries that safety should be organisational in nature and any safety systems should reflect an organisational approach to change (Sujan, 2015).

6.2.4 International learning and safety

The present thesis highlights that international learning is viewed as important and central to an international patient safety approach. International learning shared from healthcare organisations was also identified as a significant gap in the literature, as this form of learning in relation to safety has not been effectively achieved across nations to date (Hegarty et al., 2021). The reasons underlying this lack of an international approach to safety learning are numerous and complex, emerging from many social, cultural, and organisational factors across healthcare organisations and settings (Hegarty et al., 2021). Key barriers and challenges include heterogeneity in data collected for patient safety, including a lack of standardisation of data nomenclature and taxonomies, as well as the nature of data collection, reflecting the sources of data, how they are generated, and how they are communicated for analysis (Carini et al., 2020). This thesis noted that similar observations were made by experts from safety-critical industries and by those working within the healthcare setting of Kuwait, where shared taxonomies and clarity over the type of data and the analysis of that data were perceived to be crucial for guiding learning. It has been noted that learning that results from these data is inconsistent across healthcare settings, with little standardisation of outputs of safety learning and reliability in the link between reported safety events and actionable outputs (Kitson et al., 2019).

Data on international learning from patient safety incidents are also limited, and the potential for organisations in different countries to coordinate safety learning in a collaborative manner remains an important challenge in healthcare settings. This was largely reflected in the present thesis, although safety experts and frontline healthcare staff found the prospect of the proposed safety and learning system to be acceptable for application in their country, suggesting a will to drive improvement in this context. Furthermore, it may be argued that the way data are analysed or used to inform learning may reflect a lack of clarity in the purposes of an international PSLS. The core purposes of an international PSLS described in this thesis were to improve safety based on systematic detection and prevention processes, and then learning from and sharing learning from patient safety incidents with stakeholders. These purposes are aligned with the wider literature included in the systematic literature review (Chapter 2).

The benefits of learning internationally were also supported by the findings of this thesis, adding to the wider knowledge base through direct contact with experts in healthcare and safety-critical industries. Learning at the international level involves large data sets,

through which safety incidents are assessed, and the promotion of collaborative and communicative approaches to enact effective measures to improve safety (WHO, 2020).

These insights, from the findings of this thesis, are essential, as there is a relative paucity of literature on the purpose and benefits of an international PSLS specific to healthcare.

6.2.5 Attempts to promote organisational and international patient safety learning in healthcare: principles and limitations

Implementing a framework for international safety learning in practice may be considered an overarching goal of efforts to conceptualise safety and learning on an international basis. The present thesis adopted the framework of national learning developed by Benn et al. (2009) as a basis for exploring the features and functions of an international learning system. This framework has been instrumental in guiding safety system design over time and has influenced approaches to national learning approaches in practice (WHO, 2021). While this form of framework may be considered a fundamental shift in how health organisations operate and view safety, the introduction of complex interventions like a PSLS on an international level has largely not been captured in frameworks of organisational learning (Kuosmanen et al., 2019).

Several organisations have attempted to develop strategies to facilitate international learning for patient safety in recent years. For instance, the WHO (2021) Patient Safety Action Plan for 2021-2030 aims to instil a safety culture as part of supporting learning and developing policy across healthcare organisations on an international basis. The WHO action plan has the advantage of appreciating culture as a driver of safety and associated learning, while also recognising that identifying and targeting the individual situated within a socio-technical context (i.e., human factors) is crucial in efforts to improve safety. Human factors refer to the way in which individuals behave based on their interactions with each other and their environment, with a focus on optimising human performance by understanding these interactions and optimising them (Carayon et al., 2014).

The human factors approach favours participatory approaches, person-centred safety development, and design-driven approaches to learning and implementation of safety, rather than a focus on measures and guidelines for the whole system (WHO, 2021). It has been recognised that a human factors approach to safety may be challenging to implement in healthcare, as the need to optimise safety may cause conflicts with the need to respect and follow the wishes of the individual patient (Fawcett & Rhynas, 2014). Balancing the need to drive safety with complex care decisions, uncertainty and variability,

all of which reflect a person-centred approach to healthcare. This remains challenging in practice and may serve as a barrier to applying the WHO action plan to healthcare when compared with other safety-critical industries where a person-centred approach is not pursued. For instance, in aviation, the focus is on a group of passengers being safely flown from point A to point B, all of whom share the same exposure and experiences on the aircraft and within the wider safety context. However, patients within healthcare systems have many inter-individual differences in experiences, risk factors, behaviours and exposures during their receipt of care. Therefore, applying simple measures may not be feasible or straightforward in practice.

The Canadian Patient Safety Institute (CPSI) is a WHO Collaborating Centre focused on patient safety and patient engagement, with a key role in leading policy, strategic development, and technical advancement amongst 800 WHO collaborating centres across 80 countries (CPSI, 2021). The CPSI (2021) has developed a framework for guiding the improvement of patient safety, which has three main components: enable, enact, and learn. The learning domain has four categories: education/capacity building, incident reporting/management/analysis, operational improvements, and safety/quality measurement/reporting (CPSI, 2021). All these categories must be addressed by healthcare organisations to improve patient safety, according to expert consensus and evidence informing the overarching framework. However, while the domains proposed may facilitate learning on a local or national basis, there is little clear guidance or evidence provided relating to initiatives for the sharing of patient safety learning internationally.

Drawing on literature and practice from safety-critical industries, there is a lack of clarity in how knowledge could be generated, shared, and then used to guide change in healthcare organisations across countries. Multi-national corporations could, however, engage in safety learning efficiently and immediately, due to several important features of data sharing, analysis, and implementation of outcomes. Firstly, standardisation of all data related to safety is a recognised feature of this coordinated approach to sharing information across settings and nations (Rivard et al., 2006). Standardisation in terms of the taxonomy used and the sources of information can overcome language barriers and cultural factors, leading to one shared system which can facilitate information exchange and comparison (Edwards, 2017). This was a notable finding of the present thesis, whereby safety-critical industry experts and staff in the Kuwait healthcare system acknowledged the need for clear communication that was based on a shared taxonomy of safety terminology. Indeed, one of the main outcomes of this thesis is the need for

standardisation of practice and data reporting, as well as how data are processed and interpreted. A feature of international corporations is the structured approach to the analysis of the information that is collected, with clarity in defined roles of organisation members, processes for engaging with data, and methods of practice to encourage consistency in interpretation of the data (Edwards, 2017). Finally, these corporations share an approach to producing outputs that are relevant and consistent in promoting learning and which may be implemented through established practices. Even where different nations have variations in regulatory requirements or practices that may impact on how outputs are used at the local level, these factors do not impair safety within a multi-national setting due to the existence of clear standardised methods of practice and integration of data collection, analysis, and outputs with socio-technical aspects of the corporation. Within the context of healthcare, learning should be reflective of the local needs of the organisation (i.e., patient characteristics and healthcare resources in the national or local setting), and the learning process should be aligned with an international perspective to accommodate maximal information sharing and opportunities for practice development.

6.3 Thesis findings and novel contributions

6.3.1 Key findings: overview

Table 6.1 outlines novel contributions to the literature by the thesis.

Table 6.1 Novel contributions of the thesis

Chapter	Study design	Primary objectives	Contribution to research
2	Systematic literature review	To answer questions about the nature and form of international reporting and learning systems in non-healthcare safety-critical industries to inform a working proposal for the purpose and key requirements of an international safety incident reporting and learning system in healthcare.	Identified gaps in the literature and application of the principles of safety to an international context. Recognised building on the established and well-accepted framework of Benn et al. (2009) could provide an opportunity to focus on the complementary and value-added functions of an international reporting and learning system.
3	Semi-structured Key informant interviews	To address the identified gaps in the literature. Broad aim of focusing and developing an in-depth understanding from the perspective of experts, including patient representatives. Identification of the purpose and key requirements for an international patient safety learning system from the perspective of experts from safety-critical industries.	Identified unique insights into how trust, culture, and organisational approaches to data sharing may influence incident reporting and learning system implementation and perceived utility. This includes the adverse effects of mistrust and poor safety cultures on reporting and the strategies that organisations may use to support staff and wider cultures of safety.
4	Modified Online Delphi study	To gain consensus agreement from a broad panel of international healthcare experts, including patient representatives, regarding the key elements that would be required for a potential international patient safety learning system, with or without an incident reporting function.	Established international healthcare expert consensus on the purpose(s), key functions and features, and feasibility of a potential international PSLS. This included a novel list of potential patient safety incidents/risks that might be of international concern for sharing and learning, in addition to another novel list of the criteria that should be used when deciding what learning should be shared internationally.
5	Cross-sectional Quantitative survey	To assess the acceptability of a proposed international patient safety learning system (PSLS) with potential end-users working in the Governmental healthcare sector in the State of Kuwait.	Determined the concept of acceptability for the adoption of the purposes and functions of a potential international PSLS among Kuwaiti staff in frontline and safety directorate positions within the healthcare sector. The assessment of prospective acceptability was based on a conceptual framework that provided a robust insight into various dimensions of acceptability and could be a promising approach to assessing acceptability for future studies. The findings indicated that staff are broadly accepting of an international PSLS, in both frontline and directorate contexts.

The findings of this thesis can be considered within the context of expanding an appreciation of international learning in healthcare systems, based on observations from safety-critical industries and expert insight. Furthermore, appreciation of barriers and enablers to international learning specific to patient safety was a key outcome of the thesis. Overall, the findings of this thesis not only inform an understanding of how learning may be re-conceptualised in organisational safety contexts, but also how this may facilitate a system underlying international learning and the feasibility of such a system in practice.

6.3.2 Relationship between the proposed framework for an international PSLS and the framework of Benn et al. (2009)

Figure 6.3 outlines the potential relationship between the proposed framework for an international PSLS, an output of the PhD, and the framework of Benn et al. (2009), which was discussed in Chapters 1 and 2. The proposed international PSLS could be seen as a link between multiple national systems that would, ideally, follow the framework developed by Benn et al. (2009) for a national reporting and learning system, thus expanding the framework and adding an international layer to it. The following section (6.4) considers the implications of the findings for policy and practice.

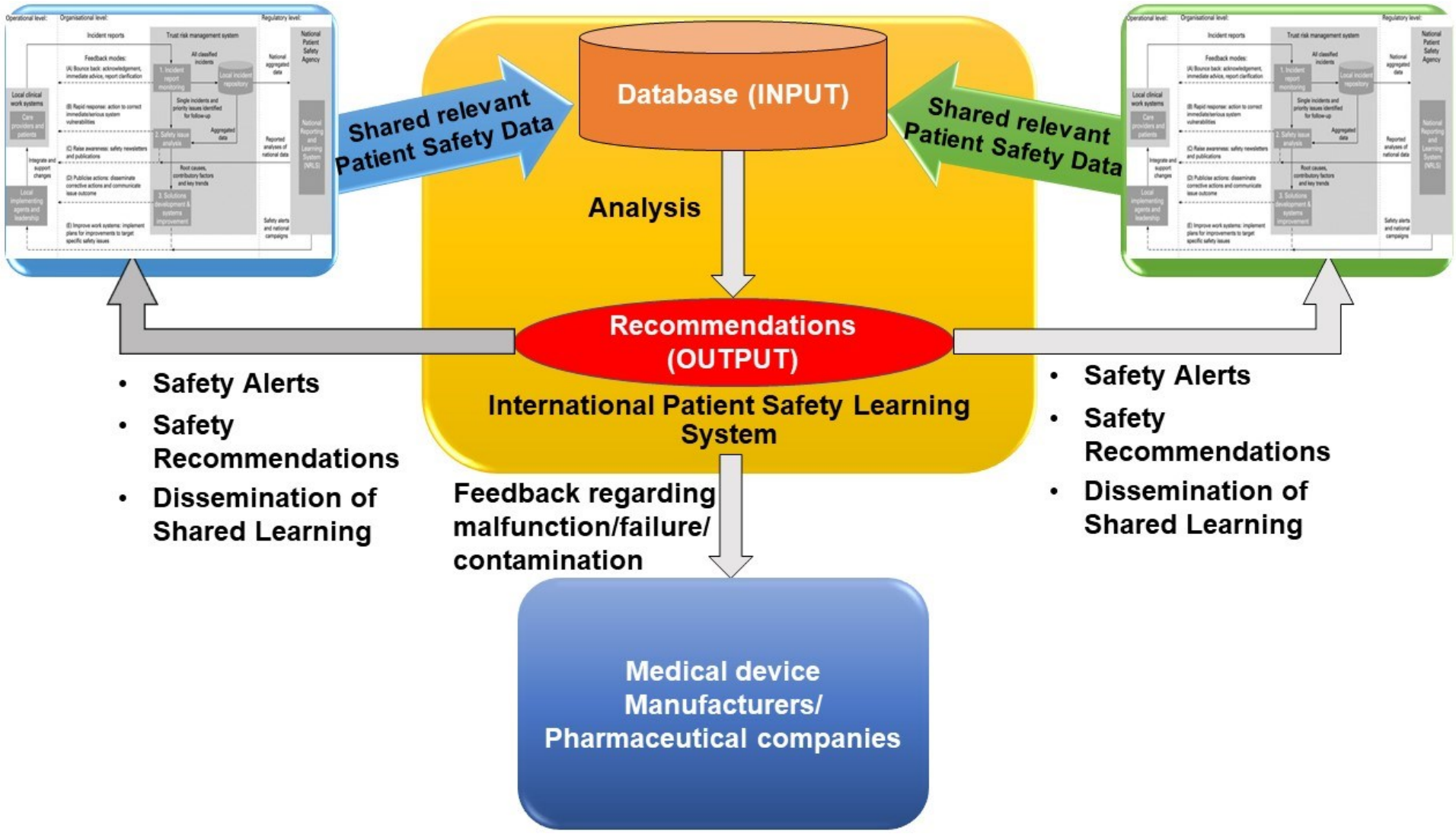

Figure 6.3 The proposed international PSLS in relation to the framework of Benn et al. (2009)

6.4 Implications for policy and practice

From policy and practice perspectives, key implications relate to the design and implementation of an international PSLS and how learning may be facilitated on an international level. This section considers the main implications of the findings of the thesis, focusing on: the key features and functions of an international PSLS, the generation and implementation of interventions to improve safety based on learning, and the barriers and enablers of an international PSLS.

6.4.1 Key features and functions of an international PSLS

Key features and functions of an international PSLS were also defined using the wider literature and expert insights, with close alignment between the two data sources. According to these insights, an international PSLS should have core features and functions that facilitate the achievement of two main purposes: incident evaluation, and learning based on safety information. The features and functions include a shared taxonomy and data collection/analysis process that can ensure consistent approaches to information sharing, leading to valid outputs in response to those data. Features should include a clear incident reporting process within the country, a clear analytical process to aid and enable the transferability of findings, targeted actions in response to systematic weaknesses, and sharing of knowledge with stakeholders, including feedback mechanisms. Functions of an international PSLS include the presence of these feedback mechanisms, organisational culture (both within and between organisations), legislative support methods to facilitate shared learning, a platform, the presence of analytical capabilities, and the key role of personnel at all levels. Hence, the findings suggest that a general approach to developing safety systems that is broadly consistent with the literature should be employed in practice.

Interestingly, the greatest level of support within the modified online Delphi study (Chapter 4) among healthcare experts was seen for features and functions of an international PSLS that facilitated learning based on shared databases, analysis of data from across nations, methodological development, and an understanding of factors underlying safety risk. This contrasts with a lower level of support seen for sharing exemplars of safety, triggering alarms, and formulation of specific recommendations from the system. Overall, one interpretation of these findings would be that the international PSLS is a key database for safety learning, rather than a system that should generate general safety recommendations, warnings, or alerts in its own right. This interpretation would be consistent with the system as a method of practice that facilitates drawing on international

lessons learnt and wisdom during the development of national-level responses to incidents and safety issues that have been identified, promoting learning on a national or local level.

6.4.2 Generating and implementing interventions for safety in healthcare settings

The implementation of interventions to improve outcomes should be based on delivering information to the stakeholders for whom learning will be of greatest value, including staff within national safety organisations, as well as pharmaceutical companies, medical devices companies, and other stakeholders linked to medical safety and patient safety. Importantly, it was noted in the modified online Delphi study (chapter 4) that outcomes of the PSLS should not only be directive in nature (i.e., a prescribed change in practice) but also encompass the development of methodologies and processes to investigate safety risks identified by an international PSLS, to facilitate learning through a variety of formats, and to facilitate identification of factors that can enable learning from patients, family members, and incidents related to safety.

There is a logic to the focus on national or local development of safety recommendations and changes in practice, reflecting the unique features of healthcare systems globally. Resource variations are notable across care settings, which may influence the feasibility of implementing uniform strategies to promote safety in response to incidents identified internationally (Sujan, 2018). Furthermore, prioritisation of safety changes and modifications to practice should be aligned with the needs of the local population (Reis et al., 2018). In context, safety reporting for issues related to medical processes or procedures may have less relevance in low-income nations where such procedures are not economically feasible or widely used. Similarly, if infectious disease management issues are flagged as a safety concern, they may only be relevant where such infectious diseases are endemic, which can vary significantly across the globe (Cresswell et al., 2013). Therefore, the PSLS may serve as a system through which information sharing is facilitated, and actions can be coordinated, allowing for local organisations and health settings to utilise data appropriately when determining outputs of relevance to local learning and practice.

One of the challenges facing the use of an international PSLS in this manner is the potential for existing variations in healthcare quality and safety across nations to be perpetuated or exacerbated (Cresswell et al., 2013). Indeed, where resources are limited and the technical aspect of the socio-technical learning environment is impaired, inequalities in healthcare outcomes may be anticipated relative to other nations (Reis et

al., 2018). Further consideration of barriers and enablers of an international PSLS are presented in the following section.

6.4.3 Barriers and enablers of an international PSLS

Barriers to the adoption of the international PSLS were explored in this thesis, using a review of the literature, views from safety-critical industry experts, and safety directorate and frontline staff in the Kuwaiti healthcare system. These included inefficiencies in reporting incidents, barriers to reporting, lack of a safety culture (obstructing incident reporting), and lack of support and legislative input to support such a system. Overall, it is evident that national barriers can impact on patient safety reporting, which may in turn influence international sharing of information and the use of that information. However, when looking beyond the national challenges, it is apparent that any system needs to operate within a culture of transparency and open reporting, which should be embedded in the principles and practice of international learning (Edwards, 2017). The issues of culture and transparency in safety reporting are specifically discussed in the following section. The final part of this thesis focused on evaluating an initial stage in the use of complex interventions in practice, whereby prospective acceptability of the proposed framework of an international PSLS was assessed by potential end-users. The Kuwaiti healthcare system was used as a pilot nation for the assessment of the prospective acceptability of an international PSLS. Based on the responses of frontline medical staff and safety directorate staff, it was notable that an international PSLS was considered acceptable. The Theoretical Framework of Acceptability (TFA; Sekhon et al., 2017) was used to determine prospective acceptability, and, for all seven defined domains, the acceptability was consistently high in the sample. Barriers to adoption of an international PSLS may, therefore, not be fully realised until an evaluation is conducted following the implementation of the system or a more detailed phase of planning for change. Furthermore, barriers seen in the Kuwaiti healthcare system may not reflect those seen in other nations, highlighting the limitations of this assessment.

It should be considered that the results of the modified online Delphi study (Chapter 4) emphasised that barriers may include difficulty in funding systems, challenges in aligning stakeholders with the wider goal of international learning, resource issues, cultural issues, privacy issues, and the ability to coordinate and regulate national systems within a coherent and functional international PSLS. These potential barriers represent complex factors that will take considerable action on a national level to address, particularly in relation to healthcare resources, funding, and cultures. Issues regarding the privacy of

information shared during learning on an international basis may be particularly important as healthcare systems become increasingly reliant on electronic information sharing, and patient data are more widely shared across settings (Sharma et al., 2018). Regulating information sharing in this manner may be approached by local and national bodies but may require considerable international oversight to standardise information sharing, confidentiality, and associated learning outputs (Sharma et al., 2018; Kemp et al., 2021).

Interestingly, another possible barrier that influences the acceptability of a system relates to how national reputations and healthcare system reputations may influence information sharing. Variations in the quality of healthcare systems are notable internationally. Payne et al. (2019) have noted that health information exchange practices within nations may be vulnerable to issues of reputation and trust, which may influence the way information is shared. Similarly, trust in the way others use data and the potential for safety outcomes to reflect poorly on an organisation may influence information sharing acceptability and practices, undermining the value of an open and transparent system (Ayatollahi & Zeraatkar, 2020). Overcoming issues of trust and reputation in health information sharing and safety learning will be crucial in coordinating international learning efforts, and strategies to approach this delicate and complex issue need to be considered in the future. However, the COVID-19 pandemic has shown that countries are able to share internationally relevant data for learning. For example, the WHO COVID-19 dashboard (WHO, 2022b) offers up-to-date data, which are essential for international learning, especially in the decision-making of healthcare policies and actions to be taken by individual countries.

Enablers of an international PSLS were noted as the presence of methods to share lessons learnt from incidents, common communication networks and platforms, and common data formats and classification systems. These findings are consistent with the literature on information sharing across organisations and the need for a shared taxonomy and method of standardising information (WHO, 2016; WHO, 2020). Importantly, expert insights on these enablers of an international PSLS aligned with subsequent assessment of a framework incorporating these elements (Chapter 4), indicating that the development of standardised approaches to safety reporting is a crucial feature for the development of this system.

6.5 Reflection on strengths and limitations

Although the implications for policy and practice must be directly linked to the findings presented in this thesis, it is important to note both strengths and limitations of the studies undertaken to guide further research in this field. One of the strengths of this thesis related to the novel approach towards addressing patient safety and associated learning in healthcare organisations by viewing these through the lens of safety-critical industries and international learning models. This also includes a wider discussion of multi-national corporations and other entities where safety practice may be more advanced than in healthcare organisations, with a focus on international learning that is elusive in healthcare systems globally.

Another strength is the systematic approach to developing a framework for an international PSLS, based on the framework of Benn et al. (2009). It has been noted that this framework has influenced safety learning at a local and national level, but it lacks a focus on how international learning may be facilitated. By utilising this framework, it was possible to logically evaluate key components and processes within a learning system, with a focus on applying those to an international context. Furthermore, this thesis considers limitations in existing models and frameworks for safety learning internationally (e.g., WHO, 2021) and adds to the knowledge base by emphasising contrasts between existing models and the findings of the thesis.

Finally, from a methodological perspective, this thesis benefits from the use of multiple research methods and triangulation of those methods to inform a nuanced process of framework development. Qualitative and quantitative methods were combined to validate the framework (Figure 6.2) and the data collected, which adds to the value of this framework in healthcare systems, where human factors underlie safety and can be interpreted qualitatively and quantitatively (Valdez et al., 2017).

Limitations to this thesis should also be considered when interpreting the findings and assessing their significance for future practice and policy. While the approach to draw on insights from safety-critical industries and literature from non-healthcare organisations was intended to add value, it is important to consider the main context of healthcare system operation and delivery of individual patient care. Expert insights from safety-critical industries add value and novel perspectives to healthcare industry safety, but further insights from healthcare staff are needed to ensure these findings are appropriately contextualised for a healthcare context. It should also be noted that the developed framework was partly consistent with the general literature on safety across industries but

may lack details where issues have not been explored in depth in the literature to-date. Empirical support for any framework should be pursued (based on the quality of the evidence underpinning that framework), and therefore, paucity of literature and empirical studies may limit the validity of the framework. This includes how data may be analysed and how multi-national reporting and learning processes actually operate. Any barriers to applying these processes to the healthcare environment also need to be addressed in greater detail, as there is a paucity of literature on this specific point.

The importance of an international perspective on learning was promoted in this thesis and was derived from the literature, as well as expert insights. However, many insights from experts and the wider literature were nationally focused, rather than international, and hence it should be considered that some challenges may exist to generalising ideas largely influenced by national-level experience to an international context. Acceptability of the framework was only assessed in one national population sample and the perspectives of staff in the safety directorate and health system of Kuwait may not be generalisable to other nations. The structure of the Kuwaiti health system and the culture of safety within the system may have particular characteristics that reflect the idiosyncrasies of this national system, which may limit generalisability to other nations and international learning. Finally, it is important to consider the implications of the findings of acceptability in Kuwait, as acceptability may reflect overall positive attitudes towards the concept of an international PSLS but may not reflect a willingness to implement the system or a commitment to international learning. The evaluation of acceptability in this context is limited by the conceptual nature of the change; as an international PSLS was not actually implemented in practice, acceptability applies only to the concepts of the international PSLS and underlying assumptions about how this may operate and influence practice (Corry et al., 2013).

6.6 Recommendations for further research

Further research should be considered in multiple areas to not only support the findings presented here, but to build on these findings and provide a basis for piloting an international PSLS. Specifically, this includes the need for research that promotes further analysis of learning as an international process and the need to assess the acceptability and feasibility of the framework in other nations.

6.6.1 Expansion of the acceptability assessment to include nations other than Kuwait

This expansion will not only allow for the comparison of acceptability across nations but may be helpful in identifying cultural factors linked to safety on an international basis. For instance, perspectives from safety professionals and staff in Kuwait may be informed by their personal experiences and deficits or challenges inherent to the Kuwaiti healthcare system. In order to reliably and robustly compare how these factors may influence the acceptability of an international PSLS, evaluation in other nations should be completed using the same methodological approach. In addition, studies may be used to analyse components that vary across nations to highlight how enablers and barriers may feature on an international level, adding to the literature and insights from experts, which largely have a national (compared with international) focus.

6.6.2 Need to assess other aspects of the implementation of complex interventions guided by the Medical Research Council (MRC) framework

Acceptability alone does not predict implementation success in practice and there is a need to conduct a feasibility assessment in the future to align with guidance on the introduction of complex interventions (Craig et al., 2008). Other aspects of the MRC framework, including ‘implementability’, cost effectiveness, scalability and transferability would need to be evaluated. Other nations may also be used as specific examples, to build on and contrast with the findings of the Kuwait-specific investigation in this thesis. A multi-country feasibility study would then be needed to ensure that an international PSLS can be applied to an international context successfully on a practical basis, permitting a comparison of national perspectives and potential enablers and barriers to implementation. Furthermore, implementation studies (e.g., feasibility study) would be needed to clarify the practical implementation of the framework and the potential impact on practice and learning (Peters et al., 2013; Skivington et al., 2021).

6.6.3 Developing the capacity to promote reliability in learning generation

Methodological development is an important future research need, with a specific focus on methods to promote the reliability of the international PSLS to generate opportunities for learning. There is a need for research evaluating the international use of features of national safety systems in healthcare, including the consistency of use of standards and models of safety reporting, such as the Minimal Information Model for Patient Safety (MIM PS; WHO, 2018a). Furthermore, learning from everyday care experiences is critical within

any model to allow for a wider appreciation of how safety impacts patients in routine care. Analysis of the use of an international PSLS and the development needs to ensure that learning can be facilitated in contributing nations will also be important. Ultimately, there is a need to ensure that countries engaging with an international PSLS have suitable infrastructures, experiences, skills, and resources to reliably promote learning at a local and national level.

It is also important to further evaluate how quality improvement, and individual/group level learning may be driven by the outputs of an international learning system. Quality improvement and patient safety education are considered vital in supporting the development of knowledge, skills, and attitudes towards patient safety in healthcare settings (Firth-Cozens, 2001; Jones et al., 2015). Applying theories of safety education to an international context requires consideration of how learning is facilitated at a different level than on an individual basis. Organisational learning at the macro- or meso-level needs to be considered to guide the development of systems that consider complexity in learning. Patient safety cannot be adequately achieved by the actions of the individual alone, as working with a system exposes patients to safety risks during multiple stages of their care journey and due to multiple factors influencing that system (Lawton et al., 2012). Therefore, while learning theories applied to facilitate safety approaches at an individual level undoubtedly have value in promoting a culture of safety (Kristensen et al., 2020), wider approaches to organisational safety learning are needed to provide a structure in which safety cultures can develop, and learning can be promoted (Glette & Wiig, 2021).

Within this context, there is also a need to ensure that safety learning is aligned with the needs of the local population and national context. Identifying international safety incidents that are of relevance and which are valuable to an international PSLS will be a specific future research challenge. Identifying these incidents, and developing suitable taxonomic methods for their classification, will allow for clarity in aligning data collection with the potential for outcomes of data analysis to be implemented successfully. There is also a need to evaluate how workforces may be optimised and capacity built within health systems to facilitate learning from safety data and to plan improvements in care.

6.7 Conclusions

This thesis sought to explore and address gaps in an increasingly important aspect of healthcare provision: learning from unsafe healthcare (patient safety) and communicating that learning to stakeholders responsible for acting on such learning. The review of the background literature and assessment of expert opinions identified that organisational learning and approaches to safety improvement were lacking in healthcare, notably with regards to collecting data consistently, ensuring data were in a standardised format, and then utilising data to generate relevant outcomes for practice and safety improvement as part of the learning process. A structured approach to investigating how safety-critical industry insights could be used to inform learning on an international level in healthcare was then adopted, highlighting specific novel features regarding the inputs and outputs of a learning system applied internationally.

Importantly, standardisation of data inputs was considered important in ensuring the potential for learning across nations, with a shared taxonomy deemed essential, as seen in other safety-critical industries. Barriers to establishing this consistent approach included the existence of heterogeneity in national-level safety reporting processes and inconsistencies and incompatibilities between those systems. Furthermore, there was an identified need for clear inputs and safety information to guide learning, which could then be used to generate specific outputs including: recommendations, safety alerts, and shared learning outputs. Analysis of safety data and the formulation of shared learning outputs require consideration of international learning strategies. Furthermore, it was recognised that the facilitation of data collection, analysis, and output generation may be challenging, based on resource availability, national support, and patient safety cultures on a national basis, as well as internationally.

The framework developed in this thesis provides an important first step in understanding how patient safety learning may be facilitated internationally, building on current work by the WHO and other bodies aiming to establish criteria for international safety reporting systems and associated learning. The initial assessment of this framework, based on a sample of staff from the Kuwaiti healthcare system, suggests that this is an acceptable framework through which an international PSLS may operate. One potential challenge is the burden placed on staff to engage with patient safety at this level, including the likely need for changes to reporting and learning practices that harmonise with other nations.

Despite the acceptability of the framework, further evaluation is needed to assess the feasibility and actual implementation challenges in the future. This includes expanding the

assessment of acceptability to other nations representing a broader range of resource contexts, appreciating the influence of local influences on patent safety learning, and ensuring alignment of any framework with WHO values and guidance on patient safety.

Drawing on literature from wider safety-critical industries and implementing key practice measures seen in those industries should be explored in terms of acceptability, feasibility, and the potential to benefit patient safety.

The unique nature of healthcare provision can be overlooked when applying international learning approaches from other industries. The person-centred approach to health underlies a complexity in care provision that may only be partially captured through organisational approaches to safety learning and risk mitigation. Organisational learning theories and practices should be developed to facilitate this international approach and to further develop the proposed framework.

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Appendices

Appendix 2.1: PRISMA checklist

Section and topic	Item No.	Checklist item	Achieved
Title	1	Identify the report as a systematic review	YES
Abstract	2	Abstract structure and content	N/A
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	YES
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses	YES
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	YES
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted	YES
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used	YES
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	YES
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	YES
Data items Study risk of bias assessment	10a 10b	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect. List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	YES YES
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	YES
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	YES
Synthesis methods	13a 13b 13c 13d	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)). Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions. Describe any methods used to tabulate or visually display results of individual studies and syntheses. Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used. Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	YES YES YES YES

	13e	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
	13f		N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases)	YES
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	YES
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded	NO
Study characteristics	17	Cite each included study and present its characteristics.	YES
Risk of bias	18	Present assessments of risk of bias for each included study.	YES
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots	N/A
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	YES
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	NO
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	NO
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	YES
	23b	Discuss any limitations of the evidence included in the review.	YES
	23c	Discuss any limitations of the review processes used.	YES
	23d	Discuss implications of the results for practice, policy, and future research	YES
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	YES
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	YES
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	YES

Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review	N/A
Competing interests	26	Declare any competing interests of review authors	N/A
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review	N/A

Appendix 2.2: Systematic Review Protocol

Title:

A systematic review and thematic synthesis to understand how the processes of knowledge generation, and the implementation and sharing of learning are utilised in international incident reporting and learning systems from healthcare and safety critical industries.

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Citation:
Not available yet (Qasem, J., Edwards, A., Wood, F., Carnegie, K., & Carson-Stevens, A. (2018). A systematic review and narrative synthesis to understand how the processes of knowledge generation, and the implementation and sharing of learning are utilised in international incident reporting and learning systems from healthcare and safety critical industries.)

Background
At the turn of the millennium, seminal reports by the US Institute of Medicine (now Academy of Medicine) and the UK Department of Health catapulted patient safety to the attention of healthcare leaders and policymakers internationally (Institute of Medicine, 1999; Department of Health, 2000). Under the endorsement of the World Health Assembly in 2002, the World Health Organization (WHO) launched a patient safety programme to learn about and action interventions to minimise the risks of preventable healthcare-associated harm to patients. The field of patient safety emerged as the coordinated effort to prevent harm, caused by the process of health care itself, from occurring to patients.

Incident reporting systems have been considered a keystone of patient safety improvement initiatives (Kohn, Corrigan, & Donaldson 1999; World Health Organization, 2005; Donaldson, 2000; Institute of Medicine, 2004). Organisations in numerous nations have founded local, state or national incident reporting systems as repositories of data about patient safety incidents (medical errors and system failures) to learn valuable lessons that will assist in preventing the recurrence of similar incidents (Pham et al., 2010). National systems demonstrated that safety incidents appearing in one institution occurred in very similar ways in other institutions. The classification of patient safety concepts and terms have seen numerous taxonomies proposed, but none have been broadly applied (Runciman, 2006; Cohen, & Hilligoss, 2010; Chang, Schyve, Croteau, O'Leary, & Loeb, 2005; McElroy, 2016; Donaldson, 2011). Reducing the dissemination of improvements made by distinctive fields, this lack of standardisation has hindered the capability to aggregate, synthesize and compare information across disciplines (McElroy, 2016). This absence of standardisation in patient safety has restricted the ability to organise, compare, and aggregate information across disciplines, consequently reducing the dissemination of learning improvements made by distinctive medical fields (McElroy, 2016). Recognising the need for international sharing and learning about ways to minimise patient safety risks to patients, the WHO commissioned a consensus on definitions for key concepts to understand patient safety incidents called the International Classification for

Patient Safety (ICPS) (Donaldson, 2009; Sherman et al., 2009; Thomson et al., 2009; Runciman et al., 2009), and a Minimal Information Model which defines the essential information which should be included in every patient safety incident report (WHO, 2014; Carson-Stevens et al., 2015a).

Incident reporting systems are used in many high-risk industries to learn from error and permit the organisation to make changes to reduce future risk to workers and customers. Systems in aviation and aerospace travel, railway, and nuclear power industries report remarkable success (Pham et al., 2013). Despite the intention to mirror this success in healthcare, there is little evidence that reporting systems can be used to improve patient safety through a process of organisational learning and improvement, in addition to offering a means to frontline staff to raise concerns (Pham, Girard, & Pronovost, 2013). There are examples of local and national-level learning loops (Learning Loop is a tool that helps in defining how work/action taken now informs future work/action) in health care; however, to our knowledge, no examples of international learning-feedback loops exist. Industries like Civil Aviation have achieved this (NASA, 2016), for example, the International Civil Aviation Organisation (ICAO) adopted Aircraft Accident and Incident Investigation, an international civil aviation safety learning system (ICAO, 2016).

At a fundamental level, there is a need to be clear about what is meant by learning and what is meant by knowledge, as the two are not the same (McFarlane, 2006; Spender, 1996). For example, in the context of a healthcare organisation, knowledge can be viewed as the evidence – if organised - or incident reporting data that is being collected by the organisation, while learning comes from actions taken by the organisation based on the data and evidence that might result in change in staff behaviour or the creations of new policies and procedures that would prevent certain incidents from happening again (learning behaviour). To better describe or characterise how a learning system works, it is crucial to understand how it is set up, how resources are utilised, the reporting mechanism used, and the processes of generating knowledge, and implementing and sharing learning.

The purpose of this review will be to systematically identify existing processes for identifying and disseminating learning, as well as monitoring the outcomes as a result of those processes.

Health care systems have started to tackle safety by seeking to learn from regional and national reporting systems; however, the evidence of impact in terms of improved patient safety is questionable, both regionally, nationally, and internationally. Part of the problem may be inconsistent methods or concepts (McElroy, 2016), and also resources devoted to responding to it. Healthcare is arguably behind other safety critical industries, some of these have demonstrated that they use the learning at regional, national, and international levels. So, the gap is, what can be learned from these industries that could help healthcare?

The review questions are:

- How are the constituents of a learning system defined? (Objective 1)
- What are the key factors that enable the transfer of learning from one organisation to another, including multi-organisational sharing? (Objective 2)
- What is the purpose of a learning system at a local, national, and international levels? (Objective 3)
- When setting up the learning system, what are the barriers and enablers that have been defined? (Objective 3)
- Can the incident reporting and learning system be transferred and applied to other industries and settings? (objective 4)
- What are the essential features of an incident reporting and learning system that is operated locally, nationally, and internationally? (objective 5)

OBJECTIVES

1. To inform a literature search and review of existing literature from healthcare and safety critical industries, and to map out the constituent elements of a learning system.
2. To identify key factors (set-up, resources, mechanism of reporting of incidents, process of generating knowledge, process of implementing learning, process of sharing learning) that enable learning from one organisation to be transferred to another, including multi-organisational sharing.
3. Explore the purpose, barriers and enablers to development, and implications of the transfer and implementation of learning in a reporting and learning system at a local, national, and international level, across organisations and multi-organisations.
4. To assess projected applicability/ transferability of the incident reporting and learning system to other industries / set-ups.
5. To make recommendations for international incident reporting and learning systems in healthcare.

METHODS

Criteria for considering studies for this review

The "SPIDER" search tool (**S**ample, **P**henomenon of **I**nterest, **D**esign, **E**valuation, and **R**esearch type) will be used as it is designed to specifically identify relevant qualitative and mixed-method studies (Cooke, Smith, & Booth, 2012; Methley, Campbell, Chew-Graham, McNally, & Cheraghi-Sohi, 2014), which are relevant for this review. Table 1 lists the "SPIDER" headings and search categories.

Table 1 search categories and SPIDER headings

SPIDER	
Sample	Incident reporting and learning systems in healthcare organisations and safety critical industries
Phenomenon of **I**nterest	How knowledge, generated from reporting and learning, is transferred and implemented in those systems across organisations in different industries
Design	Descriptive and Analytical designs
Evaluation	Outcome measures (satisfaction, experience, cost reduction, level of harm, system improvements).
Research type	Qualitative, Quantitative, and Mixed-Methods

Sample:

The sample of interest includes two elements:

- Healthcare organisations and safety critical industries (for example, Aeronautics, Civil aviation, Military aviation, Railway, Maritime operations, Offshore oil/exploration, Chemical process industry, Energy/Nuclear power) that operate on local, national, and international levels, which include cross-country and cross-continental operations.
- Incident reporting and learning systems within the above-mentioned settings. The understanding here is that a learning system is where there is reporting of incidents, which generate knowledge, analysis of these incidents, actions taken based on the analysis, and there is a feedback mechanism that involves service users and operators on multiple levels (local, national, and international).

Phenomenon of Interest:

The phenomenon of interest is how knowledge, generated from reporting and learning, is transferred and implemented in those systems across organisations in different industries, including how that knowledge is transferred and used, in addition to its barriers and enablers.

Design:

Study designs are to include both descriptive, such as survey (cross-sectional) and qualitative designs, and analytical, such as experimental (randomised parallel group or crossover) and observational (cohort study, cross sectional, case-control study) designs. The reason for such a broad selection of study designs is to capture as much evidence available as possible because there is no known international healthcare reporting and learning system.

Evaluation:

The outcomes of the learning system are essential in strengthening the rationale about patient safety, patient experience, and costs based on what is already known in the literature (Stavropoulou, Doherty, & Tosey, 2015). Additionally, there is interest from healthcare quality and safety experts in knowing what evaluations of that learning system have been done, what improvements have been made based on the learning process.

Research type:

Given the nature of the review questions, which aim at gaining insights about processes to improve outcomes, the range of research type will be expanded to be more comprehensive, and include qualitative, quantitative, and mixed-methods research types. This will ensure that the review will cover the full range of perspectives that these different research types offer, along with their challenges, when it comes to data analysis.

Search methods for identification of studies

Electronic searches

We will search the following sources from 1999 to the present:

- EMBASE, MEDLINE, ASSIA, PsycINFO, SCOPUS, Global Health, Web of Science, HMIC (Health Management Information Consortium), ICONDA (International Construction Database), OpenGrey, and Grey literature of websites belonging to accident investigation organisations for each safety critical industry (e.g. healthcare, aviation, nuclear power, rail, chemical industries, ministry of defence, NASA).

For detailed search strategies see Appendix 1, which has been developed and discussed with subject librarians to get accurate and relevant search results. If additional relevant key words are detected during any of the electronic or other searches, the electronic search strategies will be modified to incorporate these terms and changes will be documented.

Searching other resources

Other potentially eligible articles or supplementary publications will be identified by searching the reference lists of retrieved included articles, (systematic) reviews, and meta-analyses, as well as hand searching key journals (e.g. BMJ Quality & Safety, Safety Science). In addition, industry experts will be consulted to identify any relevant articles.

Data collection and analysis

Selection of studies

Records will be imported into EndNote, and duplicates will be removed. There are two phases to the selection process:

Phase one: Two review authors (JQ, KC) will independently scan the title, abstract, or both, of every record retrieved, to determine which studies should be assessed further based on the inclusion and exclusion criteria presented in Table 2.

Phase two: All potentially-relevant articles will be investigated as full text and assessed further based on the inclusion and exclusion criteria presented in Table 2.

Any discrepancies will be resolved through consensus or recourse to a third review author (ACS). Authors of studies will be contacted in cases where more clarification is required to resolve disagreement. An adapted PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of study selection is presented in Figure 1.

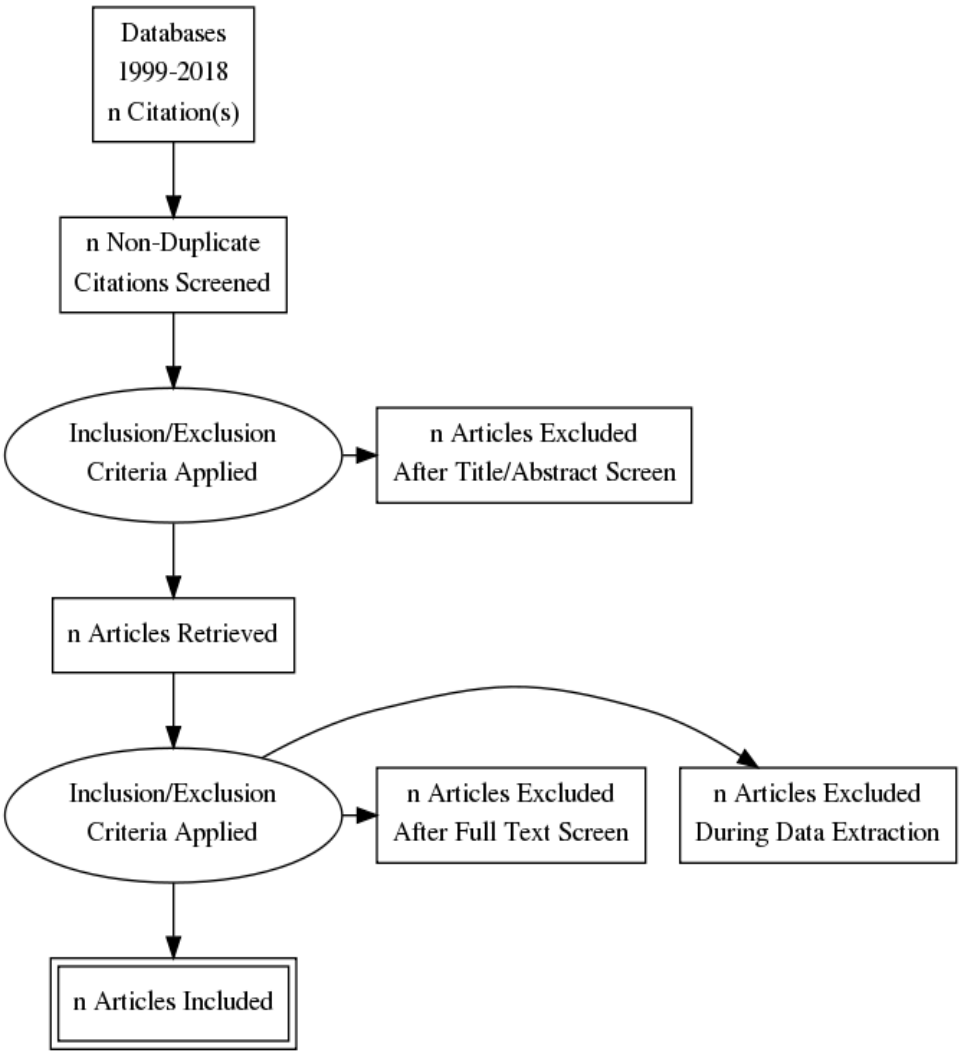

Figure 1. Study flow diagram

Inclusion and exclusion criteria

Inclusion and exclusion criteria have been developed on the basis of a systematic review and are presented in Table 2. The criteria for inclusion are intentionally specific to target studies/articles that would answer the review questions and help in achieving the review objectives. In addition, time period will be set to include publications between 1999 and present time (2018). The reason behind this time period is because of the release of the seminal reports that catapulted

patient safety to the attention of healthcare leaders and policymakers internationally Institute of Medicine, 1999; Department of Health, 2000). Furthermore, language will be restricted to studies in English, mainly because of the proficiency of the authors. As mentioned in the selection of studies section, inclusion and exclusion will be determined in a two-phase process of title and abstract screening, and full text review.

TABLE 2 Inclusion and exclusion criteria

Criterion	Inclusion	Exclusion
Sample	Healthcare organisations and Safety-critical/ High-risk industries (Aeronautics, Civil aviation, Military aviation, Railway, Maritime operations, Offshore oil/exploration, Chemical process industry, Energy/Nuclear power), single or multi-organisation operating at local, regional, national, and international levels. Learning system(s) such as: Incident reporting system(s) Safety learning system(s) Accident and incident investigation system(s) Reporting system(s)	Any other organisations or industries (non-healthcare, non-high-risk/safety-critical e.g. road traffic, diving, trucking, roofing, forestry, construction, etc.). Analysis of incident reports rather than an explicit focus on the reporting system.
Phenomenon of Interest	How reporting and learning is achieved in those systems, including how learning is used, and transferred, in addition to barriers and enablers of learning.	No mention of how reporting and learning is transferred or achieved.
Design	Descriptive and Analytical designs such as: Empirical studies Theoretical studies Reports Policy documents Descriptive papers	Opinion papers Editorials Reviews Conference abstracts Protocols Book chapters
Evaluation	Outcome measures relevant to review questions (e.g. components of learning system, barriers and enablers, satisfaction, experience, cost reduction, level of harm, system improvements, etc.).	No outcome measures.
Research type	Qualitative, Quantitative, and Mixed-Methods	None
Time period	November 1999 - 2018	Any study outside these dates
Language	English	Non-English
Other	Full-text available	Full-text unavailable

Data extraction

For studies that fulfil inclusion criteria, data relating to study design, findings and quality will be extracted by one reviewer (JQ) and independently checked for accuracy by a second reviewer (KC). Study details will be extracted using a standardised data extraction form (see appendix 2), with any disagreements to be resolved by discussion, or if required by a third author. Attempts will be made to contact authors for missing data, if required. Data from studies presented in multiple publications will be extracted to a data extraction form in MS Word document and reported as a single study with all relevant other publications listed.

Data evaluation

Evaluation of quantitative and qualitative studies will be done by using the appropriate Critical Appraisal Skills Programme (CASP) checklist (CASP, 2018), while mixed-methods studies will be evaluated using the Mixed Methods Appraisal Tool (MMAT; Pluye, Robert, Cargo, & Bartlett, 2011). Two authors will undertake quality appraisal of included literature and the third author will be involved in cases of discrepancy.

Data synthesis

The results of the data extraction and quality assessment for each study will be presented in structured tables and as a narrative summary. Identified learning systems will be grouped and presented according to the following criteria:

- Industry/sector
- Location (local, regional, national, international)
- Outcomes
- Transferability

Narrative synthesis will be done and carried out using a framework which consists of four elements;

1. Developing a theory of how the learning works, how is learning shared within the system, who is responsible for it, and who regulates it.
2. Developing a preliminary synthesis of findings of included studies (study grouping, thematic analysis).
3. Exploring relationships in the data within and between studies (subgroup analysis, concept mapping, exploring the effects of heterogeneity).
4. Assessing the robustness of the synthesis (formal quality assessment, GRADE process).

Results of the data synthesis will be utilised to come up for recommendations for local/ national/ international incident reporting and learning systems in healthcare, and these recommendations will be fed into a future process in the shape of a Delphi consensus survey.

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APPENDICES

Appendix 1. Search strategies

Search terms using SPIDER tool

SPIDER tool[1]	Search terms
S	("local" OR "regional" OR "national" OR "international" OR "single" OR "multi*" OR "cross-country" OR ") AND ("Healthcare" OR "Health Care" OR "High-Risk" OR "High Risk" OR "Safety Critical" OR "Safety-critical" OR "Aeronautics" OR "Civil aviation" OR "Railway" OR "Military aviation" OR "Maritime" OR "Offshore oil" OR "Offshore exploration" OR "Chemical process" OR "Nuclear power") AND ("organisation*" OR "organization*" OR "industr*" OR "operations"
P of I	("learning" OR "organisational learning" OR "organizational learning" OR "organisational knowledge" OR "organizational knowledge" OR "organisational memory" OR "organizational memory" OR "knowledge mobilisation" OR "knowledge mobilization" OR "knowledge transfer" OR "incident" OR "accident" OR "investigation" OR "reporting") AND ("system*" OR "system learning")
D	"case reports" OR "cohort studies" OR "randomised controlled trials" OR "randomized controlled trials" OR "systematic review*" OR "meta-analysis" OR "interview" OR "focus group*" OR "thematic analysis"
E	"patient satisfaction" OR "patient experience*" OR "staff satisfaction" OR "employee satisfaction" OR "staff experience" OR "employee experience" OR "cost reduction" OR "improved outcome*" OR "improved outcome measure*" OR "reduced harm" OR "harm reduction" OR "patient safety improvement" OR "improvement in patient safety" OR "patient outcome*" OR "system improvement*" OR "improvement* in the system"
R	"qualitative" OR "qualitative research" OR "qualitative stud*" OR "qualitative analysis" OR "qualitative method*" OR "quantitative" OR "quantitative research" OR "quantitative stud*" OR "quantitative analysis" OR "mixed-method*" OR "mixed-method* research" OR "mixed-method* stud*"

[1][S AND P of I] AND [(D OR R) AND E]

Appendix 2. Standard data extraction form

Standard data extraction form (Noyes, & Lewin, 2011)
Country
Aims of study
Ethics – how ethical issues were addressed
Study setting
Theoretical background of study
Sampling approach
Participant characteristics
Data collection methods
Data analysis approach
Key themes identified in the study (1st order interpretations)
Data extracts related to the key themes
Author explanations of the key themes (2nd order interpretations)
Recommendations made by authors
Assessment of study quality

Appendix 2.3: List of websites searched for grey literature

Table 1 List of organisations/systems based on industry

Industry	Organisations/systems
Aviation	Aviation safety reporting system (ASRS): https://asrs.arc.nasa.gov/
	Confidential human factor incident reporting programme
	British airways safety information system
	Military incident reporting system
	ICAO: www.icao.int
	Annex 13 — *Aircraft Accident and Incident Investigation*
	EU Aviation Safety Reporting: http://www.aviationreporting.eu/AviationReporting/
	Civil Aviation Authority (UK): https://www.caa.co.uk/Our-work/Make-a-report-or-complaint/MOR/Mandatory-occurrence-reporting/
	The UK Confidential Reporting Programme for Aviation and Maritime (CHIRP): https://www.chirp.co.uk/
	EASA, European Aviation Safety Agency: https://www.easa.europa.eu/easa-and-you/safety-management/occurrence-reporting
Nuclear Power	IAEA
	EU Nuclear Safety: https://ec.europa.eu/energy/en/topics/nuclear-energy/nuclear-safety
	Nuclear Power Plants – International Reporting System for Operating Experience (IRS): https://nucleus.iaea.org/Pages/irs1.aspx
	Fuel Cycle Facilities – Fuel Incident Notification and Analysis System (FINAS)
	Research Reactors – Incident Reporting System for Research Reactors (IRSRR)
	IAEA/NEA
Transport/rail	Confidential Reporting System for Transport (CIRAS): http://www.ciras.org.uk/about-us/
	Rail Safety and Standards Board (RSSB): https://www.rssb.co.uk/risk-analysis-and-safety-reporting/reporting-systems
	Safety Management Intelligence System (SMIS)
	National Incident Reporting (NIR on-line)
	Close Calll System
	Computerized Accident Incident Reporting System (CAIRS): https://www.energy.gov/ehss/policy-guidance-reports/databases/computerized-accident-incident-reporting-system
Military Aviation	Military Aviation Authority: https://www.gov.uk/government/organisations/military-aviation-authority
	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/577618/MAS_Issue_5.pdf
	http://www.isss-tvc.org/121017_Trumble_SMS_Paper.pdf
	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/578278/MAA01_Issue_6.pdf
	http://www.defence.gov.au/DASP/Docs/Media/Focus/FocusonDASR.pdf
	https://pdfs.semanticscholar.org/9a82/fdbc39cd7a6e9c9f5525b0e2e5f38c7501a5.pdf

Table 2 List of grey literature websites of safety-critical industries

Main website	URL
https://asrs.arc.nasa.gov/	https://asrs.arc.nasa.gov/docs/ASRS_ProgramBriefing.pdf
	https://asrs.arc.nasa.gov/overview/summary.html
	https://asrs.arc.nasa.gov/docs/JO7200.20.pdf
	https://asrs.arc.nasa.gov/docs/AC%2000-46E.pdf
	https://asrs.arc.nasa.gov/overview/outputs.html
	https://asrs.arc.nasa.gov/docs/cb/cb_439.pdf
	https://asrs.arc.nasa.gov/docs/cb/cb_435.pdf
	https://asrs.arc.nasa.gov/docs/cb/cb_414.pdf
	https://asrs.arc.nasa.gov/docs/rs/62_Cross_Industry_Applications_of_Reporting_Model.pdf
	https://asrs.arc.nasa.gov/docs/rs/60_Case_for_Confidential_Incident_Reporting.pdf
	https://asrs.arc.nasa.gov/international/overview.html
https://sma.nasa.gov/sma-disciplines/nsrs	https://nodis3.gsfc.nasa.gov/HQDQMS_Docs/QMS/HQ_OWI_8710_GD000_017_D_.pdf
	https://nodis3.gsfc.nasa.gov/displayDir.cfm?t=NPR&c=8715&s=1A
	https://nodis3.gsfc.nasa.gov/npg_img/N_PR_8715_003D_/N_PR_8715_003D_.pdf
	https://nodis3.gsfc.nasa.gov/npg_img/N_PR_8715_001A_/N_PR_8715_001A_.pdf
	https://ntrs.nasa.gov/archive/nasa/casi.ntrs.nasa.gov/20160013187.pdf
	https://ntrs.nasa.gov/archive/nasa/casi.ntrs.nasa.gov/20140016374.pdf
	https://www.nasa.gov/topics/nasalife/features/fra_asrs.html
https://www.chirp.co.uk/	No pdf files
	https://www.skybrary.aero/bookshelf/books/3514.pdf
	https://www.skybrary.aero/index.php/Confidential_Human_Factors_Incident_Reporting_Programme_(CHIRP)
	https://www.chirpmaritime.org/wp-content/uploads/2016/09/MFB-29.pdf
	https://publicapps.caa.co.uk/modalapplication.aspx?catid=1&pagetype=65&appid=11&mode=detail&id=7271
	https://publicapps.caa.co.uk/docs/33/InformationNotice2016030.pdf
	http://www.legislation.gov.uk/uksi/2018/321/pdfs/uksi_20180321_en.pdf
http://asj.nolan-law.com/	Aviation Safety Journal, nothing about reporting system, Archives last update is July 2011
	http://publicapps.caa.co.uk/modalapplication.aspx?catid=1&pagetype=65&appid=11&mode=list&type=subcat&id=23
	Searched for relevant documents
	http://publicapps.caa.co.uk/modalapplication.aspx?catid=1&pagetype=65&appid=11&mode=detail&id=7576
	http://publicapps.caa.co.uk/docs/33/CAP%201457%20OCT16.pdf
	http://publicapps.caa.co.uk/modalapplication.aspx?catid=1&pagetype=65&appid=11&mode=detail&id=733
	http://publicapps.caa.co.uk/modalapplication.aspx?catid=1&pagetype=65&appid=11&mode=list&type=subcat&id=22
	http://publicapps.caa.co.uk/modalapplication.aspx?catid=1&pagetype=65&appid=11&mode=detail&id=6616
	http://publicapps.caa.co.uk/docs/33/CAP795_SMS_guidance_to_organisations.pdf
	http://publicapps.caa.co.uk/modalapplication.aspx?catid=1&pagetype=65&appid=11&mode=detail&id=214

	http://www.caa.co.uk/Our-work/Make-a-report-or-complaint/MOR/Mandatory-occurrence-reporting/
	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1018&from=EN
	https://ec.europa.eu/transport/modes/air/safety_en
	https://eur-lex.europa.eu/resource.html?uri=cellar:f0a0e4cd-9ce8-11e5-8781-01aa75ed71a1.0020.02/DOC_1&format=PDF
	https://eur-lex.europa.eu/resource.html?uri=cellar:f0a0e4cd-9ce8-11e5-8781-01aa75ed71a1.0020.02/DOC_2&format=PDF
	https://ec.europa.eu/transport/modes/air/encasia_en
	https://ec.europa.eu/transport/modes/air/safety/safety_management_en
	https://www.easa.europa.eu/easa-and-you/safety-management/accident-and-incident-investigation-support/legal-and-regulatory-framework
	https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:295:0035:0050:EN:PDF
	https://www.easa.europa.eu/easa-and-you/safety-management/safety-management-system-sms
	https://www.easa.europa.eu/easa-and-you/safety-management/safety-management-system/sms-international
	https://ec.europa.eu/transport/sites/transport/files/modes/air/safety/doc/guidancematerial376.pdf
https://www.icao.int/Pages/default.aspx	
	https://www.easa.europa.eu/sites/default/files/dfu/ICAO-annex-19.pdf
	https://www.skybrary.aero/index.php/Safety_Management_International_Collaboration_Group_(SM_ICG)
	https://www.skybrary.aero/bookshelf/books/644.pdf
	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0670&from=EN
	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011SC1261&from=EN
	https://www.gov.uk/government/publications?departments%5B%5D=air-accidents-investigation-branch&page=5 website search for documents, few identified
	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/524516/Guidance_Overseas_Territories.pdf
	https://www.gov.uk/government/publications/definition-of-aircraft-accident-and-serious-incident/definition-of-aircraft-accident-and-serious-incident
	https://ec.europa.eu/transport/modes/air/international_aviation/european_community_icao_en
	http://publicapps.caa.co.uk/modalapplication.aspx?appid=11&mode=detail&id=7672
	http://publicapps.caa.co.uk/docs/33/CAP%201496%20APR18.pdf
	http://publicapps.caa.co.uk/docs/33/InformationNotice2016030.pdf
	http://publicapps.caa.co.uk/docs/33/CAP795_SMS_guidance_to_organisations.pdf
	http://publicapps.caa.co.uk/docs/33/CAP%201059%20SMS%20for%20small%20organisations%20(p).pdf
https://aviation-safety.net/index.php	
	https://aviation-safety.net/investigation/aaibs.php
http://www.tsb.gc.ca/eng/securitas/	
	http://tsb.gc.ca/eng/securitas/index.asp
	http://www.tsb.gc.ca/eng/securitas/securitas-20130313.pdf
http://www.atsb.gov.au/voluntary/repcon-aviation.aspx	

	http://www.atsb.gov.au/voluntary/asrs/asrs_more.aspx
	https://www.atsb.gov.au/media/47745/asrs_memo.pdf
	https://www.atsb.gov.au/media/36699/casa_regs.pdf
	https://www.atsb.gov.au/media/36888/state_casa_regs.pdf
	https://www.atsb.gov.au/media/36522/act_2004.pdf
	https://www.atsb.gov.au/media/47739/asrs_form.pdf
	Brazillian and Japanese aviation sites no English
	https://www.asc.gov.tw/sub_en/docDetail.aspx?uid=401&pid=396&docid=32 no pdf files
	http://ojs.library.okstate.edu/osu/index.php/IJPATTR/article/download/460/1529
	https://commons.erau.edu/cgi/viewcontent.cgi?article=1037&context=db-theses
http://www.airsafety.or.kr/	Korean aviation voluntary incident reporting system
	https://air.ts2020.kr/airsafety/download/KairsReportingForm(Eng)R.pdf reporting form for foreigners
	http://www.airsafety.or.kr/
https://www.mot.gov.sg/about-mot/transport-safety-investigation-bureau/aaib/the-sincair-programme	Singapore
http://www.srs.org.es/en/	http://www.srs.org.es/en/que-es-el-srs/ no pdf
http://www.caa.co.za/Pages/Information%20for%20the%20Public/CAHRS.aspx	
	https://www.skybrary.aero/bookshelf/books/237.pdf
	https://flightsafety.org/files/automated_systems.pdf
	British airway system, no data available
	https://pdfs.semanticscholar.org/9a82/fdbc39cd7a6e9c9f5525b0e2e5f38c7501a5.pdf

Table 3 List of healthcare industry's grey literature websites

Healthcare websites
http://www.bcpft.nhs.uk/documents/policies/i/860-incident-reporting/file
https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2015/01/how-to-guide-ss-at-incident-reporting.pdf
https://www.lincolnshirecommunityhealthservices.nhs.uk/application/files/9215/1783/7466/P_RM_01_Incident_Reporting_Policy.pdf
https://manchesterccg.nhs.uk/wp-content/uploads/CCG-Incidents-Policy.pdf
http://www.homerton.nhs.uk/media/848132/Incident-and-Serious-Incident-2.pdf
https://improvement.nhs.uk/news-alerts/development-patient-safety-incident-management-system-dpsims/
https://improvement.nhs.uk/documents/2194/20171221_Development_of_the_Patient_Safety_Incident_Management_System_-_Alpha__WL9a8gA.pdf
https://improvement.nhs.uk/documents/843/OPSIR_guidance_notes_March_2017.pdf
http://www.who.int.abc.cardiff.ac.uk/patientsafety/topics/reporting-learning/en/
http://www.who.int.abc.cardiff.ac.uk/patientsafety/topics/reporting-learning/mim/user-guide/en/
http://apps.who.int/iris/bitstream/handle/10665/255642/WHO-HIS-SDS-2016.22-eng.pdf;jsessionid=28A89DA32A343311A34FB119878499B7?sequence=1
http://www.who.int.abc.cardiff.ac.uk/patientsafety/implementation/IMPS_working-paper.pdf
http://www.who.int.abc.cardiff.ac.uk/patientsafety/implementation/WHO-EU_rls.pdf
http://apps.who.int/iris/bitstream/handle/10665/255146/WHO-HIS-SDS-2016.21-eng.pdf?sequence=1
http://apps.who.int/iris/bitstream/handle/10665/70882/WHO_IER_PSP_2010.2_eng.pdf?sequence=1
http://www.who.int.abc.cardiff.ac.uk/patientsafety/topics/reporting-learning/conceptual_framework/en/
http://apps.who.int/iris/bitstream/handle/10665/255146/WHO-HIS-SDS-2016.21-eng.pdf?sequence=1
http://www.who.int.abc.cardiff.ac.uk/patientsafety/topics/reporting-learning/mim/euconsultation/en/
http://www.who.int.abc.cardiff.ac.uk/patientsafety/implementation/taxonomy/mimps-report.pdf
http://www.who.int.abc.cardiff.ac.uk/patientsafety/implementation/IMPS_summary-report.pdf

Appendix 2.4: Search strategies

All search strategies are limited to references from 1999 to present, and in English only.

Table 1 search strategy for MEDLINE, EMBASE, PsycInfo, Global Health, and HMIC

ID	Search string	n Results				
	Keyword Facet A: Healthcare and Safety Critical Industries	**MEDLINE**	**EMBASE**	**PsycInfo**	**Global Health**	**HMIC**
1	Healthcare.mp OR Health Care.mp OR High Risk industries.mp OR Safety Critical industr*.mp OR Safety/ OR Safety Management/ OR Aviation/ OR "Extraction and Processing Industry"/ OR industry/ OR Army/ OR military.mp OR Aeronautics.mp OR Railway.mp OR Railroads/ OR Maritime.mp OR Offshore oil.mp OR Offshore exploration.mp OR Transportation/ OR Chemical process industr*.mp OR nuclear power plants/ OR nuclear reactors/ OR nuclear industry.mp OR power plants/	680739	1453433	200323	150085	34334
	Keyword Facet B: Reporting systems					
2	incident report*.mp OR risk Management/ OR reporting system*.mp OR Accident report*.mp OR Accidents/ OR Accidents, Aviation/ OR Accident investigation*.mp OR incident investigation*.mp	26246	54923	7499	6047	2556
	Keyword Facet C: Learning					
3	Learning/ OR learn*.mp	292765	395938	317155	22566	10174
	Keyword Facet D: Knowledge mobilisation					
4	knowledge management/ OR organi*ational knowledge.mp OR translational medical research/ OR knowledge mobile*ation.mp OR knowledge transfer.mp OR information dissemination/ OR diffusion of innovation/ OR Knowledge/	40401	65905	8084	16849	1106
5	A and B and C	611	1277	153	111	136
6	A and B and D	117	301	10	43	3
	Total	728	1578	163	154	139

OVID EMBASE 1947-Present
OVID HMIC
OVID MEDLINE®ALL 1946 to July 13, 2018
OVID PsycINFO 1806 to July Week 2 2018
OVID Global Health 1973 to 2018 Week 27

Table 2 search strategy for ICONDA

ID	Search string	n Results
	Keyword Facet A: Healthcare and Safety Critical Industries	**ICONDA**
1	Healthcare.mp OR Health Care.mp OR High Risk industries.mp OR Safety Critical industr*.mp OR Safety.mp OR Safety Management.mp OR Aviation.mp OR Extraction industry* OR Processing industry* OR industry.mp OR Military.mp OR Army.mp OR Aeronautics.mp OR Railway.mp OR Railroads.mp OR Maritime.mp OR Offshore oil.mp OR Offshore exploration.mp OR Transportation.mp OR Chemical process industr*.mp OR nuclear power plants.mp OR nuclear reactors.mp OR nuclear industry.mp OR power plants.mp	36165
	Keyword Facet B: Reporting systems	
2	incident report*.mp OR risk Management.mp OR Accident report*.mp OR Accidents.mp OR Accident investigation*.mp OR incident investigation*.mp	1737
	Keyword Facet C: Learning	
3	learn*.mp	6968
	Keyword Facet D: Knowledge mobilisation	
4	knowledge management.mp OR organi*ational knowledge.mp OR knowledge mobile*ation.mp OR knowledge transfer.mp OR Knowledge.mp	4495
5	A and B and C	37
6	A and B and D	89
	Total	126

OVID ICONDA 1976 to June 2018

Table 3 search strategy for Web of Science

ID	Search string	n Results
	Keyword Facet A: Healthcare and Safety Critical Industries	**Web of Science**
1	TI=(Healthcare OR “Health Care” OR “High Risk industries” OR “Safety Critical industr*” OR Safety OR “Safety Management” OR Aviation OR “extraction industr*” OR “processing industry*” OR industry OR “Ministry of defence” OR Army OR Military OR Aeronautics OR Railway OR Railroads OR Maritime OR “Offshore oil” OR “Offshore exploration” OR Transportation OR “Chemical process industry*” OR “nuclear power plants” OR “nuclear reactors” OR “nuclear industry” OR “power plants”)	390178
	Keyword Facet B: Reporting systems	
2	TS=(“incident repor*” OR “risk Management” OR “reporting system*” OR “Accident report*” OR Accidents OR “Accidents, Aviation” OR “Accident investigation*” OR “incident investigation*”)	124163
	Keyword Facet C: Learning	
3	TI=(Learn*)	270813
	Keyword Facet D: Knowledge mobilisation	
4	TI=(“knowledge management” OR “organi*ational knowledge” OR “knowledge mobile*ation” OR “knowledge transfer” OR Knowledge)	178668
5	A and B and C	214
6	A and B and D	128
	Total	342

Web of Science Core Collection: Citation Indexes

- Science Citation Index Expanded (SCI-EXPANDED) --1900-present
- Social Sciences Citation Index (SSCI) --1956-present
- Arts & Humanities Citation Index (A&HCI) --1975-present
- Conference Proceedings Citation Index- Science (CPCI-S) --1990-present
- Conference Proceedings Citation Index- Social Science & Humanities (CPCI-SSH) --1990-present

- Emerging Sources Citation Index (ESCI) --2015-present
  Data last updated: 2018-07-13

Table 4 search strategy SCOPUS

ID	Search string	n Results
	Keyword Facet A: Healthcare and Safety Critical Industries	**SCOPUS**
1	Healthcare OR Health Care OR High Risk industries OR Safety Critical industr* OR Safety OR Safety Management OR Aviation OR Extraction and Processing Industry OR industry OR Ministry of defence OR Army OR Military OR Aeronautics OR Railway OR Railroads OR Maritime OR Offshore oil OR Offshore exploration OR Transportation OR Chemical process industr* OR nuclear power plants OR nuclear reactors OR nuclear industry OR power plants	447
	Keyword Facet B: Reporting systems	
2	incident report* OR risk Management OR Accident report* OR Accidents OR Accident investigation* OR incident investigation*	38816
	Keyword Facet C: Learning	
3	Learn*	3493150
	Keyword Facet D: Knowledge mobilisation	
4	knowledge management OR organi*ational knowledge OR knowledge mobile*ation OR knowledge transfer OR Knowledge	1349517
5	A and B and C	83
6	A and B and D	80
	Total	163

ID	Search string	n Results	
	Keyword Facet A: Healthcare and Safety Critical Industries	**ASSIA**	**IBSS**
1	Healthcare.mp OR Health Care.mp OR High Risk industries.mp OR Safety Critical industr*.mp OR subject("Safety") OR subject("Safety Management") OR subject("Aviation") OR subject("industry") OR Aeronautics.mp OR Railway.mp OR subject("Railroads") OR Maritime.mp OR Offshore oil.mp OR Offshore exploration.mp OR subject("Transportation") OR Chemical process industr*.mp OR subject("nuclear power plants") OR subject("nuclear reactors") OR nuclear industry.mp OR subject("power plants")	30023	126402
	Keyword Facet B: Reporting systems		
2	incident report*.mp OR subject("risk Management") OR reporting system*.mp OR Accident report*.mp OR subject("Accidents") OR subject("Accidents, Aviation") OR Accident investigation*.mp OR incident investigation*.mp	3624	17156
	Keyword Facet C: Learning		
3	Subject("Learning") OR learn*.mp	30543	26428
	Keyword Facet D: Knowledge mobilisation		
4	subject("knowledge management") OR organi*ational knowledge.mp OR subject("translational medical research") OR knowledge mobile*ation.mp OR knowledge transfer.mp OR subject("information dissemination") OR subject("diffusion of innovation") OR subject("Knowledge")	11934	38799
5	A and B and C	22	24
6	A and B and D	24	34
	Total	46	58

ASSIA 1987 – current
IBSS 1951 – current

Appendix 2.5: Modified data extraction form

General description (fill in or select from options, as appropriate)	
Reviewer's initials (JQ/KC)	
Date of data extraction (dd/mm/yyyy)	
Title	
Citation	
First author	
Year	
Principal domain/sector	- Healthcare - Civil Aviation - Military Aviation - Mining and mineral/ore processing - Maritime operations - Offshore oil/exploration - Chemical process industry - Energy/Nuclear power - Manufacturing/Production - Construction/engineering - Multiple/Generic/Cross industry perspective - Other non-healthcare (specify)
Healthcare sub-division/specialty or industry/sector sub-division, if specified. E.g. surgery or leave blank if not specified/article applies to higher level domain surgery	
Country of origin/nationality of subject group/country in which described operations are based	- UK - Europe - Australasia - US - S. America - Africa - Asia - Other (specify)
Safety monitoring/control system(s) described	Indicate which category the article falls into: - Case: report of specific system implementation including findings/experience of operation in actual practice (please record the principal safety/quality/incident reporting systems or programmes described within the article). - Generic: general description or commentary on safety systems/processes not based upon specific case implementation.
Study and content type	
Aim/objectives of the study	
Article/publication type (e.g. journal article, conference abstract)	- Journal: peer reviewed published journal article - Report: research report submitted to commissioning body - Policy: healthcare guidelines. Policy documentation from specific national agency - Book: published book chapter, entire volume, reference work or educational text book. - Grey: specify – e.g. conference papers, commentary articles, editorials, research notes, other non-peer reviewed publications.

Study type/design	- Literature review or synthesis of existing research knowledge utilising a comprehensive review approach (secondary sources). [Review] - Primary research involving empirical data collection and recognised methods of investigation/data analysis (primary sources): • Qualitative research methods based upon either: interviews, focus groups, document review, other recognised information sources. [Prom-Qual.] • systematic quantitative data collection. [Prim-Quant.] • report of intervention in practice, pilot study, new system/technology/innovation implementation, case-study, etc. [Prim-Intervent.] - conceptual, expert opinion article/publication that comments upon theoretical issues, provides an overview of a specific knowledge area aimed at broad audience (likely to include books and book chapters, as well as some journal publications – secondary sources). • Single domain (expert) opinion/conceptual article that is grounded within one specific industry sector or area of application [Domain-Opinion] • Multiple domain (expert) opinion/conceptual article that draws upon knowledge of multiple industry sectors [Multi-Opinion] - Policy statement documents, special interest or sector-specific reports/publications and domain-specific descriptions of best working practices for limited audiences/communities of practice (non-research study publications, e.g. NPSA policy documents, DoH reports – secondary sources). [Policy] - Unclear
Content type and focus	In addition to the categories below, please include a brief indication of the main content theme that is relevant to the review aims. This item is important in determining relevance of article content, with IRS (Incident Reporting System) being of highest priority. - Incident reporting and learning processes: description of specific incident reporting/safety monitoring systems or focus upon general incident reporting schemes/processes. [IRS] - Other quality/safety control processes: focus upon whole/aspects of the quality/safety feedback control loop (not referring specifically to incident reporting) e.g. quality/safety management systems other than incident reporting programmes. [Q/S]
In-depth information extraction	
Reference code (EndNoteID-1st author&year-Reviewer) e.g. 1024-Runciman2003-JQ	
Level of operation (of safety monitoring/incident reporting system)	- Department/specialty group/local work team or unit (Low level – local improvements, tailored to specific work systems, direct impact, isolated learning) - Organisational unit/hospital/installation - Organisation-wide/trust regional - National/centralised - Multi-national industry/sector-wide (High level – policy developments, generic guidelines/recommendations, indirect impact, broad learning). - None specified/generic.
Specific feedback content/information flows identified	

Organisational bodies/agents responsible	
Requirements for effective safety feedback	
Supporting evidence	
Any further relevant content	
Intervention and setting	
Outcome data/results	
Recommendations made by authors	
Assessment of study Quality	
Questions	**Text within reference relevant to the questions**
*How are the **constituents** of a learning system defined?*	
*What are the key factors that enable **the transfer of learning from one organisation to another,** including multi-organisational sharing?*	
*What is **the purpose of a learning system** at a local, national, and international levels?*	
*When setting up the learning system, what are the **barriers and enablers** that have been defined?*	
*Can the incident reporting and learning system be **transferred and applied to other industries** and settings?*	
*What are the **essential features of an incident reporting** and learning system that is operated locally, nationally, and internationally?*	

Appendix 3.1: Participant information sheet

School of Medicine
Ysgol Meddygaeth

PARTICIPANT INFORMATION SHEET

Developing a conceptual framework for an international incident reporting and learning system: Semi-structured key informant interviews

You are being invited to take part in a semi-structured interview as part of a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read this information sheet. If there is anything that is not clear, if you would like more information or if you have any queries, please contact us. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this information sheet.

What is the background and purpose of the study?

Incident reporting systems have been considered a keystone of patient safety improvement initiatives. National incident reporting and learning systems have demonstrated that safety incidents appearing in one institution can occur in similar ways in other institutions. The classification of patient safety concepts and terms have seen numerous taxonomies proposed, but none have been broadly applied. The absence of standardisation in patient safety has restricted the ability to organise, compare, and aggregate information across disciplines, consequently reducing the dissemination of learning improvements made by distinctive medical fields. Recognising the need for international sharing and learning about ways to minimise patient safety risks to patients, the WHO commissioned a consensus on definitions for key concepts to understand patient safety incidents called the International Classification for Patient Safety (ICPS), and a Minimal Information Model which defines the essential information which should be included in every patient safety incident report.

Incident reporting systems are used in many high-risk industries to learn from error and permit the organisation to make changes to reduce future risk to workers and customers. Systems in aviation and aerospace travel, railway, and nuclear power industries report remarkable success. There are examples of local and national-level learning feedback loops in healthcare; however, to our knowledge, no examples of international learning-feedback loops exist. Industries like Civil Aviation have achieved this international learning-feedback loop via the International Civil Aviation Organisation's (ICAO) adopted Accident/Incident Data Reporting (ADREP) system.

The focus of this semi-structured interview is to obtain input from safety critical industry experts to complement research findings to develop a conceptual framework for an international incident reporting and learning system for healthcare.

We are looking for your opinion to participate in a semi-structured interview, which will address identified gaps in the research literature.

Why have I been chosen to participate?

You have been invited to participate in this study due to your expert knowledge in one or more of the following areas:

- Patient Safety
- Incident reporting/ learning systems
- Organisational learning/knowledge mobilisation
- Healthcare services

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Additionally, if you feel that we should invite a particular expert, please forward your suggestions to the PhD student and researcher, Dr Jaafer Qasem, via the contact details listed below.

What will happen to me if I take part and what do I have to do?

The interview is anticipated to take place between June and July 2019. You will be asked to give your informed consent to participate during June 2019. The interview should last for a maximum of 30 minutes; however, it could be extended, if you wish so, depending on your availability. The interview will be conducted by Dr. Jaafer Qasem, via Skype voice (video or phone call options are available), and will be recoded for transcription and analysis purposes. You may receive a reminder to respond to the interview invitation and give your informed consent, should you need prompting to do so. The findings of this interview and reviewed literature will inform a Delphi Study.

What are the possible benefits of taking part?

The benefit of taking part in this study is that you will be participating in research which explores the development of a conceptual framework for an international incident reporting and learning system that is operated in healthcare. Should this be developed, it will be evidence based as a result of your participation, making it potentially more suitable for use and of worth to the wider community.

What about confidentiality?

Any data you give will be protected and secured confidentially by the research team. Reported quotes will not identify the contributor. The data collected throughout this study will be kept securely in line with Cardiff University's Research Integrity and Governance Code of Practice.

Are there any risks?

There are no risks involved in participating, however, the interview will take up some of your time.

What will happen to the results of the research study?

We hope that the results of this study will address identified gaps in the literature with regards to developing a conceptual framework for an international incident reporting and learning system operating in healthcare. The results of this study will feed into a Delphi Study, which will direct the development of a conceptual framework for such a system, summarise expert driven consensus and direct future research.

Who is organising and funding the research?

The semi-structured key informant interviews are being organised by Dr Jaafer Qasem (PhD student, Cardiff University, Sponsored by the State of Kuwait Government). Dr Qasem's main supervisor is Dr Andrew Carson-Stevens (Clinical Reader of Patient Safety and Head of PISA Group, Cardiff University) and co-supervisors are Professor Adrian Edwards (Professor of General Practice, Cardiff University) and Dr Fiona Wood (Reader of Medical Sociology, Cardiff University).

Contact for Further Information

Should you have any complaints, concerns or questions at any time, you may contact the PhD student and researcher or the primary supervisor via the contact details below. You can also use these contact details to inform the research team of your withdrawal should you so wish.

PhD Student:
Dr Jaafer Qasem, M.D., MSc.
Patient Safety Research Group,
Division of Population Medicine,
School of Medicine
Cardiff University
8th floor, Neuadd Meirionnydd,
Heath Park,
Cardiff
CF14 4YS
United Kingdom
Tel: +44(0)xxxxxxxxxx
E-mail: xxxxx@Cardiff.ac.uk

Primary supervisor:
Dr Andrew Carson-Stevens MB BCh, MPhil, PhD, MRCGP, HonMFPH
Clinical Reader of Patient Safety and Quality Improvement, Head of Patient Safety Research Group,
Division of Population Medicine
School of Medicine
Neuadd Meirionnydd,
University Hospital of Wales,
Heath Park,
Cardiff,
CF14 4YS
Tel: +44 (0)29 2068 xxxx
E-mail: xxxxxx@cardiff.ac.uk

If you are happy to participate in this study, please complete the attached consent form and return them to the research team.

Participation in this study is entirely voluntary.

Thank you for reading this information sheet which is yours to keep.

Appendix 3.2: Consent form

School of Medicine
Ysgol Meddygaeth

CONSENT FORM

Project title: Developing a conceptual framework for an international incident reporting and learning system: Semi-structured key informant interviews
Research team: Dr. Qasem, J., Prof. Edwards, A. Dr. Wood, F., Dr. Carson-Stevens, A.

This semi-structured key informant interview tackles identified gaps in the literature regarding the development of a conceptual framework of an international incident reporting and learning system operating in healthcare. The interview will be conducted via Skype voice (video option or phone call options available), and will last for a maximum of 30 minutes. The aim is to form an outline for the above-mentioned frame, which will inform further research in the shape of a Delphi study. You are invited to contribute to this study.

Please initial box

1. I confirm that I have read and understand the information sheet dated 11/06/2019 (version 1.4) for the above research project and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that all the information I provide will be treated in confidence. ☐
4. I agree that my anonymised quotes can be used as part of the research project. ☐
5. I agree to take part in the above research project. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Appendix 3.3: Invitation e-mail

School of Medicine
Ysgol Meddygaeth

Dear……,

Re: Developing a conceptual framework for an international incident reporting and learning system: Semi-structured key informant interviews

Incident reporting systems have been considered a keystone of patient safety improvement initiatives. Systems in aviation and aerospace travel, railway, and nuclear power industries report remarkable success. There are examples of local and national-level learning feedback loops in health care; however, to our knowledge, no examples of international learning-feedback loops exist. Industries like Civil Aviation have achieved this international learning-feedback loop via the International Civil Aviation Organisation's (ICAO) adopted Accident/Incident Data Reporting (ADREP) system. We are currently exploring the potential need and capability for an international healthcare incident reporting and learning system.

In view of your experience and expertise in either patient safety, incident reporting and learning systems, organisational knowledge/knowledge mobilisation, and healthcare services, you are invited to participate in a semi-structured interview to provide your knowledge and experience, which would complement our research findings to develop a framework for an international incident reporting and learning system for healthcare. The interview will be conducted and by Dr. Jaafer Qasem via Skype voice (video or phone call options are available), and is expected to last for a maximum of 30 minutes, depending on your availability. The interview will be recorded for transcription and analysis purposes.

Please be assured that your responses will be treated in the strictest confidence and anonymity will be preserved during analysis and in the final report. The study has been approved by Cardiff University School of Medicine Research Ethics Committee.

Your participation will be valuable in informing the development of a model of how an international incident reporting and learning system that is operated in healthcare. Should this be developed, it will be evidence-based as a result of your participation, making it potentially more suitable for use and of worth to the wider healthcare community. You will be provided with feedback on the study results should you wish to receive it.

If you are willing to participate and/or able to nominate colleagues with expertise in patient safety, incident reporting and learning systems, organisational knowledge/knowledge mobilisation, and healthcare services that would be interested in participating in the study, please contact Dr. Jaafer Qasem or Dr. Andrew Carson-Stevens by either e-mail or telephone to receive further information.

Thank you for your time and attention.

Yours sincerely,

Dr. Jaafer Qasem
PhD Student, Patient Safety Research Group, Division of Population Medicine, Cardiff University

School of Medicine, Neuadd Meirionnydd, Cardiff University, Heath Park. Cardiff. CF14 4XW
Telephone: +44(0)xxxxxxxxxx
E-mail: xxxxxx@cardiff.ac.uk
Skype ID: xxxxx

Dr. Andrew Carson-Stevens
Clinical Reader of Patient Safety and Quality Improvement, Head of Patient Safety Research Group, Division of Population Medicine, Cardiff University

School of Medicine, Neuadd Meirionnydd, Cardiff University, Heath Park. Cardiff. CF14 4XW
Telephone: 029 2068 xxxx
E-mail: xxxxxxxxxx@cardiff.ac.uk

Appendix 3.4: Interview schedules

Healthcare expert version

Opening

Hi [confirm identity]. Thank you for making some time to allow me to interview you.

Before we start, would you mind confirming how much time you have?

I have reviewed research articles and relevant documents, but I recognize that not everything gets into the academic literature, and you, as an expert, have a unique perspective.

As mentioned in the shared participant information sheet, I am conducting this interview as part of my research project of developing and testing an international incident reporting and learning system for healthcare.

There are six main topics that emerged from the reviewed research articles, which we will discuss. Your input will help in refining the results of the review as well as add and/or make changes accordingly.

Note: Ask for their verbal consent if consent form was not sent and ask them to send it afterwards.

Body

let us explore the purpose of an international incident reporting and learning system…

Topic 1: Purpose of an incident reporting and learning system

Questions
- In your opinion, what do you consider as a purpose of an incident reporting and learning system at an international level?
- Please, could you provide example of such a system or a system that you think might be closely related?

Moving on ….

Topic 2: Functions of incident reporting and learning system

Questions
- In your opinion, what are the main functions of an international incident reporting and learning system?
- Let us examine each of those functions in turn. Please, could you describe [term used by the expert]?

Topic 3: Key features of an incident reporting and learning system

Questions
- what do you believe is relevant feedback to be shared at the international level? - Next, would you mind sharing some relevant examples of such feedback?
- Moving on, what features do you feel are essential for an international incident reporting and learning system? - [follow up if database is mentioned] That is interesting, now, what should the database include? [examples, reported incidents or safety solutions, or both]
- what should be the main priorities of an international incident reporting and learning system?

Topic 4: Enabling factors of the transfer of learning

Questions
- In your opinion, what do you believe is necessary to enable the transfer of learning at an international level?

Topic 5: Transferability

Questions
- In your opinion, is there an incident reporting and learning system that can be transferred and applied to healthcare at the international level? - Please describe it, briefly.

Moving on …

Topic 6: barriers and enablers to setting up an incident reporting and learning system

Questions
- In your opinion, what are the main enabling factors for setting up an incident reporting and learning system at the international level?
- Let us examine each of those factors in turn. Please, could you describe [term used by the expert]?
- Next, in your opinion, what are the main barriers for setting up an incident reporting and learning system at the international level?
- Let us examine each of those barriers in turn. Please, could you describe [term used by the expert]?

Moving on to the last topic…

Topic 7: Patient Safety Incidents relevant for an International IRLS

Questions
- what **safety incidents** are deemed essential for **learning at the international level**?

Closing

Thank him/her for his time

I have really learned a lot. Are you happy for me to acknowledge you in the publication and in the write-up of my thesis? Please be assured, no quotes are going to be attributed to you directly. Goodbye.

Aviation expert version

Opening

Hi [confirm identity]. Thank you for making some time to allow me to interview you.

Before we start, would you mind confirming how much time you have?

I have reviewed research articles and relevant documents, but I recognize that not everything gets into the academic literature, and you, as an expert, have a unique perspective.

As mentioned in the shared participant information sheet, I am conducting this interview as part of my research project of developing and testing an international incident reporting and learning system for healthcare.

There are five main topics that emerged from the reviewed research articles, which we will discuss. Your input will help in refining the results of the review as well as add and/or make changes accordingly.

Note: Ask for their verbal consent if consent form was not sent and ask them to send it afterwards.

Body

I have read Annexes 13 and 19, as well as the Safety Management Manual, and would like to know your opinion about …

Topic 1: Key features of an incident reporting and learning system

Questions
- what do you believe is relevant feedback to be shared at the international level? - Next, would you mind sharing some relevant examples of such feedback?
- Moving on, what features do you feel are essential for an international incident reporting and learning system? - [follow up if database is mentioned] That is interesting, now, what should the database include? [examples, reported incidents or safety solutions, or both]
- what should be the main priorities of an international incident reporting and learning system?

Moving on, let us explore the purpose of an international incident reporting and learning system…

Questions
- In your opinion, what do you consider as a purpose of an international incident reporting and learning system?
- Please, could you provide example of such a system or a system that you think might be closely related?

Topic 2: Functions of incident reporting and learning system

Questions
- In your opinion, what are the main Functions of an international incident reporting and learning system?
- Let us examine each of those Functions in turn. Please, could you describe [term used by the expert]?
- When you think about safety, what does “learning” mean?

From my research, there was no clear agreement on whether reporting safety incidents should be confidential or anonymous, particularly at the international level…

Questions

- When it comes to reporting safety incidents at an international level, which is more relevant, confidentiality or anonymity? - Could you explain the reason behind the preference?

Next, regarding access to an international incident reporting and learning system ….

Questions
- Who do you believe should have access to the system?
- Interesting, and how would [identified person] be enabled to access the system?

Topic 4: Enabling factors of the transfer of learning

Questions
- In your opinion, what do you believe is necessary to enable the transfer of learning at an international level?

Topic 5: Transferability

Questions
- In your opinion, is there an incident reporting and learning system that can be transferred and applied to healthcare at the international level? - Please describe it, briefly.

Topic 6: barriers and enablers to setting up an incident reporting and learning system

Questions
- In your opinion, what are the main enabling factors for setting up an incident reporting and learning system at the international level?
- Let us examine each of those factors in turn. Please, could you describe [term used by the expert]?
- Next, in your opinion, what are the main barriers for setting up an incident reporting and learning system at the international level?
- Let us examine each of those barriers in turn. Please, could you describe [term used by the expert]?

Moving on to the last topic…

Topic 7: Patient Safety Incidents relevant for an International IRLS

Questions
- what **safety incidents** are deemed essential for **learning at the international level**?

Closing

Thank him/her for his time

I have really learned a lot.

Are you happy for me to acknowledge you in the publication and in the write-up of my thesis? Please be assured, no quotes are going to be attributed to you directly.

Goodbye.

Appendix 3.5: Matrix table of charted interview data

	Topic 1	Topic 2	Topic 3	Topic 4	Topic 5	Topic 6	Topic 7
	Purpose of an international IRLS	**Key functions of an international IRLS**	**Key features of an international IRLS**	**Transferability of learning between organisations/countries**	**Enabling factors for an international IRLS**	**Barriers to the set-up of an international IRLS**	**Patient Safety Incidents relevant to an International IRLS**
Participant 1	*"if it's a surgical incident, and how would we go about improving, fixing things, and I think there's also something about the fact that when things go wrong and they're sufficiently worrying or serious, they need to be looked at in more detail"* *"And the analysis function has to be able to understand what's getting reported, understand what the common themes are in that, understand where the system has broken down. And then link to something that will improve that."*	"You know one of the things that X airlines was always very good at was you know the safety data that they had, I mean they had some telemetry and the like from every flight you know, they would review and they would look at it in a searching way and they would talk through with, you know pilots. Now, I don't think we're, you know it's not the same in healthcare"	"She just come off shift and said, you know I'd sit down at the end of the day, and I spent ages you know messing around with DATIX reporting something. So I think, if we want people to report readily, we have to make reporting straightforward and easy to do."	N/A	"So you need enough information in there to see is it relevant to your particular scenario, your particular situation? whether that's at local, national or international level."	"I think one of the big cultural challenges over the next you know ten to twenty years is getting people more interested in the data"	N/A

Participant 2	N/A	“I’d prefer anonymity. Anonymity lowers the barriers in reporting. This way all information is better handled, available and easier to share when there are not restricting confidentiality issues.”	“Well maintained database in which the recommendations are openly available for anyone. Recommendations should have a national follow-up in the country in which the recommendation was issued. Other countries should have a process to keep itself up to date of new recommendations. Interface and the database itself should be simple enough. National databases should be separate and only the relevant information should be transferred to the international database." “Access should be open for everyone to read the information that helps organisations and individuals learn. Maybe there should be only one named responsible organisation in each country.”	N/A	N/A	“Main priority should be to develop simple enough system and get as many possible countries to be committed. Important question is, which organisation can be responsible for the system? Maybe within the EU or the UN." Someone should take strong leadership and invite organisations from each country to collaborate. It should be accepted that many countries will not attend, and the quality of shared information will be variable. Maybe there should be requirements from the EU”.	“In my opinion at the international level there should be learning at three categories, all most serious incidents (resulting in the death of several persons), clear technical problems (they can be solved worldwide), learning from statistics (incidents resulting in serious consequences).”

Participant 3	“I suppose, big picture-wise, it's learning from other people's mistakes before you make them yourself. It is that sharing of information, and it's an awareness of what else is going on.”	“I think they should be anonymous, or I think people should have the option to make them anonymous. I think the names, and the location, apart from maybe the country where it happened, isn't particularly relevant”.	“A responsible organisation should be found in each nation, the commitment of participants national processes to investigate and collect information, guidelines and definition which kind of information is wanted into the database.”	“So you know, having an international conference or, getting the people around the table, they all feel that their voice is being heard, in terms of the preparation. I don't know, five or six years, having to expense of it eventually, but every word would be debated, you know, and that's why you've got such a great document, that the wording is accepted in 190 states around the world."	“I think everything should start with a good quality investigation”	“I think the more transparent you can make that, the better.”	“Well I don't think it needs to have resulted in harm, but it just has to have the potential for it”.
Participant 4	“I think the standardisation. So, the way we see things reported is very non-standard. And that makes any sort of analysis difficult so standardisation of the way things are reported.”	N/A	“Something that’s easy for people to access, something that’s intuitive for clinicians’ other people to understand. Something that's designed to make it, to make it easy to report in a standardised way ."	“I think the standardisation. So, the way we see things reported is very non-standard. And that makes any sort of analysis difficult so standardisation of the way things are reported.”	N/A	“Or if operators are afraid to report. So people won't report if it's too much work, difficult to do, they're afraid”	“I think we need to be very clear about addressing, reporting the things that have either the most actual or potential for harm.”

Participant 5	“So for the time being the main purpose would be, learning from reported incidents"	N/A	“You want it to be fairly user friendly from that front with minimal pages, a minimum number of pages, minimum number of options, free text entries”	“Yeah, I fully agree so common language would be a facilitator, a taxonomy of important words would be a facilitator, a common you know like taxonomy that would make things easier, so you understand cos you’re using the same terms”	“If you were to have adoption of learning across systems and countries what you need is those boundary spanners. So your knowledge mobilisers, you need people who have a stake hold in those different healthcare systems so they've got buy-in in different healthcare systems.	“The fact that it may be too cumbersome to just report things because I mean it is a problem we face in the UK so it's not user friendly at times and there are too many different drop-down menus. If you have to report something alongside looking after your patients and it takes you away from the frontline so you end up doing it in your own time”	N/A
Participant 6	“for the international level the main purpose is I think to detect, rare and emerging incidents so the purpose of the system is to be less focused on the really big problems that we know exist, but more on rare or emerging incidents"	“It’s really important in that mechanism, that risk surveillance and review and response mechanism, you need clinicians, subject matter experts and human factor experts to interrogate and understand the data.” “An agreed high level, classification system, not too detailed, it needs to be useable so that they, you know it doesn’t take too long to, make a report.”	N/A	N/A	“Probably the other thing that's missing there is the governance of it. So, you have to have overarching governance, around that database and you need representation from the countries who are submitting data"	"and it needs to be trusted you know, from that community and that governance process needs to have good representation from people”.	“For the international level, the main purpose is I think to detect, rare and emerging incidents and you don’t know until you see it, so, but thinking about categories, erm, it’s rare or emerging incidents”

Participant 7	"it would facilitate learning from events, patterns of error, learning from events, which could be fed back to redesign. So, learning can mean setting up bodies to deal with safety, it can also mean new procedures, new rules, new regulations, new Government"	"Safety solutions are or, or recommendations, I don't think, I think that might be too much for, for an instant reporting system, I think that's something that probably should be supplied by the team who do the investigation. "	"what are the, the top level of sig, significant events, we're trying to prevent"	"Each with it's own little culture and each with it's own um, set of professional you know, rules um and I often say that healthcare is very tribal, ...if you're gonna have effective learning, then you know, you really need to have um those people aligned with those things."	N/A	"And then nothing comes back, I think people if they report something, they're entitled to know how it's been dealt with, and how, has it been dealt with, has it been investigated?".	"Well never events, I guess, things which are the most commonly occurring serious events, so retained instruments, medication errors, blood transfusion errors, those sorts of things and even accounts, I think whatever the definition somewhere is of a never event in the NHS, that's probably the starting point, because they're the most severe risks, and then, unfortunately, they're the ones that reoccur all the time, so".

Participant 8	"One would be to identify levels and types of harm, how it might be different for different types of healthcare systems and what are the events that are occurring most frequently internationally. You could look at factors like how health services are delivered and whether types of adverse events or levels of adverse events differ"	"I think feedback mechanisms are critical in kind of local, reporting systems, but they don't work very effectively-currently I don't think and often that's, as you'll know from the literature, that's a complaint that reporters of incidents have that they report, they spend time, they make the effort to do it and they never hear anything about it again."	"Some basic standardisation I think of those processes to make an international reporting system possible I think."	N/A	"we'd need to have a look at the quality of the recommendations and, the number of recommendations, if you're producing a recommendation every week, at a global level then I think that could be problematic."	"Less developed countries probably have limited resources"	N/A
Participant 9	"So in my view, you know again it comes back to this issue of trying to standardise how reporting is done to enable people to get the most benefit."	"Well the priority should be to establish some sort of you know quality standard around the reporting of incidents and the types of recommendations, the analysis process that leads to the recommendations"	"I think that mechanism for reporting should also really strongly encourage patients to report …"	N/A	"So that's kind of, again it runs from a description of the incidents, the description of the recommendations to a description of the implementation that comes from those recommendations".	"National Health Service requirement for reports, er, currently to be, erm, er, so they're not anonymous are they, so people have to, erm, put a name or a, er, an NHS number …" "adversarial nature of that process"	"Common procedures globally."

Participant 10	"to establish and log what has happened, almost as a quality assurance um, step I suppose. But also as a ... as a part of a means to an end, in order to be able to explain to those involved, what's happened, and then if necessary, go on and identify learning that may be needed, in order to stop repeat of whatever it is that's happened in, you know, in the future, or in other places."	N/A	"generation of any knowledge that contributes to furthering exactly that, you know, to furthering patient safety"	"feedback to those that were involved"	N/A	"combination of share, of blame, or bullying or scapegoating, either by your peers or your managers, or the regulators" "litigation" "a culture that doesn't care, I won't ever know whether they've done anything or not, so what's the point? I won't get any feedback and I don't believe anything will change, then why would you report? And I think that's probably the single biggest barrier to patient safety, or staff safety, full stop"	"…the issues which cross borders. And cross cultures, so obviously things like anti microbial resistance, um, is global concern, and the pandemic type things"
Participant 11	"Yeah, I would say it is to get an overview of the most important, risk areas and be able to learn across countries I would say, it's not necessary to go into all kind of incidents, but it's more of an overview to learn across countries."	"mandatory for some people to actually report …"	"the main propriety is to get, erm, reliable data into the system and try to feed back to the, er, policy makers which I think is the most important perhaps for international and then have different forms of feedback to, and give priority to feedback"	"So to be able to translate knowledge into practice you need to take into account the contextual conditions in each country, so a lot of work will probably have to go into, er, to adapt, er, learning information through to the, relevant for different countries."	"there needs to be some kind of a common definition of, er, incidents across countries …"	"resources, er, competence to, er, to analyse the information …" "it's an enabler depending on if you succeed or not."	"under reporting, er, which is a barrier all over the place …"

Appendix 4.1: Initial survey invitation e-mail template

Dear……,

Re: Exploring the purpose and feasibility of an international patient safety learning system: an electronic Delphi Study

My name is Jaafer Qasem and I am a PhD student working with Dr Andrew Carson-Stevens at the School of Medicine, Cardiff University in Wales, United Kingdom.

In view of your experience and expertise in patient safety and healthcare services, you are invited to participate in an electronic Delphi study to develop an expert consensus on the purpose, key requirements and feasibility of an international patient safety learning system.

The concept of 'learning' from unsafe healthcare has been at the heart of efforts to inform the design of safer systems for future patients. Most healthcare organisations aspire to become 'learning organisations'.

At a local level, for example, learning occurs when healthcare organisations review different sources of safety data to identify trends in patient safety incidents that warrant further investigation and / or quality improvement activity. At a national level, patient safety incident reports from NHS organisations in England and Wales are collated in the National Reporting and Learning System where trends in the data is used to identify national-level priorities for patient safety improvement. Similarly, efforts to tackle common patient safety problems also occur via local and national efforts, and even international collaborations such as the WHO patient safety challenges.

This project explores the purpose and feasibility of an international patient safety learning system to capture learning from efforts to, for example, investigate patient safety and the actions taken to mitigate risk to patients, from different levels within and between countries.

This will involve the completion of up to three iterations of a **confidential** questionnaire asking you to rank agreement with different elements of a potential international patient safety learning system. Generally, a consensus is achieved after two rounds.

- Each round of the questionnaire takes around 30 minutes to complete, which you can complete over as many sessions as you like, using the link below. The survey platform will automatically save your responses so that you may return to continue the survey or change your answers before submitting them.
- You will have two weeks to submit your answers. There are no right or wrong answers to any of the questions and issues raised in the questionnaire.
- We anticipate there will be up to three rounds of questionnaires approximately 2 weeks apart. A reminder will be sent prior to each deadline for completion of survey rounds.
- We are purely interested in your thoughts, opinions and relevant experiences about the purpose, key requirements, and feasibility of an international patient safety learning system.
- Please be assured that your responses will be treated in the strictest confidence and anonymity will be preserved during analysis and in the final report. The study has been approved by Cardiff University School of Medicine Research Ethics Committee.

The results will be further explored with potential users of such a system to inform further research initiatives to pilot test the system. You will be provided with a summary of the e-Delphi study results should you wish to receive it.

What do you need to do?
Step 1: If you are willing to participate, please review, download and save the participant information sheet, accessed by clicking HERE.
Step 2: Please complete the online survey by 07/09/2020**; the** online survey is accessible via: (LINK)
If you would like further information about the study or are able to nominate colleagues within patient safety that would be interested in participating in the study, please contact Dr. Jaafer Qasem by e-mail for further information.

Thank you for your time and attention.

Yours sincerely,

Dr. Jaafer Qasem
Primary Researcher, PISA Group, Division of Population Medicine, Cardiff University

School of Medicine, Neuadd Meirionnydd, Cardiff University, Heath Park. Cardiff. CF14 4XW

Telephone: +44(0)xxxxxxxxxx

E-mail: xxxxxx@cardiff.ac.uk

Dr. Andrew Carson-Stevens
Clinical Reader, Division of Population Medicine, Cardiff University

School of Medicine, Neuadd Meirionnydd, Cardiff University, Heath Park. Cardiff. CF14 4XW

Telephone: 029 2068 xxxx

E-mail: xxxxxxxxx@cardiff.ac.uk

Appendix 4.2: Participant information sheet

PARTICIPANT INFORMATION SHEET

Exploring the purpose and feasibility of an international patient safety learning system: A Delphi Study.

You are being invited to take part in a research study being carried out as part of Dr Jaafer Qasem's PhD thesis. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read this information sheet. If there is anything that is not clear, if you would like more information or if you have any queries, please contact us. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this information sheet.

What is the background and purpose of the study?

Unsafe healthcare is a recognised international threat to public health and wellbeing. Globally, as a result of patient safety incidents, defined as, "an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient" (WHO, 2009), millions of patients are at risk of experiencing healthcare-associated harm annually.

Worldwide, most healthcare organisations seek to learn from unsafe care in order to design safer systems for future care delivery. Within healthcare, multiple different types of data are collected about patient safety to inform learning from unsafe healthcare. For example, audits of care, incident reporting systems, mortality review case conferences, patient reported survey instruments and narratives. There are examples of local and national-level learning from efforts to analyse such data sources. How learning can local and national-level learning can be shared reliably and consistently at an international level is unclear.

Like in healthcare, safety incident reporting systems exist in aviation and aerospace travel, railway, and nuclear power industries, where staff can report concerns. These safety critical industries learn from accidents and communicate changes across the organisation (nationally and internationally) to make changes to reduce future risk to workers and customers. However, unlike organisations like the International Civil Aviation Organisation, which investigates accidents in aviation and has a process for sharing the lessons learnt internationally, we have been unable to identify (systematic review and interviews with experts) any examples of international learning loops in healthcare.

The purpose of this international Delphi study is to achieve expert consensus about the possible expectations from, and the related requirements of an international patient safety learning system. The contents of the Delphi study were generated from a systematic review of the literature and semi-structured key informant interviews with healthcare and safety critical industry experts.

We are seeking your opinion, as part of an anonymous expert panel, to participate in up to three rounds of an online Delphi survey. You are kindly asked to answer the survey questions based on your personal conceptualisation of the purpose and function of an international patient safety learning system.

Why have I been chosen to participate?

You have been invited to participate in this study due to your expert knowledge in one or more of the following areas:

- Patient Safety
- Incident reporting/ learning systems
- Organisational learning/knowledge mobilisation
- Healthcare services

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Additionally, if you feel that we should invite a particular expert, please forward your suggestions to the primary researcher, Dr Jaafer Qasem, via the contact details listed below.

What will happen to me if I take part and what do I have to do?

The first round of the online survey is anticipated to take place on 24/Aug/2020. You will be asked to give your informed consent to participate on 17/Aug/2020. You will have time to give your informed consent and submit your answers until the deadline of 07/Sept/2020. The online Delphi survey should take around 30 minutes to complete, which can be done over as many sessions as you like as the online platform will save your responses, and you will have a period of two weeks per round to submit your answers. The survey platform allows for you to return back to previous page to change

your answers by clicking on the blue arrows near the progress bar. Definitions of some key terms will appear by hovering over the text. You will also have the opportunity to suggest further questions/statements to be put forward to the panel. You will be given two weeks to complete and submit your considered responses. You may also receive a reminder to complete the survey should you need prompting to do so.

Dr. Jaafer Qasem will collate and evaluate all responses and discuss them with the supervisory team. We anticipate that there will be some questions/statements which may or may not reach group consensus. Consensus will be considered achieved when panellists reach ≥70% agreement on all items with the same ranking.

Two weeks after the submission deadline for the first survey, you will be sent a link to a short report from the first round of the survey and a second online survey. This second survey will contain questions that may not have achieved consensus during the first round of questioning. You will be asked to review your initial response and be given the opportunity to amend your initial response should you wish to, based upon the overall response reported from the entire panel. There may also be additional questions added to this second survey based upon additional questions suggested by the panel during the first round of questioning. You will be given two weeks to complete and submit this survey with your considered responses.

After the second round, responses will be collated and evaluated, and a short report will be produced. If consensus is not reached on all items, a third and final round of the online survey will be conducted. You will be sent a copy of the second short report and be given two weeks to complete and submit the third round of the survey.

A final report will be produced and sent to you, if you wish to receive it. We anticipate that a final published research paper will also arise as a result of this research. If you opt to receive the final report, you will also receive a copy of such a paper.

What are the possible benefits of taking part?

The benefit of taking part in this study is that you will be participating in research which explores the purpose and feasibility of an international patient safety learning system. Should such as system be developed, your contribution will help to ensure it is potentially more suitable for use and of worth to the wider healthcare community.

What about confidentiality?

Any data you give will be protected and secured confidentially by the research team. Other members of the panel will not know who else is participating. The public will not know who has participated, and any quotes reported will not identify the contributor. The data collected throughout this study will be kept securely in line with Cardiff University's Research Integrity and Governance Code of Practice.

Are there any risks?

There are no risks involved in participating, however, completing the study surveys will take up some of your time.

What will happen to my Personal Data?

The secure online consent form that you will complete before participating in this research project will ask for your name and signature (typed full name). This information will be used to share reports of survey rounds, and to share the published paper, should you request it.

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:

- your rights
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office; may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection

Under data protection law we have to specify the legal basis that we are relying on to process your personal data. In providing your personal data for this research we will process it on the basis that doing so is necessary for our public task for scientific and historical research purposes in accordance with the necessary safeguards, and is in the public interest. The University is a public research institution established by royal charter to advance knowledge and education through its teaching and research activities. Our charter can be found on the Cardiff University website.

After the conclusion of the study in November 2020, the research team will anonymise all the personal data it has collected from, or about, you in connection with this research project, with the exception of your consent form. Your consent form will be retained for two years post publication and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised

information will be kept for a minimum of two years but may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research purposes.

You have a number of rights under data protection law and can find out more about these on our website. Note that your rights to access, change or move your personal data are limited, as we need to manage your personal information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

Completed survey data before withdrawal from the study will be anonymised and used as part of the study. Incomplete survey data will not be used. Please note that it will not be possible to withdraw any anonymised data that has already been published.

What will happen to the results of the research study?

We hope that the results of this study will form a consensus on the purpose, key requirements, and feasibility of an international patient safety learning system. The results of this study will summarise expert driven consensus and direct future research.

Who is organising and funding the research?

The Delphi Study is being organised by Dr Jaafer Qasem (PhD student, Cardiff University, Sponsored by the State of Kuwait Government). Dr Qasem's main supervisor is Dr Andrew Carson-Stevens (Clinical Reader of Patient Safety and Head of Patient Safety (PISA) Group, Cardiff University) and co-supervisors are Professor Adrian Edwards (Professor of General Practice, Cardiff University) and Professor Fiona Wood (Professor of Medical Sociology, Cardiff University).

Contact for Further Information

Should you have any complaints, concerns or questions at any time, you may contact the primary researcher or the primary supervisor via the contact details below. You can also use these contact details to inform the research team of your withdrawal should you so wish.

Primary Researcher:
Jaafer Qasem, M.D., MSc.
PISA Group, Division of Population Medicine,
Cardiff University
5th floor, Neuadd Meirionnydd,
Heath Park,
Cardiff
CF14 4YS
United Kingdom
Tel: +44(0)74xxxxxxxx
E-mail: xxxxxx@Cardiff.ac.uk

Primary supervisor:
Andrew Carson-Stevens PhD MRCGP
Clinical Reader of Patient Safety and Quality Improvement
School of Medicine
Neuadd Meirionnydd,
University Hospital of Wales,
Heath Park,
Cardiff,
CF14 4YS
Tel: +44 (0)29 2068 xxxx
E-mail: xxxxxxxxx@cardiff.ac.uk

If you are happy to participate in this study, click on the survey link included in the e-mail to complete a consent form before proceeding to the survey. Please note that the survey link is personalised to be only used by you.

Participation in this study is entirely voluntary.

Thank you for reading this information sheet which you should download and save.

Appendix 4.3: Consent form

School of Medicine
Ysgol Meddygaeth

CONSENT FORM

Project title: Exploring the purpose and feasibility of an international patient safety learning system: A Delphi Study

Research team: Dr. Jaafer Qasem, Prof. Adrian Edwards, Prof. Fiona Wood, Dr. Andrew Carson-Stevens.

This Delphi study explores the purpose, key functions and features, and the feasibility of a potential international patient safety learning system. The study will include up to three rounds of an online Delphi survey, offered to a group of expert panellists. Questionnaire responses will be analysed in order to ascertain the direction in which the development of an international patient safety learning system should proceed. The aim is to form an expert consensus of opinion on this matter. You are invited to join the expert panel who will contribute to this study.

	Please initial box
1. I confirm that I have read and understand the information sheet dated 28/07/2020 (version 1.4) for the above research project and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.	☐
3. I understand that all the information I provide will be treated in confidence.	☐
4. I agree that my anonymised quotes can be used as part of the research project.	☐
5. I agree to take part in the above research project.	☐

Name	
Date	
Digital signature (type name)	

Appendix 4.4: E-mail sent to interviewed expert

Subject: RE: Follow up - Phd study – Developing a conceptual framework for an international incident reporting and learning system

Dear [expert],

Thank you for participating in our study.

I hope that you are well.

As we are preparing for a Delphi study, we can across a question that we hoped you might be able to help us answering, from your experience.

- When it comes to reporting incidents to an international reporting and learning system (in safety-critical industries other than healthcare), how do you decide whether it is an international threat or not?

- Are there any criteria for deciding whether something is an international concern or is it a gut feeling?

- What are the things driving the decision to report internationally?

Thank you again for participating and for your willingness to help.

Regards,

Jay

Appendix 4.5: Pilot invitation e-mail

Dear ……..,

Thank you for agreeing to pilot test our online Delphi survey.

Some questions I would like to get your feedback on include:

- Is the layout of the survey easy to follow, and read?
- Are the questions / statements easy to understand?
- Are there any changes you would make to the survey?
- How do you feel about the time it took to complete the survey?
- Does the following e-mail invitation give explicit instructions about what is required of the participants?
- Are there any changes you would make to the invitation?

In addition, if you have any further feedback regarding the survey, it would be really helpful to share it to arrive at a final draft of the survey, based on your testing.

If you could provide this feedback in the next 7 days (by 27/07/20) that would be greatly appreciated. A reminder will be sent prior to the deadline.

The participants will be sent the following invitation:

Dear…….,

Re: Exploring the purpose and feasibility of an international patient safety learning system: A Delphi Study

Patient safety learning systems have been considered a keystone of patient safety improvement initiatives. Systems in aviation and aerospace travel, railway, and nuclear power industries report remarkable success. There are examples of local and national-level learning feedback loops in health care; however, to our knowledge, no examples of international learning-feedback loops exist. Industries like Civil Aviation have achieved this; for example, the International Civil Aviation Organisation (ICAO) adopted Aircraft Accident and Incident Investigation, an international civil aviation safety learning system. Therefore, there is a need to explore the key requirements and feasibility of an international patient safety learning system.

In view of your experience and expertise in either patient safety, incident reporting and learning systems, and healthcare services, you are invited to participate in a Delphi study to develop an expert consensus on the purpose, key requirements and feasibility of an international patient safety learning system. This will involve the completion of up to three iterations of a **confidential** questionnaire asking you to rank agreement with themes that would form the basis of a potential international patient safety learning system. Generally, a consensus is achieved after two rounds. Each round of the questionnaire takes around 40 minutes to complete, which you can complete over as many sessions as you like, using the link below. You will have two weeks to submit your answers. There are no right or wrong answers to any of the questions and issues raised in the questionnaire. We are purely interested in your thoughts, opinions and experiences about the purpose, key requirements, and feasibility of an international patient safety learning system. Please be assured that your responses will be treated in the strictest confidence and anonymity will be preserved during analysis and in the final report. The study has been approved by Cardiff University School of Medicine Research Ethics Committee.

Your participation will be valuable in exploring the key requirements and feasibility of an international patient safety learning system. Should this system be developed and tested in the future, it will be evidence-based as a result of your participation, making it potentially more suitable for use and of worth to the wider healthcare community. The results will be further explored with potential users of the system to inform further research initiatives to pilot test the system, in a potential collaboration with the WHO. You will be provided with feedback on the study results should you wish to receive it.

What do you need to do?
Step 1: If you are willing to participate, please review the participant information leaflet and consent form, accessed by clicking HERE . We anticipate there will be up to three rounds of questionnaires approximately 2 weeks apart.
Step 2: Please send the completed consent form to xxxxxx@cardiff.ac.uk prior to proceeding to complete the online survey by the 15/08/2020 (deadline).
Step 3: The online survey is accessible via: (LINK)
A reminder will be sent prior to each deadline for completion of survey rounds.
If you would like further information about the study or are able to nominate colleagues with in patient safety, incident reporting and learning systems, and healthcare services that would be interested in participating in the study, please contact Dr. Jaafer Qasem or Dr. Andrew Carson-Stevens by e-mail further information.
Thank you for your time and attention.

Yours sincerely,

Dr. Jaafer Qasem
Primary Researcher, PISA Group, Division of Population Medicine, Cardiff University

School of Medicine, Neuadd Meirionnydd, Cardiff University, Heath Park. Cardiff. CF14 4XW

Telephone: +44(0)xxxxxxxxxx

E-mail: xxxxx@cardiff.ac.uk

Dr. Andrew Carson-Stevens
Clinical Reader, Division of Population Medicine, Cardiff University

School of Medicine, Neuadd Meirionnydd, Cardiff University, Heath Park. Cardiff. CF14 4XW

Telephone: 029 2068 xxxx

E-mail: xxxxxxxxx@cardiff.ac.uk

Appendix 4.6: Round one questionnaire

Exploring the purpose and feasibility of an international patient safety learning system: A Delphi Study

The purpose of this international Delphi study is to achieve expert consensus about the possible expectations from, and the related requirements of an international patient safety learning system.

We are seeking your opinion, as part of an anonymous expert panel, to participate in up to three rounds of an online Delphi survey.

There are four main sections representing what the literature and key informant interviews outlined to be essential to a potential international patient safety learning system.

The sections are as follows:

- Section 1: Purpose(s) of an international patient safety learning system
- Section 2: Key functions/features of an international patient safety learning system
- Section 3: Patient Safety incidents relevant for international sharing and learning
- Section 4: Enablers and challenges to the set-up of an international patient safety learning system

Note: please refer to Participant Information Sheet v1.4 for further information, if you have not read it.

Experience

Please note: this section will not identify you personally, and it aims to demonstrate how your experience and expertise contributed to the results of the study.

i.	Experience	
i.a	Profession:	
i.b	Country:	
i.c	How many years of experience do you have in the field of patient safety/quality improvement (including academic/clinical/other):	
i.d	Do you have any experience in patient safety at a national/international level? Please give details:	
i.e	Do you have any experience in leadership roles within healthcare or patient safety organisations? Please give details:	

ii.	Do you wish to receive feedback regarding the result of this study?	YES (click)	NO (click)

SECTION 1: Purpose(s) of a potential international patient safety learning system

1. Please rate the extent to which you agree that the purpose of an international patient safety learning system (PSLS) is:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
1.01 Identification of patient safety risks relevant internationally.									
1.02 Surveillance of patient safety incidents to detect potential risks relevant internationally.									
1.03 Process learning from investigations of patient safety incidents so that transferable learning between countries can be identified.									
1.04 Generate systems improvement strategies based on documented efforts to mitigate risk in other countries.									
1.05 Learn from reported common patient safety risks to coordinate efforts internationally to mitigate and address those risks.									
1.06 Learn from reported common patient safety risks internationally and work with other countries to innovate solutions to prevent those risks from reaching patients in similar healthcare contexts.									
1.07 Awareness of frequently occurring patient safety incidents in other countries.									
1.08 Drive up standards in learning from patient safety incidents									
1.09 Standardise the way learning from investigating patient safety incidents is reported.									
1.10 Coordinate the design of initiatives / interventions to mitigate commonly identified risk.									
1.11 Provide an overview of the most important risk areas and be able to learn with and from other countries.									
1.12 Focus on assimilating learning about patient safety incidents that provide serious and specific insights into system safety.									

- **Where you have selected a value of 6 or below, please justify you answer(s).**
- **Are there any changes or additions to the stated purposes that you think should be included? Please provide your suggestion.**

SECTION 2: Key features and functions of a potential international patient safety learning system (PSLS)

2. Please rate the extent to which you agree that the following features and functions of an international patient safety (PSLR) are important:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
2.01 Generate safety recommendations with solutions that can be shared with countries and considered for adoption in different contexts in healthcare systems.									
2.02 Collate patient safety data / reports / resources in the interest of enabling international-level learning.									
2.03 Coordinate and launch international-level efforts to tackle common patient safety risks									
2.04 A proactive approach for identifying patient safety risks that require international action.									
2.05 Ability to analyse and make recommendations based on shared patient safety data to identify transferable learning from countries responding to patient safety risks.									
2.06 Ability to use filters to search multiple sources of data / evidence / outputs to get to required information quickly.									
2.07 A repository for reports describing how interventions to mitigate risk work and how to support others to support implementation elsewhere.									

2.08 Ability to trigger an alarm that deploys a notification to countries about serious identified patient safety risks.									
2.09 Compile and consolidate information from multiple countries.									
2.10 Analyse information and generate reports based on inputs from multiple countries and consolidating the 'meta-learning' (i.e. the overall learning from the country-level learning).									
2.11 Ability to share reported patient safety incidents/risks relevant to international learning.									
2.12 Shared database of resources that could support risk mitigation / prevention.									
2.13 Support improvements in collection of patient safety data through sharing exemplars.									
2.14 Support improvement in incident reporting and learning through sharing exemplars.									
2.15 Develop instructional manuals on how to investigate and learn from patient safety incidents.									
2.16 In the case of patient safety incidents related to equipment and or medication, manufacturers will be informed to take action to mitigate and contain any further risk.									
2.17 Ability to identify contributing factors to patient safety risks that can be transversal to certain types of incidents, contexts, and case studies.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated features and functions that you think should be included? Please provide your suggestion.

SECTION 3: Patient safety Incidents relevant to international sharing and learning

There have been examples where researchers from multiple countries have pooled patient safety incident report data to maximise opportunities to learn from unsafe care. If a potential international mechanism existed which permitted confidential, information-governance compliant data sharing, which types of patient safety incidents could be relevant and essential for international learning.

3. Please rate the extent to which you agree that the following types of safety incidents are essential for international learning (shared learning):	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
3.01 All adverse events (an incident that results in harm to a patient) (WHO, 2009)									
3.02 A near miss (events where no harm was done, but there could have been if people had done the same thing, and allowed it to go a stage further, it could have led to somebody's death).									
3.03 Incidents relevant to current international campaigns or challenges e.g. the WHO patient safety challenges									
3.04 Incidents identified by multiple countries as common sources of unsafe care and therefore a potential priority to learn from and tackle collectively.									
3.05 Tubing misconnections/misconnection errors (e.g. non-luer connected devices).									
3.06 Nasogastric tube positioning errors/incidents.									
3.07 Ten times medication errors (refer to definition above)									
3.08 Incidents related to manufacturing and supply chain (e.g. contaminated vaccine/IV fluids/injections/drugs)									
3.09 Incidents related to faulty medical devices (including IVDs) or equipment failure.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated patient safety incidents that you would like to make/add? If so, please provide your own changes.

ii. In your opinion, what are the criteria for deciding whether an incident is an international concern (global priority), particularly for international learning?

SECTION 4: Enablers and challenges to setting up an international patient safety learning system (PSLS)

When planning to set up a learning system, especially at the international level, there are potential challenges and enabling factors that could support or hinder the process of setting up such as system. Anticipating some of these factors beforehand would help in determining the feasibility of such a system in the future.

4. a. Please rate the extent to which you agree that the following are key enablers for setting up an international patient safety learning system:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
4.01 Governments, agencies, and organisations have clear legislation, regulations and guidelines that are supportive of and encouraging of sharing of patient safety data relevant for international learning.									
4.02 An independent body/organisation responsible for operating and maintaining the international PSLS.									
4.03 Country-level will to learn with and from other countries.									
4.04 Funded by partner countries.									
4.05 Having buy-in from healthcare systems within each individual country.									
4.06 Having buy-in from international organisations with a role and interest in patient safety.									
4.07 Broad support from the clinicians and the societies that make up the international patient safety community.									
4.08 Involvement of important knowledge mobilisers (e.g. Institute for Healthcare Improvement, World Health Organization).									
4.09 To have representation from countries that are submitting data to the international system (e.g. national co-ordinators).									
4.10 Existence of international standards / convention for sharing patient safety data.									
4.11 For users and/or contributors to the system to be able to access it in an easy, secure way.									
4.12 Multiple input methods are available (e.g. online, phone, e-mail…etc).									
4.13 The system is accessible for everyone to read the information that helps organisations and individuals learn (e.g. web page open for everyone).									
4.14 Access for input to the system should be limited and discussed nationally, with only one named responsible organisation in each country.									
4.15 Password-controlled access to an online platform.									
4.16 Automation of as many functions as possible.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated enabling factors that you would like to make? If so, please provide your own changes.

4.b. Please rate the extent to which you agree that the following are key challenges/barriers to setting up an international patient safety learning system:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
4.17 Finding the responsible international organisation to set up the system and relevant national organisations that will commit to co-operate.									
4.18 At the international level, big cultural factors and different types of healthcare systems might present a challenge.									
4.19 Lack of a sense of ownership in a system the end-user has not been involved in developing.									
4.20 Having too many different bodies which are involved.									
4.21 Limited resources in less developed countries.									
4.22 Issues about national reputation, healthcare system reputation issues, which might create barriers.									
4.23 Concerns regarding privacy issues when sharing learning from investigations of patient safety incidents.									
4.24 Lack of common format / approach to sharing learning about patient safety risks and / or efforts to mitigate / prevent harm to patients.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated challenges/barriers that you would like to make? If so, please provide your own changes.

Appendix 4.7: Round two questionnaire

Exploring the purpose and feasibility of an international patient safety learning system: A Delphi Study

In this second round of the Delphi study you will have the opportunity to revise your rating for statements from the first round, and you will also be able to rate new statements suggested by fellow panellists, including yourself.

The sections for this round are as follows:

- Section 1: Purpose(s) of an international patient safety learning system
- Section 2: Key functions/features of an international patient safety learning system
- Section 3: A - Patient Safety incidents relevant to international sharing and learning
  B – Criteria for deciding what patient safety risk is of international concern
- Section 4: Enablers and challenges to the set-up of an international patient safety learning system

SECTION 1: Purpose(s) of a potential international patient safety learning system

1. Please rate the extent to which you agree that the purpose of an international patient safety learning system (PSLS) is:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
1.01 Awareness of frequently occurring patient safety incidents in other countries. [Your 1st round score = ; group median = 8]									
1.02 Identify evidence-practice gaps that are occurring in similar contexts in other countries in order to develop interventions together.									
1.03 Learn from patients and families about risk, harm, response, and remediation.									
1.04 Standardise the way learning from investigating patient safety incidents is reported. [Your 1st round score = __; group median = 7]									
1.05 Coordinate the design of initiatives / interventions to mitigate commonly identified patient safety risk. [Your 1st round score = __; group median = 8]									
1.06 Bolster capability of those seeking to improve safety by benefitting from the shared learnings of those that have achieved improvements in safety in similar care contexts.									
1.07 Learn with and from countries about efforts to improve patient safety in terms of what works and how.									
1.08 Identify priorities for research and development to focus international efforts and resources where they are needed most.									
1.09 Co-ordinate efforts of national patient safety organisations in collaboration with WHO.									
1.10 Sharing affordable design-based interventions.									

- **Where you have selected a value of 6 or below, please justify you answer(s).**
- **Are there any changes or additions to the stated purposes that you think should be included? Please provide your suggestion.**

SECTION 2: Key features and functions of a potential international patient safety learning system (PSLS)

2. Please rate the extent to which you agree that the following features and functions of an international patient safety (PSLR) are important:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
2.01 Ability to use filters to search multiple sources of data / evidence / outputs to get to required information quickly. [Your 1st round score = __; group median = 8]									
2.02 Develop instructional manuals on how to investigate and learn from patient safety incidents. [Your 1st round score = __; group median = 7]									
2.03 Facilitate learning and support through a range of formats (e.g. instructional manuals, train-the-trainer workshops, webinars, onsite learning)									
2.04 Develop a structured process for investigating patient safety risks identified by the international learning system.									
2.05 Ability to identify contributing factors to patient safety risks that can be transversal to certain types of incidents, contexts, and case studies. [Your 1st round score = __; group median = 8]									
2.06 Develop methodologies to evaluate practices to learn from patients and family members in all facets of patient safety, including prevention, response, recovery, and remediation.									
2.07 Support the progression of countries towards a proactive and personalised clinical risk management approach i.e. moving from a reactive to a proactive mindset.									

2.08 To develop methodological approaches for assimilating a range of descriptive patient safety data to build a more complete understanding of safety within countries.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated features and functions that you think should be included? Please provide your suggestion.

SECTION 3: Patient safety Incidents relevant to international sharing and learning

Knowing types of patient safety incidents/risks that are essential for international sharing and learning is helpful. Therefore, knowing the criteria for deciding what patient safety risk is of international concern is key to gain maximum benefit from the international PSLS.

3. a. Please rate the extent to which you agree that the following types of safety incidents are essential for international learning (shared learning):	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
3.01 All adverse events (an incident that results in harm to a patient) (WHO, 2009). [Your 1st round score = ; group median = 8]									
3.02 Incidents where risk of severe harm or death is likely, should the same incident reoccur.									
3.03 A near miss (events where no harm was done, but there could have been if people had done the same thing, and allowed it to go a stage further, it could have led to somebody's death). [Your 1st round score = __; group median = 7]									
3.04 Incidents that result from relatively novel contributory factors e.g. pandemics, electricity outage, internet outage, civil unrest, war, funding issues, natural disasters, deliberate sabotage, criminal activity.									
3.05 Patient safety risks that are new and/or have not been reported before in your country.									
3.06 Patient safety risks related to diagnostic errors.									
3.07 Incidents related to drug and equipment safety.									
3.08 Any incident type that impacts paediatric patients.									
3.09 Incident involves a product or device that might be a major contributing factor to the incident.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated patient safety incidents that you would like to make/add? If so, please provide your own changes.

3. b. Please rate the extent to which you agree that the following criteria are essential for deciding whether an incident is of international concern, particularly for international learning:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
3.10 Morbidity and mortality from patient safety risks/events (i.e. impact and severity)									
3.11 Stakeholders' interest on specific patient safety incidents / risks.									
3.12 Ease of measurement of the identified patient safety risk(s) in multiple countries.									
3.13 The availability of evidence to support unequivocal preventability.									
3.14 Identified patient safety risk(s) is / are relevant to more than one country e.g. supply of material/medicine/raw materials/devices originating in another country.									
3.15 Risk of harming a large number of individuals in multiple countries if no intervention is taken.									
3.16 Identified patient safety risk(s) is / are relevant to more than one country facing similar clinical challenges e.g. prevention and control of infectious disease.									
3.17 The proposed patient safety solution need international action, e.g. action from major pharmaceutical companies.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated patient safety incident criteria that you would like to make/add? If so, please provide your own changes.

SECTION 4: Enablers and challenges to setting up an international patient safety learning system (PSLS)

When planning to set up a learning system, especially at the international level, there are potential challenges and enabling factors that could support or hinder the process of setting up such as system. Anticipating some of these factors beforehand would help in determining the feasibility of such a system in the future.

4. a. Please rate the extent to which you agree that the following are key enablers for setting up an international patient safety learning system:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
4.01 Access for input to the system should be limited and discussed nationally, with only one named responsible organisation in each country. [Your 1st round score = __; group median = 7]									
4.02 Password-controlled access to an online platform. [Your 1st round score = __; group median = 7]									
4.03 Having political will to generate and co-ordinate patient safety interventions of international concern.									
4.04 Having internationally comparative patient safety data.									
4.05 Encouraging and funding cross-jurisdictional studies of strategies designed and evaluated to understand better system functioning and implementation impact.									
4.06 Having a standardised international patient safety taxonomy.									
4.07 Having the patient experience as a facilitator around which common definitions of harm and their priority for mitigation are set.									
4.08 The benefits for those who are supposed to feed the information to the system are very clear.									
4.09 Deploying resources/learning where they are needed most.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated enabling factors that you would like to make? If so, please provide your own changes.

4.b. Please rate the extent to which you agree that the following are key challenges/barriers to setting up an international patient safety learning system:	1 (strongly disagree)	2	3	4	5 (neutral)	6	7	8	9 (strongly agree)
4.10 Many countries have multiple reporting and learning organisations.									
4.11 Many countries are at very different maturity levels with respect to just/safety culture.									
4.12 Difficulty with funding this learning system even from participating countries.									
4.13 The "what's in it for me" problem, i.e. to find the value proposition/business case in the various and varied jurisdictions.									
4.14 Potential cost of establishing and maintaining the system.									
4.15 The information collected by this system will have limited utility if it is relying on system centric versions of patient harm without explicitly including the patient perspective of harm.									
4.16 Lack of a data / information governance strategy.									

- Where you have selected a value of 6 or below, please justify you answer(s).

i. Are there any changes or additions to the stated challenges/barriers that you would like to make? If so, please provide your own changes.

Appendix 5.1: Invitation e-mail

Dear……,

Re: Exploring the acceptability of an international patient safety learning system: an online survey

Worldwide, most healthcare organisations seek to learn from unsafe care in order to design safer systems for future care delivery. Within healthcare, multiple different types of data are collected about patient safety to inform learning from unsafe healthcare. For example, audits of care, incident reporting systems, mortality review case conferences, patient reported survey instruments and narratives. There are examples of local and national-level learning from efforts to analyse such data sources. How learning can local and national-level learning can be shared reliably and consistently at an international level is unclear.

Like in healthcare, safety incident reporting systems exist in aviation and aerospace travel, railway, and nuclear power industries, where staff can report concerns. These safety critical industries learn from accidents and communicate changes across the organisation (nationally and internationally) to make changes to reduce future risk to workers and customers. However, unlike organisations like the International Civil Aviation Organisation, which investigates accidents in aviation and has a process for sharing the lessons learnt internationally, we have been unable to identify (systematic review and interviews with experts) any examples of international learning loops in healthcare.

We have asked international experts to consider the purpose and functions of such an international patient safety learning system in healthcare. Now, in view of your experience and expertise in either patient safety, incident reporting and learning systems, quality improvement, risk management, and / or healthcare management within the Kuwaiti healthcare systems, you are invited to participate in an online survey to determine the acceptability of an international patient safety learning system, as proposed by a panel of experts in a previously conducted Delphi study.

Your participation will involve the completion of one confidential online survey asking you to answer questions that would measure your acceptability of key functions/features of a proposed international patient safety learning system. The survey will take less than 9 minutes to complete. You will have until 15/Mar/2021 to submit your answers. There are no right or wrong answers to any of the questions and issues raised in the survey. Please be assured that your submitted responses will be confidential. Anonymity will also be preserved during analysis and in the final report. The study has been approved by Cardiff University School of Medicine Research Ethics Committee (SREC reference: SMREC 20/85).

Your participation will be valuable in exploring the acceptability of a potential international patient safety learning system. Should this system be developed and tested in the future, it will be evidence-based as a result of your participation, making it potentially more suitable for use and of worth to the wider healthcare community. The results will be further explored with a potential collaboration with the WHO to perform a feasibility study and potentially pilot test the system.

What do you need to do?

Step 1: If you are willing to participate, please review, download and save the participant information sheet, accessed by clicking HERE.

Step 2: Please complete the online consent form and survey by 15/Mar/2021; **the online survey is accessible via**: https://cardiff.onlinesurveys.ac.uk/acceptability-survey-qad

If you would like further information about the study or are able to nominate colleagues with experience and expertise in either patient safety, incident reporting and learning systems, quality improvement, risk management, and healthcare management within the Kuwaiti and/or Welsh healthcare systems that would be interested in participating in the study, please contact Dr. Jaafer Qasem by e-mail further information, or forward this e-mail to them.

Thank you for your time and attention.

Yours sincerely,

Dr. Jaafer Qasem
Primary Researcher, PISA Group, Division of Population Medicine, Cardiff University

School of Medicine, Neuadd Meirionnydd, Cardiff University, Heath Park. Cardiff. CF14 4XW

Telephone: +44(0)xxxxxxxxxx

E-mail: xxxxxx@cardiff.ac.uk

Dr. Andrew Carson-Stevens
Clinical Reader, Division of Population Medicine, Cardiff University

School of Medicine, Neuadd Meirionnydd, Cardiff University, Heath Park. Cardiff. CF14 4XW

Telephone: 029 2068 xxxx

E-mail: xxxxxxx@cardiff.ac.uk

Appendix 5.2: Consent form

CONSENT FORM

Exploring the acceptability of an international patient safety learning system: an online survey

SREC reference and committee: SMREC 20/85

Research team: Dr. Jaafer Qasem, Prof. Adrian Edwards, Prof. Fiona Wood, Dr. Andrew Carson-Stevens

This online survey explores the acceptability of a proposed international patient safety learning system. The online survey will include one round of a confidential questionnaire, offered to a group of potential users of the system mentioned above. Questionnaire responses will be analysed to determine the direction in which the development of an international patient safety learning system should proceed. The aim is to determine the acceptability of proposed key requirements of a potential international patient safety learning system.

	Please initial box
I confirm that I have read the information sheet dated 27/01/2021 version 1.3 for the above research project.	
I confirm that I have understood the information sheet dated 27/01/2021 version 1.3 for the above research project and that I have had the opportunity to ask questions and that these have been answered satisfactorily.	
I understand that my participation is voluntary, and I am free to withdraw at any time without giving a reason and without any adverse consequences (e.g. to medical care or legal rights, if relevant).	
I understand that all the information I provide will be treated in confidence.	
I agree that my anonymised quotes can be used as part of the research project.	
I agree to take part in this research project.	

Name of participant (print) _____ Date _____ Signature _____

THANK YOU FOR PARTICIPATING IN OUR RESEARCH

Appendix 5.3: Participant Information Sheet

PARTICIPANT INFORMATION SHEET

Exploring the acceptability of an international patient safety learning system: an online survey

You are being invited to take part in a research study being carried out as part of Dr. Jaafer Qasem's PhD thesis.

Before you decide whether or not to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish. Thank you for reading this.

What is the background and purpose of the study?

Unsafe healthcare is a recognise international threat to public health and wellbeing. Globally, as a result of patient safety incidents, defined as, "an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient" (WHO, 2009), millions of patients are at risk of experiencing healthcare-associated harm annually.

Worldwide, most healthcare organisations seek to learn from unsafe care in order to design safer systems for future care delivery. Within healthcare, multiple different types of data are collected about patient safety to inform learning from unsafe healthcare. For example, audits of care, incident reporting systems, mortality review case conferences, patient reported survey instruments and narratives. There are examples of local and national-level learning from efforts to analyse such data sources. How learning can local and national-level learning can be shared reliably and consistently at an international level is unclear.

Like in healthcare, safety incident reporting systems exist in aviation and aerospace travel, railway, and nuclear power industries, where staff can report concerns. These safety critical industries learn from accidents and communicate changes across the organisation (nationally and internationally) to make changes to reduce future risk to workers and customers. However, unlike organisations like the International Civil Aviation Organisation, which investigates accidents in aviation and has a process for sharing the lessons learnt internationally, we have been unable to identify (systematic review and interviews with experts) any examples of international learning loops in healthcare.

Results from previously conducted systematic literature review, semi-structured key-informant interviews, and Delphi study have outlined key requirements and feasibility of an international patient safety learning system.

The purpose of this online survey is to further support, enhance and refine findings offered by the previously conducted studies concerning the key requirements and feasibility of an international patient safety learning system. Additionally, the survey explores the applicability and external validity of the findings from the previously conducted Delphi study from potential users of the system, as a mean to validate the findings.

We are seeking your opinion as a potential user/contributor to an international patient safety learning system, to participate in a confidential online survey.

Why have I been chosen to participate?

You have been invited to participate in this study due to your experience and expertise in one or more of the following areas:

- Patient Safety;
- Incident reporting/ learning systems;
- Healthcare quality improvement;
- Healthcare risk management;
- Healthcare management; and/ or,
- Working experience in Kuwaiti healthcare systems.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given a link to view or download this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Additionally, if you know of any potential participants that meet the requirements above, please forward your suggestions to the primary researcher, Dr. Jaafer Qasem, via the contact details listed below or forward this sheet along with the link to the consent form and survey.

What will happen to me if I take part and what do I have to do?

The online survey will be open between 01/Feb/2021 and 15/Mar/2021. You will be invited to participate in the survey via e-mail, which will include a link to view and download this information sheet, and another link to give your informed consent to participate prior to completing the survey by the end date. The consent form and the survey will be accessible via the same link. The online survey should take less than 10 minutes to complete, however you will have the opportunity to expand upon your answers to your own extent.

We anticipate that a final published research paper may also arise as a result of this research. You can opt in to be sent an electronic copy of the paper when you complete the survey.

What are the possible benefits of taking part?

The benefit of taking part in this study is that you will be participating in research which explores the acceptability of a proposed international patient safety learning system. Should such as system be developed, your contribution will help to ensure it is potentially more suitable for use and of worth to the wider healthcare community.

What about confidentiality?

Any data you give will be protected and secured confidentially by the research team. Other participants will not know who else is participating. The public will not know who has participated, and any quotes reported will not identify the contributor. The data collected throughout this study will be kept securely in line with Cardiff University's Research Integrity and Governance Code of Practice.

Are there any risks?

There are no risks involved in participating, however, completing the study surveys will take up some of your time.

What will happen to my Personal Data?

The secure online consent form that you will complete before participating in this research project will ask for your name and signature (typed full name). This information will only be used by the research team and will be separated from your survey responses prior to data analysis.

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:

- your rights
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection

Under data protection law we have to specify the legal basis that we are relying on to process your personal data. In providing your personal data for this research we will process it on the basis that doing so is necessary for our public task for scientific and historical research purposes in accordance with the necessary safeguards, and is in the public interest. The University is a public research institution established by royal charter to advance knowledge and education through its teaching and research activities. Our charter can be found on the Cardiff University website.

After the conclusion of the study in March 2021, your consent form will be retained for two years post publication and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised information, such as your survey response, will be kept for a

minimum of two years but may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research purposes.

You have a number of rights under data protection law and can find out more about these on our website. Note that your rights to access, change or move your personal data are limited, as we need to manage your personal information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

Completed survey data before withdrawal from the study will be anonymised and used as part of the study. Incomplete survey data will not be used. Please, note that it will not be possible to withdraw any anonymised data that has already been published. The process of anonymising your submitted survey response include the separation of the consent form from the actual survey data.

What will happen to the results of the research study?

We hope that the results of this study will determine the acceptability of a proposed international patient safety learning system from the viewpoint of potential end-users. The results of this study will direct future research of testing the feasibility of the proposed system.

Who is organising and funding the research?

The online survey is being organised by Dr. Jaafer Qasem (PhD student, Cardiff University, Sponsored by the State of Kuwait Government). Dr. Qasem's main supervisor is Dr. Andrew Carson-Stevens (Clinical Reader of Patient Safety and Head of the Patient Safety (PISA) Group, Cardiff University) and co-supervisors are Professor Adrian Edwards (Professor of General Practice, Cardiff University) and Professor Fiona Wood (Professor of Medical Sociology, Cardiff University).

Contact for Further Information

Should you have any complaints, concerns or questions at any time, you may contact the primary researcher or the primary supervisor via the contact details below. You can also use these contact details to inform the research team of your withdrawal should you so wish.

Primary Researcher:
Dr Jaafer Qasem MD MSc

PISA Group, Division of Population Medicine,
Cardiff University
5th floor, Neuadd Meirionnydd,
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CF14 4YS
United Kingdom
Tel: +44(0)xxxxxxxxxx
E-mail: xxxxx@Cardiff.ac.uk

Primary supervisor:
Dr Andrew Carson-Stevens MRCGP PhD
Clinical Reader of Patient Safety and Quality Improvement
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Neuadd Meirionnydd,
University Hospital of Wales,
Heath Park,
Cardiff,
CF14 4YS
Tel: +44 (0)29 2068 xxxx
E-mail: xxxxxxx@cardiff.ac.uk

If you are happy to participate in this study, click on the survey link included in the e-mail to complete a consent form before proceeding to the survey.

Participation in this study is entirely voluntary.

Thank you for reading this information sheet which you should download and save.

Appendix 5.4: Initial survey flow

Exploring the acceptability of an international patient safety learning system: an online survey.

A panel of international patient safety experts have outlined some key functions of an international patient safety learning system (IPSLS), and the next step is to explore the acceptability of these functions in relation to the kinds of work you do as part of your professional role in an effort to improve patient safety.

The purpose of this confidential online survey is to explore the acceptability of a proposed international patient safety learning system. Potential users of the system will be invited to complete the survey. The results of the survey will help to determine the direction of development for an international patient safety learning system. Specifically, we hope to determine the acceptability of the proposed key requirements of the system.

We define an end-user is someone who has experience in:

- Patient safety management
- Healthcare management
- Quality improvement
- Risk management

As part of your professional role, we want you to consider, hypothetically, what the implications could be of the proposed IPSLS on your work.

The survey is divided into three main sections. The first section is related to your background and experience in healthcare, and the remaining two sections will present scenarios followed by questions.

Note: you may wish to refer to Participant Information Sheet v1.3 for further information.

Background:

i.	Experience	
i.a	Profession:	Healthcare manager / quality improvement manager / risk manager / patient safety manager / other
i.b	Country:	Kuwait / other
i.c	How many years of experience do you have in the field of patient safety/quality improvement (including academic/clinical/other):	< 5 / 5 - 9 / 10 – 14 / 15 – 19 / 20+ years
i.d	At what level do you have experience in patient safety?	Primary / secondary / tertirary healthcare setting / other

Please take some time to read the following scenario which outline the key functions and features of the proposed IPSLS

Scenario 1:

You are contacted by the WHO, as a prospective end-user, to test a proposed international patient safety learning system (IPSLS). Based on extensive research and inputs from international patient safety experts, the following are examples of proposed key functions and features of the IPSLS:

- **Generating safety recommendations with solutions** that can be shared with countries and considered for adoption across different contexts in healthcare systems.
- **Supporting countries** towards a proactive and personalised clinical risk management approach i.e. **moving from a reactive to a proactive mindset for improving patient safety**.
- **Facilitating learning** and support through a range of formats (e.g. instructional manuals, train-the-trainer workshops, webinars, onsite learning)
- **Shared database** of resources that could support risk mitigation / prevention.
- **A repository for reports** describing how interventions to mitigate risk work and how to support others to support implementation elsewhere.
- **Ability to use filters to search multiple sources** of data / evidence / outputs to get to required information quickly.
- **Ability to identify contributing factors to patient safety risks** that can be transversal to certain types of incidents, contexts, and case studies.
- **Ability to trigger an alarm** that deploys a notification to countries about serious identified patient safety risks.
- **Support improvements in collection of patient safety data** through sharing exemplars.
- In the case of patient **safety incidents related to equipment and or medication**, **manufacturers will be informed to take action to mitigate and contain any further risk**.

For a complete list of proposed key functions and features click here.

1. Please rate the extent to which you agree with the following statements, based on your experience and as a potential user of the proposed system:	1 (strongly disagree)	2	3 (neutral)	4	5 (Strongly agree)
1.01 I think that an international system with such features and functions would be acceptable for my use.					
1.02 Using such a system would not require too much effort from me.					
1.03 I think it would be important to share learning from our organisation with others, internationally					
1.04 It is clear to me how the proposed features and functions of an international PSLS would help in improving patient safety at my organisation.					
1.05 Using the proposed system would not interfere with my other priorities.					
1.06 I believe that the outlined features and functions of the proposed IPSLS would effectively achieve its purpose of improving patient safety.					
1.07 I would feel confident about using the system to improve patient safety at my organisation and share learning with the international community.					

- **Do you have any comments or feedback that you would like to share? Please provide them below (optional)**

Please take some time to read the following scenario which outline patient safety data that are relevant for international sharing and learning

Scenario 2:

Now that you are aware of the key features and functions of the proposed international patient safety learning system (IPSLS), you are informed about the type of patient safety data that are to be shared by users to facilitate learning at the international level. Such data might include the following:

- Incidents that involve a **product or device that might be a major contributing factor** to the incident.
- Incidents where **risk of severe harm or death is likely**, should the same incident reoccur.
- Incidents related to **drug and equipment safety**.
- Incidents related to **manufacturing and supply chain** (e.g. contaminated vaccine/IV fluids/injections/drugs)
- Incidents related to **faulty medical devices** (including IVDs) or **equipment failure**.
- Incidents that result from **relatively novel contributory factors** e.g. pandemics, electricity outage, internet outage, civil unrest, war, funding issues, natural disasters, deliberate sabotage, criminal activity.
- Patient safety **risks that are new and/or have not been reported before in your country**.

For a complete list of proposed patient safety data to be shared click here.

2. Please rate the extent to which you agree with the following statements, based on your experience and as a potential user of the proposed system:	1 (strongly disagree)	2	3 (neutral)	4	5 (Strongly agree)
2.01 I feel that sharing these types of patient safety data would be beneficial to improving patient safety.					
2.02 Sharing such data would not require too much effort from me.					
2.03 Sharing the proposed patient safety data would be ethical and in line with my personal values.					
2.04 It is clear to me how sharing learning from patient safety data at the international level would help the IPSLS improve patient safety.					
2.05 I would not have to give up something else important to use the proposed IPSLS					
2.06 I believe that sharing the proposed patient safety data would help the IPSLS improve patient safety at my organisation.					
2.07 I would feel confident about using the system to share the suggested patient safety data to improve the safety of healthcare delivery at my organisation.					

- **Do you have any comments or feedback that you would like to share? Please provide them below (optional)**

Appendix 5.5: Final Survey Flow

Exploring the acceptability of an international patient safety learning system: an online survey.

A panel of international patient safety experts have outlined some key functions of an international patient safety learning system (IPSLS), and the next step is to explore the acceptability of these functions in relation to the kinds of work you do as part of your professional role in an effort to improve patient safety.

The purpose of this confidential online survey is to explore the acceptability of a proposed international patient safety learning system. Potential users of the system will be invited to complete the survey. The results of the survey will help to determine the direction of development for an international patient safety learning system. Specifically, we hope to determine the acceptability of the proposed key requirements of the system.

We define an end-user is someone who has experience in:

- Patient safety management
- Healthcare management
- Quality improvement
- Risk management

As part of your professional role, we want you to consider, hypothetically, what the implications could be of the proposed IPSLS on your work.

The survey is divided into three main sections. The first section is related to your background and experience in healthcare, and the remaining two sections will present scenarios followed by questions.

PARTICIPATION

Your participation is this survey is voluntary. The survey will take approximately 9 minutes to complete.

BENEFITS AND RISKS

The benefit of taking part in this study is that you will be participating in research which explores the acceptability of a proposed international patient safety learning system. Should such as system be developed, your contribution will help to ensure it is potentially more suitable for use and of worth to the wider healthcare community.

There are no risks involved in participating, however, completing the study surveys will take up some of your time.

CONFIDENTIALITY

Any data you give will be protected and secured confidentially by the research team. Other participants will not know who else is participating. The public will not know who has participated, and any quotes reported will not identify the contributor. The data collected throughout this study will be kept securely in line with Cardiff University's Research Integrity and Governance Code of Practice.

Note: you may wish to refer to Participant Information Sheet v1.3 for further information.

CONTACT

Should you have any complaints, concerns or questions at any time, you may contact Dr. Jaafer Qasem via the contact details below. You can also use these contact details to inform the research team of your withdrawal should you so wish.

E-mail: xxxxx@cardiff.ac.uk

WhatApp: +44xxxxxxxxxx

ELECTRONIC CONSENT

By ticking the box below, you indicate that

- You have read the above information
- You voluntarily agree to participate
- You understand that all the information that you provide will be treated in confidence.
- You agree that your anonymised quotes can be used as part of the research project.

Section 1: Background

i.	Experience	
i.a	Profession:	Healthcare manager / quality improvement manager / risk manager / patient safety manager / other
i.b	Country:	Kuwait / other
i.c	How many years of experience do you have in the field of patient safety/quality improvement (including academic/clinical/other):	< 5 / 5 - 9 / 10 – 14 / 15 – 19 / 20+ years
i.d	At what level do you have experience in patient safety?	Primary / secondary / tertirary healthcare setting / other

Section 2: Please take some time to read the following scenario which outline the key functions and features of the proposed IPSLS

Scenario 1:

You are contacted by the WHO, as a prospective end-user, to test a proposed international patient safety learning system (IPSLS). Based on extensive research and inputs from international patient safety experts, the following are examples of proposed key functions and features of the IPSLS:

- **Generating safety recommendations with solutions** that can be shared with countries and considered for adoption across different contexts in healthcare systems.
- **Supporting countries** towards a proactive and personalised clinical risk management approach i.e. **moving from a reactive to a proactive mindset for improving patient safety**.
- **Facilitating learning** and support through a range of formats (e.g. instructional manuals, train-the-trainer workshops, webinars, onsite learning)
- **Shared database** of resources that could support risk mitigation / prevention.
- **A repository for reports** describing how interventions to mitigate risk work and how to support others to support implementation elsewhere.
- **Ability to use filters to search multiple sources** of data / evidence / outputs to get to required information quickly.
- **Ability to identify contributing factors to patient safety risks** that can be transversal to certain types of incidents, contexts, and case studies.
- **Ability to trigger an alarm** that deploys a notification to countries about serious identified patient safety risks.
- **Support improvements in collection of patient safety data** through sharing exemplars.
- In the case of patient **safety incidents related to equipment and or medication**, **manufacturers will be informed to take action to mitigate and contain any further risk**.

For a complete list of proposed key functions and features click here.

1. Please rate the extent to which you agree with the following statements, based on your experience and as a potential user of the proposed system:	1 (strongly disagree)	2	3 (neutral)	4	5 (Strongly agree)
1.01 I think that an international system with such features and functions would be acceptable for my use.					
1.02 Using such a system would not require too much effort from me.					
1.03 I think it would be important to share learning from our organisation with others, internationally					
1.04 It is clear to me how the proposed features and functions of an international PSLS would help in improving patient safety at my organisation.					
1.05 Using the proposed system would not interfere with my other priorities.					
1.06 I believe that the outlined features and functions of the proposed IPSLS would effectively achieve its purpose of improving patient safety.					
1.07 I would feel confident about using the system to improve patient safety at my organisation and share learning with the international community.					

- **Do you have any comments or feedback that you would like to share? Please provide them below (optional)**

Section 2: Please take some time to read the following scenario which outline patient safety data that are relevant for international sharing and learning

Scenario 2:

Now that you are aware of the key features and functions of the proposed international patient safety learning system (IPSLS), you are informed about the type of patient safety data that are to be shared by users to facilitate learning at the international level. Such data might include the following:

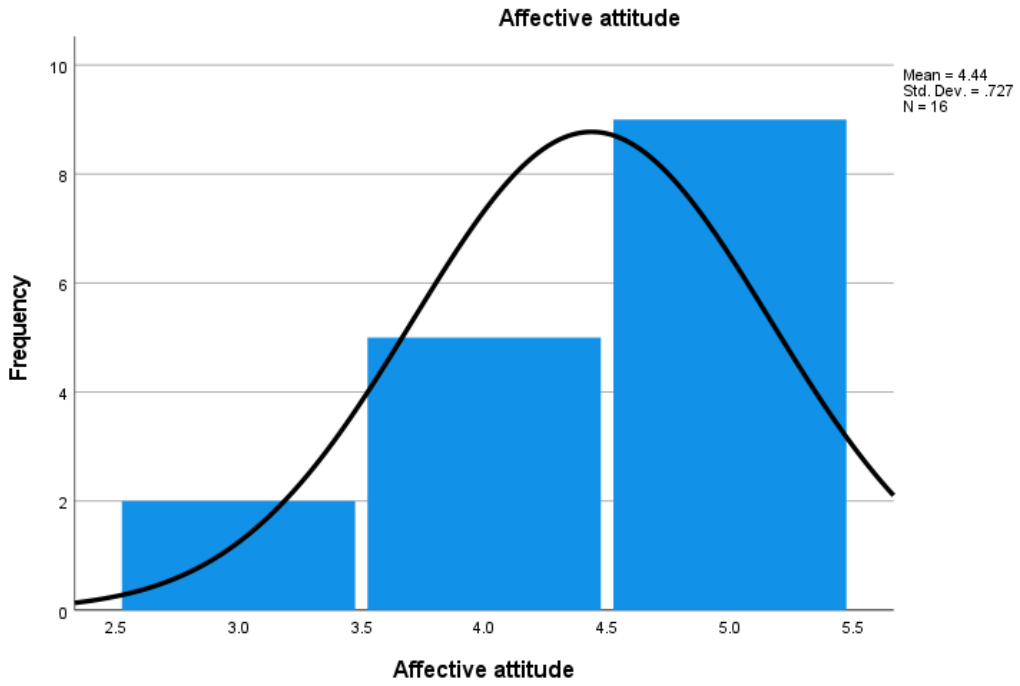
- Incidents that involve a **product or device that might be a major contributing factor** to the incident.
- Incidents where **risk of severe harm or death is likely**, should the same incident reoccur.
- Incidents related to **drug and equipment safety**.
- Incidents related to **manufacturing and supply chain** (e.g. contaminated vaccine/IV fluids/injections/drugs)
- Incidents related to **faulty medical devices** (including IVDs) or **equipment failure**.
- Incidents that result from **relatively novel contributory factors** e.g. pandemics, electricity outage, internet outage, civil unrest, war, funding issues, natural disasters, deliberate sabotage, criminal activity.
- Patient safety **risks that are new and/or have not been reported before in your country**.

For a complete list of proposed patient safety data to be shared click here.

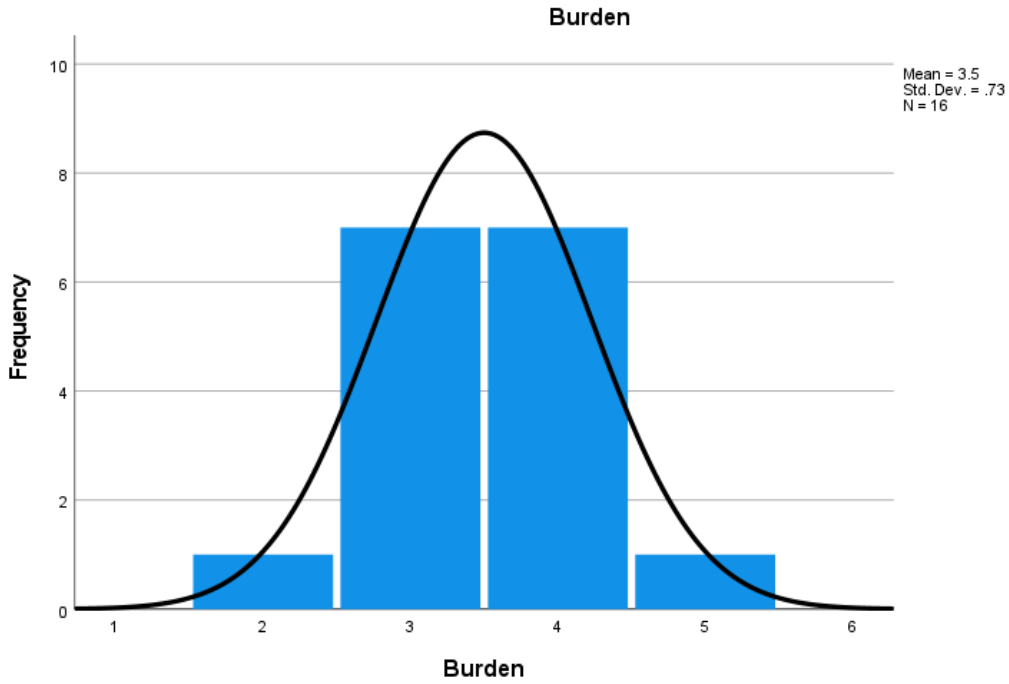
2. Please rate the extent to which you agree with the following statements, based on your experience and as a potential user of the proposed system:	1 (strongly disagree)	2	3 (neutral)	4	5 (Strongly agree)
2.01 I feel that sharing these types of patient safety data would be beneficial to improving patient safety.					
2.02 Sharing such data would not require too much effort from me.					
2.03 Sharing the proposed patient safety data would be ethical and in line with my personal values.					
2.04 It is clear to me how sharing learning from patient safety data at the international level would help the IPSLS improve patient safety.					
2.05 I would not have to give up something else important to use the proposed IPSLS					
2.06 I believe that sharing the proposed patient safety data would help the IPSLS improve patient safety at my organisation.					
2.07 I would feel confident about using the system to share the suggested patient safety data to improve the safety of healthcare delivery at my organisation.					

- **Do you have any comments or feedback that you would like to share? Please provide them below (optional)**

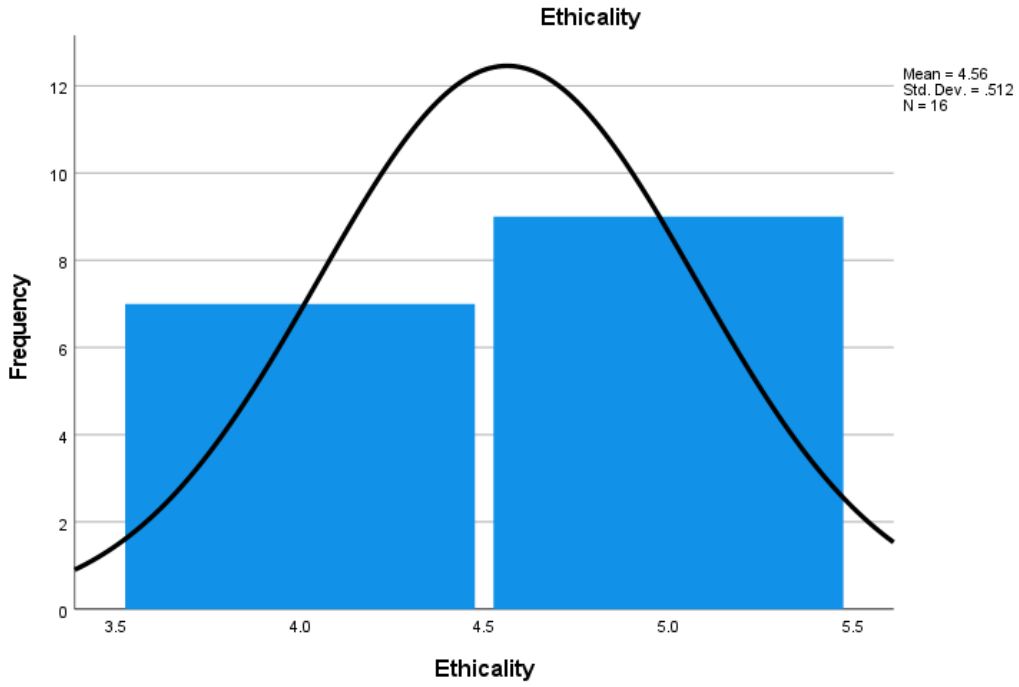
Appendix 5.6: Histograms of the seven constructs of the TFA for section one of the survey



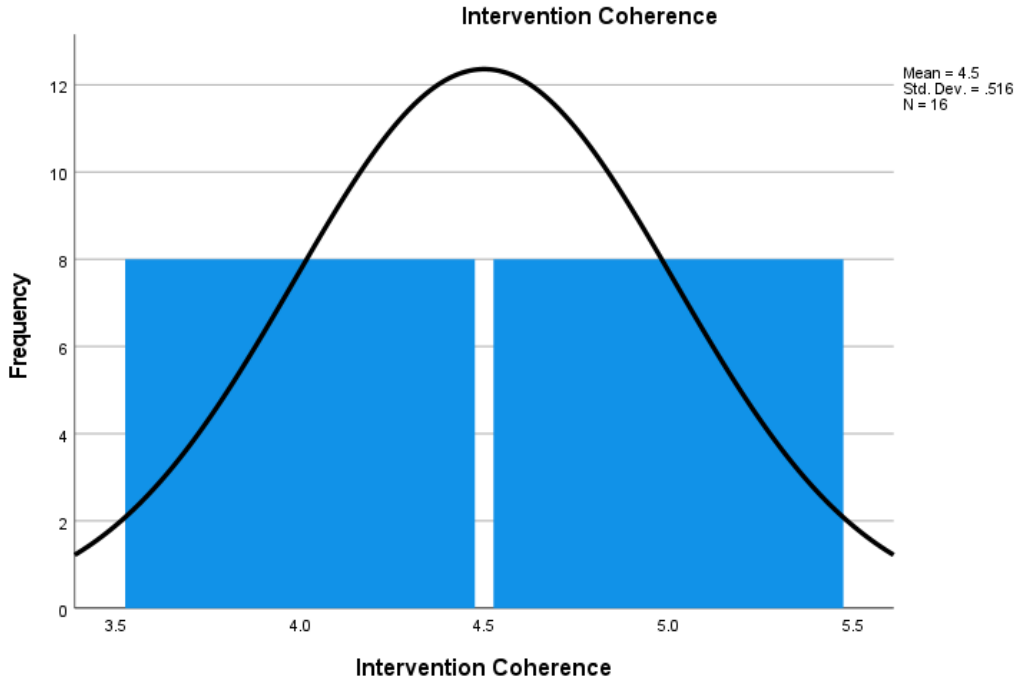
Histogram of Affective attitude construct for section one of the survey



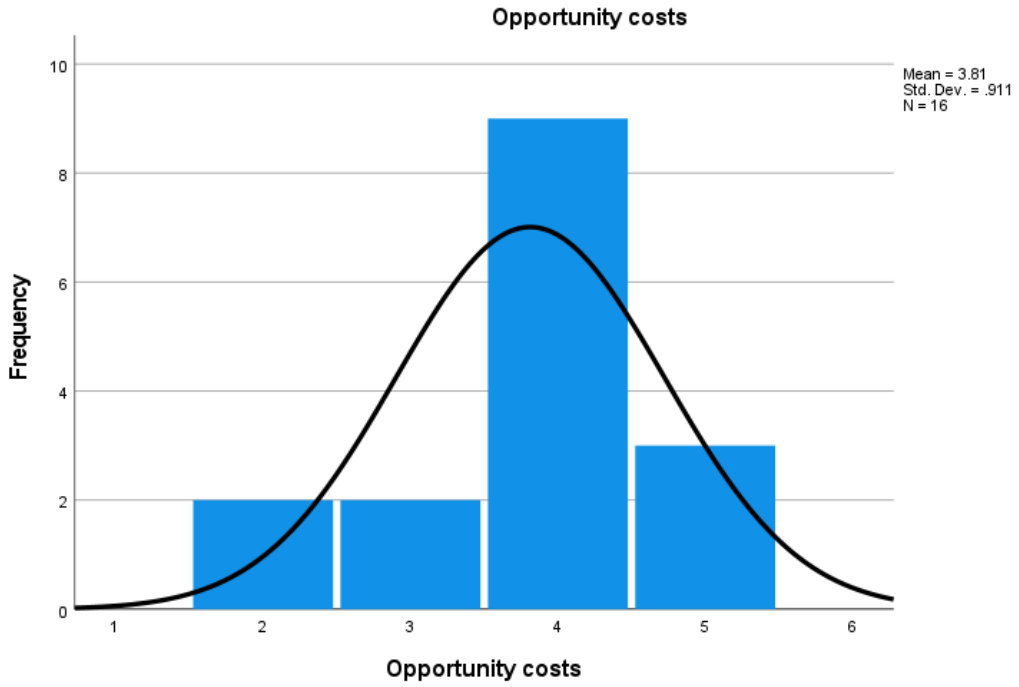
Histogram of Burden construct for section one of the survey



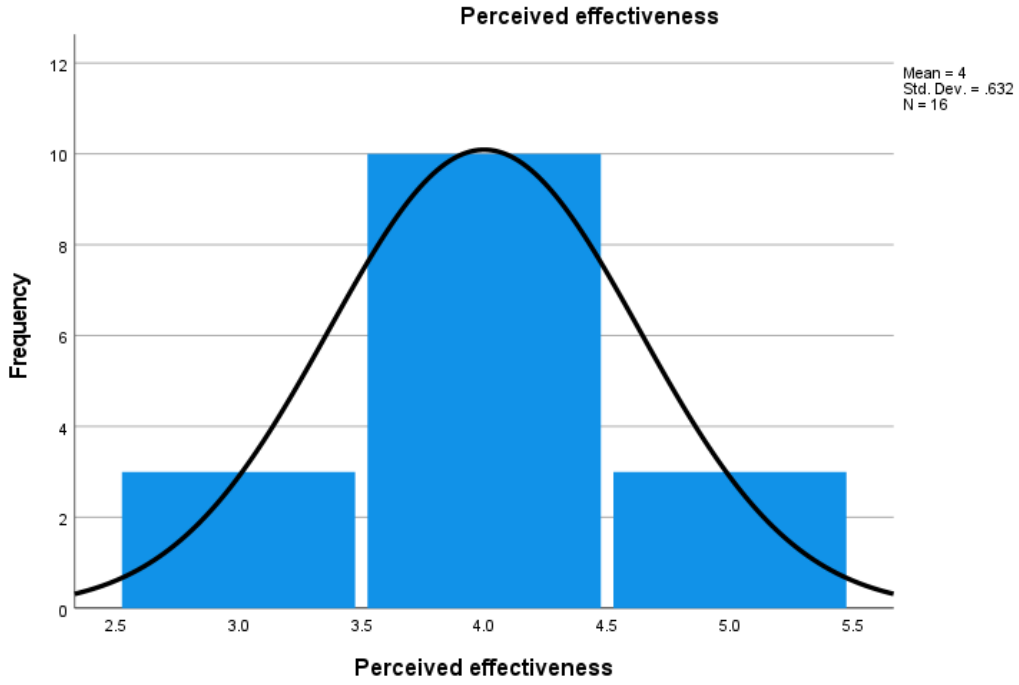
Histogram of Ethicality construct for section one of the survey



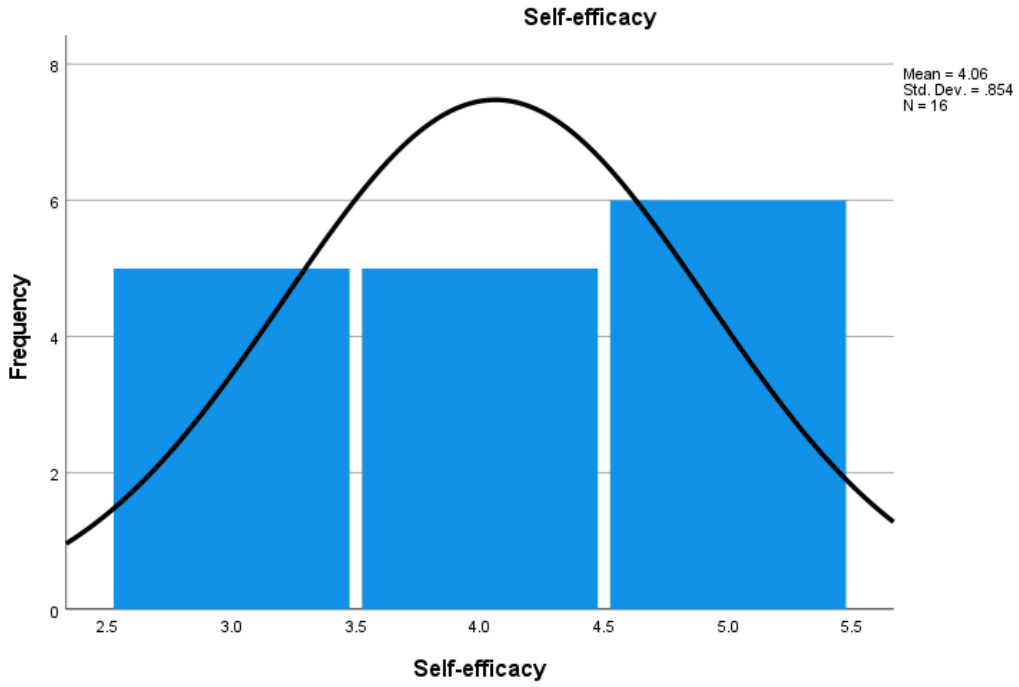
Histogram of Intervention Coherence construct for section one of the survey



Histogram of Opportunity costs construct for section one of the survey

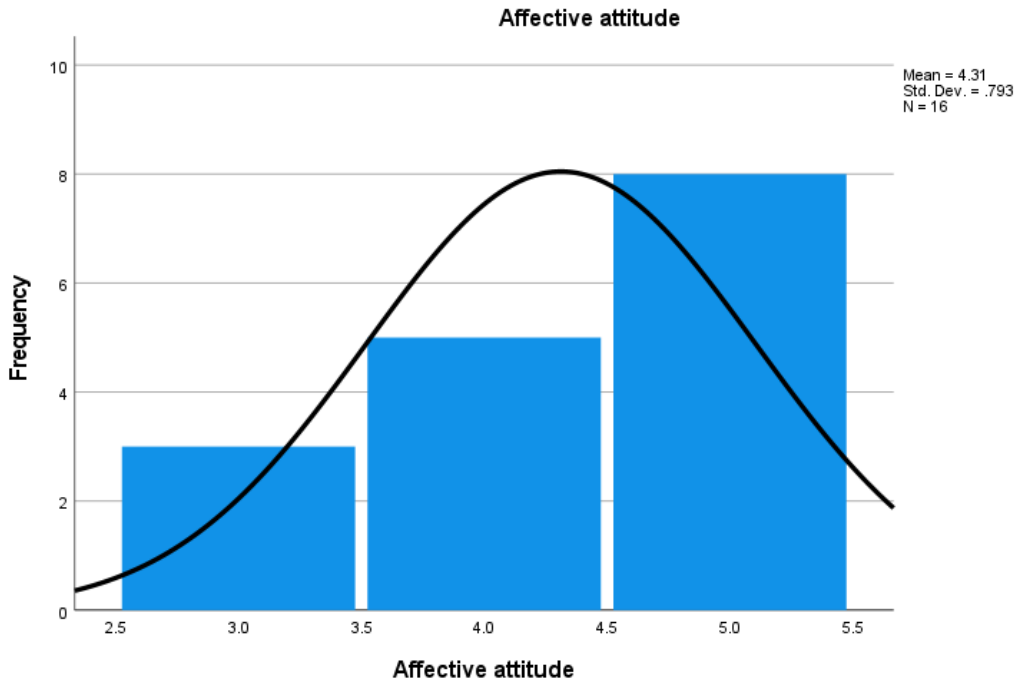


Histogram of Perceived effectiveness construct for section one of the survey

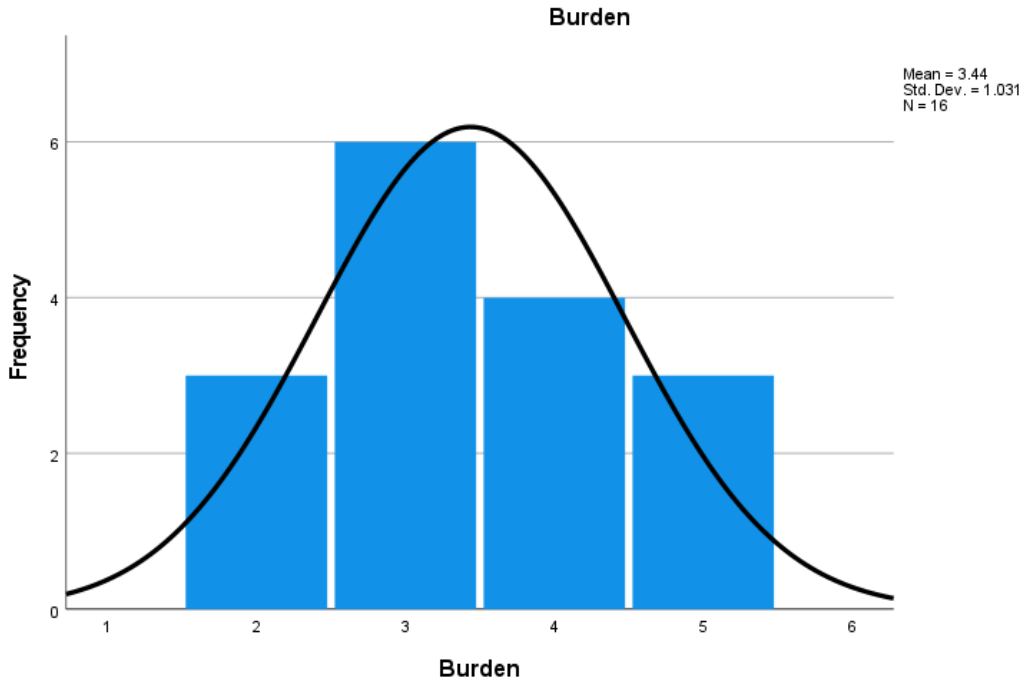


Histogram of Self-efficacy construct for section one of the survey

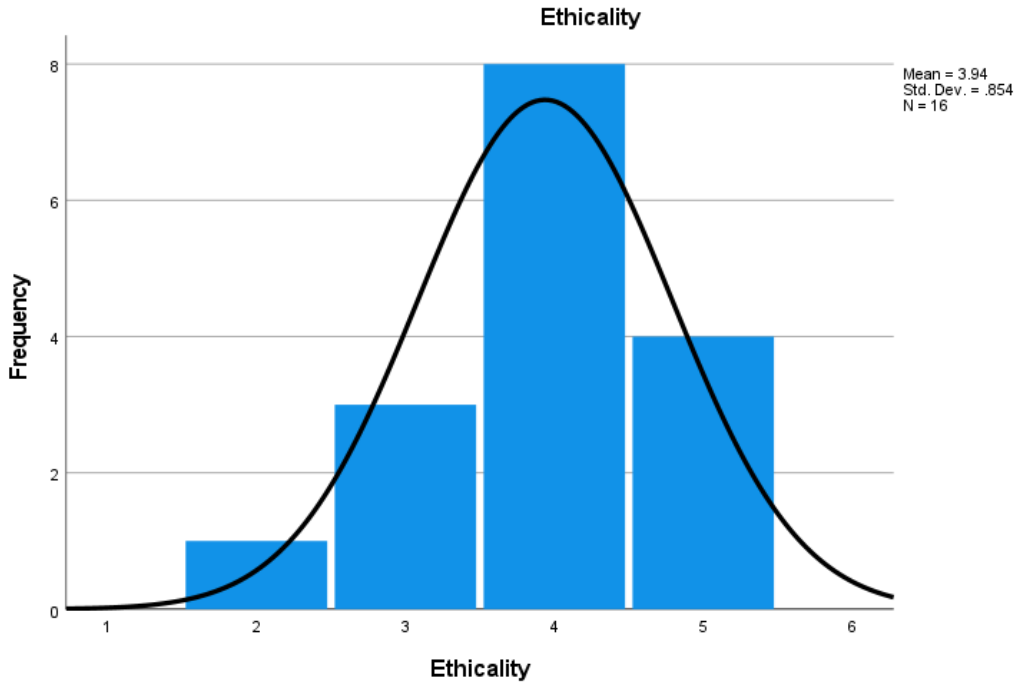
Appendix 5.7: Histograms of the seven constructs of the TFA for section two of the survey



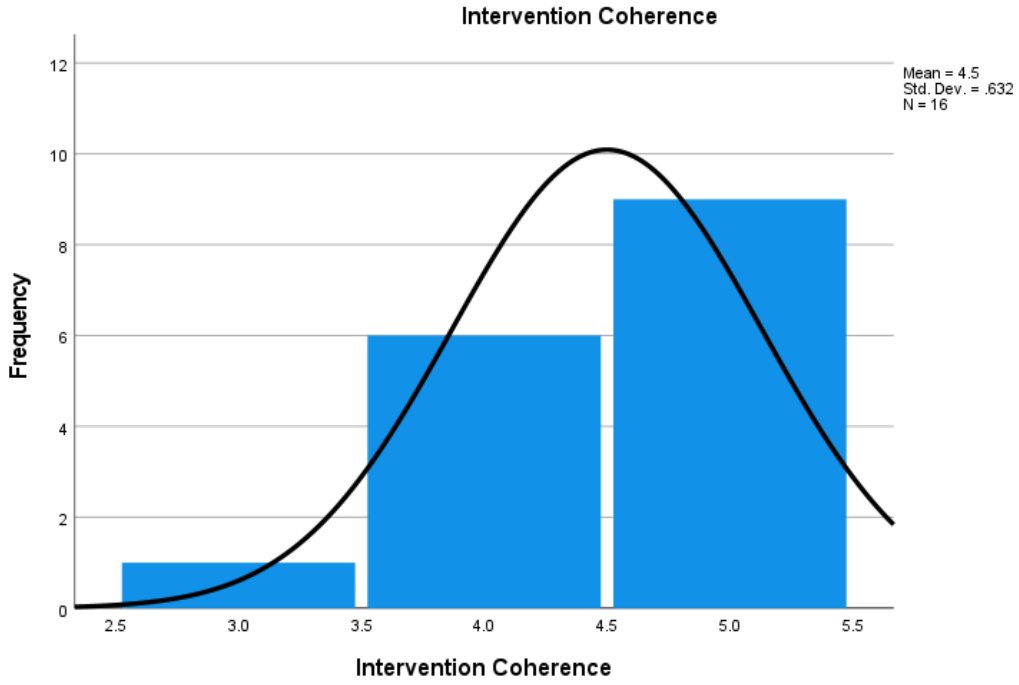
Histogram of Affective attitude construct for section two of the survey



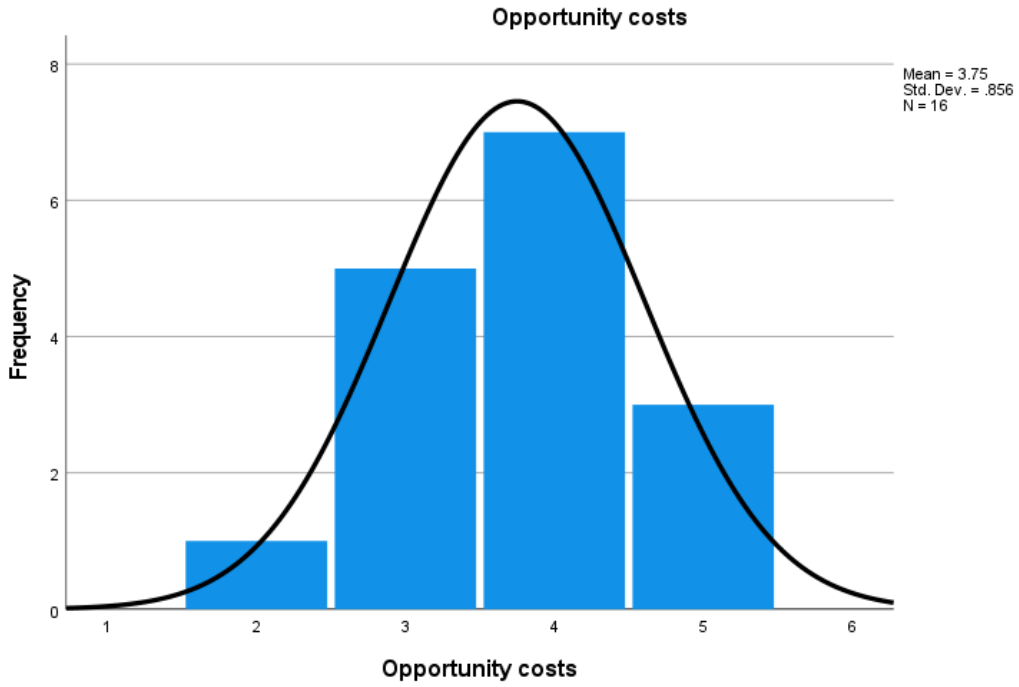
Histogram of Burden construct for section one of the survey



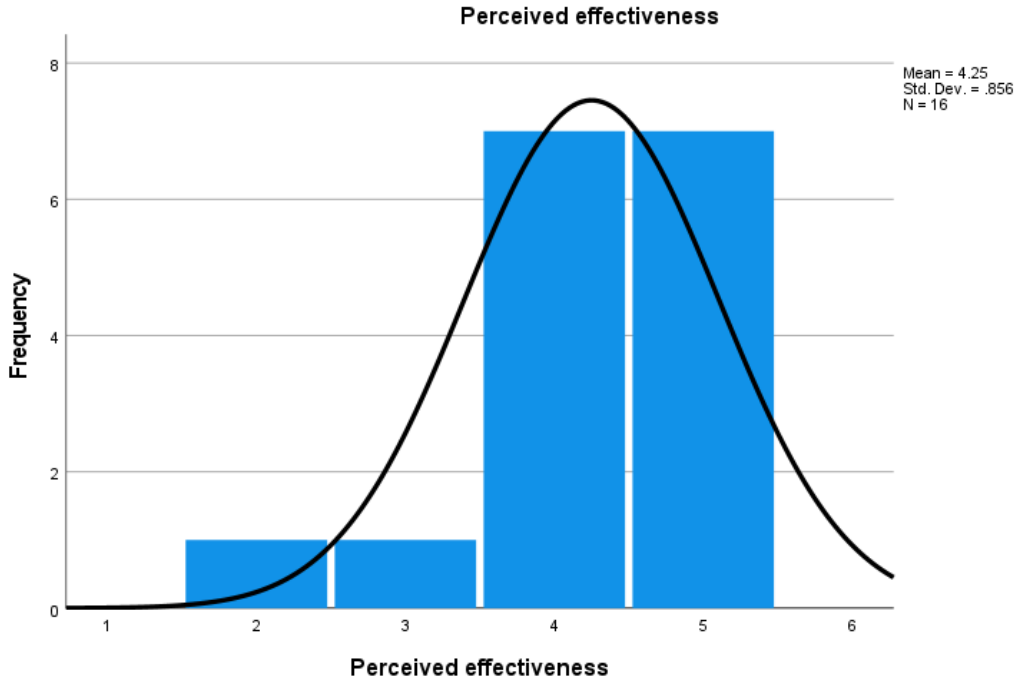
Histogram of Ethicality construct for section one of the survey



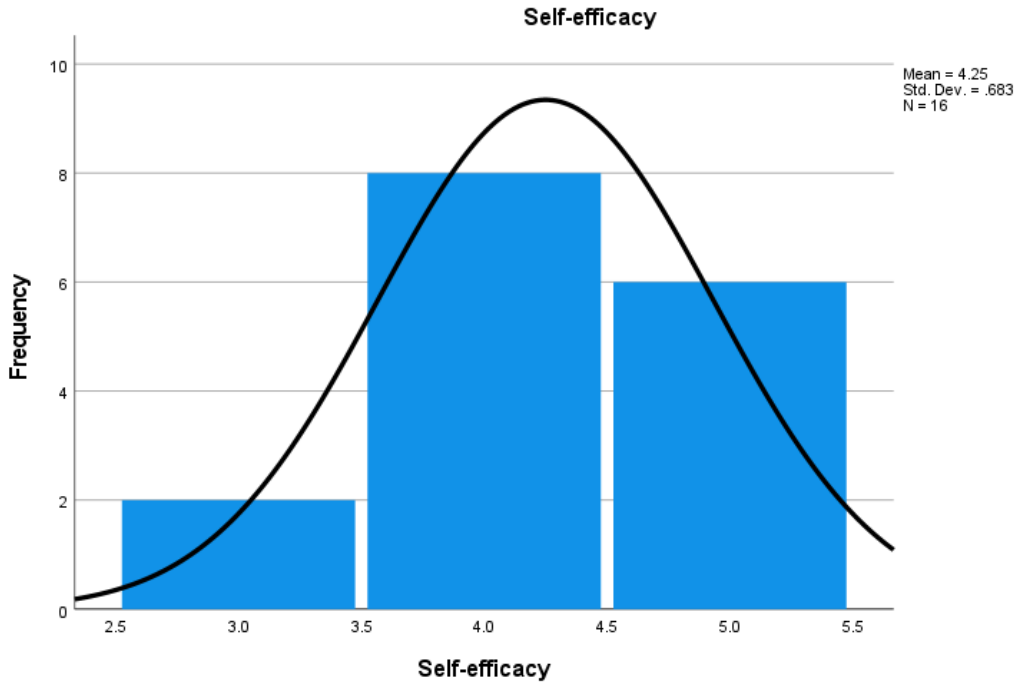
Histogram of Intervention Coherence construct for section one of the survey



Histogram of Opportunity costs construct for section one of the survey



Histogram of Perceived effectiveness construct for section one of the survey



Histogram of Self-efficacy construct for section one of the survey

Appendix 5.8: Respondent validation survey

Exploring the acceptability of an international patient safety learning system: an online survey

The purpose of the survey was to measure the anticipated acceptability of a proposed international patient safety learning system (IPSLS) from the viewpoint of potential end-users.

The survey utilised the Theoretical Framework of Acceptability (Sekhon, Cartwright, & Francis, 2017), which is composed of seven distinct constructs.

These constructs are defined in table 1 and were measured for each scenario in the survey.

Table 1. the seven constructs of the Theoretical Framework of Acceptability (TFA)

Construct	Definition
Affective attitude	How an individual feels about the intervention, prior to taking part
Burden	The perceived amount of effort that is required to participate in the intervention
Ethicality	The extent to which the intervention has good fit with an individual's value system
Intervention Coherence	The extent to which the participant understands the intervention and how it works
Opportunity costs	The extent to which benefits, profits, or values must be given up to engage in the intervention
Perceived effectiveness	the extent to which the intervention is perceived to be likely to achieve its purpose
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention

In order to complete the analysis of the survey, there are a couple of issues that I would like your feedback on. These are outline below.

Burden:

Based on your response, Burden had a median of 3.5 and 3 in both sections of the survey (3 = Neutral, 4 = Agree, 5 = strongly Agree), while other constructed had medians of 4 and above.

I think this might be because of the following:

- The amount of effort required to use the international system was not specified.

Do you agree with this assumption?

Please provide your opinion on that in the box below.

I also think that it could be because of this:

- The system might not be easy to use and/or user-friendly and thus requiring too much effort to use such a system.

Do you agree with this assumption?

Please provide your opinion on that in the box below.

Section 2 of the survey: patient safety data that are to be shared by users to facilitate learning at the international level

Based on your response, there is a statistically significant difference ($p= 0.042$) in the perceived effectiveness construct.

I think that this might be because of the following:

- Lack of clarity as to what those working in healthcare facilities might consider as essential patient safety learning data.

Do you agree with this assumption?

Please provide your opinion on that in the box below.
