Assessment of measuring and monitoring safety in healthcare in Ireland and Saudi Arabia

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in fulfilment of the requirements for the degree of Doctor of Philosophy

By

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Declaration

This work is submitted to fulfil the requirement of the degree of Doctor of Philosophy, at the University of Galway. No part of this thesis has been previously submitted at this or at any other university. There is a declaration at the beginning of each chapter to identify my contribution to each study.

Signed: Date 21 July 2023

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Summary of Thesis

In the past two decades, governments worldwide have prioritised the improvement of health care quality and safety as a primary policy goal. However, progress towards achieving this goal has been limited. The provision of poor care and the prevalence of high levels of harm persist in hospitals. Measurement is considered a crucial and essential initial step in the process of improving patient safety. However, while measuring and monitoring patient safety is widely recognised, there is a lack of agreement on how to achieve it. In this thesis, a multi-method approach was taken to address the dimensions in the Measuring and Monitoring Safety (MMS) framework developed by Vincent et al. to provide a structure for understanding how safety is measured and monitored in hospitals in Ireland and Saudi Arabia.

Study 1 is a scoping review of patient safety research carried out in the Republic of Ireland (RoI). It examines the extent, range, and nature of patient safety research activities carried out in the RoI; makes recommendations for future research; and considers how these recommendations align with the Health Service Executive's (HSE) patient safety strategy. Study 2 considers how safety is measured and monitored in Irish hospitals and offers recommendations for how it can be improved. Study 3 is a scoping review that maps the quantity and nature of current patient safety research in Saudi Arabian hospitals, as well as identifies gaps in the existing literature. Finally, study 4 assesses the Saudi Arabian healthcare safety surveillance system in hospitals using the MMS framework.

The findings from the four studies conducted in this thesis demonstrate the availability of an adequate amount of safety data, the availability of diverse methods for collecting safety data, and the expertise necessary to improve safety. The challenge is to identify the most efficient methods for generating key and high-quality data that can help multidisciplinary teams in developing effective interventions tailored to specific health contexts.

Acknowledgements

While this thesis has been a long and very challenging journey for me, from being locked down in my first weeks here in Ireland due to a global pandemic to developing health issues in my final year of doing a PhD, I still think it was an invaluable opportunity overall, from which I gained many important intellectual, academic, and life lessons. I'd like to take this opportunity to express my gratitude to the people who helped and encouraged me during this difficult yet interesting journey; without them, none of this would have been possible.

My most sincere gratitude goes to Dr. Paul O'Connor, my research supervisor. Paul, you have been extremely helpful, welcoming, and patient with me as a new research student and as an international student who was unfamiliar with Galway and Ireland. I have learned so much from you, including research skills, academic writing, an outstanding work ethic, courageous leadership, and dedication. I also consider myself really fortunate to have had you not just as a research supervisor but also as a great person whom I respect so much and look up to. Your unwavering support was critical to my completing my PhD, and I appreciate you knowing that there is more to life than a PhD, especially for a young couple who has just moved to a new country with a small child.

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student and colleague with whom I've shared many fruitful hours of work and from whom I've learned a great deal.

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I want to thank my parents for their unending encouragement and support throughout my life. I appreciate all they have done for me and my siblings, and I know they would go to any length to ensure our happiness and success in life. I simply wanted to say that, despite the ups and downs, I have always seen you as heroic, kind, and exceptional individuals, and I can only hope that this provides you with some happiness and satisfaction. To my brothers and sisters, I am grateful that you have never stopped believing in me and supporting me.

Last but not least, I want to express my greatest thanks to my wonderful wife Alaa and our amazing son Abdullah for their love, support, and patience throughout the years. I know it hasn't been easy, but we made it, and for that and for all you've done for me, I will be forever thankful.

I have spent over 15 years away from my home country, Saudi Arabia, and from family and friends in pursuit of a higher education and more promising career prospects. This seems like an unbelievable moment to me, but I guess it's happening.

Dedication

I would like to dedicate this to my parents, my wonderful wife Alaa, and our amazing son Abdullah.

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List of Abbreviations

CBAHI	Central Board for Accreditation of Healthcare Institutions
CPOE	Computerised Physician Order Entry
CRM	Crew Resource Management
FMEA	Failure mode and effect analysis
HIQA	Health Information and Quality Authority
HROs	High Reliability Organisations
HRT	High-Reliability Theory
HSE	Health Services Executives
HSPSC	Hospital Survey on Patient Safety Culture
ICPS	International Classification for Patient
IRSs	Incident Reporting Systems
JCAHO	Joint Commission on Accreditation of Healthcare Organisations
KFHU	King Fahd Hospital of the University
KFSH&RC	King Faisal Specialist Hospital and Research Centre
LTI	Lost time injury
MMS	Measuring and Monitoring Safety
NSP	National Service Plan
OECD	Organisation for Economic Cooperation and Development
OECD	Organisation for Economic Co-operation
PRISMA-ScR	Preferred Reporting Items for Systematic Reviews and Meta- Analyses extension for Scoping Reviews
QMD	Quality Management Division
RCA	Root Cause Analysis
RoI	Republic of Ireland
SAQ	Safety Attitudes Questionnaire
SSC	Surgical Safety Checklists

Chapter 1

General Introduction

General Introduction: The Importance of Patient Safety

Maintaining high standards of patient safety is a core principle of all healthcare systems [1]. The increased focus on patient safety in recent times can be attributed to the publication of landmark reports such as the 1999 Institute of Medicine report 'To err is human' in the US and the 2000 Department of Health 'An organisation with a memory' report in the UK, which brought the issue of medical error and patient harm into the public eye [1]. However, despite substantial investments in patient safety initiatives in recent years [1], international studies have found that rates of patient harm remain high, with 3%–17% of admissions associated with an adverse event caused by medical management, negligence, or substandard care [2,3]. The number of patients experiencing harm from services that are intended to improve health is concerning. This is evident particularly in low-income and middle-income countries, with 134 million adverse events occurring annually due to unsafe care in hospitals, contributing to approximately 2.6 million deaths [4,5]. This means one in four patients in low-income and middle-income countries experience avoidable harm, compared to one in ten in high-income countries [1,5]. Such data has resulted in significant efforts internationally to tackle and reduce this avoidable harm.

Harm that reaches the patient, however, may range from minor such as a wound caused by a patient's fall in a hospital, requiring only minor treatment such as stitches and a dressing [6], to an adverse event, which is defined as an injury caused by healthcare management that leads to prolonged hospitalisation, disability on discharge, or death [7]. It has been found that a relatively high proportion of adverse events are preventable. Early studies in the 1980s found that 58% of adverse events were preventable [8]. Disappointingly, recent studies have shown similar results, with most adverse events examined classified as preventable (e.g., over 70% in Ireland and 91.6% in Saudi Arabia are deemed to be preventable) [9,10]. Beyond the human cost, patient harm places a significant financial burden on healthcare systems and social costs on

patients and their families. Recent estimates suggest that 15% of hospital expenditure in Organisation for Economic Cooperation and Development (OECD) countries is spent on managing the consequences of failures in the safety of healthcare [11]. Furthermore, the social costs (e.g., lost income or lost household production) of preventable harm can be valued to US$ 17 billion to US$ 29 billion a year [8].

With the agreed importance of reducing preventable harm and the associated human and economic, and the social costs, there has been an increasing focus on patient safety within the research literature in recent years, with a growing body of literature describing different approaches and initiatives to improve patient safety [12]. The spike in the number of publications and journals dedicated to the issue of patient safety in the past two decades was also accompanied by several governments' reactions to safety concerns by making significant efforts, such as the establishment of national patient safety agencies [13]. Additionally, patient safety has been a priority within national health strategies [14-16], and in recognising that improving patient safety is a major challenge to health service delivery globally, the WHO developed a global patient safety action plan titled ‘towards eliminating avoidable harm in health care’ with the aim of achieving the maximum potential reduction in preventable harm caused by unsafe health care globally over the next 10 years (2021–2030) [4]. This global action plan calls on governments to prioritise patient safety in healthcare policies and programmes in order to provide safe care to all patients. The plan consists of 35 strategies designed to achieve seven strategic objectives. The sixth strategic objective is concerned with providing a continuous flow of information and knowledge to help with risk mitigation, reducing preventable harm, and improving safety. However, the lack of high-quality information systems is a significant obstacle to international, national, and local efforts to achieve this objective. One of the plan's strategies for achieving this objective is to create a patient safety information system that is integrated with existing health management information systems and is based on all available data on risks and harm related with healthcare

delivery [1] Because most patient safety data is currently used in a reactive manner, with significantly less emphasis placed on efforts that utilise such data for anticipative, proactive learning, the plan asks for a more in-depth examination of safety measurement, which should be based on data received from multiple sources on a routine basis [1]. Collaboration with researchers on measurement and improvement research is an action proposed by the plan to reach this objective, as this will generate the knowledge required to help better understand safety measurement and the various sources of valid and reliable data to perform key activities (e.g., setting safety priorities, benchmarking, and tracking safety performance) [1]. This is expected to improve the capability of both healthcare systems and healthcare practitioners to improve safety.

Therefore, reducing errors, preventing harm, and developing high-reliability health systems and organisations that protect patients from risks are universally regarded as core objectives of patient safety [4]. A number of impediments exist to realising these objectives, such as the availability of technology and resources for healthcare workers, the presence of a blame culture, and the focus on individual actions as opposed to the underlying systemic issues that contribute to medical error and patient harm [17]. One of the primary obstacles is that health organisations are not regularly measuring and monitoring patient safety appropriately and accurately [18]. This is a crucial activity because it assesses if the health service provided is safe, tracks progress, compares safety performance across different units or departments, and evaluates the effectiveness of safety initiatives. Implementing appropriate systems for measuring and monitoring safety is therefore essential to reducing the occurrence of avoidable harm. Accordingly, the examination of systems of measuring and monitoring patient safety in hospitals within two healthcare systems is the core focus of this thesis.

Chapter Overview

Having offered an introduction to the issue of avoidable harm in healthcare settings, this chapter will now move to defining the key patient safety terminology that will be used throughout the thesis. Subsequently, it will discuss healthcare provision in secondary care settings, emphasising the nature and scale of harm in secondary care settings in comparison to other levels of healthcare. This will be followed by an overview of the Irish and Saudi Arabian healthcare systems, given that the data collected and offered in the remaining PhD chapters is derived from these two healthcare systems. Then, the Vincent et al's Measuring and Monitoring Safety (MMS) framework [18,19] will be introduced, along with an explanation of how it can be used to appraise safety in healthcare. Finally, the chapter will conclude with a presentation of the aims of this thesis, how they relate to the MMS framework, and how they contribute to patient safety research.

Definitions of Concepts within this Thesis

Patient Safety

In the literature on patient safety, it is common for the same term to have several definitions; thus, as a means of elucidation, and to provide a shared understanding for the studies that follow, I will define some of the most often used terms in this thesis.

Although 'quality' and 'patient safety' are related concepts, they are not interchangeable [20]. Safety is one of the six key domains of quality, which also include effectiveness, patient-centeredness, timeliness, efficiency, and equity [21].

Patient safety can be defined as "the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the process of healthcare" (p.31) [22]. As indicated in the definition, harm may be used to differentiate between patient safety concerns and broader quality of care concerns. When compared to other quality issues, safety is

thought to be what patients are most concerned about, simply because they do not want to be harmed by the services that are supposed to help them [20]. However, defining harm, on the other hand, has been arguably a difficult issue due to several reasons, including the difficulties of determining whether harm was due to the health service provided or the health condition of the patient; some treatments are necessarily harmful to patients, such as chemotherapy; harm from healthcare may not immediately be detected or may only gradually become apparent; and if a patient is harmed, this does not necessarily point to any deficiencies in care [20].

As noted, some treatments are necessarily harmful, and therefore, it is important to understand the concept of preventable harm. A review aimed at surveying the medical literature for existing and emerging definitions of preventable harm concluded that the most common definition is “presence of an identifiable, modifiable cause of harm” [23]. For the reasons stated above, it is argued that if we are to make progress in patient safety, the focus of patient safety efforts should be on preventing harm rather than errors. A commitment to eliminating preventable harm in healthcare features in the WHO’s Global Patient Safety Action Plan 2021–2030 [1] detailed earlier, which aims to reduce preventable harm from unsafe healthcare globally.

Error is defined as “failure to carry out a planned action as intended or application of an incorrect plan” [24]. Previously, the healthcare industry, like many others, strove to avoid discussing errors. However, it wasn't until Leape published “Error in Medicine” in the early 1990s which aimed to shift healthcare workers' perspective away from seeing errors as moral failings and towards seeing them as the results of a system failure [24,26]. The author suggested that the presence of a blame and punishment policy after an individual mistake by a healthcare worker was the main reason why error was a red flag for many healthcare workers, and its discussion was avoided. Furthermore, healthcare workers have been taught that they should never make a mistake and that

if they do, it is a reflection of their own failings. However, Leape (2021) argues that any system reliant on error-free operation is guaranteed to fail [25] since human error is inevitable.

Secondary Care

The focus of this thesis is on secondary care. Secondary care is mainly hospital-based and focuses on acute care, maternity, and specialist services. In comparison to primary care, levels of patient harm in secondary care are larger in volume and more severe in nature [27,28]. These factors may explain why most patient safety research has focused on hospital-based care settings rather than primary care settings [29,27,28].

Irish and Saudi Arabian Healthcare Systems

Health care systems can be categorised based on their financing arrangements, and they vary from a free market with little or no government involvement to a government monopoly system funded by taxation [30]. This thesis draws upon data collected from, and about, the Irish and Saudi Arabian healthcare systems.

Irish healthcare system. The Irish healthcare system is a mixed system of funding and provision structures, and is difficult to categorise it as either a private insurance model, which is defined by the absence of state input, or a national health service model, which is defined by universal coverage funded by general taxation, such as the United Kingdom [30]. The system has elements of both of these models. However, the responsibility for providing health services falls on the Health Services Executives (HSE), the largest organisation in the state, whose objective is to efficiently implement the resources available to them to deliver services that improve, promote, and protect the public's health and welfare [31,32]. In terms of hospitals, Ireland has three types of hospitals: statutory public hospitals that are owned and funded by the HSE; voluntary public hospitals that are funded through service level agreements; and independent private hospitals where healthcare services

are purchased via insurance companies or through patients' out-of-pocket payments [30]. There are 48 public hospitals and 21 private hospitals serving a population of 5,123,535 people in Ireland [32].

Saudi Arabian healthcare system. In Saudi Arabia, the government is committed to providing universal coverage through a network of healthcare facilities provided primarily by the Ministry of Health. According to the most recent data from 2021, Saudi Arabia has a total of 497 hospitals serving a population of 34,110,821 people. Of these hospitals, 287 are MoH hospitals, compared to 51 other government agencies hospitals, and 159 private hospitals. The MoH is taking the lead in the delivery of health services, as it provides 57.8% of hospitals in the country [33].

Comparison of these healthcare systems. The analysis of patient safety within these two healthcare systems was carried out largely as a result of circumstances and convenience rather than by design. The original plan for my PhD was to focus only on measuring and monitoring safety (MMS) in Saudi Arabia and carry out a co-design project in order to identify the methods of MMS that stakeholders in Saudi Arabian healthcare believe should be used to MMS within their hospitals. However, I started my PhD just as Ireland and the rest of the world were locking down due to the COVID-19 pandemic. Due to travel restrictions and the high workload of healthcare workers, it was not possible to complete all of my research in Saudi Arabia as I had originally planned. Therefore, a pragmatic decision was made, and supported by my supervisors and the Graduate Research Committee, to consider MMS in both healthcare systems as part of this thesis.

Although the decision to consider MMS in Ireland and Saudi Arabia was not the original plan for the thesis, there is clear value in considering how MMS is carried out in these two healthcare systems. First, by comparing data from two countries with distinct economies (a developed economy in Ireland and a developing economy in Saudi Arabia) [34], healthcare systems (a mixed system of financing in Ireland compared to a publicly

financed system in Saudi Arabia), I will be able to consider and examine differences as well as common issues; this is important in clarifying and supporting the generalizability of my thesis findings. Second, both countries' healthcare systems are undergoing national healthcare reform programmes, with the first fundamental steps starting in 2021. In Ireland, the National Service Plan (NSP) for 2021, which outlines the types of healthcare services to be provided, emphasises the improvement of the quality and safety standards of acute healthcare and the continuation of the National Patient Safety Strategy 2019–2024 as a priority. In Saudi Arabia, the National Transformation Program 2020, which defines government actions for participating entities to achieve Saudi Arabia's Vision 2030 goals, includes the Ministry of Health's strategic objective to improve patient safety standards. Therefore, improving patient safety is one of the primary goals of both of these national programmes. Therefore, the information offered in this thesis will be timely, relevant, and engaging, and it will enable researchers, policymakers, and healthcare providers to understand the present strengths and weaknesses and, in the future, to evaluate long-term progress in patient safety. Third, this comparison will illuminate learning opportunities. For example, what one country excels at in terms of research, policy, or practices that another country might learn from. In contrast to Saudi Arabia, Ireland, for example, has research centres whose mission it is to develop evidence, particularly on patient safety and its application in practice within the context of the Irish healthcare system. This indicates the recognised importance of context for the implementation and effectiveness of safety interventions. Access to such resources may be one of the reasons why Ireland, rather than Saudi Arabia, is likely in a better position to generate more research into safety interventions and their effectiveness.

Measuring and Monitoring Safety in Healthcare

The Significance of Patient Safety Measurement

Measurement is the first step in improving patient safety [35], and the significance of patient safety measurement in healthcare may be underscored by the famous management maxim, "you can't improve what you can't measure" [36,37]. There is a legitimate practical need to assess safety, and healthcare providers and organisations need a mechanism to show the presence of safety objectively and practically in the care they provide. This requires a form of measurement to ascertain whether the care is safe, monitor improvement, analyse disparities in safety performance between departments, and evaluate the efficacy of safety initiatives [38]. For these reasons, healthcare organisations consistently, though not always systematically, gather safety information in an effort to look for assurance in this data [38]. However, most healthcare organisations in most countries have yet to achieve comprehensive patient safety measurement that extends beyond past harm measurement, which is often accomplished via incident reporting [4,39]. The availability of data from multiple sources is essential for comprehensive safety measurement and the evaluation of the impacts of safety improvement initiatives [4].

Measuring patient safety is a multidimensional process [40]. Thus, numerous studies in the literature indicate that healthcare organisations should use balanced and comprehensive frameworks to measure and monitor patient safety, such as the Vincent et al., MMS framework [41-44]. Rather than focusing just on assessing past harm using incident reporting as the dominant measure, as is commonly done, such a framework would ensure consideration of the multifaceted nature of safety and include multiple safety measures that are retrospective, present-looking, and prospective [45,46]. A typical approach that focuses primarily on past harm provides only a partial perspective, leaving policymakers ill-equipped to adopt appropriate and effective initiatives, perhaps leading in resource misallocation and false reassurance [47].

Therefore, it is vital that we continue to strengthen the robustness and comprehensiveness of patient safety measurement in order to provide a more credible assessment of success based on a fuller picture of safety [47]. However, comprehensive safety measurement requires a solid information infrastructure to ensure the availability of timely safety data collected through valid and reliable patient safety measurement and monitoring methods. [48,49]. The lack of high-quality safety information derived from valid and reliable methods of MMS is a substantial impediment to informed decision-making and action, and it impedes attempts to enhance patient safety [49].

How can safety be measured and monitored?

It has been suggested that learning from how other high-risk industries measure safety can be extremely informative to healthcare organisations. However, little attention is paid to how this might be achieved in practice [18,19]. The Measuring and Monitoring Safety (MMS) framework developed by Vincent et al., [18,19] offers a comprehensive conceptual model to guide health organisations in the measurement and monitoring of safety. Academic research and practical experience, including three scoping reviews covering safety measurement in high-risk industries, such as aviation and nuclear industries, interviews with senior healthcare managers in national organisations, case studies, conceptual methods and models of system safety, and research on measuring safety in healthcare, were all part of the development process of the framework [18,19].

Even though the tools and approaches used in industries such as aviation, oil, nuclear, construction, food, and manufacturing may not be entirely applicable to healthcare, the authors focused on identifying sources and knowledge that would specifically assist healthcare organisations in learning from how these industries measure safety. The following paragraphs will describe the key concepts learned from other industries and influenced the development of and theories informing Vincent et al.'s MMS framework.

Reactive and proactive measures

One of the most basic safety measures that has been used since the 1970s is concerned with calculating the rates of injuries or deaths. In aviation, for example, it is often heard that 'aeroplanes are the safest form of transportation' and this is based on measures such as deaths per billion passenger journeys. This may be categorised as a reactive measure because it takes into consideration safety events that have already occurred. Other similar measures often used in construction and manufacturing settings include the lost-time injury (LTI) frequency rate or incident reporting [18,19]. In healthcare, measures of harm are deemed the most frequently used and often form the foundation of a healthcare organisation's safety management system [50]. Harm in healthcare is typically assessed using incident reporting systems, which are considered the most prominent method compared to all other methods of MMS. However, it is inaccurate to assess or monitor an organisation's overall safety based just on the number of incidents, injuries, or deaths. This is because these methods are considered reactive and are only concerned with past safety incidents [18,19].

An effective safety surveillance system should use both reactive and proactive methods to evaluate safety (i.e., incident reporting systems and prospective risk assessment) [18,19]. For example, many industries, including healthcare, use behavioural-based observations, typically direct observations of performance, as a proactive measure of safety. At a construction site, for instance, an occupational and health safety supervisor will use a checklist to evaluate each behavioural item and record whether it has been performed safely [18,19]. This is similar to some standardised practices in healthcare, such as compliance with hand hygiene procedures, which are often monitored by the infection control departments in health organisations. It is important to note here that these proactive methods do not necessarily require collecting only quantitative data, such as the rate of injuries or deaths or the number of behavioural items that have been performed safely, but also qualitative data, which can be as simple as talking to patients or having conversations with

clinical teams [18]. An example of this is the newly introduced "Walk and Talk" improvement initiative in Ireland, which aims to capture personal stories of healthcare workers and patients regarding patient safety and communicate them as podcasts on social media platforms [51]. Another important proactive measure is the evaluation of safety culture. Safety culture reflects the attitudes, beliefs, perceptions, and values that employees have regarding safety. [52,53]. Safety culture is often assessed using surveys administered at different points in time to monitor and analyse trends in areas of strengths and weaknesses related to safety culture [54]. Another form of proactively assessing safety is using safety cases. Safety cases are defined as "a documented body of evidence that provides a convincing and valid argument that a system is adequately safe for a given application in a given environment" [18]. Safety cases are required when there is a potential for a tragic outcome. They are used in the aviation, oil, and gas industries to demonstrate that a system is developed safely before it is put into operation. In healthcare, for example, they are required prior to RCTs and operating medical devices and are usually regulated by a national organisation such as the Food and Drug Authority in Saudi Arabia and the USA, which determines when a safety case is needed and provides guidance on how to develop a safety case [18,19].

To sum up, healthcare and other high-risk industries can use both reactive and proactive methods to acquire the data needed to assess safety. Some of the methods described above are used in healthcare as well as other high-risk industries like aviation and construction, showing that there is a potential for transferable knowledge across industries.

Six Conceptual Approaches Related to Safety

There are a variety of conceptual models and theories of safety available in the wide body of safety literature, each with its own distinct focus. These models were developed to emphasise the need for a systems approach to safety, which entails considering all the factors that impact safety across all system levels as well as the external environment. While

developing their framework, Vincent et al. identified six models that inform how safety should be measured and monitored in healthcare. These models contributed significantly to the development of the framework and are essential for understanding each dimension and its importance. Each of these models is summarised below.

James Reason's organisational accident model. Reason's system model was one of the early approaches that has gained attention in healthcare because it shifts the focus of failure away from the accountable individual towards a systemic understanding of organisational factors that contribute to human error [55]. Reason postulates that accidents occur because of both 'active' and 'latent' conditions. Active failures are caused by human operators near the actual event. They often result in a safety event but are typically the outcome of 'latent' system conditions. The existence of latent conditions is a direct result of the planning and execution of systems, procedures, and management policies [55,56]. The model suggests that there are three stages that contribute to the progression of accidents: the organisational factors stage, the local workplace factors stage, and the unsafe acts stage. Organisational factors can include strategic decisions such as planning, regulating, and scheduling (i.e., planning workforce and workload). Any failure resulting from these organisational processes is transferred to the local workplace (i.e., the intensive care unit), where they create the local conditions (i.e., a high workload and an inexperienced workforce). Many unsafe acts can be committed on an individual level, and some will penetrate the layers of defences and harm a patient [55-57]. Hence, many of the underlying causes of accidents in high-risk organisations may be traced back to decisions made long before the accident occurred. To demonstrate this, researchers who analysed 2000 reported incidents found that 90% of accidents were attributed to organisational factors [58]. That's why it makes sense that Reason's belief that improving overall safety may be achieved by monitoring latent conditions and addressing evident system flaws is logically sound.

Vincent's framework for the analysis of clinical incidents (London Protocol). Vincent's framework for clinical incident analysis, commonly known as the London Protocol, expands on Reason's organisational accidents model to include examples of health sector failure types [59,60]. The London protocol provides a framework for investigating potential system factors that may contribute to active failures. These factors may be environmental, contextual organisational, task, and team factors. The protocol aim is to provide a structured approach that ensures a thorough investigation and analysis of an incident, going beyond the typical identification of fault and accountability [59,60]. It is intended for use by clinicians, risk and patient safety managers, researchers, and others who want to reflect on and learn from clinical accidents. The protocol has gained widespread popularity compared to other alternative approaches because of several properties: it addresses human factors in healthcare; it is simple to apply; it involves less time and resources; and it is context-free, allowing it to be applied in a variety of work settings [61].

High-Reliability Theory (HRT). The High-Reliability Theory (HRT) was developed in the late 1980s by a group of researchers at the University of California Berkeley who were interested in investigating safety in high-hazard sectors [62]. The HRT has been helpful to safety experts since it also places emphasis on system factors, which can be major triggers of incidents. A core aspect of HRT is the term 'high reliability organisations' (HROs), which are described as those that share particular cultural features that allow them to function in extremely risky settings while maintaining a nearly perfect safety record [63]. The study of HROs started with researchers examining safety in high-risk sectors, particularly aviation and nuclear power, due to their good safety record and low failure rate. These researchers sought to determine how organisations may attain consistent, failure-free performance over extended time periods in the face of dynamic and challenging conditions [64]. These safety experts believe that meeting such challenges requires key measures and organisational culture features such as robust basic

procedures, frequent redundant checks, prompt feedback for control decisions, and high levels of communication among workers [63-65]. However, despite a strong emphasis on protocols and procedures, senior management must still have the authority to immediately modify the course of operations. Hence, reliability is attained not only via standardisation, but also through adaptation to the circumstances, recognising current needs, and making timely judgements [63-65]. Research that aimed to apply the HRT as a framework to common hospital safety practices such as medication double-checking, crew resource management (CRM), computerised physician order entry (CPOE), incident reporting, and root cause analysis (RCA) indicates that HRT can significantly contribute to improving patient safety in hospitals [65].

Collective Mindfulness. Based on their research of high-reliability organisations (HROs), Weick and Sutcliffe developed the concept of "collective mindfulness" which they describe as a persistent commitment to revise routines, processes, perceptions, expectations, and behaviours in light of observations and thoughtful preparation [64]. The researchers suggest that there are five key indicators of collective mindfulness in HROs. The first indicator is concerned with a ‘preoccupation with failure’ which means that HROs are always on the lookout for signals that a safety issue is emerging, and near misses are seen as evidence of issues rather than confirmation that systems have adequate safety measures. The second indicator is ‘reluctance to simplify interpretations’ which indicates that HRO staff are aware that safety issues can be multifaceted, and they reject the tendency to simplify observations and instead focus on identifying root causes of errors. The third indicator is ‘sensitivity to operations’ which suggests that HROs discover early signs of organisational performance issues, which commonly arise as minor operational changes, and ensure that staff involved in operations always report deviations from expected performance. The next indicator is 'commitment to resilience' which requires HROs to spot and fix faults rapidly, preventing them from becoming serious hazards, and for leaders

and staff to be trained to react to such faults and correct failure-causing practices. Finally, the ‘deference to expertise’ indicator requires that HROs have systems in place to determine who among its members has the most relevant expertise for handling a new threat and delegate decision-making power to them [64]. In addition to these five indicators, Hales (2016) discovered that HROs also have "fast, accurate, and robust information systems" [66]. The author contends that these characteristics are required of HROs as the sixth indicator of effective communication, which supports the previous five indicators [66].

System dynamics and safety. This approach differs from the others outlined above in that it considers safety and reliability as a process of compensation and reaction to dynamic change rather than a single state or group of properties [18,67]. Rene Amalberti developed an important model based on his research on safety management in several high-risk industries. This model portrays how dynamic forces drive a system gradually closer to the thresholds of safe operation over time. The author claims that rules and standards violations (defined as intended deviations from standard instructions) cause more accidents than unintentional errors [18,67]. The author adds that non-adherence varies according to the type of instruction, the nature of the task, and the social and organisational context, all of which are affected by individual motivation as well as broader social and organisational processes [18,67]. The Amalberti model is particularly important for health care because rules tend to be less binding and explicit than in other high-hazard industries. Even though many guidelines and policies exist, these are often viewed as recommendations rather than strictly enforced rules [18]. A major strength of this model is that it combines a dynamic systems view of safety and risk with a psychological appreciation of the behavioural drivers underlying violations. At the social level, deviations may become normalised and from then on accepted as routine, if provoked by consistent and persistent conditions over time. According to Macrae, professionals in charge of improving and regulating patient safety often overlook, misinterpret, or disregard organisational and sociocultural

factors that may serve as early warnings or indicators of growing risks. For them, identifying, interpreting, integrating, and acting on such early warnings represents a serious challenge [68]. However, the author suggests that before we can investigate these factors, we must first understand the types of data that are typically noticed, disseminated, and given attention to, as well as those that are considered and ignored [69].

Safety as resilience. In the same vein as the system dynamics approach, the concept of 'resilience' is defined as the capacity of individuals, groups, and organisations to detect, respond to, and recover from both expected and unexpected disturbances to continue safe operation. Resilience and resilience engineering place an emphasis on proactive measures as opposed to reactive measures that analyse past failures, and because resilience is dynamic, system dynamics models have typically been used to explore resilience in organisational systems. Hollnagel, for example, distinguishes resilience engineering from other approaches used in healthcare by using the concepts of 'Safety 1' and 'Safety 2'. Safety 1 is concerned with 'what may go wrong' and how to prevent it. It focuses on analysing and managing past failures to prevent reoccurrences and negative outcomes. Safety 2 aims to avoid negative outcomes as well, but it focuses on 'what goes right' particularly the system's capacity to respond to expected and unexpected flaws 'in order to be resilient' [69]. The authors also explain that distinguishing 'work as imagined' from 'work as done' is crucial as safety science advances from the 'Safety 1' approach to the 'Safety 2' approach that focuses on excellence. "Work as imagined" refers to the collective understanding of how designers, managers, regulators, and authorities believe work occurs or should occur, as articulated by a set of standards and rules outlining how things should work. It makes the erroneous assumption that if standard operating procedures are properly carried out, safety will naturally follow. Work as done, on the other hand, is how the work is described by those who actually do it; in the healthcare industry, this would be the healthcare providers who interact with patients [18].

To summarise, the conceptual models of system safety presented above contributed to the development of the MMS framework. While these models and approaches are drawn from the broader safety literature, which includes industries other than healthcare, they are useful informative resources because they provide novel ideas about safety that have the potential to significantly impact approaches taken to improve safety in healthcare [18,19].

Measurement of safety in other relevant industries

In addition to Vincent et al.'s research into system safety models and approaches, including some of the important ones outlined above, Vincent et al. also looked at how other industries measure safety as part of the framework development process. While many would argue that not all safety-measuring methods used in other high-risk industries are applicable to healthcare practice, nonetheless, the authors proposed two fundamental concepts that help healthcare professionals understand the approaches that might be used to measure safety. The first concept is "lagging indicators," which is a term used in industrial workplaces to describe the actions taken after a safety event has occurred (i.e., incident reports). On the other hand, the second term is ‘leading indicators’ which refers to methods that proactively monitor essential industrial workplace activities and are considered to reduce hazards and ensure safety (i.e., safety walk-rounds). Since these industries are believed to be ahead of healthcare in terms of safety initiatives, it has long been assumed that lagging indicators must be supplemented with leading indicators.

Modern patient safety frameworks

The measuring and monitoring safety framework (MMS) is one of several frameworks in the literature that all aim to improve patient safety. This section will discuss the relationship between the MMS framework and key patient safety frameworks. First is the Patient Safety Incident Response Framework 2022 (PSIRF), which describes the NHS's strategy for building and maintaining efficient systems for addressing patient

safety issues and enhancing patient safety through learning and development [70]. The PSIRF advocates for the use of data from various sources, including impacted patients, to facilitate learning and also integrates patient safety incident response into improvement efforts [70]. It calls for healthcare organisations to reconsider incident investigation and instead employ the framework to promote learning as opposed to analysing what went wrong [70]. However, the framework retains the use of a safety I approach, in which improvements are derived from past failures, as opposed to the safety II approach, which was designed to revolutionise the way safety is conceptualised in complex systems such as healthcare [62]. Safety II approaches propose that healthcare organisations could potentially gain further insights into safety by conducting an analysis of both routine operations as well as past incidents [62]. Past incidents are often used on a global scale for learning purposes, but an effective safety monitoring system should include both reactive and proactive measures [1]. In fact, the World Health Organisation advises against over-reliance on past incidents as the only basis for safety monitoring systems [1]. Instead, they advocate a balanced approach that incorporates proactive safety measures [1]. Similarly, Wood et al., 2023 argue that the newly implemented PSIRF is but one element in a pathway for learning and enhancement. The authors believe that the application of the Safety II approach is still in its early phase, despite the longstanding recognition of the concept in the literature on patient safety [71].

Similarly, nearly all of the Patient Safety Indicators (PSIs) developed by the Agency for Healthcare Research and Quality (AHRQ) in the United States are intended to monitor patient safety events that could have been prevented in the hospital setting [72]. These indicators use automated screening of administrative data to identify areas for improvement in care delivery. However, the PSIs primarily focus on reactive methods, such as the in-hospital fall-associated fracture rate and pressure ulcer rate [72]. Moreover, there is little research on the validity of PSIs outside the United States, and those studies that do exist only cover a limited number

of PSIs [73]. The challenge arises from the fact that healthcare systems across the world do not adhere to the same standards for administrative data, coding, and clinical processes as those in the United States [73]. The coding quality, in particular, which is a vital factor in determining the success of PSIs, differs across countries and healthcare organisations [73]. Thus, healthcare professionals outside of the United States encounter significant challenges when attempting to employ these PSIs. To illustrate, a large Swiss study that analysed 16 out of the 18 PSIs and compared their validity in nine hospitals revealed significant variations across hospitals [73]. Similarly, the use of AHRQ-PSIs in English hospital data posed significant challenges, mostly due to disparities in data quality and coding practices [74]. The MMS framework acknowledges reactive methods, such as those discussed above, but it categorises them only into one dimension, "past harm." The MMS framework stands out due to its incorporation of additional dimensions for safety assessment, including, for example, “anticipation and preparedness”. This dimension covers proactive methods such as evaluating staffing levels and skill mix [18,19].

The Manchester Patient Safety Framework (MaPSaF) is another useful framework developed for understanding the relatively new concept of a safety culture in healthcare [75]. This framework was developed specifically for healthcare organisations to pause and reflect on their safety culture and understand at what level the culture is at [75]. It allows them to determine the degree to which their safety culture falls within a spectrum that ranges from the "pathological level," characterised by a dismissive attitude towards patient safety issues, to the "generative level," characterised by the incorporation of patient safety into every aspect of their operations [75]. The framework primarily emphasises safety culture, which is widely regarded as fundamental to any endeavours aimed at enhancing safety. It consists of ten dimensions that healthcare organisations should consider in order to identify the strengths and weaknesses of their patient safety culture [75]. However, the designers of the framework explicitly state that it should not be used for

performance management or assessment purposes [75]. Furthermore, similar to the previously mentioned indicators and frameworks, it fails to recognise the complex nature of patient safety and the several components that must be considered when evaluating it, opting instead to concentrate on a single component. In contrast, the MMS framework stands out as an overarching framework that considers all the key dimensions of patient safety and the methods to evaluate each dimension [18,19]. The next section goes into further detail about the five safety dimensions included in the MMS framework.

The Measuring and Monitoring Safety Framework

Past harm. The first dimension of the MMS framework focuses on the question, "Has patient care been safe in the past?" and can be addressed by examining rates of past harm to patients, both physical and psychological. Previously, patient safety has been centred on approaches that focus on learning from and avoiding mainly past tragic safety events [20]. Patient safety, however, has been extensively researched in the last two decades, and it has become evident that it encompasses considerably more than just preventing such tragic yet rare events [20]. This means that all areas of healthcare delivery that may cause harm must be addressed. Basically, because patients may be harmed in a variety of ways when receiving medical care [18], Vincent et al. grouped these ways into six categories. The six categories of harm include treatment-specific harm (e.g., adverse effects of chemotherapy), harm due to over-treatment (e.g., overuse of antibiotics), general harm from healthcare (e.g., healthcare-acquired infection), harm due to failure to provide appropriate treatment (e.g., failure to give prophylactic antibiotics before surgery), harm resulting from delayed or inadequate diagnosis (e.g., either the patient delaying contacting the doctor, or the primary care doctor misdiagnose the case and doesn’t refer the patient to a hospital), psychological harm and feeling unsafe (e.g., awareness of unsafe care leading patients to losing trust of health services and avoiding

vaccinations or receiving transfusions) [18]. Given the wide range of potential sources of patient harm, it is important to use a variety of methods to measure different types of patient harm and to develop more specific and nuanced methods of measuring harm that can be applied in a variety of clinical settings. Despite the vast number of methods that can be used to measure various types of harm, Vincent et al., grouped the methods into four broad categories. Among these are mortality statistics (i.e., these methods are used for the purpose of documenting deaths and conducting comparative analyses among hospitals mortality rates), record-review-based methods (i.e., these reviews start initially when healthcare providers see patients notes, they look for warning signs of any adverse events. A specialist is consulted when notes indicate concerning symptoms, such as a readmission to intensive care. These reviews are often repeated over time, and patterns are investigated in order to identify and monitor certain types of adverse events.), staff reporting-based methods (i.e., mandatory, and voluntary reporting systems are employed in order to mitigate the occurrence of adverse events and reduce harm) [18], and the use of routine databases (i.e., these extensive administrative databases provide key quality and patient safety indicators. These databases are usually created by national healthcare organisations and made available to hospitals for information sharing, peer performance comparison, and mutual learning.).

Reliability of safety critical processes. The second dimension of safety focuses on the question, "Are our clinical systems and processes reliable?". This dimension involves two broad areas where reliability should be measured and monitored: the reliability of clinical systems and the reliability of human behaviour. Reliability of clinical systems refers to the procedures that healthcare workers need to carry out reliably, in which reliability refers to failure-free operations over time. In a healthcare setting, these procedures will include things like adherence to hand hygiene procedures or the timely administration of antibiotics before operations. Assessments of reliability in healthcare are typically performed using clinical audits, which aim to measure clinical

performance against agreed-upon standards and use the results to improve practice. The other area within this dimension is concerned with the reliability of human behaviour. This refers to the capacity of the staff to follow safety critical procedures. Even though flexibility and deviations from the rules are sometimes required in healthcare, delivering safe care requires a balance between discipline and necessary adaptation. A minor unnecessary deviation from best practice can lead to harmful events (e.g., variations in routine anaesthetic care processes). In addition to clinical audits, methods such as observation of safety critical behaviour is commonly used to monitor the attitudes and behaviours of staff.

Sensitivity to operations. This dimension of safety is concerned with addressing the question "is care safe today?". Healthcare is a very dynamic industry, with changes often being the norm rather than the exception. This signifies that an organisation may have been safe in the past, but no longer is. A lot might change on a daily or even hourly basis, such as staff fatigue or medical equipment failure. As a result, being vigilant not just to past harm or the reliability of processes over time, but also to day-to-day problems that might influence patient safety is crucial. Safe organisations entail individuals working together to build and improve an accurate perception of the environment they operate in, while also keeping an eye out for anything that seems out of the ordinary. This will allow for the early detection of issues, allowing for action to be taken before they jeopardise patient safety. Teams and organisations that place a high value on sensitivity to operations invest in resources and set up methods of measurement and monitoring that provide them with a real-time picture of what's happening and an understanding of its significance and potential impact. In such organisations, the necessity of a timely, clear, and transparent exchange of information is widely acknowledged. These organisations employ methods such as safety walk-throughs, talking to patients, and routine reviews of working conditions in order to achieve this goal.

Anticipation and preparedness. As previously mentioned, healthcare is characterised by constant changing conditions; thus, a health organisation should be prepared for and capable of responding to any future safety hazards. To accomplish this, a forward-thinking approach to the question "Will care be safe in the future?" is required. Even though it's commonly agreed that humans have no ability to see into the future and predict with certainty how future challenges will evolve, it's nevertheless beneficial to attempt to anticipate broader organisational safety problems. For example, healthcare organisations may learn from other organisations' failures by reviewing past safety events involving serious risks to patient safety and assessing whether their existing rules and practices constitute a similar risk. There are various methods for anticipating future safety hazards, but the ultimate objective should be to provide employees with the opportunity to analyse their needs and anticipate possible future problems. Human reliability analysis, structured reflection, indicators such as safety culture, and staffing level assessment to detect possible safety threats owing to staff shortages are just a few of the methods used to aid future scenario development and proactive actions on potential threats.

Integration and learning. The last dimension of safety addresses the question, "Are we responding and improving?". A great deal of information on patient safety is gathered at several organisational levels, including clinical teams, clinic departments, and boards. What matters most is learning how to successfully integrate and analyse this data, and then utilising that analysis to help the organisation learn and make long-term improvements. Similarly, understanding the nature and purpose of these data sources requires familiarity with their target audience, the kind of feedback and action that is desired, and the level at which they operate. For example, if a patient safety issue arises in a specific unit, it should be addressed there before being escalated to higher levels in the organisation. At the organisational level, instead of relying on a single incident or indicator to make suggestions, it is preferable to look at methods to collect and analyse various safety data sources from across

the organisation to drive continuous improvement. Data sources could include incident reports, patient safety indicators, clinical audits, or informal conversations with patients, families, and staff. Commonly used methods for assessing this dimension include aggregated analysis of incidents, claims, and complaints, as well as feedback and the implementation of safety lessons by clinical teams.

Applications of the measuring and monitoring safety framework

Initial piloting. The authors conducted preliminary testing of the framework with several organisations in the course of their work. Two acute care trusts and one integrated care trust had positive outcomes from workshops with their boards, management, and frontline carers. Everyone agreed that the framework may be valuable, and they could all think of ways to put it to use. Members of the board saw the framework as providing structure and clarity when reflecting on their current approach to measuring and monitoring safety, and the five dimensions allowed them to analyse patient safety processes and data through new "lenses" and broaden their perspectives about safety [18,19].

Putting the framework into practice. Following the development of Vincent et al.'s MMS framework, a large-scale programme was carried out to evaluate the value and effect of putting the framework into practise in healthcare settings. This programme included nine English and Scottish healthcare organisations that differed in service provision, location, organisational structure, and patient safety progress. The programme explored how the framework was applied across the nine sites, how it affected participants' awareness and knowledge of safety, how it affected organisations practises, and the implications for broader adoption and use of this new approach to measuring and monitoring safety. Semi-structured interviews with 28 senior and frontline participants from nine healthcare organisations answered these questions. Participants' views on how their organisation actively manages safety changed significantly. They stated that the framework provided a

common language and facilitated a more comprehensive understanding of the different safety dimensions.

Use in practice to support improvement. The MMS framework was also used within a hospital as part of a safety development plan. The three components of this safety improvement plan included an overarching theme, a disease-specific area, and a safety-specific area. The MMS framework was used in a prioritisation process to determine these themes. This led the hospital to shift its measurement approach, which had previously depended on learning from past harm and reliability, to one that leverages the 'sensitivity to operations' and 'anticipation and preparedness' dimensions of the MMS framework [76].

Use to support the involvement of patients. Another programme that aimed to answer the question, "How do we know care is safe?" considered the role of patients and citizens in risk identification, measurement, and safety monitoring, as well as how they may be involved in the framework's five dimensions [77].

Use in training and education. The framework was used as part of training healthcare workers on non-technical skills. For example, the Scottish Quality and Safety Fellowship, an international programme for leadership development, used the MMS framework by presenting it to fellows during the human factors and ergonomics component of this education programme [78].

Use to support the development of a Safer Culture Framework. The MMS framework was used in developing a Safer Culture Framework, which is intended to assist healthcare organisations in clarifying what is required to create a safety culture, Kilcullen et al. identified factors influencing safety culture and linked them to the dimensions offered in the MMS framework as safety outcomes that safety leaders may target to improve [79].

Use to support reviews of the literature. Furthermore, a systematic review aimed at identifying measures that could be used as indicators of safety for quality monitoring and improvement in older adult residential or nursing care homes mapped these indicators into the five dimensions of the MMS framework [80]. Similarly, another review that sought to identify methods of measuring and monitoring patient safety in prehospital care mapped the methods into the MMS framework's five dimensions [54]. The MMS framework was also used in a meta-review of systematic reviews of patient safety measures in primary care. This meta-review examined methods of measuring and monitoring safety and used the framework to classify the methods of measuring and monitoring safety in the included systematic reviews using the five safety dimensions of the MMS framework [49].

Use to develop and describe a safety intervention. Another application of the framework is evident in a study that sought to develop an intervention to promote safe surgery. The MMS framework was used in this study to outline the measures and approaches that were employed in the intervention for each of the five dimensions of the MMS framework [81].

Use to support the identification of risks. Other researchers that looked at the measurement of safety in older adult care homes used the MMS framework as an organising framework for the analysis of their findings. The purpose of their study was to determine the variety of safety concerns highlighted in incident reviews and map those issues into the MMS framework dimensions to demonstrate which elements of safety are reflected in reports of failures in nursing homes [82].

Use in doctoral research. In addition, the MMS framework has been used in several doctoral theses. For example, Al Nadabi (2019) highlights the progress towards the development of a multidimensional approach to evaluate the quality and safety of care in maternity hospitals in Oman by employing two of the five dimensions of the MMS framework namely "past harm" and "anticipation and preparedness". In his research, the

author focused on three monitoring approaches: measuring patient safety culture, measuring patient satisfaction, and monitoring caesarean section rates [83]. Likewise, Curran (2019) used two of the five MMS framework dimensions, namely "anticipation and preparedness" and "integration and learning". In her doctoral thesis, Curran's (2019) aimed to answer the following questions: could measures to assess the dimensions of "anticipation and preparedness" and "integration and learning" of the MMS framework be used to improve patient safety in primary care, and what are the general issues associated with improving patient safety in primary care [84]. Meanwhile, Zadeh (2018) conceptualised the MMS framework as a roadmap for conducting her doctoral research, which focuses on risk managers' roles in managing inappropriate behaviours among hospital staff and makes recommendations in alignment with the MMS framework [85].

In conclusion, the MMS framework has been employed in a range of applications. This includes improving patient safety practises in healthcare organisations, identifying potential risks, training clinicians, developing a framework for establishing a culture of safety, involving patients, designing interventions, and conducting patient safety research.

Thesis Focus and Research Aims

Health care quality and safety have been policy priorities for governments throughout the world for over two decades, but progress towards these goals has been slow [1]. People are still subject to poor care and rates of harm in hospitals remain high [2,3]. One major barrier to improving healthcare safety is a dearth of high-quality information that allows organisations, teams, and individual healthcare practitioners to assess how they are performing and where there are gaps and risks. [18] Understanding and improving patient safety necessitates the availability and application of valid and reliable methods for measuring and monitoring patient safety [54]. While the need of measuring and monitoring safety is widely acknowledged, there is no consensus on how to achieve it. This thesis will address the dimensions in the MMS

framework [18,19] with the purpose of improving current understanding of the measuring and monitoring of patient safety in hospitals.

Research Aims

The aim of my thesis is to apply the MMS framework [18,19] to provide a structure for understanding how safety is measured and monitored in hospitals in Ireland and Saudi Arabia, in order to:

1. identify whether the MMS framework is a useful approach to evaluating national safety surveillance systems;
2. identify whether the MMS framework is useful for evaluating patient safety research;
3. compare and contrast the safety surveillance systems, and safety research, in Ireland and Saudi Arabia;
4. make recommendations for the development of the safety surveillance system and future patient safety research in Ireland and Saudi Arabia; and
5. consider the implications of the findings from the research, and scoping reviews, for MMS beyond these two jurisdictions.

These aims will be addressed through the application of the MMS framework to examining the safety monitoring system in Ireland (chapter 3, study 2), and Saudi Arabia (chapter 5, study 4), and scoping reviews of the patient safety research carried out in Ireland (chapter 2), and Saudi Arabia (chapter 4).

Conclusion

Maintaining high standards of health care quality and safety have been policy priorities for governments throughout the world for over two decades, but progress towards these goals has been slow [1,86]. People are still subject to substandard care and rates of harm in hospitals remain high [2,3]. To enhance patient safety, it is vital to assess the methods of safety measuring and monitoring utilised by safety surveillance systems, which are designed to evaluate safety performance, identify areas for improvement, and determine if improvements have been made. These

systems must be comprehensive and cover the many ways in which health care might fail. Nonetheless, the majority of healthcare organisations in most countries have not yet established comprehensive patient safety surveillance systems that go beyond past harm measurement, which is often done via incident reporting [1]. Similarly, patient safety research has been criticised for its focus on retrospective methods of safety assessment, with less emphasis placed on studies aimed at strengthening the design of safety management systems [54]. In the next chapter, the state of patient safety research in the Republic of Ireland will be reviewed in terms of quantity and nature, which will give guidance to researchers, healthcare providers, and health service managers on how to expand on existing research to enhance patient safety.

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Chapter 2: Study 1

A scoping review of patient safety research carried out in the Republic of Ireland

A scoping review of patient safety research carried out in the Republic of Ireland

Declaration

Where This Fits in with the Thesis

The goal of conducting research on patient safety is to produce new knowledge that enhances the capacity of healthcare systems, organisations, and healthcare workers to address and reduce harm, as well as to offer effective solutions for unsafe care [1,2]. However, in order to determine what further research is required for the future, it is imperative to assess the extent and nature of patient safety research conducted thus far in the Republic of Ireland (RoI). The absence of an overview of patient safety research in the Republic of Ireland (RoI) impedes the understanding of existing strengths and limitations, thereby impeding the establishment of research priorities for the future. Hence, this first study is a scoping review that aims to: (1) examine the extent, range, and nature of patient safety research activities carried out in the RoI; (2) make recommendations for future research; and (3) consider how these recommendations align with the Health Service Executive's (HSE) patient safety strategy.

Peer-reviewed Publication

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The following chapter is a formatted version of the submitted manuscript to the journal.

Authors' Contributions

This study was led by PC and SL. All authors involved in the design and planning of the review. RD developed the search strategy. YK conducted the searches. YK, ROM, and ESP were responsible for completing the data extraction. YK drafted the initial manuscript. All authors assisted

with redrafting the manuscript. All authors reviewed and approved the manuscript prior to submission to the journal.

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Abstract

Background. Maintaining the highest levels of patient safety is a priority of healthcare organisations. However, although considerable resources are invested in improving safety, patients still suffer avoidable harm.

Aims. (1) To examine the extent, range, and nature of patient safety research activities carried out in the RoI; (2) make recommendations for future research; and (3) consider how these recommendations align with the Health Service Executive's (HSE) patient safety strategy.

Methods. A five-stage scoping review methodology was used to synthesise the published research literature on patient safety carried out in the RoI: (1) identify the research question; (2) identify relevant studies; (3) study selection; (4) chart the data; and (5) collate, summarising, and reporting the results. Electronic searches were conducted across five electronic databases.

Results. A total of 31 papers met the inclusion criteria. Of the 24 papers concerned with measuring and monitoring safety, 12 (50%) assessed past harm, 4 (16.7%) the reliability of safety systems, 4 (16.7%) sensitivity to operations, 9 (37.5%) anticipation and preparedness, and 2 (8.3%) integration and learning. Of the six intervention papers, three (50%) were concerned with education and training, two (33.3%) with simplification and standardisation, and one (16.7%) with checklists. One paper was concerned with identifying potential safety interventions.

Conclusions. There is a modest, but growing, body of patient safety research conducted in the RoI. It is hoped that this review will provide direction to researchers, healthcare practitioners, and health service managers, in how to build upon existing research in order to improve patient safety.

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Introduction

A commitment to improving safe healthcare features in governmental policies worldwide. However, progress in delivering on this aspiration have been modest, with patients still suffering avoidable harm [1]. A major challenge to improving safety is the lack of high quality information to allow healthcare organisations, teams, and individuals to evaluate how they are performing, and where there are deficits and risks [2]. This safety information is complex and multi-faceted, yet vitally important if safety is to improve [3].

In the Republic of Ireland (RoI), "*maintaining the highest levels of patient safety is a fundamental priority for patients and for healthcare organisations*" (p.5) [4]. The need for proactive approaches to patient safety has been identified by the Irish Health Service Executive (HSE)[4]. There is a recognition that such an approach requires high-quality data that will support learning from patient safety incidents, identification of hazards or risks, and the implementation of interventions to improve safety [4]. It is only through effective measurement and monitoring of safety (MMS) that comparisons can be made between the safety performance of different healthcare organisations, the impact of safety interventions can be assessed, and there can be a shift to a more proactive approach to safety.

In addition to efforts to improve the MMS, there is also a need to consider the effectiveness of patient safety interventions. There has been considerable investment in patient safety improvement efforts, for which there may be limited evidence of effectiveness [5]. It has been found that the majority of safety interventions tend to be person-focused (e.g. education and training), with more effective systems focused interventions far less commonplace [6]. Moreover, high quality research on the effectiveness of safety intervention is lacking [5]. Therefore, there is a need for rigorous assessment of the effectiveness of interventions to ensure that they are having the desired effect, and the resources required to implement such interventions are justified. Crucially, given the recognised impact of context

on intervention implementation and effectiveness, such assessments must be conducted within different healthcare systems and services [7].

The purpose of this scoping review is to examine the extent, range, and nature of patient research activities carried out in the RoI. Research is fundamental to improving practice, particularly within an applied science such as patient safety [8]. Accordingly, the findings from this review will be used to make recommendations for future patient safety research, and the alignment between these recommendations and the HSE patient safety strategy 2019-2024 [4] will be delineated.

Methods

This scoping review is conducted using the five-stage approach proposed by Arksey and O'Malley [9] and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist [10]. Scoping reviews provide an increasingly popular option for synthesising and mapping evidence in healthcare research [11].

Stage 1: Identify the Research Question

The purpose of the review was clearly defined with concept of interest (i.e., patient safety research), target population (i.e., healthcare staff and patients in secondary care) and location (i.e., RoI).

Stage 2: Identify Relevant Studies

Search strategy. Electronic searches were conducted across five electronic databases in July 2021: Medline, CINAHL, Embase, PsycInfo and Web of Science. The search strategy was finalised by a Research Librarian (RD). The search strategy comprised Medical Subject Headings terms along with free-text keywords, and was altered as necessary for the remaining databases (see Supplementary Data 1 (Appendix 1) [12] for the Medline search strategy). In addition to electronic searches, the reference lists of all studies identified as eligible for inclusion from the electronic searches were screened to identify any other potentially suitable articles.

Stage 3: Study Selection

Titles and abstracts of all articles identified during the electronic searches were screened by one of three authors (ROM, YK, or ESP) in July 2021. The full-texts of articles that appeared eligible for inclusion, or articles in which the title and abstract did not provide sufficient information for the determination to be made, were reviewed in full to confirm their eligibility. For papers where inclusion was unclear, all members of the research team reviewed the paper, and decisions on eligibility were made through discussion.

Inclusion Criteria. Inclusion criteria required that studies: (1) were focused on patient safety in hospitals in the RoI including, but not limited to, the measurement of safety or implementation of initiatives aimed at improving safety; (2) reported original research; (3) were published in a peer-reviewed journal; and (4) were written in English.

Exclusion Criteria. Studies were excluded if they: (1) focused on patient safety in the context of patients with a particular medical condition only (e.g. patients with cancer); (2) focused on the safety of one process only (e.g. medication errors); (3) were conducted in healthcare settings other than hospitals; (4) were conducted in a country other than the RoI or a sample of countries including the RoI where RoI-specific data could not be extracted; (5) only employed one item/question relating to patient safety as part of a larger survey or assessment (i.e., studies had to use a full measure of patient safety), or; (6) did not report original research. No limits were placed on the publication year.

Stage 4: Chart the Data

A preliminary data charting form was developed and, in accordance with best practice [13] and piloted by two authors (YK, ROM). The form was used to extract data on: author(s), year of publication, study location, study aim, methods, sample, intervention (if included), comparator (if included), outcome measures, and key reported outcomes. Data were extracted by

three authors (ROM, YK, & ESP), with two of these authors extracting data independently for each included article. Disagreements were resolved through discussion.

Stage 5: Collate, Summarise and Report the Results

The characteristics of the included studies were collated and summarised across several key descriptors: location; aim; methods; sample; type and duration of intervention (if applicable); comparators (if applicable); outcome measures; and key outcomes.

Included studies were summarised according to one of two different frameworks. Studies that involved MMS were categorised using the five domains of Vincent et al. [3,14] MMS framework (see Table 1). It was possible for both studies and measures described to be categorised under more than one MMS dimension.

Table 1. Description of the MMS and hierarchy of intervention effectiveness frameworks.

MMS Framework [3,14]
1. *Harm*: has patient care been safe in the past? (e.g., case record review, patient safety indicators)[14].
2. *Reliability of safety critical processes*: are our clinical systems and processes reliable? (e.g., audit of equipment availability, observations of safety critical behaviour)[14].
3. *Sensitivity to operations*: is care safe today? (e.g., talking to patients, ward rounds)[14].
4. *Anticipation and preparedness*: will care be safe in the future? (e.g., human reliability analysis, safety culture assessment)[14].
5. *Integration and learning*: are we responding and improving? (e.g., regular integration and review by clinical teams, feedback and implementation of safety lessons)[14].
Hierarchy of intervention effectiveness framework [15]
1. *Forcing functions*: designing processes so that errors are virtually impossible or difficult to make (e.g., removing potassium chloride for injection concentrate from all patient care areas)[15].
2. *Automation and computerisation*: automating and computerising processes and tasks to lessen human fallibility by limiting reliance on memory (e.g., use of technologically, computerised drug information systems)[145].
3. *Simplification and standardisation*: developing and implementing protocols and standardised order forms to guide the safety of processes by eliminating problems with illegible handwriting and standardising safe order communication (e.g., development of protocol for transferring patients)[15].
4. *Reminders, checklists, and double checks*: developing tools that can reduce the risk of error by standardising processes and/or having one person independently check another's work (e.g., independent double check systems)[15].
5. *Rules and policies*: establishing and enforcing rules and policies related to error prevention and safety (e.g., implementing policies around safe medication use)[15].
6. *Education and training*: educating and training healthcare staff to reduce errors and to promote and ensure patient safety (e.g., intervention on improving attitudes towards patient safety)[15].

Studies of a safety intervention were classified using the hierarchy of intervention effectiveness framework [15] (see Table 1). The framework delineates interventions according to six levels of effectiveness from 1 (most effective) to 6 (least effective). The hierarchy of intervention effectiveness framework was first discussed by the Institute for Safe Medication Practices, and has since been referenced a number of patient safety organisations as an approach to guide the identification of suitable safety interventions (e.g. Incident Analysis Collaborating Parties [16], Health Information and Quality Authority [17]). The hierarchy of interventions was extended by Woods et al [18], who added three additional levels (staff organisation, risk assessment, learning from errors, and personal initiative) as this was deemed necessary in order to appropriately classify solutions to improving clinical communication and patient safety. However, for the purposes of this scoping review we used the original six level framework due to our focus on interventions, rather than solutions (see Table 1).

The categorisation of study content via these two frameworks was carried out independently by three reviewers (ROM, YK, & ESP). Where disagreements arose, the study was discussed by all members of the review team and a decision on the categorisation was made by consensus. Following completion of all data charting and coding, the meaning of the findings and their implications were appraised within the context of the broader literature in this area, and the HSE patient safety strategy [4].

Results

A total of 6,515 articles were identified from electronic database searches (see Figure 1), with 170 full-texts examined and 27 papers ultimately meeting the inclusion criteria. Four additional studies were identified through reference list screening, resulting in the inclusion of 31 studies (published 2003-2021). Study characteristics are outlined in Table 2, and a summary of the main findings from the studies is provided in Table 3.

Figure 1. PRISMA flowchart of the search and screening process

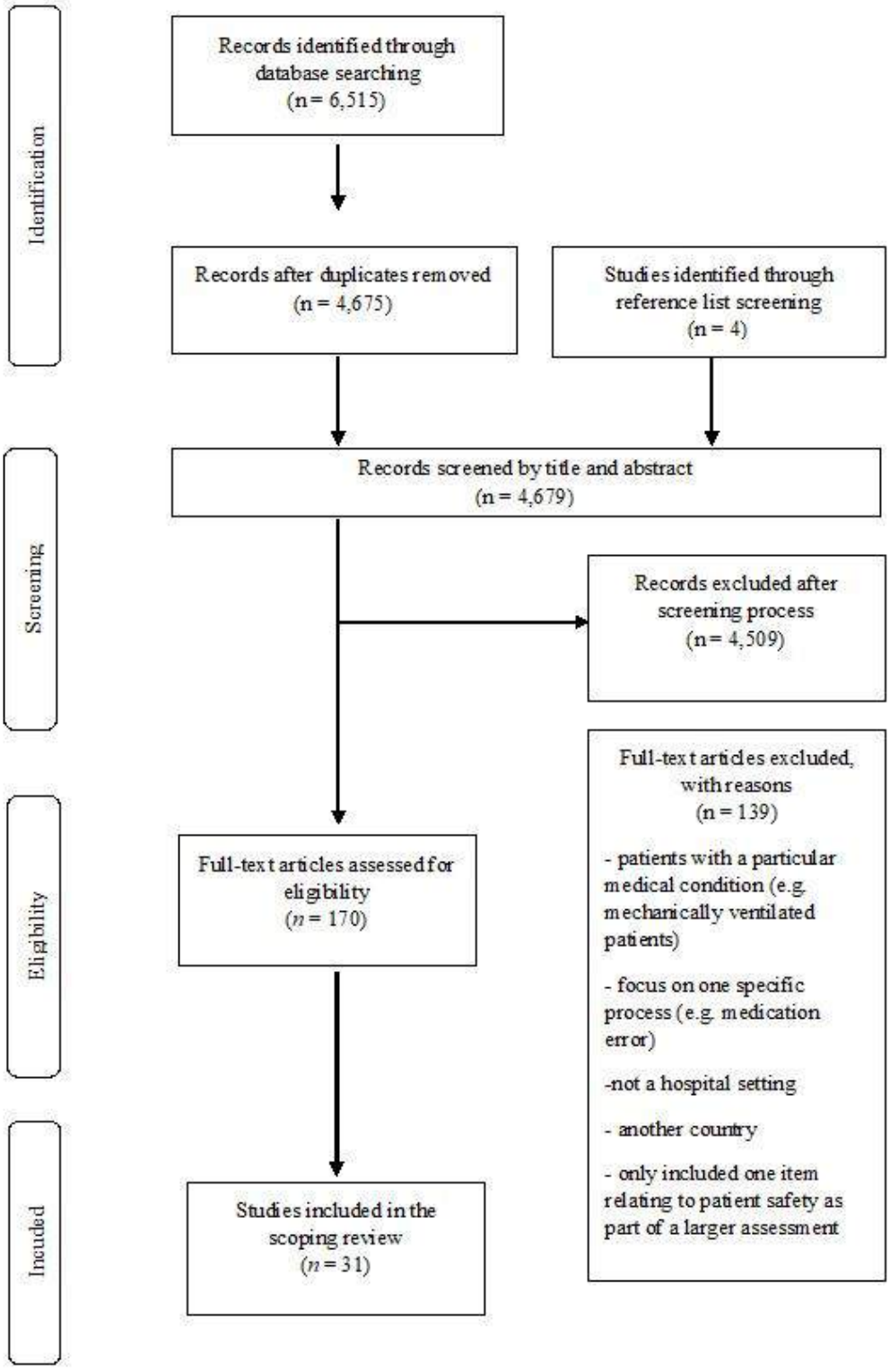

Table 2. Summary of the characteristics of the included studies.

Characteristics	Studies n (%)
Year of publication	
2000-2004	1 (3.2)
2005-2008	0 (0)
2009-2012	7 (22.6)
2013-2016	8 (25.8)
2017-2020	12 (38.7)
From January to May 2021	3 (9.7)
Type of data collected	
Quantitative	23 (74.2)
Qualitative	4 (12.9)
Quantitative and Qualitative	4 (12.9)
Categorisation of MMS studies (*n*=24)	
Past harm	12 (38.7)*
Reliability of safety critical processes	4 (12.9)
Sensitivity to operations	4 (12.9)
Anticipation and preparedness	9 (29.0)
Integration and learning	2 (6.5)
Categorisation of intervention studies (*n*= 6)	
Forcing functions	0 (0)
Automation and computerisation	0 (0)
Simplification and standardisation	2 (6.5)
Reminders, checklists and double checks	1 (3.2)
Rules and policies	0 (0)
Education and training	3 (9.7)
Other types of study (*n*=1)	
Intervention development study	1 (3.2)

* These figures do not total to 24 because some of the studies related to more than one dimension of the MMS framework [3, 13].

Table 3. Summary of key findings resulting from included studies.

Categories	Key findings
Past harm	• Adverse events are not uncommon [1,19,20,23-25] • The prevalence of adverse events was 12.2% in 2009 [1] to 14% in 2015 [25]. • The prevalence of preventable adverse events was 9.1% in 2009 to 7.4% in 2015 [25]. • Slips/trips and falls account for the majority (32%) of all adverse outcomes reported with medication errors and perioperative incidents making up the 2nd and 3rd most common respectively [29]. • The economic cost of adverse events to the health service in Ireland is estimated to be between €91.3 [26] to €194 million [25]. • Ireland was above the mean number of secondary diagnoses for three out of five patient safety indicators: catheter-related bloodstream infection; postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT), and postoperative sepsis rates. Ireland was below the mean for accidental puncture or laceration, and foreign body left in during procedure [27]. • Across surgical specialties, the majority of reported adverse events occur in orthopaedic and general surgery (73% of all claims)[29]. • Nurses and midwives report adverse events with a much greater frequency than doctors [29]. • Reluctance to report is influenced by fears of retribution [23,24]. • A survey of junior doctors found that 60.5% of respondents reported making an error that 'played on their mind' [28]. • Burnout is associated with higher rates of self-reported medical error [21,22].

Reliability of safety critical processes	• The use of surgical checklists was high in Ireland [30,32]. • Participating in Time Out as a team was reported as occurring in 57% of cases [30]. • Although attitudes towards the effect of the checklist on safety and teamwork were positive [30,31], barriers to use such as lack of time were reported [30,31]- particularly among nurses [31].
Sensitivity to operations	• Healthcare providers described the poor working conditions in the hospital, but also recognised the importance of teamwork and communication in maintaining patient safety and had a strong appetite for change regarding the safety culture in the hospital [34]. • 8-9% nurses gave their hospital a poor or failing safety grade [19,20,33].
Anticipation & preparedness	• Studies that used the Safety Attitudes Questionnaire (SAQ) found that hospitals scored higher than international benchmarks in the domains: 'Teamwork Climate'[35-37]; 'Safety Climate'[35-37]; 'Job Satisfaction'[35-37], 'Stress Recognition'[35-37]; 'Perceptions of Management'[35-37]; and 'Working Conditions'[35,37]. • At ward level, factors such as the ward practice environment and the proportion of nurses with degrees were found to significantly impact safety outcomes [20]. • Nurses' main concern was how to minimise risk [38,39]. • Many healthcare providers reported not feeling supported by hospital management [34], and doubted that safety was a management priority [19]. • In situ simulations was used to identify latent safety hazards [40]. • Over 85% of staff liked their job and would feel safe being treated at the hospital as a patient [35].

Integration & learning	• Statistically significant changes in clinical activity were identified in the 28 days following five of the six severe perinatal adverse events [41]. • A steady improvement in transfer time was demonstrated between the first and last simulation of a series of four simulations aimed at identifying latent safety hazards [40].
Intervention studies	• The percentage adherence to the Good Surgical Practice Guidelines was higher in an intervention group that received an adhesive ward round checklist 1186 (91%) in comparison with the control group 718 (55%)[47]. • Participating in the Online Patient Safety Education Programme resulted in immediate improvement in skills such as knowing when and how to complete incident forms and disclosing errors to patients, in self-rated knowledge and attitudes towards error reporting [44]. • Of 72 incident forms received in the first four months of the Clinical Risk Management project, 25.3% related to actual clinical incidents and 12.6% related to near misses. Potential risk was present in 62% of the reports [45]. • The implementation of a 30-day complication proforma led to a 73% increase in morbidities reported using the proforma as compared with traditional Morbidity and Mortality reporting (547 vs 316), and an increase of 10.8% in the reporting of mortalities [46]. • The implementation of training based on Crew Resource Management was associated with a significant increase in knowledge as a result of the training, and there was some evidence to support a shift in attitudes in the desirable direction relating to the need to speak up to seniors. No effect of the training was found on behaviour [43]. • A significant change in the reporting behaviour of junior doctors was observed in one of the two hospitals following the intervention, a serious board game 'PlayDecide patient safety' [42].

Studies Focused on Past Harm

Past harm was the most frequently assessed dimension of the MMS framework, and was measured in 12 studies (see Tables 2 and 3, and Online Supplementary Material 2 (Appendix 2) [12]). Six studies employed surveys to measure past harm. Two of these studies, conducted as part of a European study, used surveys to estimate the frequency of a range of adverse events [19] and to examine nurse adverse event reporting rates [20]. Of the four remaining studies that used a survey design, two examined the association of burnout with self-reported medical error and poor quality care [21,22], and two studies explored nurse incident reporting [23,24]. Four studies measured past harm by retrospectively reviewing patient records. Two of these record reviews were undertaken as part of the Irish National Adverse Events studies [1,25], and examined trends in adverse event rates in the Irish healthcare system. The two remaining record reviews were conducted to estimate the economic cost of nurse sensitive adverse events [26] and to compare the health system performance of 15 Organisation for Economic Co-operation (OECD) countries across seven patient safety indicators [27]. Further, one study used a combination of survey and interview methods to examine the nature and frequency of medical error among junior doctors [28], and one study comprised a review of medico-legal claims to identify current adverse event reporting trends in Irish surgical specialties [29].

Studies Focused on Reliability of Safety Critical Processes

Four studies assessed the reliability of safety critical processes (see Tables 2 and 3, and Online Supplementary Material 2 2 (Appendix 2) [12]). Of the two studies that used a survey design to monitor reliability, one study employed surveys to examine the implementation of Surgical Safety Checklists (SSC) in Irish operating theatres [30] while the other study used interviews to develop a survey evaluating the attitudes of theatre staff towards a surgical checklist [31]. Two studies used patient record review methodology to assess reliability, one of which reviewed patient records to assess the prevalence of surgical checklist use in Europe [32] while the other study used hospital data to improve the international comparability of

patient safety indicators [27].

Studies Focused on Sensitivity to Operations

Four studies included a measure that assessed sensitivity to operations (see Tables 2 and 3, and Online Supplementary Material 2 (Appendix 2) [12]). Three of these studies used surveys and asked nurses to give their ward an overall safety grade [19, 20, 33]. One study conducted interviews to explore aspects of safety culture that were important to staff at the time of the interviews [34].

Studies Focused on Anticipation and Preparedness

Almost a third of the included studies focused on anticipation and preparedness (see Tables 2 and 3, and Online Supplementary Material 2 2 (Appendix 2) [12]). Five studies used surveys to assess patient safety culture. Three of these studies employed the Safety Attitudes Questionnaire (SAQ)[35-37], and two studies used items from the Agency for Healthcare Research and Quality's Hospital Survey on Patient Safety Culture [19,20]. Interviews and/or observations were used by three studies to investigate healthcare workers' perceptions of the safety culture [34] and to explore how nurses promote safety in perioperative settings [38-39]. One study used in situ simulation to examine latent safety hazards in response to preparation for an expected COVID-19 surge [40].

Studies Focused on Integration and Learning

Integration and learning was assessed by two studies (see Tables 2 and 3, and Online Supplementary Material 2 2 (Appendix 2) [12]). McNamara et al [41] reviewed patient records to objectively demonstrate if a change in labour ward clinical activity occurred following serious adverse perinatal events. Jee et al. [40] identified system errors and latent safety hazards using in situ simulation and described the resulting corrective measures taken to improve their pandemic response locally.

Intervention Studies

Six studies were categorised as intervention studies. Studies employed

several different types of intervention of varying effectiveness (see Tables 2 and 3, and Online Supplementary Material 2 (Appendix 2) [12]). Three studies comprised interventions that focused on improving patient safety through education and training [42-44]. One of these studies implemented a board game to educate junior doctors about patient safety and the importance of reporting safety concerns [42]. The second educational intervention was concerned with training aimed at improving interns' attitudes towards, and ability to, 'speak up' to senior physicians [43], and the third comprised an online patient safety education programme for junior doctors [44].

Two of the studies implemented interventions focused on improving safety through simplification and standardisation. Both of these studies involved the implementation of an incident/near miss reporting form [45] or complication proforma [46]. Finally, one study sought to improve patient safety by implementing an intervention focused on reminders, checklists, and double checks. This intervention involved the development and implementation of an adhesive surgical ward round checklist [47].

There was one study included in the review that was not concerned with MMS or constituted an intervention itself. Rather, the focus of this study was on the development of a collective leadership intervention for healthcare teams to improve team performance and patient safety culture [48].

Discussion

This scoping review has demonstrated that, although overall modest in size, there is a growing body of research on patient safety in the RoI published in peer reviewed journals- particularly in recent years. This growth is consistent with the action from the HSE patient safety strategy "*to support patient safety research and publish and act on the results*" (p.19) [4]. The majority of the research on MMS in the RoI was focused on measuring past harm (particularly adverse events), and anticipation and preparedness (particularly assessments of safety culture/climate). Most of the intervention

studies were concerned with education and training. We will make recommendations for areas of future research based on the findings from the scoping review, and identify how these recommendations align with relevant aims from the HSE patient safety strategy 2019-2024 [4].

The focus on adverse events as a method of measuring past harm is consistent with the substantial increase in research publications on this approach to measuring safety in healthcare [49]. Staff surveys are a commonly used source of information on adverse events. However, a survey approach is constrained by the extent to which conclusions can be drawn about adverse event prevalence. Patient record review has been considered the 'gold standard' patient safety research method [50], and was used in four of the reviewed studies. Such data are useful in demonstrating the scope of the problem in the Irish healthcare system, allows for international comparisons, and for an assessment of any changes over time. However, patient record review data are limited in terms of identifying specific areas for safety improvement [50,51]. Therefore, there is a need for measures tailored to distinct aspects of patient harm (e.g. specific care-related injuries, missed diagnoses that lead to harm) [50]. Such data is important to address the HSE goal to "*measure and monitor safety, to evaluate the effects of safety improvement initiatives, and to inform further emerging priorities*" (p.19) [4]. Data on specific aspects of patient harm will allow the alignment of adverse events with failures in care, and the development and evaluation of interventions to address these issues [52].

Safety culture/climate surveys were the most frequently used approach to measuring and monitoring anticipation and preparedness. Again, this is consistent with the large amount of research devoted to these types of measures more broadly in the safety literature [53,54]. Safety culture/climate data is useful in identifying areas of both strength and weakness. However, it has been suggested that such survey measures may be best viewed as a trusted 'wet finger' to find out which way the wind blows [55], and do not identify specific areas for improvement. To illustrate, working conditions were identified as an area for improvement across three

of the included studies [34-37]. However, further data is required to identify the specific working conditions that should be prioritised for change. This is why, in some safety culture interventions, the survey data is used to inform discussion in qualitative safety culture workshops to identify the specific issues that need to be addressed [56]. It is recommended that future research should consider how to measure safety culture/climate in a way that is practical, sufficiently specific to identify areas for safety improvement, and can be used to measure whether improvements have occurred. This will likely require a combination of quantitative and qualitative data collection methodologies. A consideration of how to measure safety culture/climate is particularly important in the RoI as this has been identified as a specific action in the HSE patient safety strategy [4].

Compared to the MMS dimensions of past harm and anticipation and preparedness, a lower number of studies in our scoping review were concerned with MMS in the other three safety dimensions- particularly integration and learning. These proportions are similar to the findings from a systematic review of MMS in prehospital care [51]. Although the studies in our scoping review that assessed one of these three dimension of MMS provided informative data, they were largely based upon staff survey responses. Only one study [41] utilised clinical data. It is suggested that consideration should be given to the identification of feasible methods to MMS in these three under-researched dimensions beyond that derived only from survey data. A robust safety surveillance system should comprise multiple methods and address all five MMS domains. Research is recommended to critically appraise the existing safety monitoring system in the RoI healthcare system in order to identify blind spots as well as where there may be duplication of effort. Such research is consistent with the HSE patient safety strategy aim to "*further develop and enhance local and national suites of key patient safety indicators*" (p. 19) [4].

Although MMS is important, what is also essential is that this data is used to identify and evaluate the effectiveness of interventions to improve patient safety and quality of care [52]. In fact, there is arguably little point in

collecting safety data if it is not then used to bring about improvement. Three out of the six safety interventions identified were focused on education and training- a person focused intervention at the lowest level of the hierarchy of intervention effectiveness [15]. Although two interventions [45,46] with a focus on simplification and standardisation were identified, no interventions were found at the highest two levels of the hierarchy- forcing functions, automation and computerisation. The evaluations of the interventions included in the review were positive. However, similar to the majority of assessments of patient safety interventions, the quality of the evidence of effectiveness was low, with limited evidence of an impact on patient outcomes [5,57,58]. It is recommended that future research focuses on the evaluation of more effective system-focused interventions. It is further recommended that interventions are closely aligned to appropriate, and meaningful, measures of MMS in order to support rigour in evaluation of the impact of interventions on patient safety. This alignment will be necessary to achieve the HSE patient safety aims of putting in place appropriate actions to mitigate risks to patients, prioritising specific safety improvement initiatives, and evaluating the effects of safety improvement and risk mitigation initiatives [4]. It is also suggested that the co-design approach used by Ward et al [48] may offer a useful approach to identify specific interventions that healthcare staff believe will improve safety.

Limitations

There are a number of limitations of our scoping review. Firstly, a quality assessment was not carried out, although this absence is consistent with the majority of other scoping reviews [59]. Secondly, our scoping review provided a more descriptive summary of the literature than would be the case from a systematic review. This is a result of the goal of a scoping review to provide a map of existing research, rather than to answer a specific question [60]. Thirdly, as in any synthesis of the literature, scoping reviews are at risk for bias [60]. Fourthly, studies that focused on patient safety in the context of patients with a particular medical condition or focused on the safety of one process were excluded from our review. The rationale for this exclusion was that it would have been impossible to devise

a search strategy that included every possible medical condition, and process. Therefore, we chose to take an approach that included all papers that met the inclusion criteria rather than an approach that, although broader, may have missed particular studies. Finally, we did not carry out a search of the grey literature. These searches were not carried out as there are methodological issues with including grey literature searches in systematic reviews (e.g. compromised methodological reproducibility, difficulties in interpreting these publications [61]).

Conclusion

There is a modest, but growing, body of patient safety research conducted in the RoI. This scoping review has demonstrated the variety of patient safety research being carried out in the RoI. It is hoped that this review will provide direction to researchers, healthcare practitioners, and health service managers, in how to build upon the existing research in order to improve patient safety and quality of care.

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Chapter 3: Study 2

Measuring and monitoring patient safety in hospitals in the Republic of Ireland

Measuring and Monitoring Patient Safety in Hospitals in the Republic of Ireland

Declaration

Where This Fits in with the Thesis

Monitoring and monitoring safety (MMS) in healthcare organisations is a complex matter, with no consensus on how to best implement and achieve it [1,2]. The evaluation of safety performance is critical in attempts to improve healthcare safety. Nonetheless, this process is often hampered by a lack of high-quality data [3]. The Measuring and Monitoring Safety (MMS) framework developed by Vincent et al.'s was applied in this second study to assess how safety is measured and monitored in Irish hospitals and to provide recommendations for how it might be improved. The first phase of this qualitative study used document analysis to review national MMS guidance in Ireland. The second phase included semi-structured interviews with key stakeholders on their understanding of MMS.

Peer-reviewed Publication

This study has been accepted and published in a peer-reviewed journal.

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The following chapter is a formatted version of the submitted manuscript to the journal.

Authors' Contributions

This study was led by YK. All authors were involved in the design and planning of the study. YK and SL developed the search strategy. YK conducted the initial searches. YK, POC, and SL were responsible for completing the data extraction. YK and DM completed the interviews and transcribing. YK, POC, and DM conducted the analysis of the interview data. YK drafted the initial manuscript with POC, SL, and DM reviewing and assisting with redrafting. All authors read and approved the final manuscript prior to submission.

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Abstract

Background. Measuring and monitoring safety (MMS) is critical to the success of safety improvement effort in a healthcare. However, a major challenge to improving safety is the lack of high quality information to support performance evaluation.

Aims. The aim of this study used Vincent et al's Measuring and Monitoring Safety (MMS) framework to evaluate the methods used to MMS in Irish hospitals, and make recommendations for improvement.

Methods. The first phase of this qualitative study used document analysis to review

national guidance on MMS in Ireland. The second phase consisted of semi-structured interviews with key stakeholders on their understanding of MMS. The MMS framework was used to classify the methods identified.

Results. Six documents were included for analysis and 24 semi-structured interviews were conducted with key stakeholders working in the Irish healthcare system. A total of 162 methods of MMS were identified, with one method of MMS addressing two dimensions. Of these MMS methods: 30 (18.4%) were concerned with past harm; 40 (24.5%) were concerned with the reliability of safety critical processes, 16 (9.8%) were concerned with sensitivity to operations, 28 (17.2%) were concerned with anticipation and preparedness, and 49 (30%) were concerned with integration and learning.

Conclusions. There are wide range of methods of MMS in Irish hospitals. It is suggested that there is a need to identify those methods of MMS that are particularly useful in reducing harm, supporting action and improvement, and do not place a large burden on healthcare staff to either use or interpret.

Conflict of Interest: The authors declare no competing interests.

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Introduction

A commitment to safe healthcare is a policy goal of governments across the world. However, progress on delivering on this aspiration have been modest, with patients still suffering avoidable harm [1], and rates of harm remaining unchanged over time [2]. The impact that valid and reliable data can have on improvement is clear from many domains of healthcare [3]. Although safety data is complex and multi-faceted, it is vitally important to reducing patient harm [4]. This data is required to support the meaningful comparisons between the safety performance of different healthcare organisations, and the assessment of the impact of safety interventions [1].

A recent review found that there has been relatively little research carried out on MMS in the healthcare system of the Republic of Ireland [5]. However, there is a recognition that MMS is central to patient safety improvement. This is evident in the Irish Health Service Executive (HSE) patient safety strategy which includes a commitment to *"using information to improve safety"* (p.8) [6]. Recognising the complexity and multifaceted nature of the MMS in healthcare, Vincent et al. developed the Measuring and Monitoring Safety (MMS) framework [4,7]. The dimensions of the MMS framework are:

1. Harm: has patient care been safe in the past? (e.g. national audits).
2. Reliability of safety critical processes: are our clinical systems and processes reliable? (e.g. monitoring of vital signs).
3. Sensitivity to operations: is care safe today? (e.g. safety walk-arounds).
4. Anticipation and preparedness: will care be safe in the future? (e.g. safety culture assessment,).
5. Integration and learning: are we responding and improving? (e.g. aggregated analysis of incidents) [4,7].

The framework has been used previously to categorise studies in systematic or scoping reviews of MMS in primary care [8], prehospital care [9], and secondary care in Ireland [5] and Saudi Arabia [10]. The study reported in this paper uses Vincent et al.'s [4,7] MMS framework to classify the

methods used within secondary care in Ireland. The aims of the study reported in this paper are to: (1) examine how patient safety is measured and monitored in Irish hospitals; (2) map the methods of MMS in these hospitals onto the five dimensions of Vincent et al.'s [4,7] MMS framework; and (3) reflect on the approaches used to MMS in Irish hospitals.

Methods

Research Design

A qualitative descriptive approach was adopted for this study to support: (1) a document analysis of the guidance on MMS used in Irish hospitals; and (2) to use semi-structured interviews to explore stakeholders' perceptions about how patient safety is measured and monitored in Irish hospitals. This approach was based upon a study of methods of MMS use in Saudi Arabian hospitals [11].

Phase One: Document Analysis

Methods of MMS in Irish hospitals that are described in national healthcare governance documents were identified and classified. Document analysis is a systematic method to review or evaluating documents [12]. The 'ready materials, extract data, analyse data and distil (READ)' approach [13] was utilised.

Inclusion criteria. Inclusion criteria required that documents were: national-level documents; explicitly discussed or described how patient safety is measured and monitored in Irish hospitals; produced by a national government agency/or an organisation affiliated with a national government agency; and written in English. No publication date or period was specified. Finally, in cases where a document had multiple versions, only the latest version of the document was included.

Exclusion criteria. Documents were excluded if: they did not describe how patient safety is measured and monitored in Irish hospitals; were not produced by an Irish government agency or an organisation affiliated with a

national government agency; were focused on tracking performance progress (e.g., annual reports); were focused on the safety of one process only (e.g., medication safety); were focused on a particular method of measurement that is relevant to specific clinical practices (e.g., clinical audit); or were not written in English.

Search process. The search for relevant documents was completed in January 2022 and consisted of four steps intended to support the retrieval of government reports and policy documents:

1. an advanced google search was completed.
2. a search of the following electronic databases was conducted: Medline, CINAHL, OAIster, WHO IRIS, Lenus, and Google scholar using various combinations of terms 'measuring safety' 'monitoring safety' 'measurement of safety' (additional File 1 (Appendix 3) presents the search strategy used in complete detail).
3. searches were conducted across the Irish Health Services Executive (HSE), Irish Department of Health, and Irish Health Information and Quality Authority (HIQA) websites using both their relevant search boxes and manual search; and
4. potential further related documents were identified through hand-searching the reference lists of documents that met the inclusion criteria.

Document selection. The initial screening was completed by YK using the inclusion criteria to assess the potential for inclusion from the titles, abstracts, and/or executive summaries. Documents that appeared relevant were then downloaded for full-text review. A full-text review was completed by YK and POC to ensure the document met all items in the inclusion criteria. Decisions regarding the inclusion or exclusion of documents were agreed by consensus. All decisions were recorded in an Excel file.

Document analysis. YK and POC independently searched through each document and extracted all described methods of MMS. Only minor

differences were found between the information extracted by the two reviewers. These differences were concerned with whether a particular method was one measure or could be split into two measures. Once the final list of MMS had been identified, YK, POC, and SL reviewed each measure, and reached a decision by consensus as to which dimension of Vincent et al.'s [4,7] MMS framework it addressed.

Phase Two: Semi-structured Interviews with Key Stakeholders

The aim of the second phase of the study was to explore what key stakeholders know about how safety is measured and monitored in the Irish healthcare system.

Ethical review. The study was approved by the Clinical Research Ethics Committee, Galway University Hospitals (Ref: C.A.2604). All participants provided signed written informed consent.

Sampling and recruitment of participants. Participants for the interviews were drawn from three different stakeholder groups: (1) policymakers; (2) medical doctors; and (3) nurses. Recruitment of participants was through a combination of purposive and snowball sampling.

Development of interview guide. The semi-structured interview guide that was used is shown in Table 1. The design of the interview guide was derived from the five dimensions of Vincent et al's [4,7] MMS framework. The interview questions were prepared in accordance with best practices for the formulation of interview questions [14,15]. The interviews were conducted using an interview schedule developed to obtain information about perceptions of MMS in Saudi Arabian hospitals [11].

Table 1: Interview guide used to engage participants in discussion around measuring and monitoring safety in Ireland.

1. In the Irish healthcare system, how is harm to patients measured and monitored? 1.1. What are the strengths and limitation of methods used? 1.2. Are there other methods of measuring and monitoring harm that you think should be used? and if so, what are these and why do you think they'd be useful?
2. What methods are in place to assess whether our clinical systems, processes and behaviour reliable? 2.1. What are the strengths and limitation of each of these methods? 2.2. Are there other methods of measuring and monitoring standardised clinical practice that you think should be used?
3. What methods are in place to assess whether care is safe in hospitals in Ireland today? 3.1. What are the strengths and limitation of each of these methods? 3.2. Are there other methods of measuring and monitoring whether patient care is safe today you think should be used? and if so, what are these and why do you think they be useful?
4. What methods are in place to anticipate and reduce future risks to patients' hospitals in Ireland? 4.1. What are the strengths and limitation of each of these methods? 4.2. Are there other methods of improving the anticipation and reduction of future risk to patients that you think should be used? and if so, what are these and why do you think they be useful?
5. What methods are in place to promote learning from issues and improving the level of patient safety in hospitals in Ireland? 5.1. What are the strengths and limitation of each of these methods? 5.2. Are there other methods of prompting learning that you think should be used, and if so, what are these and why do you think they be useful?

Procedure. All interviews were carried out from January to June 2022. After receiving written informed consent, YK and DM conducted the interviews via video conference call. The audios of the calls were recorded.

Interview analysis. The purpose of the interview analysis was to identify the methods of MMS which the participants knew were being used to MMS in

Irish hospitals. These methods of MMS were categorised using Vincent et al.'s [4,7] MMS framework. The methods of MMS described by the interviewees were extracted from the transcripts by YK and DM, and then reviewed by POC. Decisions on categorisation were made by consensus.

Results

Phase One: Document Analysis

A total of six documents were found to meet the inclusion criteria. All six documents had been published from 2008. The search process for identifying documents that met the inclusion criteria is shown in Figure 1. A summary overview of these documents is provided in Table 2.

Figure 1: Flow diagram depicting study selection for document analysis

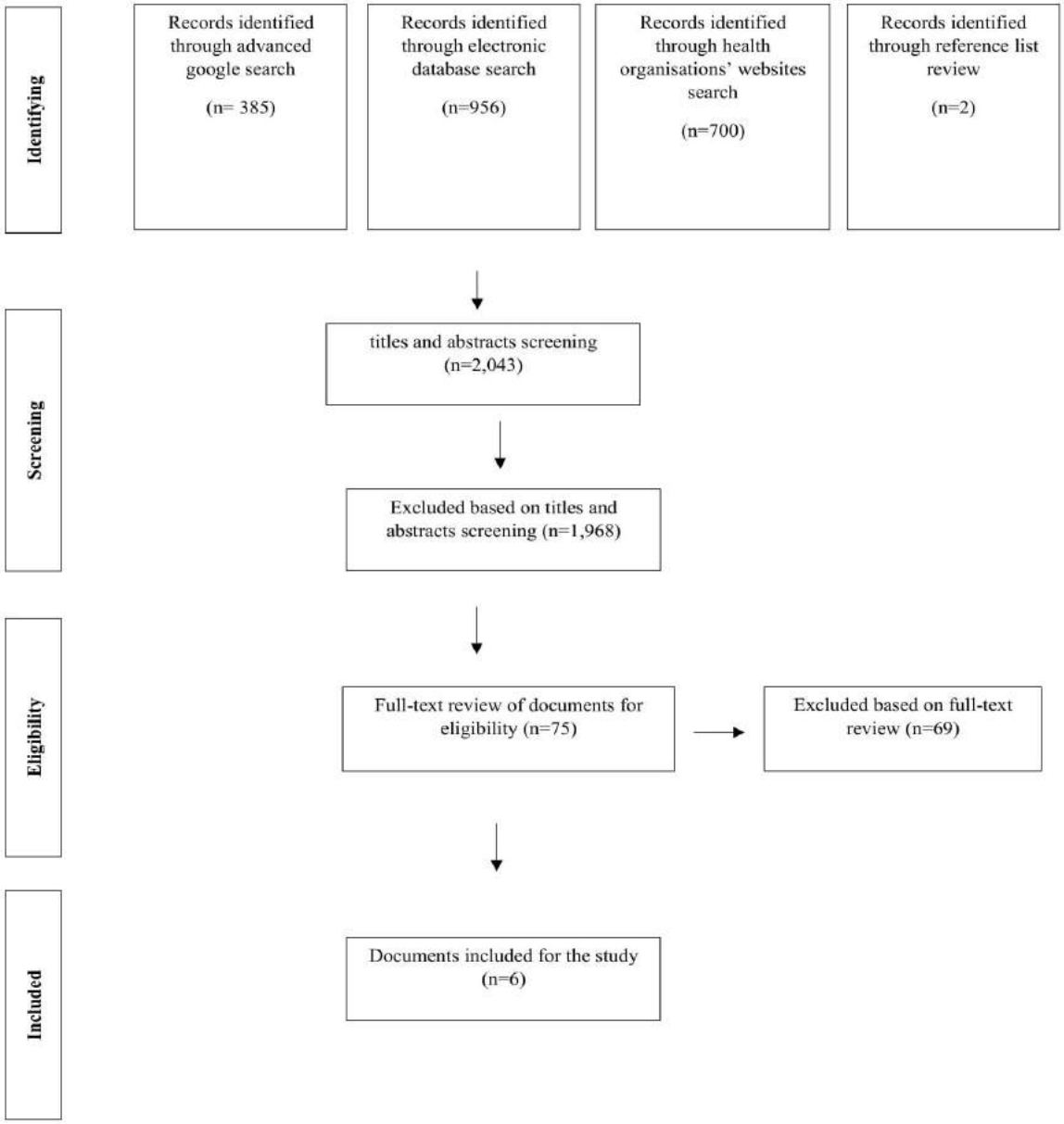

Table 2: A summary of key information of each included document.

Title of the document	Year published	Pages	Prepared by	Stated aim	Target population	Setting	Number of methods of MMS measures included
Patient Safety Strategy 2019-2024	2019	26	Health Service Executive (HSE)	To improve the safety of all patients by identifying and reducing preventable harm within the health and social care system.	'Patient' refers to all people who attend/ use health and social care services. "Staff" includes all healthcare professionals (HCPs), clinicians, support workers, managers, and administration	Every level of health and social care services, within both community and acute hospital services.	N= 52* 1. Harm; 12 (22.6%) 2. Reliability of safety critical processes; 3 (5.6%) 3. Sensitivity to operations; 10 (18.8%) 4. Anticipation & preparedness; 12 (22.6%) 5. Integration & learning; 16 (30.2%)
Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance	2008	227	Government of Ireland. The Commission on Patient Safety and Quality Assurance	To provide recommendations for a framework of patient safety and quality.	'Patient' refers to all people who use health and social care services. 'Clinician' refers to all HCPs involved in clinical work.	All levels of the health system	N= 6 1. Harm; 1 (16.6%) 2. Reliability of safety critical processes; 1 (16.6%) 3. Sensitivity to operations; 3 (50%) 4. Anticipation & preparedness; 0 (%) 5. Integration & learning; 1 (16.6%)
Acute hospitals key performance indicator metadata 2021	2021	118	Health Service Executive (HSE)	KPI Metadata templates are completed for all National Service Plan metrics and provide the most up to date information relating to KPIs.	Information includes definition, rationale, reporting frequency, and data source. They underpin data quality, accessibility, records management for data collectors and inform users of data.	Acute hospitals	N= 15 1. Harm; 5 (33.3%) 2. Reliability of safety critical processes; 10 (66.6%) 3. Sensitivity to operations; 0 (%) 4. Anticipation & preparedness; 0 (%) 5. Integration & learning; 0 (%)
National Standards for the Conduct of Reviews of Patient Safety Incidents 2017	2017	60	Health Information and Quality Authority (HIQA) and Mental Health Commission (MHC)	To promote a framework for best practice in the conduct of reviews of patient safety incidents and intend to set a standard for cohesive, person-centred reviews of such incidents.	The standards were developed with an initial focus on services-specific for acute hospitals and mental health services.	Acute hospitals under HIQA's remit and mental health services under the remit of the MHC.	N= 37 1. Harm; 2 (5.4%) 2. Reliability of safety critical processes; 16 (43.2%) 3. Sensitivity to operations; 3 (8.2%) 4. Anticipation & preparedness; 5 (13.5%) 5. Integration & learning; 11 (29.7%)

Incident Management Framework 2020	2020	42	Health Service Executive (HSE)	To provide an overarching practical approach, based on best practice, to assist providers of HSE and HSE funded services to manage all incidents (clinical and non-clinical) in a manner that is cognisant of the needs of those affected and supports services to learn and improve.	Staff, managers, and Senior Accountable Officer (SAO) and related teams/committees in HSE and HSE funded agencies.	All publicly funded health and social care services provided in Ireland.	N= 23 1. Harm; 6 (26%) 2. Reliability of safety critical processes; 5 (21.7%) 3. Sensitivity to operations; 0 (%) 4. Anticipation & preparedness; 1 (4.3%) 5. Integration & learning; 11 (47.8%)
National Standards for Safer Better Healthcare	2012	157	Health Information and Quality Authority (HIQA)	The National Standards for Safer Better Healthcare aim to give a shared voice to the expectations of the public, service users and service providers. They also provide a roadmap for improving the quality, safety, and reliability of healthcare.	Service users and services providers. The term service provider refers to any person, organisation, or part of an organisation delivering healthcare services, as described in the Health Act 2007.	These National Standards apply to all healthcare services (excluding mental health) provided or funded by the HSE including, but not limited to: hospital care, ambulance services, community care, primary care and general practice.	N= 29 1. Harm; 4 (13.7%) 2. Reliability of safety critical processes; 5 (17.2%) 3. Sensitivity to operations; 0 (%) 4. Anticipation & preparedness; 10 (34.4%) 5. Integration & learning; 10 (34.4%)

A total of 162 methods of MMS were identified across the six documents (see Table 2 and Additional File 2 (Appendix 4) for a list of these methods and how they were classified). Of these MMS methods: 30 (18.4%) were concerned with past harm; 40 (24.5%) were concerned with the reliability of safety critical processes, 16 (9.8%) were concerned with sensitivity to operations, 28 (17.2%) were concerned with anticipation and preparedness, and 49 (30%) were concerned with integration and learning. One method of MMS addressed two of the safety dimensions (past harm and integration and learning), therefore the percentages are calculated out of 163.

Phase Two: Semi-structured Interviews with Key Stakeholders

The mean duration of the interviews was 25 minutes (SD= 11 minutes 58 seconds). The 24 participants included 18 frontline healthcare workers (nine doctors and nine nurses), and six healthcare policymakers. Of the 24 participants, 14 were women and 10 were men. The participants reported a mean of 13 years of professional experience (range= 3-31 years). Twenty-one (87.5 %) of the participants worked in teaching hospitals, and three (12.5 %) in national health regulation organisations.

The MMS methods reported by interviewees are shown in Table 3. Illustrative quotes pertaining to the most commonly reported measures in each safety domain are provided in Table 4. The interviewees described a total of 76 methods of MMS. Of these methods of MMS, 14 (18.4%) were concerned with past harm, 25 (33%) were concerned with the reliability of safety critical processes, 8 (10.5%) were concerned with sensitivity to operations, 15 (19.7%) were concerned with anticipation and preparedness, and 14 (18.4%) were concerned with integration and learning.

The most frequently reported MMS method for past harm was incident reporting (mentioned by 19; 79.2% of the interviewees). In addition, incident reports were by far the most commonly reported method of MMS across all dimensions. Clinical audit was the most frequently mentioned MMS method for the reliability of safety critical processes dimension

(mentioned by 18; 75% of the interviewees). Observation and conversations with clinical teams were the most frequently described MMS method for the sensitivity to operations dimension (mentioned by 8; 33.3% of the interviewees), followed by safety walk-rounds (mentioned by 6; 25% of the interviewees) and safety huddles which were also (mentioned by 6; 25% of the interviewees). Analysis of incidents and feedback leading to the implementation of safety lessons (mentioned by 12; 50% of interviewees) was the most often reported MMS method in the dimension of integration and learning.

Table 3: Methods reported by participants to measure and monitor patient safety in Irish hospitals.

	Dimension	No.	Reported methods of measuring and monitoring safety	Number of participants reported the measure (no.) %		
				(18) 87.5%	(6) 12.5%	(24) 100%
				Front-line healthcare staff	Policy makers	All
1.	Harm	1.	Incident reporting systems	(15) 83.3%	(4) 66.6%	(19) 79.2%
		2.	National Incident Management System -NIMS	-	(1) 16.6%	(1) 4.2%
		3.	Hospital acquired complications	-	(1) 16.6%	(1) 4.2%
		4.	Hospital In-Patient Enquiry – HIPE	-	(1) 16.6%	(1) 4.2%
		5.	Mortality and morbidity rates	(5) 27.8%	-	(5) 20.8%
		6.	Patient safety indicators	(1) 5.5%	-	(1) 4.2%
		7.	Incidence of falls	(2) 11%	-	(2) 8.3%
		8.	Pressure ulcers rates	(3) 16.7%	-	(3) 12.5%
		9.	State claims agency	(1) 5.5%	-	(1) 4.2%
		10.	Medication error reporting	(3) 16.7%	-	(3) 12.5%
		11.	Rates of healthcare associated infections HCAIs	(1) 5.5%	(1) 16.6%	(2) 8.3%
		12.	Readmission rates	(1) 5.5%	-	(1) 4.2%
		13.	Patient satisfaction surveys	-	(1) 16.6%	(1) 4.2%
		14.	Patients' complaints systems	(1) 5.5%	-	(1) 4.2%
2.	Reliability of safety critical processes	1.	Monitoring compliance to hand hygiene	(1) 5.5%	(2) 33.3%	(3) 12.5%
		2.	Observation of safety critical behaviours	(2) 11%	-	(2) 8.3%

3.	Monitoring national standards	(5) 27.8%	(1) 16.6%	(6) 25%
4.	National/international accreditation	(1) 5.5%	-	(1) 4.2%
5.	Inspections to monitor compliance against standards and guideline	(4) 22.2%	(1) 16.6%	(5) 20.8%
6.	Venous thromboembolism risk assessment	(1) 5.5%	-	(1) 4.2%
7.	Key performance indicators of patient safety goals	(3) 16.7%	(1) 16.6%	(4) 16.7%
8.	Audit of equipment	(6) 33.3%	-	(6) 25%
9.	Infection control checklists	(1) 5.5%	-	(1) 4.2%
10.	Clinical audit	(14) 77.8%	(4) 66.6%	(18) 75%
11.	Patient observation charts	(4) 22.2%	-	(4) 16.7%
12.	Double checks by other staff members	(7) 38.9%	-	(7) 29.2%
13.	Monitoring of vital signs	(1) 5.5%	-	(1) 4.2%
14.	Quality and safety monthly governance meeting	-	(1) 16.6%	(1) 4.2%
15.	Patient Administrations Systems	-	(1) 16.6%	(1) 4.2%
16.	Specialty-Specific Data Management Systems	-	(1) 16.6%	(1) 4.2%
17.	Turnaround Times – TAT	-	(1) 16.6%	(1) 4.2%
18.	Early Warning Score	(6) 33.3%	(2) 33.3%	(8) 33.3%
19.	Armbands to identify patients at risk	(1) 5.5%	-	(1) 4.2%
20.	Surgical checklist	(3) 16.7%	-	(3) 12.5%
21.	Systems to check bed availability	(1) 5.5%	-	(1) 4.2%
22.	Preoperative assessment clinic	(1) 5.5%	-	(1) 4.2%
23.	Medication administration checklists	(1) 5.5%	-	(1) 4.2%
24.	Staff assessment and credentialling	(1) 5.5%	-	(1) 4.2%

		25.	Monitoring delays in treatment	(1) 5.5%	-	(1) 4.2%
3.	Sensitivity to operations	1.	Safety walk-rounds	(5) 27.8%	(1) 16.6%	(6) 25%
		2.	Talking to patients	(3) 16.7%	-	(3) 12.5%
		3.	Safety huddles	(4) 22.2%	(2) 33.3%	(6) 25%
		4.	Briefings and debriefings	(2) 11%	-	(2) 8.3%
		5.	Observation and conversations with clinical teams	(7) 38.9%	(1) 16.6%	(8) 33.3%
		6.	Ward rounds and routine reviews of patients and working conditions	(2) 11%	-	(2) 8.3%
		7.	Handover and handouts	(4) 22.2%	-	(4) 16.7%
		8.	Real time monitoring and feedback in anaesthesia	(1) 5.5%	-	(1) 4.2%
4.	Anticipation and preparedness	1.	Failure mode and effect analysis (FMEA) to identify risks	(1) 5.5%	-	(1) 4.2%
		2.	Staff assessment and credentialing	(3) 16.7%	-	(3) 12.5%
		3.	Risk registers	-	(4) 66.6%	(4) 16.7%
		4.	Anticipated staffing levels and skill mix	(7) 38.9%	-	(7) 29.2%
		5.	Screening for embolism	(1) 5.5%	-	(1) 4.2%
		6.	Timely safety alerts	-	(1) 16.6%	(1) 4.2%
		7.	Comprehensive hazard identification risk assessment	-	(1) 16.6%	(1) 4.2%
		8.	A hospital emergency management plan that is aligned with the city's emergency management plan	-	(1) 16.6%	(1) 4.2%
		9.	Comprehensive risk assessments of patient at admission	(4) 22.2%	-	(4) 16.7%
		10.	Fall risk assessment	(1) 5.5%	-	(1) 4.2%
		11.	Waterlow skin assessment	(2) 11%	-	(2) 8.3%
		12.	Malnutrition Universal Screening Tool – MUST	(2) 11%	-	(2) 8.3%
		13.	Nursing pools	(1) 5.5%	-	(1) 4.2%

	14.	Risk predictions scores in anaesthesia	(1) 5.5%	-	(1) 4.2%
	15.	Preoperative assessment of patients	(2) 11%	-	(2) 8.3%
5. Integration and learning	1.	Analysis of incidents and feedback leading to the implementation of safety lessons	(8) 44.4%	(4) 66.6%	(12) 50%
	2.	Learning from audits	(1) 5.5%	-	(1) 4.2%
	3.	Learning from patient safety alerts	-	(1) 16.6%	(1) 4.2%
	4.	Learning from patients' complaints	(2) 11%	(1) 16.6%	(3) 12.5%
	5.	Learning from meetings and discussion of sentinel events	(2) 11%	-	(2) 8.3%
	6.	Debriefing sessions to provide feedback on clinical performance	(3) 16.7%	-	(3) 12.5%
	7.	Learning from Root Cause Analysis	(2) 11%	(1) 16.6%	(3) 12.5%
	8.	Learning from excellence	-	(1) 16.6%	(1) 4.2%
	9.	Learning reported in research papers from other health organisations	-	(2) 33.3%	(2) 8.3%
	10.	learning from safety networks that involve local and national health agencies	(1) 5.5%	(2) 33.3%	(3) 12.5%
	11.	After Action Reviews (AAR)	-	(1) 16.6%	(1) 4.2%
	12.	Learning from international experience reported in the literature	-	(1) 16.6%	(1) 4.2%
	13.	Simulation sessions following patient safety incidents	(5) 27.8%	-	(5) 20.8%
	14.	Learning from mortality and morbidity reviews	(2) 11%	-	(2) 8.3%

Table 4: Example quotes from the interview transcripts.

Dimension	Example quotes
1. Harm	**Incident reports**
	'There is the Q-Pulse system, which is a self-reporting system in the hospital, and there are different categories for reporting, things related to work and things related to safety, and other related to other things to improve quality and safety and so on' (Doctor 1)
	'I suppose the most prominent method would be the use of incident report systems' (Doctor 6)
	'Within Irish hospitals, the method used to measure, and monitor harm would mainly be incident reporting systems' (Policymaker 4)
	Mortality and morbidity rates
	"One major thing would be our departments use of morbidity and mortality rates" (Doctor 6)
2. Reliability of safety critical processes	**Clinical audit**
	'Clinical audit, we have a very robust audit and quality improvement department in the hospital, doctors and nurses are invited to carry out audits' (Doctor 6)
	Early Warning Score
	"The early warning score, that was another initiative that was brought in that's countrywide as well" (Nurse 7)
3. Sensitivity to operations	**Observation and conversations with clinical teams**
	'Direct observation of procedures, whereby a senior will initially observe you performing procedure and in a structured manner and observe the different steps and analyse what you're doing and then deliver feedback afterwards' (Doctor 6)
	Safety walk-rounds
	'There are ground round or ward round. I think every senior in any team should be able to do at least one round every day with the juniors, and there should be a bigger round done every week for example in presence of all seniors' (Doctor 2)
	Safety huddles
	'There is also what we call the safety pause or the safety huddle, so during the safety huddles, we'll discuss whether there has been anything wrong, or there is something that isn't working properly, and needs to be fixed that is related to patient safety, we also discuss whether there are any new guidelines or protocols' (Nurse 2)

4.	**Anticipation and preparedness**	**Anticipated staffing levels and skill mix** ‘anticipating staffing levels, for example, during the winter, there's going to be a rise in your flu cases, so anticipating that we're going to need more staff nurses at that time’ (Nurse 9) **Comprehensive risk assessments of patients at admission** “There are assessments as soon as the admission takes place in order for us to avoid harm. We will assess several factors, and then we know, does this patient need more care?” (Nurse 3)
5.	**Integration and learning**	**Analysis of incidents and feedback leading to the implementation of safety lessons** ‘When an incident report is filed, this is discussed by specific team that manages incident reports and usually they discuss it with the person that's involved, not in terms of putting blame, but in terms of addressing how the mistake happened and how to prevent it’ (Doctor 5) **Simulation sessions following patient safety incidents** “So, I think simulation plays a big role. We certainly do that. From time to time will run multi-disciplinary simulations with the nurses and sometimes with ICU or other teams” (Doctor 8)

Discussion

A fundamental challenge to improving patient safety in healthcare is a dearth of high-quality information that allows organisations and individual practitioners to analyse their performance, define priorities, and identify areas of deficiency and risk. In this study, we examined how patient safety is measured and monitored in Irish hospitals, mapped these methods onto Vincent et al.'s [4,7] MMS framework, and reflect on the meaning of these findings for MMS in Irish hospitals.

Considering both the findings from the document analysis and interviews, it can be seen that a wide variety of methods are used to MMS in Irish hospitals. However, although there were measures from across all five of the MMS framework dimensions, there was some variability in the number of methods within the dimensions. Measures of the reliability of safety critical processes were the most commonly identified methods of MMS in the document analysis and interviews. This may reflect the amount of routine safety data that are collected in Irish hospitals. The dimension with the smallest number of measures was sensitivity to operations. A possible explanation for this finding is that these measures tend to be qualitative (e.g. talking with patients and staff, observing staff) [16]. Such 'soft intelligence' is generally more difficult to collect, and analyse, than is the case for quantitative data [17]. However, this qualitative data can provide valuable insights into issues that may not be possible to gain from quantitative methods of MMS. Automated language analysis methods are beginning to be used to analyse qualitative patient safety data [18]. Therefore, there is the potential for the analysis of qualitative data to become much easier, and faster, than in the past.

Of all measures identified by the interviewees across the five MMS safety dimensions, incident reports were the most common method of MMS-identified by almost four-fifths of the interviewees. However, the international literature suggests that healthcare organisations may overly rely on the analysis of past events and past harms as a source of safety

performance information [19-21]. Thus, whilst it is a positive that frontline healthcare workers are aware of the importance of collecting information on adverse events, it is important that the limitations of this particular measure are recognised. It is well known that reporting systems underestimate the prevalence of patient safety incidents [22] and overestimate the severity of harm [23]. Therefore, it is important to avoid an over-reliance on incident reports, and past harm more generally, as the primary source of safety data.

The second most common method of MMS identified by the interviewees was clinical audit- identified by three quarters of the interviewees. Clinical audits are widely used in many healthcare systems to assess clinical performance against pre-set standards and use the data to enhance practice [24]. Nevertheless, despite their widespread use, audits' effectiveness as a practice-improvement strategy is often presumed, rather than supported by robust evidence [24]. A review of the impact of clinical audit on healthcare workers practice and patient outcomes concluded that audits resulted in a little change, only 4% of the studies which used clinical audit resulted in an increase in the desired practise [25]. Research found that audits were more likely to be successful when there was low baseline performance, feedback was offered several times by a colleague or supervisor in both verbal and written formats, and defined objectives and an action plan were included [24]. Moreover, clinical audit places a considerable burden on staff to complete [26]. It is certainly not suggested that the health service abandons the practice of clinical audit. However, there is a need to consider how to reduce the resources, and burden, of MMS [3].

Recommendations

Our study has shown that there are methods of MMS from across all five dimensions of the framework. However, despite collecting large volume of safety data about hospital care, it still remains challenging to determine the safety of the delivery of care [4,7]. It has been suggested that healthcare stakeholders could get the information they need with a quarter of what is currently being spent on MMS [27]. The WHO has also identified the burden of collected and analysing data as a barrier to MMS [3]. Therefore,

to improve patient safety in the Irish healthcare system, we recommend a number of issues that should be addressed.

Reliability of safety data. The reliability of most safety data is unknown, and in some cases the reliability may actually be known to be problematic (e.g. hand hygiene compliance). If measures are poorly designed, this can lead to 'gaming', where targets are achieved but the intended changes in practice are not [28]. Therefore, consideration needs to be given to identifying which methods of MMS result in reliable data.

Fragmentation of data. There are a huge range of methods of MMS focused at different levels of a healthcare organisation (e.g., units, hospitals), by different organisations (e.g. HIQA, Department of Health). This fragmentation of data creates challenges for healthcare professionals and managers in identifying where improvement efforts should be made, and whether these efforts are effective [1]. It is recommended that there is a consolidation of efforts across these agencies to avoid repetition and overlap of efforts.

Quantity of safety data. A total of 162 methods of MMS were identified from the document analysis, and 76 methods of MMS identified from the interviews. This quantity of data can be overwhelming for healthcare workers and managers. There is a need for safety data to be readily interpreted so that safety issues can be identified at unit, hospital, and national levels. Measures that are too burdensome or lack credibility may alienate clinicians and lead to confusion about the impact of interventions [29]. It is suggested that the perspectives of all stakeholders in healthcare should be taken to identify key measures, from across the five MMS domains, that are particularly useful in supporting action and improvement, and do not place a large burden on healthcare staff to use.

Lack of ownership of the data. Much of the data is focused on measures generated externally to a clinical team, so the teams may not perceive the data as being related to their performance [30]. Consideration should be given to how to engage front-line clinical staff in MMS so that they feel some ownership and are empowered to act upon the data, and involving them, and other stakeholders, in identifying meaningful methods of MMS.

Limitations

There are a number of limitations of this research that should be acknowledged. The main limitation is that this paper only focused on MMS in the Irish healthcare system. However, the findings are similar to those derived from a study that utilised the same methodology to consider the MMS in the Saudi Arabian healthcare system [11]. Therefore, there would appear to be generalisability of the findings to other healthcare systems. As is the case with other qualitative approaches, our study could be critiqued due to the subjectivity of this type of research. However, these issues were mitigated through the rigorous approach we took to the data collection and analysis. The focus of the interviews was on identifying the methods of MMS, and did not include an analysis of the quality of the data collected using these approaches. Finally, we only considered national-level publications in the document analysis, containing data that applied or could be applied at a national or strategic level, rather than single-site studies, local reports, or a single process. This may have led to the exclusion of useful hospital-level documents; however, the difficulty in systematically accessing hospital-level documents was a barrier to their inclusion.

Conclusion

There are wide range of methods of MMS in Irish hospitals. However, having larger numbers of methods of MMS does not necessarily correspond to a robust safety surveillance system. It is suggested that the input of all stakeholders in healthcare are gathered to identify particularly key measures, across the five MMS domains, in order to identify those methods of MMS that are particularly useful in reducing harm, supporting action and improvement, and do not place a large burden on healthcare staff to use or interpret.

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Chapter 4: Study 3

A scoping review of patient safety research carried out in Saudi Arabian hospitals

A scoping review of patient safety research carried out in Saudi Arabian hospitals

Declaration

Where This Fits in with the Thesis

In Saudi Arabia (SA), various initiatives have been implemented with the aim of improving patient safety. However, patient safety and harm avoidance have become even more important as the number of medical liability cases throughout the country continues to escalate [1,2]. Researchers in SA have stressed the necessity of conducting additional research in order to fully understand the patterns and burden of patient safety issues within the Saudi healthcare system [3]. Therefore, in this third study, a scoping review was conducted with the aim of mapping the quantity and nature of current patient safety research in Saudi Arabian hospitals as well as identifying gaps in the existing literature.

Peer-reviewed Publication

This study has been accepted and published in a peer-reviewed journal. The citation is: Kaud Y, O'Connor P, O'Malley R, Dunne R, Lydon S. A scoping review of patient safety research carried out in Saudi Arabian hospitals. IJQHC Communications. 2022 Jul 1;2(2):lyac014.

The following chapter is a formatted version of the submitted manuscript to the journal.

Conference Presentations

Oral Presentation

Kaud Y. A Scoping Review of Research Conducted on Patient Safety in Saudi Hospitals. Paper presented at: 3rd Global Conference on Education and Teaching; 2022 Jul 15-17; Amsterdam, Netherlands.

Authors' Contributions

This study was led by YK. All authors involved in the design and planning of the review. RD developed the search strategy. YK conducted the searches. YK. and ROM were responsible for completing the data extraction. YK drafted the initial manuscript with POC and SL assisting with redrafting it. All authors reviewed and approved the manuscript prior to submission.

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Abstract

Background. In Saudi Arabia, there has been substantial investment in patient safety initiatives.

Objectives. The objectives of this scoping review were to map the quantity and nature of existing research on patient safety in Saudi Arabian hospitals and to identify gaps in the extant literature.

Methods. Electronic searches were completed using five databases. Peer reviewed studies written in English or Arabic that focused on patient safety in hospitals in Saudi Arabia were reviewed. Studies concerned with measuring and monitoring safety were categorised using the Measuring and Monitoring Safety Framework. The hierarchy of intervention effectiveness was used to categorise interventions studies.

Results. A total of 2,489 studies were screened, with 67 ultimately included. In total, 61 (91%) of included studies were focused on the measurement or monitoring of safety. Six studies (9%) considered interventions to improve patient safety. Of these, 31.3% of the studies assessed past harm, 1.5% reliability of safety systems, 7.5% sensitivity to operations, 47.8% anticipation and preparedness, and 3% (2/67) integration and learning. Of the six intervention studies, one study reported enforcing functions interventions, one simplification and standardisation, two rules and policies, and two studies applied an education and training intervention.

Conclusion. As is the case internationally, there is a paucity of evidence on interventions to improve safety in Saudi Arabia. This review has identified areas of strength, redundancy, and gaps in patient safety research in Saudi Arabia. However, the findings also have implications for the MMS in other healthcare systems.

Conflict of interest: The authors have no conflict of interest.

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Introduction

There has been an increasing focus on patient safety in secondary care in the past two decades with a growing body of literature describing different approaches and interventions to improve patient safety [1]. Nevertheless, rates of patient harm remain high with 1 in 10 patients experiencing an adverse event during hospital admission [1, 2]. In Saudi Arabia (SA), as is the case internationally, maintaining high standards of patient safety is a core principle of the country's healthcare system and there has been substantial investment in patient safety initiatives [3]. However, previous research has indicated that patient safety remains an issue, resulting in a rising numbers of medical liability claims [4, 5].

It cannot be assumed that an intervention that is successful in one country will be effective in another [6]. This issue has been recognised by the World Health Organization, which recommends that patient safety interventions are carefully tailored to the health service of the country in which the intervention is to be applied [7]. A paucity of patient safety research in developing or transitional countries has been noted as a weakness of the literature [8]. There is an urgent need for research in these nations in order to support understanding of the extent of patient safety issues and the best means of reducing the risk to patients. Accordingly, research across different countries and cultures are needed to improve our knowledge of patient safety and support policymakers and managers in implementing patient safety interventions [6] and seeking to improve safety of care [9].

Specifically in SA, scholars have emphasised that adverse events are not infrequent in the SA healthcare system and argue that additional research is essential to understand the patterns and burden of patient safety concerns within the Saudi healthcare system [10]. However, the lack of an overview of patient safety research in SA means that current strengths and weaknesses are unknown. Therefore, the aim of our scoping review was to map the amount and nature of existing research on patient safety in Saudi Arabian hospitals and to identify gaps in the extant literature. This review will

provide an understanding of the current state of knowledge regarding patient safety in SA and support the advancement of both research and practice on patient safety in SA and internationally.

Methods

Review Design

The scoping review is underpinned by Arksey and O'Malley's scoping review framework [11] and is reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist [12] (see Supplementary Material 3 (Appendix 7)). Scoping reviews are an increasingly popular methodology for synthesising and mapping evidence in healthcare research [13].

Stage 1: Identifying the Research Question

The primary research question in this review was: What is the amount and nature of existing research on patient safety in Saudi Arabian hospitals? A secondary research question was: What are the gaps in research on patient safety in Saudi Arabian hospitals?

Stage 2: Identifying Relevant Studies

Search strategy. Electronic searches were completed in May 2021 using five electronic databases: Medline, CINAHL, Embase, PsycInfo, and Web of Science. The search strategy was developed, reviewed, and enacted by a research subject librarian at our institution (RD). The full Medline search strategy is presented in Online Supplementary Materials 1 (Appendix 5) and altered as necessary for other databases. Following completion of electronic searches, reference list screening was undertaken. As part of this process, the reference lists of all studies identified for inclusion during the electronic searches were reviewed in order to identify additional, potentially relevant studies.

Stage 3: Study Selection

Papers returned from the databases were exported to Endnote©, and study

selection and review was completed in June 2021. All titles and abstracts were reviewed against the inclusion criteria by two authors (YK, ROM). A full-text review was conducted for each return that appeared eligible for inclusion, or if the relevance of the return was unclear from the title and abstract. In any instances where inclusion or exclusion was unclear, the paper was reviewed by all members of the research team and a decision was made by consensus.

Inclusion Criteria. Studies were included if they: (i) were published in a peer-reviewed journal; (ii) reported original research; (iii) were focused on patient safety in hospitals in SA including, but not limited to, the measurement of safety or implementation of interventions to improve safety, and; (iv) were written in English or Arabic.

Exclusion Criteria. Studies were excluded if they: (i) focused only on patient safety in the context of patients with a particular medical condition because these patients may have particular safety issues that are not necessarily generalisable to other patients (e.g. mechanically ventilated patients); (ii) focused only on the safety of one particular process (e.g. medication errors); (iii) focused on safety in healthcare settings other than hospitals; (iv) focused on patient safety in a country other than SA; (v) only included one item or question relating to patient safety as part of a larger survey or assessment (i.e., studies needed to use a full measure of patient safety, not just one question), or; (vi) did not report original research. Finally, in cases where a paper included patient safety data from multiple countries, we included only those in which we could extract the SA specific data. No publication date or period were specified. Duplicate were removed by using the find duplicates command in Endnote©.

Stage 4: Charting the Data

Charting the data is a similar process to 'data extraction' in systematic reviews [11] in which relevant information is taken from included studies by the review team. A data charting form was created and, in line with the Joanna Briggs Institute methodological guidelines (JBI guidelines) [14], the

form was tested by two authors (YK, ROM) on four data sources.

The data charted were as follows: author(s), year of publication, study location, aim of the study, methods, study population, intervention (if any), comparator (if any), outcome measures, and key reported outcomes. Data charting was conducted independently by two of the authors (YK and ROM) for each of the included articles, and any disagreements that emerged during comparison of the two data charting forms were resolved through discussion until consensus was achieved.

Stage 5: Collating, Summarising and Reporting the Results

The characteristics of the included studies were collated and summarised across a number of descriptors: location; aim; methods; sample; type and duration of intervention (if applicable); comparators (if applicable); outcome measures; and key outcomes.

Included studies were categorised using one of two different frameworks. Those studies that were identified as being concerned with assessing safety were classified using the Vincent et al. [15, 16] Measuring and Monitoring Safety (MMS) framework (see Table 1).

Table 1 Summary of key findings from included MMS studies

MMS dimension	Key findings
Past harm - Has patient care been safe in the past?	• Lack of time, training, or skills were frequently reported by nurses as key barriers to report incidents [23, 27, 31]. • Physicians and nurses prefer to disclose near misses or errors that did not lead to harm as compared to those that do lead to harm [23, 27]. • Review of medico-legal claims demonstrated that obstetrics was the most litigation-prone medical specialty [36]. • Unavailability or failure to implement policies and procedures was a common root cause of sentinel events [32, 33]. • Failure to follow organisational policies and procedures was the most commonly reported type of incidents in hospitals [37]. • Heavy workload and lack of education or experience were significantly higher than any other contributory factor to adverse events [39]. • A patient survey found that approximately one fifth of patient respondents say they have experienced a medical error, two thirds of the respondents did not report the error, and half of respondents did not know how to report an error [25].
Reliability of safety critical processes - Are clinical systems and processes reliable?	• Compliance to safety critical processes and measures were found to be high in two governmental hospitals. Factors such as hospital environment, work experience, job title, and previous training on patient safety were not found to impact compliance with safety critical processes [40].
Sensitivity to operations - Is care safe today?	• Moderate levels of both empowerment and willingness to speak up against unsafe practice were found amongst nurses, and willingness to speak up was correlated with participants' perceived access to support at work [43]. • Nurses experiences of uncivil acts whether from nurses or from patients and visitors negatively impact nurses' patient safety competence [44]. • Key risk factors that negatively impact patient safety include shortage of medical staff, poor design of the hospital structure, long working hours, overcrowding of patients, poor coordination between hospital departments, a blame culture, and lack of clinical practice standards [41]. • There is a need to improve several system factors that influence patient safety, including the ability to communicate suggestions regarding patient safety improvement; information technology support and training; and a confidential error reporting system [42].

Anticipation and preparedness - Will care be safe in the future?	• Studies that use the hospital survey on patient safety culture (HSPSC) found positive perceptions towards teamwork within units [45, 49, 50, 53, 55–59, 63, 65] organisational learning-continuous improvement [45, 49, 50, 53, 55, 56, 58–60, 63, 65] and feedback and communication about error [45, 46, 49, 50, 56, 59, 60, 63, 65], However, there were negative perceptions towards non-punitive response to error [48, 50–53, 56, 58, 59, 62, 63, 65] and staffing [46, 48–51, 53, 56, 58, 62, 63, 65]. • The mean score of each safety attitudes questionnaire (SAQ) dimension was <75%, demonstrating that nurses and doctors in general had less than a positive safety attitude [67]. This was especially evident in the dimensions of stress recognition and perceptions of management [66, 67]. However, job satisfaction was rated as a positive dimension of safety culture [66, 67].
Integration and learning - Are we responding and improving?	• Most healthcare workers considered that information about safety incidents should not be shared through social media [77]. • The main drivers of a positive safety culture are feedback about errors and effective communication [78].

For interventional studies, interventions or initiatives described were classified using the hierarchy of intervention effectiveness framework (see table 2) [17, 18].

Table 2 The hierarchy of intervention effectiveness [a] and key finding from the included studies

Category of intervention	Definition	Key findings
Forcing functions	Instituting safeguards within processes or systems such that making mistakes is practically impossible or very difficult.	• Implementation of a patient safety management model improved patient safety practices, patient safety indicators, and patient outcomes [79].
Automation & computerisation	Automating or computerising processes or tasks in order to reduce human error (e.g. computerised pharmaceutical information systems [17]).	• No interventions of this type in the included papers.
Simplification & standardisation	Promoting consistency in the conduct of procedures, and/or eliminating unnecessary steps, to increase likelihood of their effective conduct.	• Following implementing of a comprehensive management system, there was an increase in reporting of 'no harm' incidents from 14.2 to 28.1 incidents per 1000 patient days [80].
Reminders, checklists & double checks	Implementation of reminders, checklists, and/or double checks to ensure procedures are performed correctly.	• No interventions of this type in the included papers.
Rules and policies	Introducing new regulations or emphasising existing standards.	• Accreditation led to perceived improvements in patient safety and quality of care [19]
Education & training	Educating and informing staff for the purpose of preventing errors and improving safety.	• Implementation of a patient safety educational pro-gramme improvements were observed in safety climate, teamwork climate, nurse turnover rates on ICUs, and nurse knowledge and attitude towards patent safety [81]. • Significant improvement in incident reporting practices after the implementation of an educational programme on incident reporting [82].

[a] Adapted from the Institute for Safe Medication Practices [17] and Patient safe Implementing effective safety solutions [18].

The included studies were categorised by two researchers (YK and ROM). In any instances where there was disagreement in the classification, the study was reviewed by all members of the research team and a decision on the classification was made by consensus. Following completion of all data charting and coding, the meaning of the findings and their implications were appraised within the context of the broader literature in this area.

Results

A total of 67 articles met the eligibility criteria. Two articles [19, 20] used the same dataset to address the same research question, and so were considered as one study for the purpose of this review. Figure 1 presents the PRISMA flow diagram depicting study selection for this review, and Table 3 provides a summary of the characteristics of the included studies including publication date, types of research methodology, and research area. Overall, a far greater proportion of studies were determined to be focused on measuring and monitoring safety (61; 91%) than on interventions or initiatives to improve patient safety (6; 9%).

Figure 1. PRISMA flowchart of the search and screening process

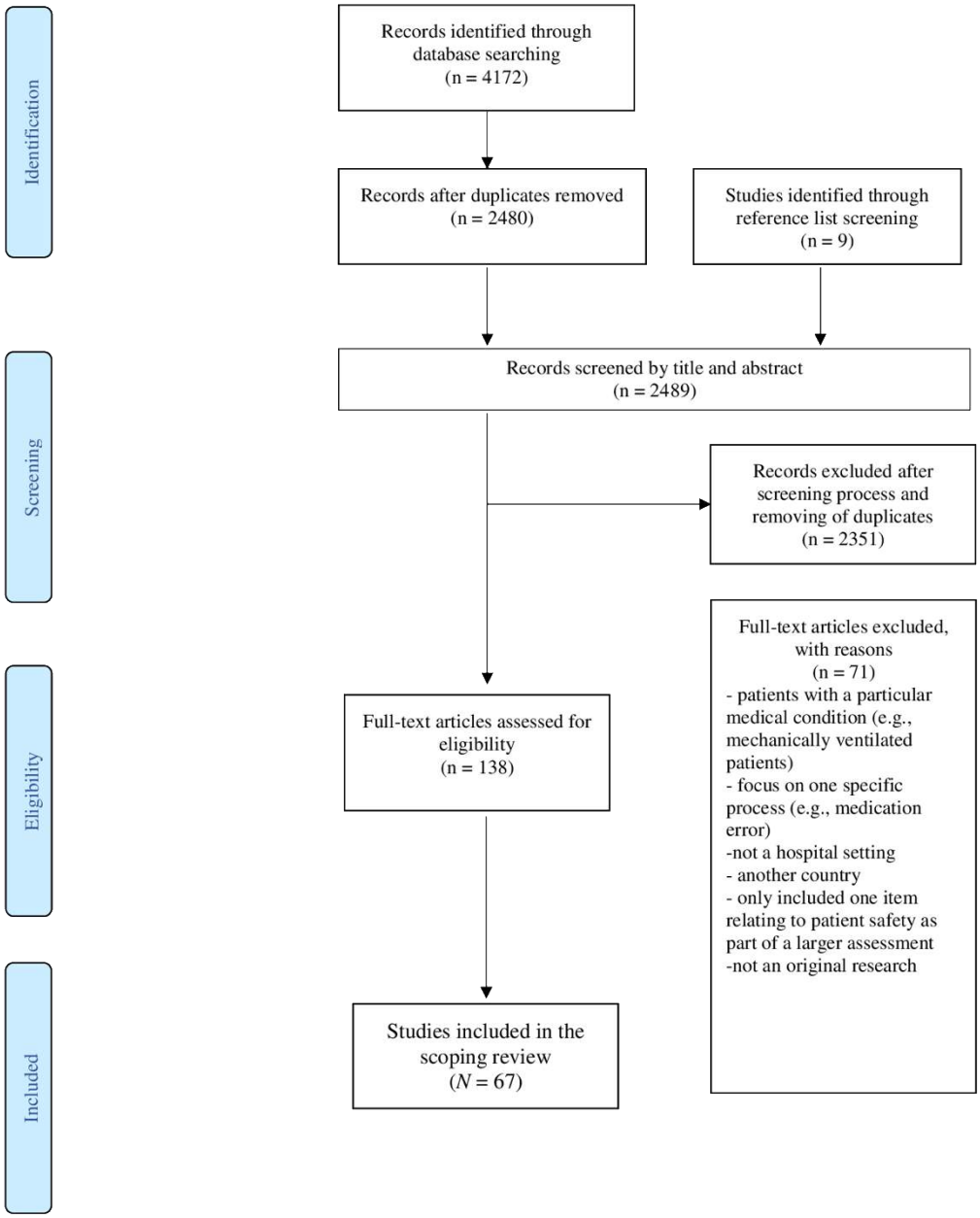

Table 3 Summary of the characteristics of the included studies.

Characteristics	Studies n (%)
Year of publication	
2000-2004	1 (1.5%)
2005-2008	1 (1.5%)
2009-2012	16 (23.8%)
2013-2016	13 (19.4%)
2017-2020	29 (43.2%)
From January to May 2021	7 (10.4%)
Method	
Quantitative	63 (94%)
Qualitative	1 (1.5%)
Mixed methods	3 (4.5%)
Categorisation of MMS studies based on Vincent et al's framework (n=61; 91%)	
Past harm*	21 (31.3%)
Reliability of safety critical processes	1 (1.5%)
Sensitivity to operations*	5 (7.5%)
Anticipation and preparedness	32 (47.8%)
Integration and learning	2 (3%)
Categorisation of intervention studies based on the hierarchy of intervention effectiveness (n=6; 9%)	
Forcing functions	1 (1.5%)
Simplification and standardisation	1 (1.5%)
Rules and policies*	2 (3%)
Education and training	2 (3%)

* One study employed measures of both past harm and sensitivity to operations [21]. Two articles [19, 20] used the same dataset to address the same research question, and so were considered as one study for the purpose of this review.

Measuring and Monitoring Safety

A total of 61 studies were concerned with MMS (see Table 3). Table 1 summarises the key findings from these studies.

Past Harm

Twenty one studies focused on methods of measuring and monitoring past harm (See Table 1, and 3 and Online Supplementary Material 2 (Appendix 6)). Eleven studies aimed to evaluate incident reporting practice and identify barriers to reporting or disclosing errors [21-31]. Nine studies used surveys only [23-31], while two studies used a mixed methods approach [21, 22]. Seven studies assessed the pattern of sentinel events and medico-legal claims at a national level using a retrospective review of incidents reports and medical liability claims submitted to the SA Ministry of Health [4, 5, 32-36]. Two studies used a retrospective review of incidents reported to examine rates and categories of incidents at a hospital level [37, 38]. One study surveyed healthcare workers across different hospitals to examine perceived contributory factors to medical error [39].

Reliability of Safety Critical Processes

Only one study addressed the reliability of safety critical processes (See Table 1, and 3 and Online Supplementary Material 2 (Appendix 6)). This study aimed to assess compliance of doctors and nurses towards safety critical processes and measures in two governmental hospitals in one region of SA [40].

Sensitivity to Operations

Five studies included measures concerned with sensitivity to operation (See Table 1, and 3 and Online Supplementary Material 2 (Appendix 6)). Two studies examined organisational and system factors that affect staff perceptions and behaviour towards patient safety [41, 42]. One study examined organisational empowerment and willingness of nurses to speak up against unsafe practice [43]. Another study investigated the effects of workplace incivility on nurses' patient safety competence [44]. Finally, one study aimed to assess the status and contributory factors to patient's awareness, knowledge, and attitude towards patient safety [25].

Anticipation and Preparedness

Thirty two of the included studies focused on anticipation and preparedness

(See Table 1, and 3 and Online Supplementary Material 2 (Appendix 6)). An assessment of safety culture or climate was performed in 29 studies. Twenty-one studies used the Hospital Survey on Patient Safety Culture (HSPSC) [45-65], five studies used the Safety Attitude Questionnaire [66-70], one study employed the Safety Climate Survey [71], and one study used a questionnaire developed by the authors [72]. One study used a qualitative approach to examine perceptions of patient safety climate using semi-structured interviews [73]. One study focused on anticipating night shifts impact on performance and patient safety [74]. Another study examined several organisational factors that influence patient safety climate [75]. The association between burnout, resilience and safety culture was assessed in one study [76].

Integration and Learning

Only two studies focused on integration and learning (See Table 1, and 3 and Online Supplementary Material 2 (Appendix 6)). One study examined healthcare workers use of social media to speak up about patient safety incidents [77], and the other focused on communication and feedback about error as key facilitators for a positive safety culture [78].

Interventions to Improve Patient Safety

Six studies focused on interventions to improve patient safety (See Tables 2, 3 and Online Supplementary Material 2). One of these studies was classified as employing a forcing functions intervention [79]. This study described the design of a model for managing patient safety across hospital departments. One study focused on simplification and standardisation. This study compared periods before and after the implementation of a management system for incident reports [80]. Two studies were concerned with the effect of accreditation of the hospital on patient safety and quality [19, 20] and were categorised as interventions relating to rules and policies. Two studies examined the impact of educational programs on improving patient safety practices. One assessed the impact of a patient safety educational program on minimising medical errors and improving patient outcome [81], the other evaluated the impact of a patient safety educational programme [82].

Discussion

Statement of Principal Findings

Overall, a relatively sizable body of research has been conducted on patient safety in SA. This research has predominantly focused on MMS, with relatively few studies considering how best to improve patient safety in hospitals. Among the research concerned with MMS, studies were typically concerned with anticipation and preparedness, particularly the assessment of safety culture using quantitative surveys. Studies concerned with measures of past harm were also frequent and constituted a third of the included studies. Other MMS dimensions have received less attention. Of the small numbers of studies evaluating interventions, there was a focus on education and training.

Strengths and Limitations

The strengths of this review are the use of a broad search strategy with no restrictions on publication date, transparent inclusion, and exclusion criteria, a comprehensive search across five key electronic databases. However, a number of limitations of the review should be noted. First, the review only focused on research pertaining to the SA healthcare system which limits the generalisability of the findings. Second, in line with the scoping review methodology, we did not include/exclude papers based on a quality assessment. Further, a search of grey literature was not carried out. There are issues with including grey literature searches within a systematic review such as compromised methodological reproducibility and difficulties in interpreting these publications [83]. Finally, studies that focused on patient safety in the context of a specific medical condition or on the safety of a single process were excluded from this review. The decision to exclude these studies was because it would have been too difficult to design a search strategy that included every possible medical condition, and process. Therefore, we opted for a strategy that included all publications that met the inclusion criteria, rather than a strategy that, although broader, but may have missed certain studies.

Interpretation within the Context of the Wider Literature

A factor limiting patient safety in SA may be the prevailing culture within hospitals. A number of pieces of evidence support this assertion: a preference for disclosing near misses or errors which did not result in harm rather than errors which did result in harm [23, 27]; identification of blame culture as a factor inhibiting patient safety [41]; safety climate data which consistently suggest punitive responses to error are not uncommon and constitute a significant concern for staff error [48, 50-53, 56, 58, 59, 62, 63, 65]; and a perceived need for a confidential incident reporting system [42].

The existence of such concerns, and potentially a 'blame' culture, is not unique to SA. A recent review focused on factors contributing to patient safety incident reporting showed that fear of adverse consequences was the most frequently mentioned barrier to incident reporting in the international literature [84]. However, some of the SA data in the included studies demonstrated that staff feel unable to speak out against unsafe practices [43] indicated a greater degree of reluctance or fear than among counterparts in other countries [85]. A lack of openness around safety and error has been shown to have a major influence on organisations ability to recognise actual levels of errors [86] and adapt or improve accordingly. Future research should therefore focus on not only conducting cultural change programs in SA hospitals in order to promote a 'just' culture, but also evaluating the impact of these interventions on the rates and types of reported incidents.

This scoping review has identified clear targets for improvement of safety in SA hospitals. In addition to fostering a just culture, other areas for focus include: clarifying of policies and protocols; issues of staffing and workload; and fostering a dialogue on patient safety between frontline workers and managers. These data align with those from a recent review on the quality of care in Saudi Arabian hospitals that indicated that improvements are needed, particularly in patient safety [87]. However, although there is a good availability of data on areas for potential improvement, this review revealed a lack of research describing

interventions to improve patient safety in SA hospitals. There is therefore a clear need to consider how healthcare workers, managers, and researchers in SA can be encouraged to evaluate interventions to improve patient safety.

Only six of the studies in the scoping review were focused on safety interventions. Moreover, these studies were most commonly focused on education and training interventions. Therefore, it is recommended that there is a need for greater consideration of interventions with a systems-focus that are likely to result in more sustained improvements than person-focused interventions like education [17]. It is also important that patient safety interventions are carefully tailored to the health service of the country in which the intervention is to be applied [7]. To illustrate, the goal of the WHO surgical checklist is to reduce surgical morbidity and mortality. However, when comparing the implementation and compliance with the checklist in high-income and low-income countries, researchers found that influences were typically related to contexts [88] (e.g., resources, work environment, structures, and systems). Therefore, leveraging implementation science approaches are vital for both informing the implementation, and evaluation, of safety improvement programmes.

Implications for Policy, Practice, and Research

For effective patient safety policy, practice, and research, stakeholder involvement particularly that of healthcare workers, is crucial. One means of encouraging this stakeholder involvement may be through supporting the establishment of quality improvement (QI) structures. Recent research on QI efforts in SA revealed a gap between institutions that provide continuing medical education and quality departments in hospitals [89], indicating the need to provide opportunities for communication, which is critical for improvement. Furthermore, researchers believe that a central authority is required to clearly lead this collaboration between the two institutions types and ensure the presence of collaborative goals that are understood and aligned with everyday work of staff and the contextual factors within the Saudi health system [89, 90]. Although the research is limited, some positive effects of engaging clinicians in QI have been described [91, 92]

and QI collaboratives, which foster shared learning and support QI efforts, may deliver significant improvements in clinical process and patient outcomes [93]. Given the potential for context to impact on both safety intervention outcomes [6] and QI outcomes [94], it is important to consider local contextual issues (e.g. culture), rather than relying solely on international research and initiatives.

There are strengths and limitations to every approach to MMS. A robust safety surveillance system should include multiple methods that cover all five domains of the MMS framework [95]. It has been postulated that healthcare stakeholders could get the information they need with a quarter of what is currently being spent on measurement [96]. A review of what methods of MMS are being used in the SA healthcare system would allow the identification of domains of safety that are being over-assessed, as well as domains in which there is a lack of information. Rather than volume of data, the aim of a safety surveillance system should be to measure only what matters and focus on learning [96]. Therefore, SA healthcare organisations should review existing safety monitoring systems in order to identify approaches to MMS that are providing useful safety information, across all dimensions of safety, and are not burdensome to implement.

Conclusion

There is considerable research on measuring and monitoring safety in Saudi Arabia, but, as is the case internationally, there is a paucity of evidence on interventions to improve safety. This review has identified areas of strength, redundancy, and gaps in patient safety research in the Saudi Arabia. Efforts to address these gaps and reduce redundancy can best be achieved through collaborations between all stakeholders in the healthcare system—policymakers, healthcare managers, healthcare providers, and patients. It is hoped that this review will provide direction to researchers, healthcare practitioners, and health service managers, in Saudi Arabia and internationally on how to build upon existing research in order to improve patient safety and quality of care.

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Chapter 5: Study 4

Measuring and Monitoring Patient Safety in Hospitals in Saudi Arabia

Measuring and Monitoring Patient Safety in Hospitals in Saudi Arabia

Declaration
Where This Fits in with the Thesis

In order to understand patient safety and facilitate essential improvements, it is necessary to have valid and reliable methods for measuring and monitoring safety [1]. The absence of robust safety surveillance systems presents difficulties in the identification and evaluation of safety initiatives [1,2]. The purpose of this fourth study was to evaluate, using the MMS framework, the Saudi Arabian healthcare safety surveillance system in hospitals. This qualitative study was conducted in two phases. During the first phase, document analysis was used to review national-level safety measurement and monitoring guidelines in Saudi Arabia. The second phase consisted of semi-structured interviews with key stakeholders to learn more about their perspectives on measuring and monitoring patient safety in hospitals.

Peer-reviewed Publication

This study has been accepted and published in a peer-reviewed journal. The citation is: Kaud Y, Lydon S, O'Connor P. Measuring and monitoring patient safety in hospitals in Saudi Arabia. BMC Health Services Research. 2021 Dec;21(1):1-2.

The following chapter is a formatted version of the submitted manuscript to the journal.

Authors' Contributions

This study was led by YK. All authors were involved in the design and planning of the study. YK and SL developed the search strategy. YK conducted the searches. YK, POC, and SL were responsible for completing the data extraction. YK completed the interviews and transcribing. YK, POC, and SL conducted the analysis of the interview data. YK drafted the initial manuscript with POC and SL assisting with redrafting it. All authors read and approved the final manuscript prior to submission.

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Abstract

Background. There is much variability in the measurement and monitoring of patient safety across healthcare organisations. With no recognised standardised approach, this study examines how the key components outlined in Vincent et al's Measuring and Monitoring Safety (MMS) framework can be utilized to critically appraise a healthcare safety surveillance system. The aim of this study is to use the MMS framework to evaluate the Saudi Arabian healthcare safety surveillance system for hospital care.

Methods. This qualitative study consisted of two distinct phases. The first phase used document analysis to review national-level guidance relevant to measuring and monitoring safety in Saudi Arabia. The second phase consisted of semi-structured interviews with key stakeholders between May and August 2020 via a video conference call and focused on exploring their knowledge of how patient safety is measured and monitored in hospitals. The MMS framework was used to support data analysis.

Results. Three documents were included for analysis and 21 semi-structured interviews were conducted with key stakeholders working in the Saudi Arabian healthcare system. A total of 39 unique methods of MMS were identified, with one method of MMS addressing two dimensions. Of these MMS methods: 10 (25%) were concerned with past harm; 14 (35%) were concerned with the reliability of safety critical processes, 3 (7.5%) were concerned with sensitivity to operations, 2 (5%) were concerned with anticipation and preparedness, and 11 (27.5%) were concerned with integration and learning.

Conclusion. The document analysis and interviews show an extensive system of MMS is in place in Saudi Arabian hospitals. The assessment of MMS offers a useful framework to help healthcare organisations and researchers to think critically about MMS, and how the data from different methods of MMS can be integrated in individual countries or health systems.

Competing interests: The authors declare that they have no competing interests.

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Introduction

Measuring and monitoring safety (MMS) is fundamental to safety improvement efforts. However, a major challenge to improving safety in healthcare is the lack of high quality information to allow organisations, teams, and individuals healthcare providers to evaluate how they are performing, and where there are deficits and risks [1]. Understanding and improving patient safety requires the availability, and application, of valid and reliable methods for measuring and monitoring safety [2]. However, MMS is not straightforward, and there is no consensus as to how it should be achieved.

The World Health Organisation developed the International Classification for Patient Safety (ICPS) to provide an approach to organising patient safety data for the purpose of aggregation, analysis, and translation into actionable information [3]. However, the ICPS is focused upon classifying and identifying the contributory factors to incidents, rather than providing a framework for evaluating a patient safety surveillance system. Recognising that most healthcare organisations lack the capacity to analyse, monitor, or learn from safety information, Vincent et al [4, 5] developed a framework to guide clinical teams and healthcare organisations in the measurement and monitoring of safety. This MMS framework was derived from three scoping reviews on safety measurement in high-risk industries, conceptual approaches and models of systems safety, and research on measuring safety in healthcare. Interviews were conducted with senior healthcare managers, and cases studies developed for services where measurement of safety is well developed (e.g. anesthesia) [4, 5]. This research cumulated in the identification of five safety dimensions that should be addressed by robust safety surveillance systems [4, 5]. These dimensions are:

1. Harm: has patient care been safe in the past? (e.g. national audits, incidence of falls or pressure ulcers, mortality and morbidity).

2. Reliability of safety critical processes: are our clinical systems and processes reliable? (e.g. monitoring of vital signs, observations of safety critical behavior).
3. Sensitivity to operations: is care safe today? (e.g. safety walk-arounds and conversations, talking to patients).
4. Anticipation and preparedness: will care be safe in the future? (e.g. safety culture assessment, structured reflection).
5. Integration and learning: are we responding and improving? (e.g. aggregated analysis of incidents, feedback and implementation of safety lessons) [4, 5].

Mapping methods of MMS onto Vincent et al's [4, 5] framework allows organisations not only to consider where safety information is lacking, but also where there is redundancy and duplication of effort. The MMS framework has been used to promote self-reflection at both board and clinical team level, to stimulate an organisational check or analysis of the gaps in safety information, and to promote discussion about safety [6]. The framework has also been applied to the classification of MMS studies in systematic reviews [2, 7]. Applying the MMS framework supports the creation of a nuanced and holistic understanding of safety, increased consciousness of safety among staff, a shared vocabulary and language around patient safety, a review of the kinds of safety data which are useful and which should be collected, and to support wider engagement in patient safety work and initiatives [6]. However, despite the potential of the MMS framework, it has not been applied to the review of a country's healthcare safety surveillance system. Therefore, the aim of the study reported in this paper is to use the MMS framework to evaluate the Saudi Arabian healthcare safety surveillance system for hospital care.

In recent years there has been substantial investment in patient safety initiatives in the Saudi Arabian healthcare system [8]. Therefore, the aims of the current study are to: (1) examine how patient safety is measured and monitored in Saudi Arabian hospitals; (2) map the methods of MMS in these hospitals onto the five dimensions of Vincent et al's [4, 5] MMS framework; (3) based on these findings, reflect on the approaches used to MMS in Saudi

Arabian hospitals; and (4) evaluate the utility of using the Vincent et al's [4, 5] framework to classify different methods of MMS.

Methods

Research Design

A qualitative descriptive approach was employed to support: (1) a document analysis of the national standards on MMS used in Saudi Arabian hospitals; and (2) an exploration of stakeholders' perceptions about how patient safety is measured and monitored in Saudi Arabian hospitals through semi-structured interviews. The research team consisted of one woman (SL) and two men (YK and POC). Two of the members of the research team (POC and SL) are PhD-level health services researchers with considerable experience in using quantitative and qualitative research methodologies. The other member of the team (YK) is a Masters-level health services researcher who was trained by POC and SL to conduct the interviews.

Phase One- Document Analysis

The purpose of the first phase of the study was to identify recommended or mandated processes of MMS in Saudi Arabian hospitals. Document analysis is a systematic procedure for reviewing or evaluating documents [9]. To ensure the completeness and accuracy of the document analysis reported herein, we adhered to a method called the 'ready materials, extract data, analyse data and distil (READ)' approach to document analysis [10].

Inclusion criteria. Documents were included if they: explicitly discussed or described how patient safety is, or should be, measured and monitored in Saudi Arabian hospitals; were produced by a Saudi Arabian national government agency or an organisation affiliated with a national government agency, and were written in English or Arabic. To allow for retrieval of older but potentially important documents, no restrictions on publication date was specified. If a document was found to have multiple versions, only the latest version of the document was included in the review.

Exclusion criteria. Documents were excluded if they: did not discuss how

patient safety is, or should be, measured and monitored in Saudi Arabian hospitals; were not produced by a Saudi Arabian national government agency or an organisation affiliated with a national government agency, or were not written in English or Arabic.

Search process. The document search was completed in May 2020 and consisted of four steps. First, an advanced google search was completed. Second, a search of the following electronic databases was conducted: Medline, CINAHL, OAIster, IMEMR, WHO IRIS, and Google scholar using various combinations of the terms 'measuring safety', 'monitoring safety', and 'measurement of safety'. Additional File 1 (Appendix 6) presents an exemplar search strategy. Third, searches were conducted across the Saudi Arabian Ministry of Health, Central Board for Accreditation of Healthcare Institutions (CBAHI) and Saudi Patient Safety Center websites using both their relevant search boxes and manual search. Last, we searched for further related documents by hand-searching the reference lists of documents that met the inclusion criteria.

Document selection. The initial screening of potentially relevant documents was completed through the assessment of the titles, abstracts and/or executive summaries. Documents that appeared relevant were exported and downloaded for full-text review. Decisions regarding the inclusion or exclusion of documents were agreed by consensus of all of the members of the research team. All decisions were recorded in a Microsoft Excel© file.

Document analysis. Two members of the research team (YK and POC) independently searched through each document and extracted all of the methods of MMS described therein. The methods of MMS extracted by each reviewer were compared. Only minor differences were found between the two reviewers. Any differences were concerned with whether a particular method was one measure or could be split into two measures. Once the final list of MMS had been identified all members of the research team (YK, POC, and SL) reviewed each measure, and reached a decision by consensus as to which dimension of Vincent et al's [4, 5] MMS framework

it addressed.

Phase Two: Semi-structured interviews with key stakeholders

The purpose of the second phase of the study was to identify what key stakeholders know about how safety is measured and monitored in the Saudi Arabian healthcare system.

Ethical review. The study was approved by the Ministry of Health Central Institutional Review Board in Saudi Arabia (Central IRB log No: 20 -74E) and was performed in accordance with the Declaration of Helsinki. All participants provided signed written informed consent before participating in the study.

Sampling and recruitment of participants. To ensure a diverse sample that represents perceptions of people in different roles in the Saudi Arabian healthcare system, participants were drawn from five different stakeholder groups: (1) policymakers; (2) doctors; (3) nurses; (4) risk managers; and (5) quality supervisors. Recruitment of participants was via a combination of purposive and snowball sampling techniques.

Development of interview guide. The semi-structured interview guide is shown in Table 1. The structure of the interview guide was derived from the five dimensions of Vincent et al's [4, 5] MMS framework. The questions for the interview were developed with reference to best practice for the development of interview questions [11-13]. The interview was piloted with a doctor and a policymaker. No changes were made to the guide as a result of the feedback from the pilot interviews. Therefore, these interviews were included in the study.

Table 1: Interview guide used to engage participants in discussion around measuring and monitoring safety in Saudi Arabia

1. In the Saudi healthcare system, how is harm to patients measured and monitored?
   1.1. What are the strengths and limitation of methods used?
   1.2. Are there other methods of measuring and monitoring harm that you think should be used? and if so, what are these and why do you think they'd be useful?
2. What methods are in place to assess whether our clinical systems, processes and behaviour reliable?
   2.1. What are the strengths and limitation of each of these methods?
   2.2. Are there other methods of measuring and monitoring standardised clinical practice that you think should be used?
3. What methods are in place to assess whether care is safe in hospitals in Saudi Arabia today?
   3.1. What are the strengths and limitation of each of these methods?
   3.2. Are there other methods of measuring and monitoring whether patient care is safe today you think should be used? and if so, what are these and why do you think they be useful?
4. What methods are in place to anticipate and reduce future risks to patients' hospitals in Saudi Arabia?
   4.1. What are the strengths and limitation of each of these methods?
   4.2. Are there other methods of improving the anticipation and reduction of future risk to patients that you think should be used? and if so, what are these and why do you think they be useful?
5. What methods are in place to promote learning from issues and improving the level of patient safety in hospitals in Saudi Arabia?
   5.1. What are the strengths and limitation of each of these methods?
   5.2. Are there other methods of prompting learning that you think should be used, and if so, what are these and why do you think they be useful?

Procedure. All interviews took place between May and August 2020. After receiving signed written informed consent from all participants, the interviews were carried out by one member of the research team (YK) via a video conference call. The audio of the call was recorded.

Interview analysis. The interview analysis was focused on identifying the methods of MMS described by the interviewees, and classifying these methods using the dimensions of Vincent et al. [4, 5] MMS framework. The transcription was carried out using Microsoft Word© by the lead author (YK) and reviewed and checked for errors by two authors (POC and SL).

The methods of MMS mentioned by the interviewees were highlighted in the Microsoft Word© document by YK, and then reviewed by POC. The comment function of Microsoft Word© was then used to record the MMS framework domain identified by the researcher. All three members of the research team reviewed a random sample of five of the interview transcripts and identified and classified the MMS methods by consensus. The remaining 16 interviews were classified by consensus between two members of the research team (either YK and POC or YK and SL).

Results

Phase One- Document Analysis

Figure 1 provides an overview of the search process for identifying documents that met the inclusion criteria. This process resulted in three documents. An overview of these documents is provided in Table 2. All three documents were written in English and had been published since 2015.

Figure 1: Flow diagram depicting study selection for document analysis

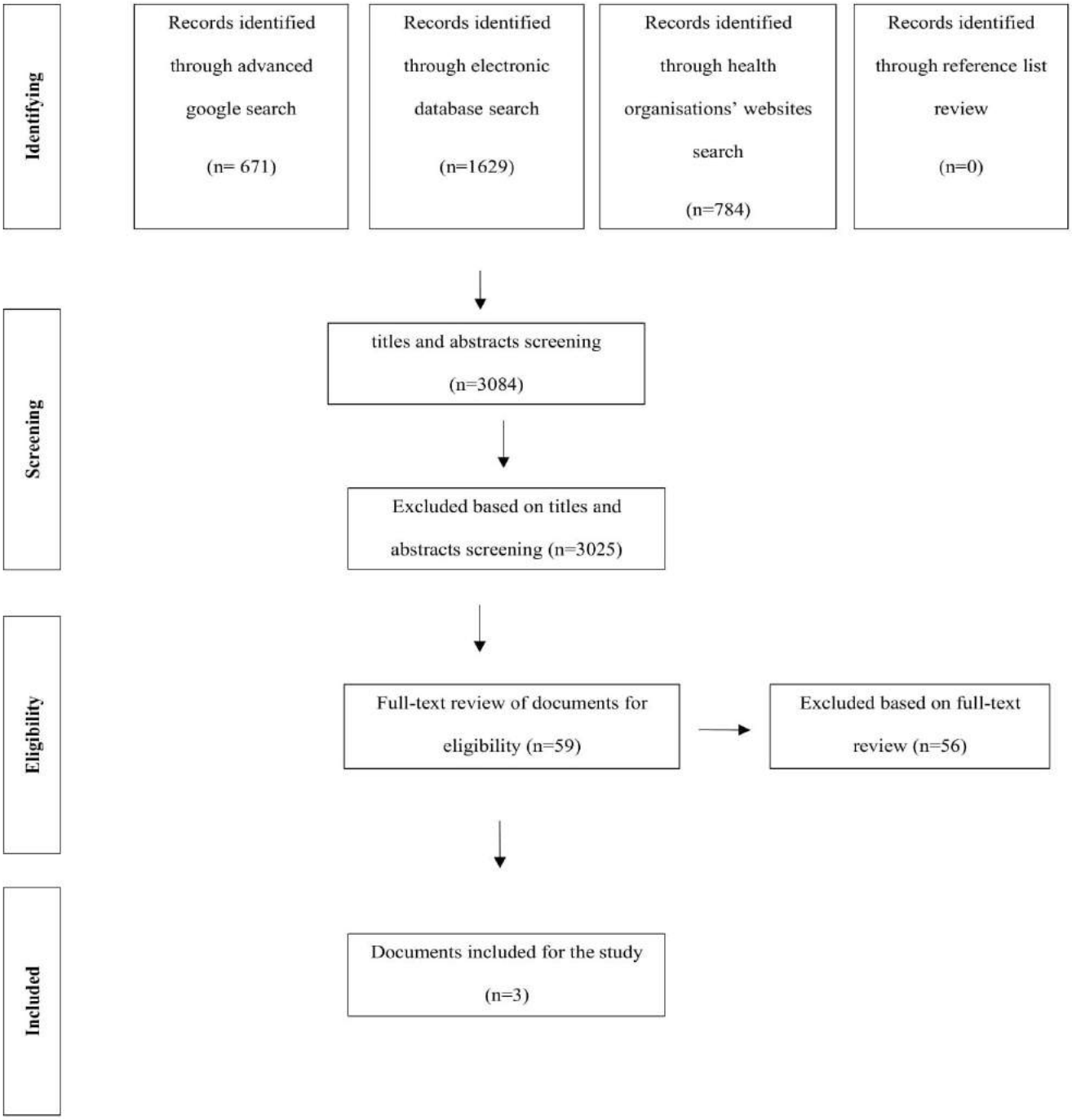

Table 2: a summary of key information of each included document.

Title	CBAHI National Hospital Standards 3rd edition	Department of Quality and Safety at King Fahd Hospital of the University (KFHU) Annual Report	Quality and Patient Safety Measures in King Faisal Specialist Hospital and Research Centre (KFSH&RC)
Year published	2015	2015	2015
Pages	265	127	Virtual document
Prepared by	The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI)	The Directorate of Quality and Safety at KFHU	Quality Management Division (QMD) at King Faisal Specialist Hospital and Research centre
Stated aim	To facilitate the process of hospital self-assessment against pre-set requirements.	To highlight the DQS achievements, establish future commitments and benchmark the hospital progress.	To continuously improve the quality of care provided; maintain a risk-free environment and assure compliance with accreditation standards.
Target population	Hospital leadership and all HCPs working in hospitals in Saudi Arabia.	Hospital leadership and HCPs working at KFHU.	All HCPs, patients, and members of the public.
Setting	All healthcare services provided by all hospitals in Saudi Arabia.	All healthcare services at KFHU.	All healthcare services at King Faisal Specialist Hospital and Research Centre.
Number of methods of MMS measures included	35	8	3
1. Harm	9 (25 %)*	3 (37.5%)	2 (66.7%)
2. Reliability of safety critical processes	12 (33.3%)	3 (37.5%)	1 (33.3%)
3. Sensitivity to operations	2 (5.6%)	1 (12.5%)	0
4. Anticipation & preparedness	2 (5.6%)	0	0
5. Integration & learning	11 (30.6%)	1(12.5%)	0

HCPs: Healthcare Professionals.
*One of the methods of MMS was classified under two dimensions, and so these percentages are calculated using a denominator of 36.

As can be seen from Table 2, methods of MMS were far more commonly described in the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) standards than in the other two documents, reflecting the purpose of the CBAHI to facilitate the process of hospital self-assessment against pre-set requirements [14].

A total of 39 unique methods of MMS were identified across the three documents (see Table 2 and Additional File 2 (Appendix 7) for a list of these methods and how they were classified). Of these MMS methods: 10 (25%) were concerned with past harm; 14 (35%) were concerned with the reliability of safety critical processes, 3 (7.5%) were concerned with sensitivity to operations, 2 (5%) were concerned with anticipation and preparedness, and 11 (27.5%) were concerned with integration and learning. One methods of MMS addressed two of the safety dimensions, therefore the percentages are calculated out of 40.

Phase Two- Semi-structured Interviews with Key Stakeholders

The mean duration of the interviews was 34 minutes and 35 seconds (SD= 12 minutes 18 seconds) The 21 participants included: three policymakers, five doctors, seven nurses, two risk managers and four quality supervisors. Of the 21 participants, 4 were women and 17 were men. The participants reported a mean of 12.4 years of professional experience (ranging from 6 months to 35 years). Nine (14.3%) of the participants worked in public hospitals, 3 (14.3%) in teaching hospitals, 3 (14.3%) in national health regulation organizations, and 2 (9.5%) in military hospitals. None of the people interviewed were colleagues of members of the research team.

Table 3 shows the methods of MMS reported by the interviewees, with Table 4 presenting exemplar quotes from the interviewees. The interviewees described a total of 37 methods of MMS (see Table 3). Of these methods of MMS, 10 (27%) were concerned with past harm, 10 (27%) were concerned with the reliability of safety critical processes, 3 (8.1%) were concerned with sensitivity to operations, 7(18.9%) were concerned with anticipation and preparedness, and 7 (18.9%) were concerned with integration and learning.

Table 3: methods reported by participants to measure and monitor patient safety in Saudi hospitals.

Dimension	No.	List of reported methods of measurement	Number of participants reported the measure (no.) %		
			(12) Front-line staff	(9) Non front-line staff	(21) All
1. Harm	1.	Incident reports	(7) 58.3%	(8) 88.9%	(15) 71.4%
	2.	Mortality and morbidity rates	(5) 41.7%	(1) 11.1%	(6) 28.6%
	3.	Patient safety indicators	(4) 33.3%	-	(4) 19%
	4.	Incidence of falls	(3) 25%	-	(3) 14.3%
	5.	Mortality review committees	(1) 8.3%	(1) 11.1%	(2) 9.5%
	6.	Meetings and discussion of sentinel events	-	(1) 11.1%	(1) 4.8%
	7.	Medication error reporting	-	(1) 11.1%	(1) 4.8%
	8.	Infection rates	-	(1) 11.1%	(1) 4.8%
	9.	National hotline to report safety concerns	-	(1) 11.1%	(1) 4.8%
	10.	Patient satisfaction surveys	-	(1) 11.1%	(1) 4.8%
2. Reliability of safety critical processes	1.	Monitoring compliance to hand hygiene	(4) 33.3%	(3) 33.3%	(7) 33.3%
	2.	Observation of safety critical behaviours	(3) 25%	(2) 22.2%	(5) 23.9%
	3.	Monitoring standards	-	(5) 55.5%	(5) 23.9%
	4.	Reaccreditation CBAHI	(1) 8.3%	(1) 11.1%	(2) 9.5%
	5.	Quality officer checks on compliance to policies and procedures	-	(2) 22.2%	(2) 9.5%
	6.	Venous thromboembolism risk assessment	(1) 8.3%	-	(1) 4.8%

	7.	Key performance indicators of patient safety goals	-	(1) 11.1%	(1) 4.8%
	8.	Audit of equipment availability by infection control staff	(1) 8.3%	-	(1) 4.8%
	9.	Infection control checklists	-	(1) 11.1%	(1) 4.8%
	10.	Clinical audit	-	(1) 11.1%	(1) 4.8%
3. Sensitivity to operations	1.	Safety walk-rounds	(3) 25%	(1) 11.1%	(4) 19%
	2.	Ward rounds and conversations with staff	(1) 8.3%	(1) 11.1%	(2) 9.5%
	3.	Talking to patients	(1) 8.3%	-	(1) 4.8%
4. Anticipation and preparedness	1.	Failure mode and effect analysis (FMEA) to identify risks	-	(2) 22.2%	(2) 9.5%
	2.	Staff assessment and credentialing	(2) 16.7%	(1) 11.1%	(3) 14.3%
	3.	Risk registers	-	(2) 22.2%	(2) 9.5%
	4.	Anticipated staffing levels	(1) 8.3%	(1) 11.1%	(2) 9.5%
	5.	Hazard vulnerability analysis	(1) 8.3%	-	(1) 4.8%
	6.	Safety culture assessment	-	(1) 11.1%	(1) 4.8%
	7.	Systems to report near misses to identify risks	-	(1) 11.1%	(1) 4.8%
5. Integration and learning	1.	Analysis and learning from incidents leading to implementation of safety lessons	(1) 8.3%	(3) 33.3%	(4) 19%
	2.	Learning from root cause analysis	(1) 8.3%	(2) 22.2%	(3) 14.3%
	3.	Learning and mitigation plans made based on FMEA data	-	(3) 33.3%	(3) 14.3%
	4.	Feedback by clinical teams following analysis of incident reports	(1) 8.3%	(1) 11.1%	(2) 9.5%
	5.	Learning from mortality and morbidity review committees	-	(1) 11.1%	(1) 4.8%
	6.	Lessons following near miss reporting	-	(1) 11.1%	(1) 4.8%
	7.	Sharing patient safety lessons at national level between hospitals	-	(1) 11.1%	(1) 4.8%

Table 4: Example quotes from the interview transcripts

Dimension	Example quotes
1. Harm	**Incident reports** "We have the incident reporting systems, you know the OVR [occurrence variance reporting], which is used in 100% of MOH hospitals at the hospital level" (Risk Manager 2).
	Mortality and morbidity rates "There is the mortality rate which is reviewed monthly. If it is high, then it will be discovered as an issue and an area that requires attention" (Risk Manager 1).
	Patient safety indicators "Almost all hospitals tend to use patient safety indicators, and even in our hospital they tend to focus on the use of patient safety indicators" (Nurse 5).
2. Reliability of safety critical processes	**Monitoring compliance to hand hygiene** "So, if we take hand hygiene for example, we have in the emergency department a nurse whose main responsibility is to observe staff, how they are adhering to the infection control procedures, and so on (Nurse 2).
	Observation of safety critical behaviours "There are observations whether they are conducted by the nursing manager, medical director, or hospital director" (Risk Manager 1).
	Monitoring standards "The MOH constructed 3 years ago, has 20 standards that are risky, and that's the essential safety requirements which is supervised by CBAHI. They are the main evaluator" (quality supervisor 2).
3. Sensitivity to operations	**Safety walk-rounds** "Safety walk-round involve the safety department, nursing department and the quality department" (Quality Supervisor 1).
4. Anticipation and preparedness	**Failure mode and effect analysis (FMEA) to identify risks** "Other tools we use is the FMEA [failure mode and effect analysis] and you know FMEA is one of the tools that have been used for a long time in aviation and now used in healthcare field, and it anticipates or predicts future risks to the patient or the organisation, and put solutions for these risks" (Policymaker 2).
	Staff assessment and credentialing "Staff credentialing which is one of the 20 standards that is applied by MOH and we were evaluated against by CBAHI in the last three years" (Quality Supervisor 2).
5. Integration and learning	**Analysis and learning from incidents leading to implementation of safety lessons** "Sometimes the reoccurrence rates of some safety events indicate to us about the necessity to implement an intervention, a project, budget, modification or take a very quick action to resolve them" (Policymaker 2).
	Learning from root cause analysis "We advise organisations to use root cause analysis because it is very intense type of analysis that leads you to the root causes of the issue and then putting action plans to prevent reoccurrence of these root causes and treat these root causes to prevent reoccurrence of these incidents" (Doctor 1).
	Learning and mitigation plans made based on FMEA data "In terms of FMEA, it is prospective, it is something you imagine to happen in the future, and you put the solutions as if these risks happened already, and you train and prepare people to use it. So this is considered future preparations for safety issues" (Policymaker 2).

The most commonly described method of MMS for past harm was incident reports (mentioned by 15 interviewees; 71.4%). Incident reports were also by far the most commonly mentioned method of MMS across all of the dimensions. The most frequently mentioned method of MMS for the reliability of safety critical processes was monitoring compliance with hand hygiene protocols (mentioned by 7; 33.3% of the interviewees), safety walk-rounds (mentioned by 4; 19% of the interviewees) was the most frequently described method of MMS in the sensitivity to operations dimension, staff assessment and credentialing (mentioned by 3; 14.3% of the interviewees) was the most frequently mentioned MMS method in the anticipation and preparedness dimension, and analysis and learning from incidents (mentioned by 4; 19% of the interviewees) was the most frequently mentioned MMS method in the integration and learning dimension.

There were differences in the level of awareness of different MMS methods between front-line staff and managers. As can be seen from Table 3, interviews that were not front-line workers were more aware of methods of MMS in the dimensions of integration and learning methods, anticipation and preparedness methods, and reliability of safety critical processes than front-line healthcare workers. However, although front-line workers were found to be less aware of the range of methods used to MMS than those in more management focused positions, front line-workers tended to blame the managers for this lack of knowledge. To illustrate, a nurse shared that *'those who are responsible for the administration of the hospital don't leave their offices to come and inform us why these indicators are important, why collecting such data is important. The quality meetings are only held between the managerial departments, charge nurses and other nurses are not part of these meetings. Like I said, managers and nurses don't share the same understanding of the measures used to assess safety'* (Healthcare provider 1).

Discussion

A major challenge to improving safety in healthcare is the lack of high quality information to allow organisations, teams, and individuals providers to evaluate how they are performing, and where there are deficits and risks. The aim of this paper was to examine how patient safety is measured and monitored in Saudi Arabia, and to evaluate the utility of using the Vincent et al [4, 5] framework to classify different methods of MMS. The data collected through document analysis and stakeholder interviews demonstrates that there is widespread collection of safety data in Saudi Arabian hospitals, though with differences in levels of awareness across stakeholder groups, and the potential to increase data collection within some of the MMS domains. The findings also suggest that there is utility in using the MMS framework to classify methods of MMS.

Taken together, the document analysis and stakeholder interviews demonstrate widespread MMS in the Saudi Arabian healthcare system. There was coverage of each MMS domain evidenced within the data, though there was substantive variability in the extent to which data was collected within the different domains. Measures of past harm were identified most frequently (30.4% of methods in document analysis, 27% of methods in interviews; e.g., incident reports, incidence of falls). This is perhaps unsurprising as the assessment of past harm often forms the foundation of a healthcare organisation's safety management system, [15] and most hospital risk management systems continue to be reactive and focused on safety events which have occurred [16]. The second most common form of MMS, was the use of measures of reliability (34.8% of methods in document analysis, 27% of methods in interviews; e.g., monitoring hand hygiene compliance, observation of safety critical behaviors), followed by measures of integration and learning (26.1% of methods in document analysis, 18.9% of methods in interviews; e.g., learning from root cause analysis, lessons following near miss reporting). Measures of anticipation and preparedness (4.3% of methods in document analysis, 18.9% of methods in interviews; e.g., failure mode and effect analysis, safety culture assessment) and sensitivity to operations (6.5% of

methods in the document analysis and 8.1% of methods in interviews; safety walk arounds, talking to patients) were used less frequently. This is not necessarily unexpected. Systematic reviews [2, 7] concerned with MMS in healthcare have noted measures of sensitivity to operations are used less frequently than measures within other MMS domains, and that measures of anticipation and preparedness are also used with a relatively low frequency and are typically limited to safety climate surveys. One possible explanation for the particularly infrequent use of measures of sensitivity to operations might be that measures of sensitivity to operations tend to be qualitative (e.g. talking with patients and staff and observing work). As such, it may be more challenging to capture this information than is the case for more quantitative data [17]. This type of qualitative information has been described as 'soft intelligence' [17, 18]. This qualitative data often escapes capture but may offer a valuable guide to potential problems [18]. Therefore, consideration should be given to how to more effectively capture this qualitative safety data within Saudi Arabian hospitals and how to triangulate this data with the more quantitative data from the other dimensions of the MMS framework.

On the whole, our data shows that there is a comprehensive system of MMS in Saudi Arabia. Engagement with MMS is crucial to facilitate identification of issues that may result in harm to patients, support implementation of effective interventions to improve patient safety, to allow for comparisons to be made between sites or even between wards within a site [4, 5]. However, it is not that more MMS is necessarily better; it has been suggested that healthcare stakeholders could get the information they need with 25% of what is currently being spent on measurement [19] and that much mandatory MMS is excessive. Indeed, it has been suggested that in spite of the collection of a massive volume of safety-related data in hospitals, that it remains difficult to actually determine how safe care delivery is [4, 5, 20]. It is therefore important that further exploration of the various methods identified within each MMS domain is undertaken in a Saudi Arabian context through engagement with stakeholders. It is crucial to understand the value and contribution of each individual method [19], and to

understand which methods should be prioritised and which are redundant [6, 21]. Which methods yield data that valuably supports learning and safety improvement? Which methods consume resources and attention without adding value to efforts to improve safety? Assessment of MMS methods in this manner, supported by engagement with stakeholders, will allow for MMS systems to be refined and optimally effective in supporting the improvement of safety in care delivery.

Some differences in the level of awareness of different MMS methods between front-line staff and those in more managerial roles emerged during the interviews. The interviewees that did not work at the front-line appeared more likely to be aware of integration and learning methods, anticipation and preparedness methods, and reliability of safety critical processes methods of MMS. This awareness may be at least partly explained by the fact that it has been traditionally the role of risk managers to identify risks and prepare response and mitigation plans [22]. However, the majority of front-line healthcare workers in our interviews expressed the belief that they should fully understand and be engaged in the risk management process. Moreover, as a result of their experience, it could be argued that front-line workers have a more valid understanding than managers who are likely to be removed from front-line operations. It is generally considered essential that managers work with front-line staff to ensure that safety data are appropriately prioritised, interpreted, and actioned [4, 5]. Greater involvement of front-line staff in MMS activities can be valuable for helping these staff members better understand and think about patient safety [4, 5], and to support realisation of the value of MMS for quality and safety improvement [6]. Risk assessment techniques, such as failure mode and effect analysis (FMEA), and incident investigations, such as Root Cause Analysis, should be carried out by a multi-disciplinary team [23, 24]. Therefore, it is suggested that consideration is given as to how to involve front-line healthcare workers in MMS in ways that are valuable and sustainable, and how to simplify complex MMS methods, and their resulting data, in order to facilitate their use by busy front-line healthcare workers [22]. We have previously suggested it is important to begin to refine

extensive MMS systems in place within the Saudi Arabia healthcare system in order to ensure these are maximally efficient and that resources invested yield data that will effectively support quality and safety improvement. It is imperative that such efforts are inclusive of all stakeholder groups, including managers and front-line workers.

The current paper offers a useful opportunity to reflect upon the patient safety practices and systems currently in operation in Saudi Arabia. As discussed above, the data collated herein demonstrate a high level of activity across each of the MMS domains. However, there are a number of areas that should be considered by those interested in advancing understanding of, and ability to improve, patient safety in the Saudi Arabian healthcare system. First, there was little evidence of patient involvement across the MMS methods identified within this paper, with only two methods identified that were inclusive of patients (patient satisfaction surveys, talking to patients). Patients and their families have valuable insights into the functioning of the healthcare system [25], with privileged access to information on continuity of care, communication failures, and respect issues [26]. The importance of involving patients in patient safety efforts have been well-explicated [20, 27]. There are various ways in which patients can provide data on safety. For example, through patient-report safety climate surveys [28], bedside interviews [29], in the review of their clinical notes for errors [30], systematic review of healthcare complaints [26], and patient incident reporting tools [31]. As work is undertaken to refine a MMS system in Saudi Arabia, it is crucial that methods that are inclusive of patients are incorporated. Second, it will be important to explore barriers and facilitators to particular MMS methods, or the domains of MMS measurement. Such data would valuably support refinement of the MMS system. However, the focus of our interviews was on the identification of methods rather than considering the value, feasibility, or attitudes towards these as perceived by different stakeholder groups. It is well established in the research literature that there are barriers associated with the implementation of different MMS methods [32-34] or systems and with patient safety interventions [35, 36]. Indeed, there is some data emerging from Saudi Arabia relating to barriers

to the use of incident reporting systems [37, 38]. Understanding barriers and facilitators associated with various processes is key to supporting effective implementation [39]. Therefore, while a relatively extensive system of MMS is in operation in Saudi Arabia, it will be important to understand engagement with, and attitudes towards, different methods of MMS. This will facilitate the effective use of individual methods and may also support refinement of an overall system of MMS. Finally, when considering how the existing MMS systems in Saudi Arabian hospitals may be refined it will be important to understand the value of the data coming from individual methods. As we have noted previously, it has been argued that much mandatory MMS is excessive and/or redundant [19]. It is important to understand what MMS methods yield data which can be actioned to support quality and safety improvement. Safety interventions can come from use of the MMS framework but this is not guaranteed and there is a baseline level of knowledge required, including expertise in improvement, to support its effective use [6]. There is a recognised need to improve quality of care in Saudi Arabia [40], including the safety of care. This is coupled with an increased focus on quality improvement in Ministry of Health hospitals [41]. It is important that there is engagement with those involved in implementing quality improvement endeavors to understand what data is being used to support these, the value of data arising from each MMS method, and perceived data gaps pertaining to safety. This work is particularly important given that participants were least likely to identify methods within the MMS Integration and Learning domain in this study's interviews.

The MMS framework was developed to provide a conceptual model to guide organizations in assessing safety [6]. It was not specifically designed to classify the methods used to MMS- although this is how we have used it in this paper, as well as in two previous systematic reviews [2, 7]. As the MMS framework was not developed for classifying methods of MMS, the dimensions are not completely operationalised, and it could be argued that the dimensions are not entirely mutually exclusive- properties that are desirable for a classification system [42]. Therefore, although we found the

MMS framework to be useful, there were some challenges in using it to classify methods of MMS. It is suggested that if the MMS framework is to be used for classification, then consideration should be given on how to operationalise the dimensions and clarification is required in order to specify which method of MMS correspond to which dimension. Vincent et al [4, 5] provide some specific examples of methods of MMS, and the dimension that they address. However, if the MMS framework is to be used as a classification system it would be beneficial if there was an exhaustive list of methods of MMS that had been classified using the five dimensions from the framework. This classification is something that could be carried out by a group of subject matter experts and then shared. Pre-classification would greatly simplify the MMS mapping process, support the consistency and reliability of the classification, and facilitate (inter)national comparison across healthcare organisations. Finally, an exhaustive list of pre-classified methods of MMS would also provide examples of methods that could be added to a safety surveillance system if deficiencies in a particular safety dimension were identified.

Limitations

There are a number of limitations of this research. The main limitation is that this paper only focused on MMS in the Saudi Healthcare system. However, the study offers a framework or process that could be replicated in other countries to support improvement of MMS processes. Only a small number of documents met the inclusion criteria and the study provides focused insights from a small number documents and a limited number of interviews. In common with other qualitative research approaches, this study could be critiqued due to subjectivity in the reporting and accuracy of the data, and the analysis. In order to address these potential issues, a rigorous approach was taken to the data collection and analysis. Second, only national-level documents were examined, having data that might be used at the national level rather than single-site studies, local reports, or one process. This may have resulted in the exclusion of potentially useful hospital-level documents. However, the difficulty of systematically accessing hospital-level documents precluded their inclusion. Finally, the

study only focused on the Saudi Arabian healthcare system. Therefore, this limits the generalizability of the findings. Nevertheless, it is suggested that there is merit in carrying out a similar exercise in other national healthcare systems in order to reflect on how safety is being measured and monitored.

Conclusion

Although there is no single perfect method of MMS, data from a large number of measures can be challenging to interpret, and lead to confusion about how safety can be improved. The document analysis and interviews conducted in the current study show an extensive system of MMS is in place in Saudi Arabia hospitals. Going forward it will be important to engage all stakeholder groups in order to refine and optimise the system for MMS to ensure it is capable of effectively supporting safety improvement. The assessment of MMS undertaken in the current study may offer a useful framework that will help healthcare organisations and researchers internationally to think critically about MMS, and how the data from different methods of MMS can be integrated in individual countries or health systems. Such thinking will support the design of a safety surveillance system that has the range of measures require to support an understanding of what is being done well, where improvements are required, and whether interventions having the desired effect.

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Chapter 6:

General Discussion

Introduction

This thesis has employed Vincent et al.'s Measuring and Monitoring Safety (MMS) framework [1, 2] for the purpose of improving our understanding of the measuring and monitoring of patient safety in hospitals across Ireland and Saudi Arabia. This thesis addresses a number of specific objectives relating to this aim. First, it assessed whether the MMS framework offered a useful approach to evaluating both national safety surveillance systems and patient safety research. Second, it sought to compare the safety surveillance systems, and safety research in the two countries and make recommendations for the development of patient safety within these two jurisdictions. Finally, it considers the implications of the findings from the research, and scoping reviews, for MMS beyond these two jurisdictions. These objectives were addressed through the application of the MMS framework to examining the safety monitoring system in Ireland (chapter 3, study 2) and Saudi Arabia (chapter 5, study 4), and the conduct of two scoping reviews of the patient safety research carried out in Ireland (chapter 2) and Saudi Arabia (chapter 4). The rationale for focusing on improving current understanding on the measuring and monitoring of patient safety in hospitals was the significance of measurement as a starting point in improving patient safety and the legitimate practical need for an approach for healthcare providers and organisations to show the presence of safety objectively and practically in the care they provide [3]. For this reason, it is important to understand the various methods of measuring and monitoring patient safety to support critical activities such as setting safety priorities, benchmarking, and tracking safety performance [4].

The latest reports from international organisations, including the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation (WHO), have acknowledged the importance of systematic safety measurement as an essential step to improve safety [5, 6]. Indeed, the World Health Organization recently urged governments in its global patient safety action plan 2021-2030 to engage in safety measurement research in order to provide the knowledge that is required to better understand, and facilitate effective, safety measurement [5].

This final chapter of the thesis will summarise the results of the four studies reported in this thesis. Then, the contribution and utility of the MMS framework across the research programme will be considered. This will be followed by an evaluation of the safety surveillance systems in Ireland and Saudi Arabia as elucidated in the research conducted and a consideration of the current body of patient safety research that exists in both countries. The chapter will also set forth implications and recommendations for policy, practice, and research. Finally, the limitations of the programme of work conducted will be discussed.

Summary of the Studies Conducted

Study 1 (Chapter 2): A Scoping Review of Patient Safety Research Carried out in The Republic Of Ireland

Producing new knowledge that enhances the ability of health care systems, organisations, and practitioners to reduce avoidable harm and offer solutions to unsafe care is a strategic goal of patient safety research [5, 7]. However, to determine what research is required going forward, the amount and nature of patient safety research that has been conducted in the Republic of Ireland (RoI) to-date must be determined. The lack of an overview of patient safety research in the RoI means that current strengths and limitations are unknown and it is difficult to establish priorities for future research. Therefore, the aim of our scoping review was: (1) to examine the extent, range, and nature of patient safety research activities carried out in the RoI; (2) make recommendations for future research; and (3) consider how these recommendations align with the Health Service Executive's (HSE) patient safety strategy. The scoping review was underpinned by Arksey and O'Malley's scoping review framework [8]. A total of 31 papers met the inclusion criteria. Of the 24 papers concerned with measuring and monitoring safety, 12 (50%) assessed past harm, 4 (16.7%) the reliability of safety systems, 4 (16.7%) sensitivity to operations, 9 (37.5%) anticipation and preparedness, and 2 (8.3%) integration and learning. Of the six intervention papers, three (50%) were concerned with education and training, two (33.3%) with simplification and standardisation, and one

(16.7%) with checklists. One paper was concerned with identifying potential safety interventions. Our results revealed a modest but growing amount of patient safety research in the RoI.

Study 2 (Chapter 3): Measuring and Monitoring Patient Safety in Hospitals in the Republic of Ireland

Monitoring and monitoring safety (MMS) is not straightforward, and there is no consensus on how healthcare organisations may best implement and achieve it [9]. Although reviewing safety performance is vital to any effort to improve healthcare safety, this process is often hampered by a lack of high-quality data [10]. In this study, I applied Vincent et al.'s Measuring and Monitoring Safety (MMS) framework to assess how safety is measured and monitored in Irish hospitals and offer recommendations for how it can be improved. The first phase of this qualitative study used document analysis to review national guidance on MMS in Ireland. The second phase consisted of semi-structured interviews with key stakeholders on their understanding of MMS. The MMS framework was used to categorise the methods identified during both phases of the study. Six documents were analysed, and 24 semi-structured interviews with key stakeholders in the Irish healthcare system were completed. There were 162 MMS methods identified, with one method addressing two dimensions. Of these MMS methods: 30 (18.4%) were concerned with past harm; 40 (24.5%) were concerned with the reliability of safety critical processes, 16 (9.8%) were concerned with sensitivity to operations, 28 (17.2%) were concerned with anticipation and preparedness, and 49 (30%) were concerned with integration and learning. The study demonstrated a broad range of MMS methods across Irish hospitals. Therefore, it is important to determine which MMS methods are the most successful in avoiding patient harm, driving action and improvement, and not imposing an overwhelming burden on healthcare workers in terms of the time required to use or analyse the safety information.

Study 3 (Chapter 4): A Scoping Review of Patient Safety Research Carried out in Saudi Arabian Hospitals

In Saudi Arabia (SA), several initiatives have been put in place to improve patient safety. Despite this, patient safety and harm avoidance have become even more important as the number of medical liability cases throughout the country continues to rise [11, 12]. Researchers in SA have emphasised that further research is essential to understanding the patterns and burden of patient safety issues in the Saudi healthcare system [13]. Therefore, this scoping review was performed to map the quantity and nature of current patient safety research in Saudi Arabian hospitals, as well as to identify gaps in the existing literature. A total of 2489 studies were screened, with 67 ultimately included. In total, 61 (91%) of the included studies were focused on the measurement or monitoring of safety. Six studies (9%) considered interventions to improve patient safety. Of these, 31.3% (21/67) of the studies assessed past harm, 1.5% (1/67) reliability of safety systems, 7.5% (5/67) sensitivity to operations, 46.3% (32/67) anticipation and preparedness, and 3% (2/67) integration and learning. Of the six (9%) intervention studies, 1.5% (1/67) reported a forcing functions intervention, 1.5% (1/67) simplification and standardisation, 3% (2/67) considered rules and policies, and 3% (2/67) detailed education and training. Our findings show that extensive research has been conducted in Saudi Arabia on measuring and monitoring safety, but there is much less evidence of interventions to improve safety. One of the most significant findings we discovered was that the culture inside Saudi hospitals still penalises for errors and does not empower healthcare workers to raise safety concerns or make suggestions. In addition, issues with enforcing and adhering to policies continue to be the primary cause of adverse outcomes. Collaborations between all stakeholders in the Saudi Arabian healthcare system are crucial to effectively addressing these gaps and reducing duplication of effort.

Study 4 (Chapter 5): Measuring and Monitoring Patient Safety in Hospitals in Saudi Arabia

Due to the lack of a universally accepted approach, this research looks at how the components of the MMS framework developed by Vincent et al. may be used to critically appraise a healthcare safety surveillance system. Understanding and improving patient safety necessitates the availability and use of valid and reliable methods of measuring and monitoring safety [10], and a lack of robust safety surveillance systems makes identifying and assessing safety efforts challenging [10]. In this research, the aim was to assess the Saudi Arabian healthcare safety surveillance system in hospitals using the MMS framework. There were two stages to this qualitative study. During the first stage, document analysis was used to review Saudi Arabian national-level safety measurement and monitoring guidelines. Stage two included semi-structured interviews with key stakeholders to learn more about their perspectives on patient safety measurement and monitoring in hospitals. Three documents were included for analysis and 21 semi-structured interviews were performed with key stakeholders working in the Saudi Arabian healthcare system. A total of 39 unique methods of MMS were identified, with one method of MMS addressing two dimensions. Of these MMS methods: 10 (25%) were concerned with past harm; 14 (35%) were concerned with the reliability of safety critical processes, 3 (7.5%) were concerned with sensitivity to operations, 2 (5%) were concerned with anticipation and preparedness, and 11 (27.5%) were concerned with integration and learning. Document analysis and interviews indicate a comprehensive MMS system is in place in Saudi hospitals. This MMS assessment provides a useful framework for healthcare organisations and researchers to consider MMS objectively and how data from different MMS methods may be integrated into national health systems.

Considering the Contribution and Utility of the Measuring and Monitoring Safety Framework across the Research Programme

The issue of, and interest in, safety spans various disciplines such as psychology, engineering, and sociology [14]. Therefore, it is crucial to have a thorough understanding of the fundamental safety components in each field as well as the methods employed to assess these key components [14]. To begin to address this complex issue in healthcare, Vincent et al.'s developed the MMS framework to offer guidance by identifying the major components of safety that healthcare workers should consider when assessing and considering safety. This framework is intended to assist healthcare organisations and teams in examining and evaluating safety performance, analysing safety data, identifying information gaps, and deciding whether to implement improvements [1, 2]. The framework is intended to support a comprehensive understanding of patient safety while also avoiding the excessive, duplicative, and purposeless collection of data. According to Vincent et al., there are five safety dimensions that healthcare organisations should assess, and the framework suggests categorising the methods used to measure and monitor each dimension. The first dimension, *past harm*, examines how often patients suffer physical and psychological harm. The second dimension is *reliability* which looks at not just the reliability of safety critical systems and processes but also the capacity of healthcare workers to follow them. The next dimension is *sensitivity to operations*, which is the information and capacity to monitor safety on an hourly or daily basis. Another dimension is *anticipation and preparedness*, which relates to the ability to foresee and prepare for potential future challenges and threats to safety. Finally, *integrating and learning* is the last dimension, and it refers to how an organisation can monitor, analyse, respond to, and improve upon safety information [1, 2].

Conceptual structure. Using Vincent et al.'s MMS framework [1, 2] in my thesis enabled me to approach the topic of MMS with more precision and clarity. Due to this conceptually clear structure, the research articles and scoping reviews reported in this thesis, as well as the methods used within these papers, were rigorously designed and are clearly reported. For several

reasons, it is certain that tackling the issue of measuring and monitoring safety would have been more complex without the application of such a framework. To begin with, there is no uniform general agreement on how to achieve good MMS, or what it should consist of, and the process is not simple [10, 15]. In addition, given that healthcare safety is multidimensional, it may have been difficult to decide how to address MMS without first understanding its major components. Lastly, healthcare safety involves a wide range of actors (e.g., organisations, individuals, and professional groups) with varying levels of safety responsibility, contributions to system-level implications, and perspectives on patient safety [16]. These different groups are likely to contribute different perspectives on what MMS should look like or what it should comprise. The framework therefore circumvents this potential delay and uncertainty by offering a clear, research-based approach to considering and addressing MMS. In short, the MMS framework is a valuable tool in providing a conceptual structure as it integrates numerous ways of assessing safety into a single framework. But even though the MMS framework has the potential to be useful as a road map that guides researchers when thinking about MMS, it must be used with a complete understanding of its components. A thorough knowledge of what each dimension is intended to measure will lead to the correct identification of methods within each dimension, allowing for a reliable and systematic assessment and understanding of the safety of a particular health setting. In this thesis, knowledge and understanding of the MMS were cultivated through understanding the conceptual models and theories of safety that Vincent et al. identified as significant in shaping the MMS framework design. I have also perused publications that document the use of the framework in practice and research. Discussions with peers and my supervisors concerning the employed methods and their alignment with the MMS framework have also played a role in enhancing my understanding.

Language and definitions. Despite the significant progress in the field of patient safety over the last two decades, there are still major disparities over the conceptualisation of the term "patient safety" and how it should be

measured [17]. According to Chang et al. [18], the inappropriate use of terminology in research publications, conference proceedings and presentations, as well as in the media, leads to the prevalence of inconsistent patient safety interpretations. Drawing from my personal observations, particularly in the context of interviewing participants, the introduction of the topic of patient safety yielded insight into very different ways of thinking about the topic and understanding of patient safety seemed to vary greatly among individuals, primarily due to the roles they had within their organisations. For instance, frontline workers, compared to managers, held diverse viewpoints regarding safety measures. To illustrate, doctors' perceptions of assessing safety mostly centred on conducting medical audits, whereas risk registers were a central area of attention for risk managers. The monitoring of vital signs was the primary focus for nurses, while policymakers thought of monitoring standards as fundamental approaches for evaluating safety. Although the methods for evaluating safety mentioned above are widely used and can be very useful, the MMS framework has demonstrated its value in facilitating discussion about safety assessment and may help us in supporting a more useful, inclusive, and productive conversation about MMS. This is due to its ability to build a common language and understanding of the core safety components among myself and the participants, as well as its ability to stimulate thinking about the methods that are employed to measure and monitor these components in an organised manner. Likewise, the value of the MMS framework has been shown in the conduct of scoping reviews, where it assisted in bringing together diverse studies and synthesising data despite authors using different language and terms.

Data analysis. The utilisation of a framework held significant value in providing a conceptual structure and a common language, as well as facilitating the analysis of research findings. Several studies and systematic reviews have employed the MMS framework as an approach of analysing their findings [10, 15, 19, 20]. The primary sources of data used in the research presented in the thesis were policy documents and interviews. This

research was carried out with adherence to the dimensions of Vincent et al.'s MMS framework [1, 2] as predetermined codes.

This approach also facilitated an efficient quantification of the diverse safety measures utilised in every dimension, resulting in a statistical summary of the given dataset. Through the use of a statistical summary, particular areas of emphasis and inadequacies in the implementation of certain safety measures were able to be discerned. A subsequent analysis was carried out to explain the frequency of certain measures and the restricted adoption of others. It is worth noting that I thought it was a good practice to quantify measures across all five MMS categories (e.g., when reviewing policy documents and conducting interviews) since it provided statistical summaries of the research included in the scoping reviews. Moreover, it was possible to compare the safety assessment methods mentioned by frontline and non-frontline workers by using quantitative approaches and numerical data collected from interviewees. Some qualitative researchers argue that the use of quantitative approaches or counting is incompatible with the essence of qualitative research [21]. They believe that the use of numbers in qualitative research weakens its fundamental nature and indicates a concern over its validity [21]. These anti-number views have led to a limited use of numbers and quantification in qualitative research [21]. However, I concur with other qualitative researchers who assert that numbers are valuable in qualitative research, as they can demonstrate the significance of a research project, document existing knowledge about a problem, and derive meaning from qualitative data [21]. Therefore, researchers should not perceive words and numbers as opposing entities.

Furthermore, I believe that using a deductive approach to analyse documents and interviews in which the dimensions of Vincent et al.'s MMS framework [1, 2] were used as predetermined codes appeared to be a pragmatic and effective strategy. A deductive approach refers to a strategy that uses an organising framework consisting of themes for the coding process [22]. This was especially valuable for identifying possible blind

spots and duplication of effort based on the MMS framework's five safety dimensions.

With a phenomenological descriptive approach in consideration, the interviews were analysed in order to uncover the core of the participants' experiences and help them articulate their evaluation of healthcare organisation safety. Phenomenology focuses on the phenomenon itself, providing a lens through which to see the world and shedding light on the phenomena inherent in everyday activities [22,23]. It aids in understanding issues by looking into the thoughts and experiences of those engaged, which is at the heart of this approach [23]. In contrast, hermeneutic phenomenology is characterised by a lesser degree of objectivity, a greater focus on reflexivity, and a heightened emphasis on the researcher's own experiences and introspection, which sets it apart from descriptive phenomenology [23].

The scoping reviews included in this thesis, which aimed to identify the extent and type of patient safety research carried out in Ireland and Saudi Arabia employed the MMS framework to classify the studies included in the scoping reviews. However, in the course of categorising the studies included in the scoping reviews, it was necessary to uphold flexibility and adaptability in our classification methodology. An additional framework was deemed necessary to be used alongside the MMS framework as the MMS framework is specific to measurement and does not consider interventions so could not capture the totality of the literature that emerged. The utilisation of an additional framework facilitated a comprehensive and systematic assessment of all relevant literature in our scoping reviews, without confining our criteria solely to studies that align with the MMS framework. The literature has documented the use of frameworks for analysing findings as a systematic process that provides well-structured outcomes of information through clear steps [24, 25]. Furthermore, the utilisation of frameworks has been demonstrated to be beneficial in cases where a team-based research project involves multiple researchers

possessing varying levels of expertise [24, 25] to ensure consistency and reliability in the work completed.

Practicality of the MMS framework. When compared to how it has been used in academic literature, the framework appears to have been used far less frequently in practice since it was first published [10, 15, 19, 20, 26-33]. One reason might be that healthcare workers or managers may not have the time or resources to fully understand its dimensions and categorise the myriad of methods utilised to evaluate each dimension. The MMS framework may be used more often in everyday practice if it is made easier to use or modified in certain ways. Based on my personal experience, the MMS framework can be viewed as a valuable tool for discussing MMS in healthcare. However, I believe that the successful implementation of this framework in healthcare settings would necessitate adequate training for the individuals who will be utilising it (e.g., via self-paced online courses). In addition, integration of the five dimensions into existing patient safety monitoring software can be another potential strategy for supporting its use in practice. This may involve presenting the methods within a drop-down list that has been pre-categorised into the MMS framework dimensions by a panel of expert stakeholders within a healthcare system in order to populate a comprehensive but finite number of measures. The introduction of such a convenient and user-friendly list has the potential to generate a dataset that is accessible and inclusive for everyone and could be of significant interest to healthcare workers who find themselves with a heavy workload and limited participation and control in the data collection and analysis processes. Another strategy involves fostering greater collaboration among researchers and healthcare providers, which may facilitate the wider adoption of the MMS framework. The World Health Organisation (WHO) has recently recognised the need to address this research-practice gap in safety measurement as a key strategic objective [5].

Evaluating Systems of Measuring and Monitoring Safety across Two Healthcare Systems

The assessment of national safety surveillance systems in Ireland and Saudi Arabia was significantly facilitated by the application of the MMS framework. Study 2 (chapter 3; Kaud et al., 2023) and study 4 (chapter 5; Kaud et al., 2021) reported in this thesis, which utilised the framework and included national-level policy documents and interviews with stakeholders as sources of data, showed a vast range of approaches taken within the two countries with respect to MMS in hospitals. Perhaps the most interesting finding is that there are several parallels in how MMS is achieved and the methods used in the two countries despite all the differences in their economies (Ireland has a developed economy while Saudi Arabia has a developing economy) [34], the organisation of their healthcare systems (Ireland has a mixed system of funding while Saudi Arabia has a publicly funded system) [35, 36].

One important finding is that the national guidelines and policies of both countries place a greater emphasis on methods of measuring and monitoring *reliability*, mainly through the establishment of national standards [9, 37]. According to research, developing a set of standards to which all hospitals must adhere is an effective strategy for encouraging hospitals to improve patient safety [38]. Indeed, patient safety initiatives in hospitals are driven primarily by their desire to obtain accreditation from a national body, which is contingent on meeting national patient safety standards [38]. However, while accreditation may stimulate hospitals to strive to fulfil standards and improve patient safety, it is important to recognise that not all hospitals are capable of doing so. As an example, it was found that in Saudi Arabia, a total of 187 out of 417 hospitals (45%) did not meet the patient safety standards required for national accreditation in 2022 [39]. This may imply that improving patient safety competency of hospitals and providing them with constructive feedback hold the same level of importance as the establishment of standards and guidelines. In this context, a significant difference between the two healthcare systems' approaches to monitoring national standards is the practice of publishing inspection reports of

individual hospitals online following each site inspection in Ireland. Not only do the reports highlight areas of compliance or noncompliance with national standards, but they also serve to showcase exemplary practices and healthcare of excellent quality, thereby presenting a valuable learning opportunity. The absence of this practice in Saudi Arabia could be attributed to the country's extensive network of hospitals, along with the necessary expertise and resources to implement such a strategy nationwide. To summarise, measuring reliability primarily via national standards may push hospitals to improve safety. However, hospitals must get training and constructive evaluations and feedback. This approach will enable both accredited and non-accredited hospitals to fulfil minimum standards, leading to sustained compliance and higher percentages of hospitals with high standards of patient safety.

A further point of similarity between the two countries pertains to the perceptions of healthcare workers, including doctors, nurses, quality supervisors, risk managers, and policymakers, regarding the safety of patients and how it should be assessed. The primary focus for MMS as per the reports of these stakeholders lies in assessing the degree of harm, in which incident reporting systems (IRSs) serve as the most widely recognised approach to achieving this goal. It is important to point out that the widespread use of reactive approaches such as IRSs is not exclusive to Ireland and Saudi Arabia. Incident reporting systems have been widely implemented in nearly all countries, and this can be attributed to the guidelines established in the report "To Err is Human" during the late 1990s [40]. The report emphasised the crucial importance of IRSs in enhancing patient safety on a national level [40]. Additionally, several researchers have stated that IRSs should be given the same priority as the healthcare budget if the healthcare sector is to learn from its failures [41]. Although IRSs have the potential to be an invaluable tool for learning about the prevalence and causes of harm in hospitals [42], it is essential to refrain from overestimating their effectiveness or creating overly high expectations regarding their impact for several reasons. First among these reasons is underreporting, which has been extensively discussed in the literature as a

significant barrier to the success of incident reporting systems in achieving their objectives [43-45]. In addition, research has demonstrated that IRSs have limited capacity to detect all patient safety issues [46], and the inadequate involvement of healthcare workers, particularly doctors, in IRSs may lead to substantial bias in the assessment of care safety [41]. Archer et al. [47] conducted a theoretical review, analysing 110 articles, in order to gain insight into the factors that impact the reporting of incidents among healthcare workers. The authors stated that the most commonly cited barrier to reporting incidents in the literature was fear of adverse consequences (defined as any unpleasant emotion such as guilt or outcome such as litigation associated with individual healthcare worker incident reporting behaviour) [47]. Study 1 (chapter 2; O'Connor et al., 2023) and study 3 (chapter 4; Kaud et al., 2022) indicated that healthcare workers in Saudi Arabia exhibit a greater degree of fear towards adverse consequences as compared to their counterparts in Ireland [48, 49]. In fact, healthcare workers in Ireland generally demonstrated a positive view of the safety culture within hospitals [49]. A positive safety culture has the potential to generate important benefits, not only for healthcare workers, who will perceive a sense of protection rather than blame and punishment, but also for patients. Research shows that a positive safety culture is associated with a decreased incidence of adverse safety events in hospitals [50].

In study 1 (chapter 2; O'Connor et al., 2023), it was noted that there is a more positive safety culture found in Irish hospitals as compared to international benchmarks [49]. This may be attributed to the implementation of safety standards and practices that are tailored to the local context and the Irish healthcare system. As a result, healthcare workers in Ireland are more likely to encounter standards that align with the healthcare system of their country. The national policies and standards of Saudi Arabia are significantly influenced by those of other developed countries, mainly the United States. Implementing safety practices or regulations originating from other countries might not necessarily improve safety [51, 52]. Hence, healthcare workers in Saudi hospitals may be susceptible to encountering rules, standards, or guidelines that they deem incompatible with their work

setting. This may partially explain the results of two large national studies conducted in Saudi Arabia, one in 2017 [53] and the other in 2021 [54], that shed light on the causes of adverse events. The former analysed sentinel events reported nationally between 2012 and 2015, while the latter examined reports from 2016 to 2019. Both studies identified non-compliance with policies, procedures, and guidelines as the main factor leading to adverse events [53, 54]. However, the matter of implementing policies and guidelines from other developed countries is not exclusive to Saudi Arabia, but rather prevalent in developing countries [51]. The authors of a systematic review aimed at examining the current knowledge of quality and patient safety in developing countries suggested that interventions carried out in developed countries be evaluated for their appropriateness in the political and social contexts and available resources of developing countries. They believe these aspects must be considered in order to develop acceptable rules, policies and guidelines as well as to design successful safety interventions [51]. To conclude, it is strongly recommended to conduct a comprehensive assessment to determine the suitability of safety interventions within their intended context in order to achieve the desired outcomes.

A further notable difference in practices around measuring and monitoring safety provided across the two healthcare systems pertains to the quantity of measures that emerged as existing for MMS. While Saudi Arabia has considerably more hospitals and healthcare workers in its healthcare system, than Ireland, the safety measures offered, are less broad than those in Ireland [9, 37]. The findings derived from the interviews conducted with policymakers in Ireland suggest that the implementation of an extensive range of safety measures for MMS requires careful consideration [37]. It has been suggested that the healthcare system in Ireland has the capacity to efficiently address ten patient safety priorities every year [37]. This prioritisation of safety issues is particularly important considering burnout and stress are major challenges faced by healthcare providers in hospitals in Ireland, as shown in previous studies [55, 56]. Furthermore, the preservation of resources can be achieved through the allocation of a reasonable

percentage of current measurement expenses. For example, it has been suggested that employing just about 25% of existing measures might efficiently provide healthcare stakeholders with the necessary safety information [57] and reduce overload, costs, and measurement fatigue. This requires evidence of the costs and effectiveness of currently used safety measures in Irish hospitals. The collection of such data is critical in the construction of an annual safety improvement hierarchy, especially in cases where all safety improvement plans cannot be implemented immediately [58]. On the contrary, Saudi Arabia has developed a succinct set of twenty national hospital measures that are deemed essential and that all hospitals must follow in order to ensure patient safety [59]. These measures are evaluated on a regular basis and are informed by the results of previous hospital assessments, the record of medical errors reported to the Ministry of Health, and the findings of international research on patient safety [59]. Adherence to these measures has been associated with a reduction in the rate of incident reports, medication errors, nosocomial infections, and post-admission mortality in Saudi hospitals [60]. Therefore, I believe that the adoption of more safety measures does not necessarily result in improved patient safety. Instead, it is imperative that we prioritise the most essential safety measures at the national level.

Profiling Patient Safety Research Across Two Countries

Undertaking research on patient safety is of crucial significance in fully understanding the scope and effects of safety issues while also providing direction for change [5]. The scoping reviews reported in this thesis, study 1 (chapter 2; O'Connor et al., 2023) and study 3 (chapter 4; Kaud et al., 2022) provided an overview of patient safety research in Ireland and Saudi Arabia with the goal of assessing the scope, nature, strengths, and limitations of the current literature. The reviews were intended to support establishing future research priorities in both countries and to contribute to advancing the research agenda. The reviews show that the studies conducted to-date on patient safety in both countries demonstrate a significant degree of similarity.

Scoping reviews, along with mapping reviews, evidence and gap maps, are used to address broad inquiries, with the goal of providing an overview rather than focusing on a specific question, as is the case with classic systematic reviews [61]. Nevertheless, although this collection of reviews shows similarities, it also presents some differences. Selecting an appropriate review methodology ensures the use of correct methods and compliance with relevant standards in both the conduct and reporting of the review [61]. The reviews' objectives primarily determined the review methodologies used for the two scoping reviews reported in this thesis. These objectives aimed to assess the scope, nature, strengths, and gaps in the existing literature, resulting in a comprehensive overview of patient safety research in Ireland and Saudi Arabia. Scoping reviews are an appropriate choice for accomplishing this goal, since they are recognised as a type of evidence synthesis that aims to systematically determine and represent the whole scope of data pertaining to a certain topic [61]. While scoping reviews and mapping reviews are similar, scoping reviews are recommended for a more in-depth analysis [61]. Scoping reviews typically involve fewer studies but extract a greater amount of data compared to mapping reviews [61]. This is a key reason why I opted for the scoping review approach, since scoping reviews include research findings in the description of relevant evidence, whereas mapping reviews merely outline what is there without collating and summarising [61,62]. The scoping reviews were performed using the five-stage methodological framework suggested by Arksey and O'Malley and documented in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist [8,63]. The Arksey and O'Malley framework is widely acknowledged as the most prominent and widely used framework for conducting scoping reviews [64]. Its popularity can be attributed to its thorough and transparent steps in the review process [64].

The majority of the publications in both reviews were related to the domains of past harm and anticipation and preparedness [48, 49]. This pattern can be attributed to the level of clarity and practicability of the methods applied to

collecting information pertaining to these two domains. For example, researchers often use retrospective reviews of incident reports to estimate the incidence rate and types of adverse events that occur within a particular healthcare setting. The retrospective review method is an approach that is widely recognised as a gold standard in academic literature for determining the frequency and types of incidents [61]. This acknowledgement of the value and importance of this approach may be one reason contributing to its popularity among researchers, as evidenced by the number of studies that use this methodology to assess harm [48, 49]. One important limitation, however, linked to the use of medical record review as a methodology for collecting and analysing safety information is the scarcity of data pertaining to the underlying causes or contextual factors behind adverse events [61]. Therefore, relying solely on medical records as a safety data source may not provide an in-depth awareness of the underlying factors, which are frequently systemic rather than individual errors, that contribute to such incidents [66]. Thus, this approach does not provide a chance for improvement through learning about these factors [61]. In my opinion, it is crucial to supplement these record review studies with additional research that investigates various systemic and contextual factors, such as the readiness to adopt change, the capacity to implement new strategies, the availability of staff and resources, and the governing rules. If studies are distributed more equitably between these two domains, we will have a deeper understanding of the causes of adverse events. Surveys were another frequently used method in numerous studies conducted in both countries. These survey studies were conducted with the aim of assessing the impact of incident reporting in healthcare settings and determining the factors that either facilitate or impede the practice of incident reporting among healthcare workers. Surveys have also been extensively used in research related to anticipation and preparedness, specifically to assess safety culture. The wide use of safety culture assessment through survey studies may be attributed to the convenience and availability of reliable, validated, and translated surveys such as the Hospital Survey on Patient Safety Culture (HSPSC) that is accepted for use in various healthcare settings and countries, and this could explain the large number of studies included in the

scoping reviews that used this method. This finding is consistent with the wider body of literature that demonstrates the HSPSC as the most commonly used survey to assess safety culture [67]. In my opinion, although retrospective reviews can give an estimate of harm rates and safety culture surveys can reveal high or low percentages of safety culture components in a given healthcare setting, qualitative approaches, such as interviews, are required to elucidate the underlying factors contributing to these quantitative findings.

One of the most surprising findings is the limited scope of research related to the learning and integration domains in both countries. This domain is concerned with organisations ability to manage, evaluate, and improve based on safety information (only 6.5% of research conducted in Ireland compared to 3% of research conducted in Saudi Arabia). One potential explanation for this issue is that there remains a prioritisation of learning approaches that focus on mitigating and addressing past adverse events and incidents [5, 68, 69]. Researchers argue that rather than concentrating on retroactively identifying errors, it is more useful for both research and practice to redirect attention towards identifying successful practices, particularly those that are carried out daily [68]. This means that healthcare organisations and researchers should prioritise the analysis of work as it is performed on a daily basis as a strategy for learning and improving safety performance at the organisational level [68]. In this context, I think it is strongly recommended to improve information dissemination by making the evaluation reports of all hospitals within the same country accessible online. The primary objective of these reports should be to promote the most successful strategies and practices for providing high-quality and safe healthcare. Access to such data will assist both researchers and practitioners in shifting their focus to learning from excellence.

One notable distinction observed in the research conducted in both countries pertains to intervention studies. In comparison to Saudi Arabia, Ireland has a comparatively higher amount and type of intervention studies (19.3% of patient safety research conducted in Ireland as compared to 9% in Saudi

Arabia) [48, 49]. A common theme observed in intervention studies conducted in both countries was the emphasis on education and training interventions [48, 49]. These interventions are deemed to be less effective and do not lead to a persistent change in comparison to interventions that aim at system-level changes, which reduce the likelihood of individual mistakes [70]. Additionally, intervention studies in both countries, as is the case internationally, lack the emphasis placed on contextual factors that have a significant impact on the success of safety interventions [64]. This step involves evaluating the applicability of patient safety interventions that have been effective in other countries, as well as those that have been effective in different hospitals within the same country. This may be accomplished by examining the organisational and environmental factors that affect the successful implementation and effectiveness of such interventions [71]. To sum up, although system-level interventions could be more challenging to implement than those that just focus on education and training, I think they will be more readily accepted and implemented if they have the support of hospital leadership. This suggests that hospital leadership support may have a far-reaching impact, opening the path for more research projects and system-level interventions.

Overall Implications and Recommendations

The findings from the studies and scoping reviews reported in this thesis were derived from various sources, including national policies, the actual day-to-day experiences of the interviewees, and published research. The findings indicate that extensive MMS systems are in place in both countries and that there are several parallels in the approaches and strategies employed to achieve MMS as well as in the nature of published patient safety research from these countries. Notwithstanding the potential of these MMS methods and published research on patient safety to further improve patient safety in hospitals, there are several impediments that hinder this endeavour in these countries and internationally. The following section will focus on these impediments and look at the implications for policy, practice, and research beyond the healthcare systems of Ireland and Saudi Arabia.

Implications for Policy

One of the major obstacles to the progress of patient safety on a global scale is the challenge of determining the roles and responsibilities relating to patient safety, as well as pinpointing the individual or group responsible for gathering and evaluating patient safety data with the aim of driving progress. Prof. Dixon-Woods has termed this issue "the problem of many hands" [16]. She believes that patient safety is facing a challenge that includes the involvement of various actors (e.g., healthcare organisations and their workers, professional bodies, manufacturers of medical products and equipment, patient advocacy groups, regulatory agencies, insurance providers, and legal organisations) that all contribute to system-level effects on patient safety, but it is still challenging to pinpoint one actor as being solely responsible for these effects [16]. To address the problem of many hands, it is suggested that the healthcare sector consider the establishment of a horizontal and collaborative organisation [16]. This approach can serve as an effective strategy to increase accountability among relevant stakeholders and facilitate significant progress in safety improvement [16]. It is important for organisations to demonstrate the capacity to facilitate cooperation among professional groups in order to arrive at a consensus on the most efficacious measures for improving safety and examine the feasibility of adapting international practices to specific local contexts [16].

Such organisations will be well-positioned to develop and finance safety dashboards that are accessible to every hospital. Safety dashboards function as a visual representation of information that enables the effective and timely dissemination of patient safety data [72,73]. Dashboards offer a comprehensive overview of essential performance indicators by aggregating data, thus facilitating the process of making informed decisions [73]. It has been found that access to such dashboards is associated with a higher quality of care, as proven by mortality indicators [74]. Dashboards are excellent tools for decision-makers because they provide precise and timely quantitative measures and allow the integration of disparate measures into a single system [75]. They are used by most hospital boards, as research shows that (72%) of boards in hospitals engage in regular reviews of

dashboards, with a majority (86%) relying on them for the purpose of tracking performance. Furthermore, research has demonstrated an association between the use of dashboards and the high-quality performance of hospitals [74,76]. The findings of a study containing 722 board chairs responsible for managing 767 hospitals revealed that a substantial majority (91%) of high-performing hospitals engaged in regular dashboard reviews compared to 61% of low performing hospitals [69]. That is why, as previously recommended, the development of dashboards by a national agency and their implementation across all hospitals is expected to result in improved safety outcomes.

While dashboards are valuable for providing quantitative metrics such as the incidence of falls or infection rates, supplementing these with qualitative measures would result in a more comprehensive approach to MMS. Thus, it is necessary to consider the combination of qualitative safety data, also referred to as 'soft intelligence' [75], which includes what is heard, seen, and perceived [77]. Policymakers and safety managers are fully aware of the value of qualitative safety data as an approach to explaining the findings from quantitative safety data [75]. However, collecting and analysing qualitative data can be challenging and resource intensive [68], and there is a scarcity of studies that investigate the challenges and benefits associated with handling soft data [75]. It is suggested that policies that regulate MMS should encourage a greater utilisation of qualitative approaches, which include the use of soft data (such as stories and observations of frontline staff and patients). One potential approach to addressing this issue is to utilise existing resources, such as automated language analysis tools, that have been developed especially for the examination of qualitative data related to patient safety. A particular example of how this can be achieved is a paper by Gillespie and Reader [78] in which an automated language processing algorithm was used to analyse written patient feedback.

Implications for Practice

Patient safety is a priority for hospitals worldwide [7, 79]. However, the task of supervising patient safety activities is usually assigned to healthcare

workers, such as doctors, nurses, or pharmacists. These professionals are often given the responsibility for patient safety in addition to their primary professional obligations- rather than employing full-time patient safety specialists. It is suggested that patient safety specialists are not required to have a medical background, since their work involves a range of tasks beyond a specific medical field [80]. The responsibilities of patient safety specialists cover important aspects such as developing the safety culture, conducting error analysis, and providing education, all of which are essential for enhancing patient safety [80]. In a study comparing healthcare providers, managers, and quality and patient safety specialists, Braithwaite et al. [81] found significant differences in responses between these three groups. The study concluded that patient safety specialists offered more suggestions to improve patient safety and that the divergent views on safety and ways to improve it stemmed from varying levels of commitment to and familiarity with patient safety issues [81]. However, frontline workers' lack of participation or understanding of patient safety issues and improvement strategies is not necessarily indicative of a lack of desire to enhance safety. Indeed, patient safety specialists should simplify complex safety tracking procedures in order to engage frontline workers, who are often preoccupied with their primary medical duties [82]. These differences in patient safety issue awareness or optimal approaches for enhancing patient safety among safety specialists, managers, and frontline workers could potentially hinder the effective implementation of patient safety initiatives [81].

Training and educational programmes can serve as a useful strategy for promoting shared awareness among both frontline and non-frontline healthcare workers with regard to patient safety issues and potential solutions [70]. Indeed, high-reliability organisations are characterised by the presence of well-trained staff and a commitment to ongoing training [82]. However, two key considerations about the impact of training and education should be well thought out. Firstly, it is unlikely for education and training to act as a high-value safety improvement intervention on their own. Research shows that in order to have a significant impact on safety, it is also necessary for an intervention to include high-value improvement

interventions that incorporate system-based changes [84]. It has been suggested that this is because errors in healthcare are often attributable to failings in the systems [82]. For example, educating medical students and practitioners about the potential risks associated with look-alike sound-alike (LASA) medications is necessary for ensuring patient safety. However, training and education should not be viewed as panaceas, but rather as supplements to system-level risk-reduction strategies, such as the implementation of online warning systems intended to detect LASA [85]. It is suggested that this combination of approaches is more likely to have a longer-term effect on safety [83]. Secondly, research indicates that the main focus of medical students' undergraduate and postgraduate courses is on diagnosing diseases and prescribing treatments. However, the delivery of healthcare requires more than just theoretical knowledge and technical competence [28]. Therefore, professional development training should focus on non-technical skills, such as communication and leadership, which can be strengthened through methods such as simulation, role-playing, and observation [86,87].

Effective communication, in particular, is a non-technical skill that is vital for healthcare practitioners, and is recognised as an essential feature of high-reliability organisations [82]. Research found that a significant percentage of adverse events (about 70%) were attributed to communication errors [88]. Improving communication among the members of clinical teams is suggested as an essential strategy for improving patient safety in hospitals [89], and this is particularly critical when dealing with difficult situations like disclosing a medical error [90]. In addition, research has demonstrated that communication styles, such as patient-centred communication, which take into account the patient's needs and preferences have been associated with positive outcomes including: better data collection; greater satisfaction among both patients and clinicians; improved adherence to treatment plans; more effective medical decision-making; and a range of positive patient health outcomes, such as improved emotional well-being and physiological measures, such as blood pressure and blood sugar levels [91]. Research evidence shows that medical professionals may benefit significantly from

simulation training, provided the simulation is adapted to their specific learning needs [92]. In brief, the importance of effective communication can be encapsulated by a comment provided by a healthcare worker with whom I had the opportunity to interview during one of my PhD studies. The interviewee stated that "*eventually, it all goes back to communication; if communication fails, there won't be implementation of quality and safety practices in any hospital. So, if you ask me, what is the most important point in order to apply all the patient safety standards in a hospital or healthcare system? It will be communication*" [37].

Implications for Research

Better healthcare services require the empowerment of patients to be actively involved in their care [93]. However, one of the most striking aspects of the extant body of patient safety literature is the fact that patient input is often neglected as a valuable source of safety information [94]. Several studies have emphasised the significance of recognising and advocating for the involvement of patients and their families in initiatives aimed at improving safety [95-98]. It is suggested that patients can be seen as potential detectors of malpractice in healthcare [99], particularly given their expressed interest in actively participating in the care process [93]. Reader and Gillespie [98] have highlighted the fact that patient safety research has predominantly relied on information produced by healthcare workers (e.g., incident reports). To investigate the potential value of patients' perspectives, they conducted a study in 59 hospitals in the United Kingdom to examine whether patient assessments of care and safety information in health care complaints accounted for the variance in excess hospital mortality beyond staff assessments and incident reports. Their results showed that patients' health care complaints about substandard clinical practices, such as neglect, explained a remarkable degree of variation in hospital mortality rates, surpassing the data generated by the staff [98]. Reader and Gillespie [98] arrived at the conclusion that safety data generated by patients in hospitals should be deemed to be both valid and supplementary.

However, safety data, whether provided by a healthcare worker or patients, should not be confined to traditional methods in which safety is determined by the non-existence of negative safety events (Safety-I) [69]. In contrast, the (Safety-II) concept, which was developed as a new way of thinking about safety in complex systems such as healthcare implies that healthcare organisations may be able to further develop their ability to learn about safety not just from past negative events such as incidents, but also by analysing ordinary daily practice [69]. Research investigating the application of (Safety-II) approaches either as standalones or in combination with traditional Safety-I approaches is currently limited [69]. According to recent research, a fundamental step towards increasing the adoption of (Safety-II) approaches is to examine frontline worker activities during normal daily operations with the objective of finding factors that lead to positive outcomes [69]. What is encouraging is that the shift towards more (Safety II) approaches has been met with widespread enthusiasm and interest among frontline workers, because these approaches have been shown to improve their sense of acknowledgement for their unwavering commitment to providing safe and excellent care to the majority of patients, even in times of crisis [100] such as the COVID-19 pandemic.

It is also important to note that, while healthcare organisations cannot assess the safety of their services in the absence of safety data [101], collecting this data is merely a means to an end, and its value is highly dependent on its quality as well as how it is interpreted and used to drive improvement [10]. The need for research that focuses on the steps following data collection, including the interpretation of safety data, stems from the fact that this interpretation plays a pivotal role in determining various important elements of the learning process, such as deciding on appropriate interventions, implementing them, and evaluating their effectiveness [69]. To advance the interpretation of safety data, key research areas such as aggregate data analysis, promoting a common patient safety language, and engaging experts from different scientific domains must be prioritised for the following reasons: First, research that investigates how data may be aggregated and analysed can illuminate system-wide problems such as

multidisciplinary collaboration, communication, policy-practice interactions, and the effect of safety interventions [102]. Second, despite the global momentum that has been observed in discussions surrounding patient safety in recent years, a shared language appears to be lacking in this domain as reported by international organisations like the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) [103]. The absence of this crucial element has impeded the ability to consistently collect patient safety data, evaluate process issues, extract relevant information such as trend and pattern analysis, and disseminate new patient safety knowledge [103]. Third, safety in the healthcare field has been criticised for lagging behind advances in safety science [71,104]. Thus, it is recommended to engage experts from various fields such as safety science, human factors and design, engineering, architecture, sociology, and public health to develop efficient safety solutions following a risk assessment [105].

Strengths and Limitations

Previous discussions in Chapters 2 through 5 covered the specific strengths and weaknesses of each of the four studies. In this final chapter, the strengths and weaknesses of the PhD as a whole will be considered. The thesis fundamental strength is triangulation which refers to the use of multiple methods and data sources [106]. This approach is recommended for adding breadth to the research, increasing the validity and confidence of research findings, promoting a more holistic understanding of the topic of the research, and strengthening the rigour of the research [106-108]. The different data sources used across the four studies included national policy and guidelines, healthcare workers everyday practice, and patient safety research. The multiple methods of data collection used in this research included qualitative approaches such as document analysis to investigate the concept of "work as imagined," and semi-structured interviews to collect personal experiences of daily practice to reflect "work as done". The scoping reviews included quantitative approaches to identify the amount and type of current patient safety research at hospitals in Ireland and Saudi Arabia. Furthermore, the research compared and contrasted two countries with different economies (a developed economy in Ireland and a developing

economy in Saudi Arabia) [34], each of which has distinct financial arrangements and organisational structures for their healthcare systems. This can help with generalizability, as the findings might still be valuable to countries other than Ireland and Saudi Arabia. Additionally, the thesis was grounded on Vincent et al.'s [1, 2] MMS framework, which was particularly designed to consider the methods used to measure and monitor healthcare safety. This framework was the outcome of three scoping reviews of safety in high-risk industries, system safety theories, and healthcare safety and has been used internationally in a range of healthcare settings and specialties [19, 26-32,109]. However, while this research exhibits several strengths, it is still necessary to acknowledge its limitations. One of the key limitations of this research, as previously mentioned in the discussion of implications for research above, is the lack of patient involvement in designing and participating in this research work. Future studies should actively involve patients in shaping patient safety research. Furthermore, while the MMS framework has yielded valuable insights into the present state of safety measures, it was mainly used as a technique for exploring problems and allowing me to assess the quantity and nature of measures currently employed. However, it has not offered direct guidance on the practical implementation, efficacy, or validity of these measures in effectively solving safety problems. The next step, or the primary focus of my future work, will look at specific measures and make recommendations on how they can be improved. Also, the worldwide breakout of the COVID-19 pandemic greatly impacted my data collection and original plan for my PhD. As a result, my research was limited to Ireland (as this is where I lived during the pandemic and where my supervisors had a network of healthcare contacts) and Saudi Arabia (where I am a citizen and have a network of healthcare contacts). Nevertheless, despite the fact that this was a convenience sample, it did demonstrate the universality of the issues in MMS across the two countries. Finally, the PhD project considered the health system as a whole, focusing on secondary care rather than specific areas, as measures and processes may vary by site (e.g., surgery or emergency). It may have been more powerful if it had been focused on one particular area.

Conclusion

Governments throughout the world have made improving the quality and safety of health care a top policy priority in the last two decades, yet advancements towards this aim have been modest [110]. Substandard care and high rates of harm continue to be significant issues for patients in hospitals [7,111]. The first fundamental stage in the process of improving patient safety is measurement [3]. Valid and reliable measuring and monitoring require robust safety surveillance systems. These systems must be specifically designed to evaluate safety performance, identify improvement opportunities, and determine the effectiveness of implemented initiatives [3]. Moreover, these systems must not be excessively burdensome to apply, but comprise data sources that are useful for safety assessment. These data must be comprehensive and account for the numerous ways that health care could fail. This thesis demonstrates the value of using the MMS framework to assess the methods used in national safety surveillance systems as well as patient safety research. The two countries considered in this thesis, Ireland and Saudi Arabia, had a high degree of similarities in their methods of measuring and monitoring hospital safety, and they conducted various levels of patient safety research. Nonetheless, the focus of safety in both countries was on approaches that limit learning largely to failures alone, most typically through assessing past negative safety events such as incidents.

There is a pressing need to shift the focus from only identifying potential risks to competently controlling or managing them with a greater emphasis on safety interventions that are suited to the unique local environment. Such a shift must be supported by an appropriate patient safety surveillance system. However, most countries lack comprehensive patient safety surveillance systems that go beyond harm measurement and use negative safety events such as incidents as their main learning tool [10,112,113]. It is crucial for researchers to promote learning from excellence as well as prioritise the identification of safety solutions aimed at addressing existing safety challenges rather than solely focusing on exploring safety issues. Healthcare organisations should consider allocating protected time for

safety, assigning safety specialists on a full-time basis, and involving patients in the design of safety activities. It is imperative for regulators to establish multi-disciplinary teams with experts in sociotechnical intervention design, such as safety scientists, human factors and design experts, engineers, architects, sociologists, and public health practitioners [105]. One could argue that an adequate amount of safety data already exists, along with the methods for data collection and the essential expertise to improve safety. The challenge is to determine the most effective method for producing important and high-quality data that can facilitate the development of efficient interventions customised to specific health contexts by teams comprising diverse disciplines. The absence of robust safety surveillance systems hampers the identification of where safety interventions are required, and the assessment of whether interventions are having the desired effect and are a good return on investment. Therefore, the implementation of valid, reliable, efficient, and practical approaches to measuring and monitoring patient safety must be prioritised by healthcare organisations.

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Appendices

Appendix 1
Supplemental Material 1: Medline (OVID) Search strategy

1. exp patient safety/
2. safe*2.mp.
3. exp medical errors/
4. ((healthcare or health care) adj error*1).mp.
5. (human* adj1 error*1).mp.
6. ((incident* or voluntary) adj1 report*).mp.
7. (medical adj3 error*1).mp.
8. (adverse adj3 event*1).mp.
9. (sentinel adj3 event*1).mp.
10. exp patient harm/
11. ((preventable or avoidable or unnecessary) adj3 harm).mp.
12. (patient adj3 harm).mp.
13. exp iatrogenic disease/
14. (iatrogenic adj disease*).mp.
15. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. exp hospital/
17. hospital*1.mp.
18. exp secondary care/
19. (secondary adj1 (care or healthcare)).mp.
20. exp tertiary healthcare/
21. (tertiary adj1 (care or healthcare)).mp.
22. 16 or 17 or 18 or 19 or 20 or 21
23. exp Ireland/
24. (eire or irish or Ireland).mp.
25. 23 or 24
26. 15 and 22 and 25
27. limit 26 to english

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

Appendix 2
Supplemental Material 2: Data charting forms

Title	Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States.
Author (s), year of publication	Aiken, L. H., Sermeus, W., Van den Heede, K., Sloane, D. M., Busse, R., McKee, M., ... & Kutney-Lee, A. (2012)
Study location	30 general acute hospitals in Ireland 1105 general acute hospitals—488 in 12 European countries and 617 in the US
Aim of the study	To determine whether hospitals with a good organisation of care (such as improved nurse staffing and work environments) can affect patient care and nurse workforce stability in European countries.
Methods	Cross-sectional study using surveys. The nurse work environment was measured using the practice environment scale of the nursing work index (revised) (PES-NWI). Burnout was measured using the Maslach burnout inventory. Other nurse outcomes and nurse reported measures were derived from survey items, including who reported that the quality of care on their ward was fair or poor rather than good or excellent . Using an item from the Agency for Healthcare Research and Quality's hospital survey on patient safety culture, nurses gave their ward an overall grade on patient safety. The Hospital Consumer Assessment of Healthcare Providers and Systems instrument to measure patient satisfaction in Europe and the US.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	1,406 nurses in Ireland across 30 hospitals & 285 patients across 10 hospitals.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Nurse outcomes; • hospital staffing • work environments • burnout • dissatisfaction • intention to leave job in the next year • patient safety • quality of care Patient outcomes; • satisfaction overall and with nursing care • willingness to recommend hospitals
key reported outcomes	The percentage of nurses reporting poor or fair quality of patient care varied substantially by country (11% Ireland), as did rates for nurses who gave their hospital a poor or failing safety grade (8% Ireland). High rates of nurse burnout (41% Ireland), job dissatisfaction (42% Ireland), and intention to leave (44% Ireland) was found. Patients' high ratings of their hospitals also varied considerably (61% Ireland), as did rates of patients willing to recommend their hospital (74% Ireland). Improved work environments and reduced ratios of patients to nurses were associated with increased care quality and patient satisfaction. Nurses and patients agreed on which hospitals provided good care and could be recommended. Improvement of hospital work environments might be a relatively low cost strategy to improve safety and quality in hospital care and to increase patient satisfaction.
Categorization based on the MMS framework (Vincent et al., 2014)	Sensitivity to operations

Title	Nurses' reports of working conditions and hospital quality of care in 12 countries in Europe.
Author (s), year of publication	Aiken, L. H., Sloane, D. M., Bruyneel, L., Van den Heede, K., Sermeus, W., & Rn4cast Consortium. (2013).
Study location	30 hospitals in Ireland. 488 hospitals in 12 European countries

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

Aim of the study	To obtain a snapshot of European nurses' assessments of their hospital work environments and quality of care in order to identify promising strategies to retain nurses in hospital practice and to avoid quality of care erosions related to cost containment.
Methods	A cross-sectional study design using surveys. Some individual survey items were derived from larger instruments, such as the Practice Environment Scale of the Nursing Work Index. The measure of the quality of the nurse work environment is a single item survey question asking nurses to rate the work environment in their unit as excellent, good, fair, or poor. Quality of care was measured in a single item question with four response categories. Nurses were asked to estimate whether specific adverse events occurred a few times a month or more. The question asking nurses to grade patient safety in their hospitals is from the Agency for Healthcare Research and Quality survey on patient safety culture.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	1,406 nurses in Ireland. 33,659 hospital medical–surgical nurses in 12 European countries.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	• Rating of work environment • Quality of patient care • Frequency of adverse events (pressure ulcers, patient falls with injuries, healthcare associated infections, complaints from patients/families, work-related physical injuries to nurses) • Grade of patient safety • Patient to nurse ratios • Nursing skill mix
key reported outcomes	Nurse concerns with workforce management and adequate resources were widespread. While most nurses did not give their hospitals poor grades on patient safety (8% Ireland), many doubted that safety was a management priority (34% Ireland). 51% of nurses felt that management that listens and responds to employee concerns. The quality of care was rated as poor or fair by 11% of nurses in Ireland. Nurses reported that important nursing tasks were often left undone because of lack of time (range of tasks 4-68% Ireland), and indicated that adverse events were not uncommon (range of AEs 2-26% Ireland). In Ireland, 47% of nurses reported that things ''fall between the cracks'' when patients are transferred between units and 44% did not feel that staff were free to question the decisions or actions of those in authority.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm, Anticipation and preparedness & Sensitivity to operations

Title	A review of adverse event reporting in Irish surgical specialties
Author (s), year of publication	Breathnach, O., Cousins, G., Dunne, D., Ryan, K., Smith, D., & O'Byrne, J. (2011).
Study location	All Irish surgical specialties in public hospitals and health services
Aim of the study	The primary aim is to identify the current overall trends in Ireland, with regard to reporting adverse events in the surgical specialties. Secondary aims include identifying the conditions surrounding an adverse error which have made it more likely for an adverse event to occur, and examining the factors which are associated with medicolegal claims processed by the CIS.
Methods	A retrospective review of medicolegal claims of patients who have had an adverse event reported across all surgical specialties to the CIS via a confidential weblink (STARSWeb) in Ireland. The timeframe under review in this study is from 1 January 2004 to 31 May 2010.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	42,094 adverse events experienced by patients
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Trends and conditions surrounding adverse events, and factors associated with claims, including: • Incidence of adverse events in surgery

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

	• Incident Type • Staff reporting adverse events • Most common type of outcome listed for all adverse events • Time of occurrence for each adverse event • Annual incidence of adverse events by specialty • Closed claims: type of incident, claims made per speciality, highest month of occurrence for incidents leading to closed claims
key reported outcomes	The majority of reported adverse events occur in orthopaedic and general surgery (73% of all cases). Slips/trips and falls account for the majority (32%) of all adverse outcomes reported with medication errors and perioperative incidents making up the 2nd and 3rd most common respectively. Nurses and midwives reported adverse events most often. Doctors report only 4% of the total number of adverse events. The month of October records the highest number of adverse events with the highest frequency of adverse events taking place before 13:00 each day. The most common incident type which resulted in a claim being closed by the CIS was the perioperative/periprocedure incident (50% of all cases). The most common outcome type for adverse events is 'no apparent injury/reaction' (80%). A pattern of adverse events being reported during 'daylight' hours gives a clear indication that routine surgical operations and procedures carry with them a risk for injury to the patient. Particular months of the year and time of the day are more likely to be associated with reported adverse events.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Title	The Irish National Adverse Event Study-2 (INAES-2): longitudinal trends in adverse event rates in the Irish healthcare system
Author (s), year of publication	Connolly, W., Rafter, N., Conroy, R. M., Stuart, C., Hickey, A., & Williams, D. J. (2021).
Study location	Eight Irish public hospitals from the four healthcare regions in Ireland (one large and one small hospital from each region)
Aim of the study	To quantify the prevalence, nature and costs of adverse events in acute Irish hospitals in 2015 and to assess the impact of the National Clinical Programmes and the National Clinical Guidelines on the prevalence of adverse events by comparing these results with the previously published data from 2009.
Methods	A retrospective two-stage review of charts examining admissions from 2015, and comparison with findings from the original INAES database, which examined admissions from 2009.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	1603 admissions in 2015, half of the reviewed admissions were surgical patients and half were medical patients as defined by the INAES protocol (3177 patient admissions reviewed in total; 1574 in 2009 and 1603 in 2015)
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	Comparison with admissions in 2009.
Outcome measures	Prevalence, nature and costs of AEs
key reported outcomes	There were 247 adverse events detected in 2009 compared with 290 adverse events detected in 2015. There was no significant change in AE prevalence from 12.2% in 2009 to 14% in 2015. There were 179 preventable adverse events in 2009 (72.7% of all AEs) compared with 161 preventable adverse events identified in 2015 (55.52% of all adverse events). The prevalence of preventable adverse events was unchanged from 9.1% in 2009 to 7.4% in 2015. The percentage of preventable adverse events related to hospital-associated infection decreased, which may represent a positive impact of the related national programmes and guidelines. The percentage of AEs that resulted in disability increased significantly from 14.6 in 2009 to 28.2% in 2015 (p=0.003). Similarly, the percentage of AEs that resulted in additional treatment or intervention increased significantly from 2.6% in 2009 to 9.2% in 2015 (p=0.03). The percentage of AEs resulting in subsequent hospitalisation, prolonged hospital stay, additional outpatient visits and contributing to death remained similar. In 2015, patients who experienced an AE were judged to have required a median additional hospital stay of 5.6 days. This is equivalent to an additional cost to the health service of approximately €4700 per AE for the hospital stay alone (this excludes litigation costs and societal costs), which when extrapolated nationally would equate to an annual cost of hospital-based AEs for adult inpatients of €190 million for 2015.
Categorization based on the	Past harm

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

MMS framework (Vincent et al., 2014)	

Title	Development of an adhesive surgical ward round checklist: a technique to improve patient safety
Author (s), year of publication	Dhillon, P., Murphy, R. K. J., Ali, H., Burukan, Z., Corrigan, M. A., Sheikh, A., & Hill, A. D. K. (2011).
Study location	A large academic teaching hospital providing emergency and acute care services.
Aim of the study	To develop an adhesive ward round checklist designed to improve patient safety through better communication, improved handovers, and improved record keeping.
Methods	Intervention study using a checklist. Surgical teams were first surveyed with written questionnaires consisting of 22 opinion directed questions on current ward round communication and documentation. Based on the results and deficits highlighted during a ward round documentation audit, a standardized adhesive ward round checklist was developed. The checklist accommodated thirteen specific variables for ward round documentation along with local hospital guidelines. Data was collected over an eight day period.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Thirty eight doctors surveyed. 1186 (91%) doctors in the intervention sticker group and 718 (55%) in the control group.
Intervention (type and duration of intervention if applicable)	Two groups, a sticker study group and a control group, each consisting of 5 consultant-led teams were randomly selected from the surgical department. Members of both the study group and the control group were educated on the importance of ward round handovers and the necessary components required to be documented. Surgical teams and allied health professionals within the sticker group were educated on its use and it was implemented into practice.
Comparator (if any)	The control group continued to enter clinical information into the medical charts by hand with no standardized structure.
Outcome measures	Adherence to checklist use, improved documentation, increased documentation, documentation by senior members of the team, adherence to Good Surgical Practice Guidelines
key reported outcomes	Percentage adherence to the Good Surgical Practice Guidelines (GSPG) was markedly higher in the sticker study group, 1186 (91%) in comparison with the control group 718 (55%). There was significant improvement of documentation across all areas measured. An adhesive checklist for ward round note taking is a simple and cost-effective way to improve documentation, communication, hand-over, and patient safety. Successfully implemented in a tertiary level centre in Dublin, Ireland it is easily transferable to other surgical departments globally.
Categorization based on the MMS framework (Vincent et al., 2014)	Intervention study (Reminders, checklists and double checks)

Title	International comparability of patient safety indicators in 15 OECD member countries: a methodological approach of adjustment by secondary diagnoses.
Author (s), year of publication	Drösler, S. E., Romano, P. S., Tancredi, D. J., & Klazinga, N. S. (2012).
Study location	Acute care hospitals in 15 countries; Belgium, Canada, Denmark, Germany, Italy, Ireland, New Zealand, Norway, Portugal, Singapore, Spain, Sweden, Switzerland, the United Kingdom, and the United States. Ireland excluded nonpublic hospitals (unknown number).
Aim of the study	To improve the international comparability of patient safety indicators based on administrative hospital data, adjustment of country-specific rates by a proxy measure of diagnostic coding intensity was tested.
Methods	A retrospective cross-sectional study using hospital administrative data was performed. Secondary data (numerator and denominator counts of 7 patient safety indicators) based on adults discharged from acute care hospitals between 2006 and 2008 was used.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Records of adult patients older than 17 years
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

Outcome measures	Comparisons of health system performance based on unadjusted patient safety indicators • Catheter-related bloodstream infection (previously known as ‘‘Selected infections due to medical care’’) • Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT) • Postoperative sepsis • Accidental puncture or laceration • Foreign body left in during procedure • Obstetric trauma——vaginal delivery with instrument (i.e., forceps or vacuum) • Obstetric trauma——vaginal delivery without instrument
key reported outcomes	Ireland was above the mean of secondary diagnoses for Catheter-related bloodstream infection, Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT), and Postoperative sepsis rates. Ireland was below the mean for Accidental puncture or laceration, and Foreign body left in during procedure. International comparisons of health system performance based on unadjusted patient safety indicators are problematic due to suspected coding or ascertainment bias. The model could be an interim approach to provide comparable information on hospital quality, with a long-term goal of improving international consistency in diagnostic reporting in administrative data.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm and Reliability

Title	Staff Attitudes towards patient safety culture and working conditions in an Irish tertiary neonatal unit.
Author (s), year of publication	Dwyer, L., Smith, A., McDermott, R., Breatnach, C., El-Khuffash, A., & Corcoran, J. D. (2018).
Study location	A stand-alone tertiary maternity and neonatal centre; the Rotunda Hospita
Aim of the study	This study aimed to explore attitudes towards patient safety culture and working conditions in neonatal units.
Methods	Quantitative, cross-sectional study using safety attitudes questionnaire (SAQ), a 30-item questionnaire that measures staff perceptions in areas including job satisfaction, working conditions and stress recognition. Data was collected between July 2016 and March 2017.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	99 members of staff including doctors, nurses, ancillary personnel (pharmacists, nursing aides and assistants, ward clerks, radiographers, dieticians, porters).
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Safety culture using the safety attitudes questionnaire (SAQ)
key reported outcomes	The hospital scored higher than international benchmarks in all domains. The ‘Stress Recognition’ domain received the highest score followed by ‘Job Satisfaction’ domain. The lowest mean scale score in the neonatal unit was for ‘Perceptions of Management’. Collaboration and Communication scores were high across all disciplines. This SAQ has highlighted a number of important areas for quality improvement and staff satisfaction in our neonatal unit; perceived lack of support from hospital management and apprehensions regarding stress recognition and working conditions. Over 85% of respondents liked their job and would feel safe being treated at the Rotunda hospital as a patient. The majority reported that medical errors are handled appropriately by the NICU. All domains surveyed scored higher than international benchmarks.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness

Title	Thirst for change in a challenging environment: healthcare providers’ perceptions of safety culture in a large Irish teaching hospital.
Author (s), year of publication	Gleeson, L. L., O’Brien, G. L., O’Mahony, D., & Byrne, S. (2021).
Study location	A large Irish acute teaching hospital.
Aim of the study	The aim of this study was to investigate healthcare workers’ perceptions of the safety culture in a large Irish teaching hospital in a climate of national under-resourcing of healthcare.
Methods	Semi-structured face-to-face interviews were carried out with healthcare professionals

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

	(HCPs). A topic guide was developed to address important aspects of safety culture, including job satisfaction, working conditions, and perceptions of support from management, and included questions on important patient safety issues and error reporting in the hospital. Interviews were conducted between February and June 2019.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	17 healthcare professionals (physicians, nurses, health and social care professionals) and healthcare assistants
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Perceptions of safety culture.
key reported outcomes	Participants negatively described the hospital working conditions due to a lack of necessary equipment, insufficient space to see patients, lack of beds for admitted patients. Insufficient staffing levels were believed to contribute towards many of the other issues faced by hospital staff, such as stress and burn- out, and to have a direct impact on patient safety. Participants reported not feeling supported by hospital management. Staff wellbeing also emerged as an important topic in the interviews, which study participants believed was linked to working conditions. Participants felt that patient care suffered the most from poor working conditions and environment. Participants perception of safety culture were mixed however they identified important aspects of safety culture such as communication, teamwork and incident reporting. Study participants described the poor working conditions in the hospital, but also recognised the importance of teamwork and communication in maintaining patient safety and had a strong appetite for change regarding the safety culture in the hospital. Hospital staff were committed to providing the best possible care for their patients but struggled to provide safe care in a challenging work environment. A clear appetite for change was identified amongst HCPs regarding patient safety culture in Irish healthcare.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness and Sensitivity to operations

Title	Safety culture in a major accredited Irish university teaching hospital: a mixed methods study using the safety attitudes questionnaire.
Author (s), year of publication	Gleeson, L. L., Tobin, L., O'Brien, G. L., Crowley, E. K., Delaney, A., O'Mahony, D., & Byrne, S. (2020).
Study location	A large Irish university teaching hospital.
Aim of the study	The aim of this study is to describe the safety culture of a university teaching hospital in the Republic of Ireland.
Methods	A mixed-methods survey study using the short-form version of the Safety Attitudes Questionnaire (SAQ), a 32-item, Likert-scaled questionnaire which is used to measure caregiver's attitudes towards safety culture across six domains. The questionnaire contained an open comments section in which respondents were asked 'What are your top three recommendations for improving patient safety in your clinical area?'.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	768 hospital staff members
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Safety attitudes measured using the Safety Attitudes Questionnaire (SAQ).
key reported outcomes	The study hospital scored higher than the international benchmark in the domains 'Teamwork Climate', 'Safety Climate', 'Job Satisfaction', 'Stress Recognition', and 'Perceptions of Management', and lower than the international benchmark in the domain 'Working Conditions'. Although the hospital scored highly in these domains of safety culture, the qualitative data provided in the open comments section of the SAQ indicated a number of areas in which patient safety could be improved. Staff perceived the major barriers to improving patient safety as the shortage of staff, the need for more patient-focused care, and the hospital environment. Respondents felt that cultivating a culture of safe error reporting and improving opportunities for

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	training and education would have a positive impact on patient safety.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness

Title	Point prevalence of surgical checklist use in Europe: relationship with hospital mortality.
Author (s), year of publication	Jammer, I., Ahmad, T., Aldecoa, C., Koulenti, D., Goranović, T., Grigoras, I., ... & Pearse, R. M. (2015).
Study location	426 sites across 28 European nations
Aim of the study	To describe the prevalence of surgical checklist use in patients recruited to the European Surgical Outcome Study (EuSOS),3 and to establish whether there is any relationship between reported use of a surgical checklist and subsequent hospital mortality.
Methods	Retrospective analysis of data describing surgical checklist use from a 7 day cohort study of surgical outcomes in 28 European nations (European Surgical Outcomes Study, EuSOS)
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	45 591 patients from 426 hospitals
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	The use of surgical checklists across European nations.
Outcome measures	Prevalence of surgical checklist use
key reported outcomes	>80% of patients were exposed to a surgical checklist in Ireland. A surgical checklist was used in 67.5% patients, with marked variation across countries (0–99.6% of patients). Surgical checklist exposure was associated with lower crude hospital mortality. Reported use of a checklist was associated with lower mortality. This observation may represent a protective effect of the surgical checklist itself, or alternatively, may be an indirect indicator of the quality of perioperative care.
Categorization based on the MMS framework (Vincent et al., 2014)	Reliability of safety critical processes

Title	COVID-19 outbreak response for an emergency department using in situ simulation
Author (s), year of publication	Jee, M., Khamoudes, D., Brennan, A. M., & O'Donnell, J. (2020).
Study location	The emergency department and anesthesiology department of a university hospital, Galway University Hospital
Aim of the study	This study aims to describe the utility of in situ simulation in identifying system errors and latent safety hazards in response to preparation for the expected COVID-19 surge. We also aim to describe the corrective measures taken to improve our outbreak response locally.
Methods	A series of multidisciplinary, in situ simulations were conducted from the 4th of March to the 25th of March 2020 to evaluate for operational errors, identify latent hazards, training and to rapidly implement change as an outbreak response. Two scenarios were designed for different purposes. After scenarios were conducted, discussions were held involving systems testing and suggestions for improvements.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	A multidisciplinary team of 39 personnel
Intervention (type and duration of intervention if applicable)	A series of multidisciplinary, in situ simulations were to evaluate for operational errors, identify latent hazards, training and to rapidly implement change as an outbreak response. Two scenarios were designed for different purposes.
Comparator (if any)	-
Outcome measures	-
key reported outcomes	A number of latent safety hazards were identified during the course of the simulations ranging from narrow hallways, unsuitable clinical spaces, stock issues, and a lack of available protocols to manage a pandemic. Throughout the simulations, a steady improvement was seen in the transfer times. A significant improvement of 40 minutes (37.09%) was seen between the first and last simulation. These improvements were a result of continuous corrective measures based on the analysis of the previous simulation. Conclusively, with the complexities and intricate structure of

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	every emergency department, we understood that preparation for an outbreak requires evaluation of the current system before implementing any changes. It is not a "one size fits all" concept. Therefore, conducting in situ simulations and the use of foresight, is pivotal as it could prevent loss of resources and time in preparing for an outbreak.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness & Integration and Learning

Title	The impact of the work environment of nurses on patient safety outcomes: a multi-level modelling approach.
Author (s), year of publication	Kirwan, M., Matthews, A., & Scott, P. A. (2013).
Study location	108 general medical and surgical wards in 30 hospitals throughout Ireland.
Aim of the study	The aim of this study is to identify ward level factors in Irish hospitals which impact on nurse-reported patient safety outcomes. To identify the impact of the nurse work environment aggregated to ward level on nurse-reported patient safety in the ward.
Methods	Cross-sectional quantitative study (RN4CAST) project was carried out using a questionnaire incorporating the Practice Environment Scale of the Nursing Work Index (PES-NWI). The nurse questionnaire was based on the International Hospital Outcomes Study (IHOS) and structured around the Practice Environment Scale of the Nursing Work Index (Lake, 2002), and included reports on aspects of nurse work-life, nurse perceptions of safety and quality of care, and of adverse incident occurrence. The Maslach Burnout Inventory (Maslach et al., 1996) was also included. An additional section examined the adverse event reporting patterns of nurses, and in-service safety training attendance. Seven items drawn from the larger Hospital Survey on Patient Safety Culture. The nurses were surveyed between September 2009 and May 2010.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	1,397 nurses in direct patient care on general medical and surgical wards
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	• Nurse graded patient safety and adverse events reporting rates. • Nurse-reported patient safety levels in the wards in which they work • Numbers of formal adverse events reports submitted by nurses in the last year • Nurse work environment and burnout, organizational safety culture • Nurse education • Attendance at patient safety training.
key reported outcomes	The study results support other research findings indicating that a positive practice environment enhances patient safety outcomes. One third of nurses stated that they did not report any adverse events, and one quarter stated that they reported more than 5. Forty three percent reported between 1 and 5 adverse events. While most nurses describe safety on their wards as ‘‘very good’’ or ‘‘excellent’’, almost 9% of nurses in the current study describe safety on their ward as either ‘‘poor’’ or ‘‘failing’’. A total safety culture score for each nurse was obtained using the 5 items related to safety culture identified as a scale above. The mean nurse level score was 3.28 (scored 1–5). The ward mean safety score ranged from 2.55 to 4.08 and significant differences were found across wards ($F = 2.75$, $p = <0.001$). At ward level, factors such as the ward practice environment and the proportion of nurses with degrees were found to significantly impact safety outcomes. The results can be used to enhance patient safety within hospitals by demonstrating factors at ward level which enable nurses to effectively carry out this aspect of their role. The importance of ward-level nurse factors such as nurse education level and the work environment should be recognised and manipulated as important influences on patient safety.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm, Anticipation and preparedness, & Sensitivity to operations

Title	Online patient safety education programme for junior doctors: is it worthwhile?
Author (s), year of publication	McCarthy, S. E., O’Boyle, C. A., O’Shaughnessy, A., & Walsh, G. (2016).
Study location	RCPI virtual learning environment

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Aim of the study	Study aims were: (1) to determine whether the programme improved junior doctors' knowledge, attitudes and skills relating to error reporting, open communication and care for the second victim and (2) to establish whether the methodology facilitated participants' learning.
Methods	Pre and post intervention design using an online patient safety program. The study cohort were required to complete the online program within the two year duration (July 2011 – June 2013) of their training scheme. Following a pilot phase, a thirteen month study time frame (January 2012 – February 2013) was established. The study was conducted between January 2012 and February 2013.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	208 junior doctors (basic specialist trainees) completed a pre-online questionnaire and 62 completed the post-questionnaire.
Intervention (type and duration of intervention if applicable)	Online patient safety programme, the "Patient Safety Online Programme for Doctors". Five modules were formed (Table 1) after consideration of established safety curricula, academic–practice interfaces and research. The core of each module is a filmed case study based on real life events supplemented by video based input from patient safety experts (family and medical representatives). Expert status was conferred by publication record, patient safety representation at national level and/or clinical career. Participants complete interactive questions during each module and for assessment purposes, multiple choice questions, based on the single best answer approach at the end of modules.
Comparator (if any)	Comparison between pre and post intervention
Outcome measures	• Demographic information • Self rated knowledge of patient safety • Attitudes towards patient safety • Views of medical safety climate • Self rated comfort level with patient safety skills • Evaluation of program content and the learning experience
key reported outcomes	Participating in the programme resulted in immediate ($p<0.01$) improvement in skills such as knowing when and how to complete incident forms and disclosing errors to patients, in self-rated knowledge ($p<0.01$) and attitudes towards error reporting ($p<0.01$). Sixty-three per cent disagreed that doctors routinely report medical errors and 42% disagreed that doctors routinely share information about medical errors and what caused them. An online training programme on medical error improved self-rated knowledge, attitudes and skills in junior doctors and was deemed an effective learning tool. Perceptions of work issues such as a poor culture of error reporting among doctors may prevent improved attitudes being realised in practice.
Categorization based on the MMS framework (Vincent et al., 2014)	Intervention study (Education & training)

Title	Using clinical risk management as a means of enhancing patient safety: the Irish experience
Author (s), year of publication	McElhinney, J., & Heffernan, O. (2003).
Study location	The emergency and orthopaedic departments of an Irish general hospital; Sligo hospital.
Aim of the study	The aim of the project was to develop and test a workable framework for Clinical Risk Management in two clinical specialties with a view to expansion to the rest of the hospital in a phased manner. The main objectives are to identify, analyse and control those risks associated with modern healthcare delivery in order to protect patients, staff, and the assets and reputation of the hospital. This will be achieved by developing a sound proactive mechanism for identifying hazards and reactively through adverse incident/near miss reports.
Methods	A descriptive study of the implementation of the CRM project. Staff were provided with education and awareness programme. Followed by the development of a clinical incident/near miss reporting form and its implementation. Risk review groups were developed to analyse identified incidents and for remedial action to be adopted.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Leading personnel from the hospital including the hospital general manager or his deputy, all three consultant orthopaedic surgeons, and consultants from the ED, anaesthetics, radiology and internal medicine, and senior managerial staff and clinical nursing staff from both departments.
Intervention (type and duration	The project is based in the emergency and orthopaedic departments and is of two years duration. It

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of intervention if applicable)	involved the development and implementation of a clinical incident/near miss reporting form.
Comparator (if any)	-
Outcome measures	Identified incidents, near misses and potential harm
key reported outcomes	25.3% of the 72 received reports in the first four months were related to actual clinical incidents and 12.6% of reports were near misses. Potential risk was present in 62% of the reports. By that point in time the recently implemented Clinical Indemnity Scheme should be well established. This should incorporate associated structures that make it mandatory for healthcare organisations to establish sound risk management standards. These standards would then be audited against strict compliance criteria with suitable adjustments being made to premiums for those with well-developed systems.
Categorization based on the MMS framework (Vincent et al., 2014)	Intervention study (Simplification and standardisation)

Title	The perceived effect of serious adverse perinatal events on clinical practice. Can it be objectively measured?.
Author (s), year of publication	McNamara, K., & O'Donoghue, K. (2019).
Study location	A large tertiary teaching hospital in Ireland; Cork University Maternity Hospital (CUMH)
Aim of the study	The aim of this study was to identify if it was feasible to design a study that could objectively demonstrate if a change in labour ward clinical activity occurred in the 28 days following a serious adverse perinatal event. If this proved possible, the second aim was to identify if these changes could be attributed to the preceding adverse event
Methods	A retrospective observational study conducted using data from a 25-month period from August 2013 to September 2015. Six of the most serious adverse perinatal events that occurred over that time period were identified from the hospital's clinical risk register, the medical records of which were reviewed and the clinical case details recorded.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Aggregate data relating to 6180 deliveries
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Change in labour ward clinical activity following adverse events
key reported outcomes	Some statistically significant changes in clinical activity was identified in the 28 days following five of the six adverse events but the authors were unable to definitively conclude if the change in activity was a direct result of each event. If further studies concur with our findings, that there are real changes in clinical practice following an adverse event, then this will further strengthen the evidence that healthcare professionals are both personally and professionally impacted by adverse events.
Categorization based on the MMS framework (Vincent et al., 2014)	Integration and learning

Title	Increasing reporting of adverse events to improve the educational value of the morbidity and mortality conference.
Author (s), year of publication	McVeigh, T. P., Waters, P. S., Murphy, R., O'Donoghue, G. T., McLaughlin, R., & Kerin, M. J. (2013).
Study location	A Univeristy hospital; Galway University Hospital
Aim of the study	The aim of this study was to investigate the impact of a validated complication proforma on surgical Morbidity and Mortality (M&M) conference reporting.
Methods	A prospective comparative pilot study introducing a paper-based proforma developed based on the ACSNSQIP platform was undertaken, collecting prospective M&M data for 2,094 of 2,209 inpatients (94.7% compliance). A comparative analysis using the proforma vs traditional M&M data collection was used to compare accuracy of M&M data reporting. Data was collected over a 6-month study period.
Study populations (e.g. healthcare workers group, type of patients group, total numbe0r	2,209 inpatients admitted under breast, vascular, colorectal, upper gastrointestinal, and general surgical services

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of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	A paper-based proforma developed based on the ACSNSQIP (American College of Surgeons-National Surgical Quality Improvement Program) 30-day complication proforma was implemented. Information and training about completion of the proforma were delivered via the M&M meeting and also electronically. Forms were updated 6 weeks after discharge to include any complications occurring up to 30 days after discharge. Data was presented at M&M conferences.
Comparator (if any)	Traditional M&M data collection; retrospective chart review of inpatient events
Outcome measures	Reporting of adverse events
key reported outcomes	There was a 73% increase in morbidities reported using the proforma as compared with M&M reporting (547 vs 316), and an increase of 10.81% (37 vs 41) in the reporting of mortalities. Of those patients with morbidities (n ¼ 278), 70.24% (n ¼ 203) had at least 1 surgical intervention. The median length of stay in patients with morbidities was 12 vs 3 days in those with no morbidities. We demonstrated that prospective standardized incident recording provides significantly more accurate assessment of M&M data compared with current reporting methods. This increased accuracy should favorably affect surgical performance indicators and casemix funding.
Categorization based on the MMS framework (Vincent et al., 2014)	Intervention study (Simplification & standardisation)

Title	Is inadequate response to whistleblowing perpetuating a culture of silence in hospitals?
Author (s), year of publication	Moore, L., & McAuliffe, E. (2010).
Study location	Eight hospitals across four Health Service Executive (HSE) regions in Ireland
Aim of the study	This study aimed to explore what would encourage or deter a healthcare professional from reporting poor care, and to provide some evidence to support the development of effective reporting systems.
Methods	An exploratory quantitative research design using an anonymous questionnaire. An adapted version of a tool, used to evaluate the experience and attitudes of nurses, doctors and general practitioners to reporting poor care in the UK was piloted, revised and distributed to target participants.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	152 nurses working in in eight acute hospitals
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Experience and attitudes of nurses to reporting poor care
key reported outcomes	This study demonstrated that 88% of respondents have observed an incident of poor care in the past six months, and that 70 per cent of those that observed an incident of poor care reported it. Nurse managers are more likely to report than staff nurses (reporting rates of 88 per cent and 65 per cent respectively). The study findings indicate that only one in four nurses who reported poor care were satisfied with the way the organisation handled their concerns. The paper shows that reporting of poor care is hampered by a fear of retribution and lack of faith in the organisation's ability to take corrective action.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Title	To report or not to report? Why some nurses are reluctant to whistleblow
Author (s), year of publication	Linda Moore and Eilish McAuliffe (2012)
Study location	Eight acute hospitals in the Health Services Executive (HSE) regions in Ireland
Aim of the study	The authors aimed to advance understanding of reporting behaviour by exploring differences between those who report incidents and those who choose not to report.
Methods	An exploratory quantitative research design using an anonymous questionnaire was utilised for the study.
Study populations (e.g. healthcare workers group, type	152 nurses (staff nurses and nurse managers)

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of patients group, total number of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	• Observed incident of poor care • Reporting an incident of observed poor care • What would encourage nurses to report an incident of poor care • Beliefs about reporting incidents of poor care, reluctance to report • Anonymity in reporting incidents • Staff nurses and nurse manager views on incident reporting
key reported outcomes	1 in 4 nurses in this sample observed an incident of poor care and did not report. The findings show that reluctance to report is mainly influenced by fears of retribution, not wanting to cause trouble and not being sure if reporting an incident is the right thing to do. Authors suggested that managers and policy makers need to provide more reassurance for staff and put in place better measures to protect staff from negative repercussions that might arise from whistleblowing.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Title	Estimating the economic cost of nurse sensitive adverse events amongst patients in medical and surgical settings
Author (s), year of publication	Aileen Murphy, Peter Griffiths, Christine Duffield, Noeleen M. Brady, Anne Philomena Scott, Jane Ball, Jonathan Drennan (2021)
Study location	Six acute adult wards within three Irish hospitals
Aim of the study	To identify the costs associated with nurse sensitive adverse events and the impact of these events on patients' length of stay.
Methods	A retrospective patient record review using administrative hospital data sourced from patient discharge record.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	5544 admitted patients aged 18 years and older who had a minimum stay of 24 h
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	• Nurse sensitive adverse events (urinary tract infection, pressure ulcers, hospital acquired pneumonia, deep venous thrombosis, upper gastrointestinal bleeding, CNS complications, hospital acquired sepsis, shock/cardiac arrest, wound infection, pulmonary failure, physiological/metabolic derangement) • Patient characteristics • Length of stay • Economic impact
key reported outcomes	Each additional nurse sensitive adverse event experienced by a patient was associated with an increase in the length of stay beyond national average. Authors estimate the average cost associated with each nurse sensitive adverse event to be €694. Extrapolating this nationally, the economic cost of nurse sensitive adverse events to the health service in Ireland is estimated to be €91.3 million annually. There is potential substantial financial return on investment for strategies that can decrease nurse sensitive adverse event occurrence.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Title	The surgical safety checklist survey: a national perspective on patient safety
Author (s), year of publication	E. Nugent, H. Hseino, K. Ryan, O. Traynor, P. Neary, F. B. V. Keane (2012)
Study location	All 61 hospitals in Ireland
Aim of the study	Authors aimed to determine (1) whether SSC is being implemented, (2) whether it promotes a

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	safer surgical environment and (3) identify problems associated with its introduction and on-going implementation.
Methods	A structured online survey study on use of the WHO Surgical Safety Checklist
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Staff in the operating departments of forty-one hospitals
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	• Use of a surgical safety checklist, type of checklist in place (WHO checklist or other) • Staff training to conduct the surgical safety checklist • Designation of a checklist coordinator • Implementation of the checklist • Staff opinion on the practicality of the checklist
key reported outcomes	The WHO SSC or modified version is in place in 78 % of operating departments that responded. Greater than 60 % of respondents reported that the SSC was difficult to introduce and implement and that its introduction was time consuming. Further training in using the SSC was reported as desirable by 84 % of respondents. The introduction of the SSC was reported to be associated with an improvement in team communication (72 %), a positive change in team behaviour (63 %), an increase in the consistency of patient care (82 %) and a positive culture of safety in theatre (81 %). Authors suggested that greater education, endorsement, teamwork, and communication will be required to optimize the potential benefits associated with this safety instrument.
Categorization based on the MMS framework (Vincent et al., 2014)	Reliability of safety critical processes

Title	Anticipatory vigilance: A grounded theory study of minimising risk within the perioperative setting
Author (s), year of publication	O'Brien, B., Andrews, T., & Savage, E. (2017).
Study location	11 operating theatres s across different Irish university teaching hospitals.
Aim of the study	To explore and explain how nurses minimise risk in the perioperative setting.
Methods	Unstructured interview study design using a classic grounded theory approach supplemented by 33 hours of non-participant observations in 3 different operating theatres. Data collection was carried out between February 2009 and April 2010.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	37 nurses working in 8 different perioperative settings
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Risk minimization.
key reported outcomes	Participants' main concern was how to minimise risk. Participants resolved this through engaging in anticipatory vigilance (core category). This strategy consisted of orchestrating, routinizing and momentary adapting. Understanding the strategies of anticipatory vigilance extends and provides an in-depth explanation of how nurses' behaviour ensures that risk is minimised in a complex high risk perioperative setting. This theory provides a guide and understanding for nurses working in the perioperative setting on how to minimise risk. It makes perioperative nursing visible enabling positive patient outcomes. This research suggests the need for training and education in maintaining safety and minimising risk in the perioperative setting.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and Preparedness

Title	Nurses keeping patients safe by managing risk in perioperative settings: A classic grounded theory study.

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Author (s), year of publication	O'Brien, B., Andrews, T., & Savage, E. (2019).
Study location	11 different hospitals in Ireland
Aim of the study	To develop and expand how nurses promote safety in perioperative settings
Methods	Unstructured interviews and 33 hours of non -participant observations. Data were collected using theoretical sampling and analysis was carried out concurrently.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	37 fulltime nurses working in the perioperative area
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Risk minimization
key reported outcomes	Orchestrating is fundamental in promoting safety and minimizing risk of errors and adverse events in the perioperative setting. Nurses achieve this through four categories: macro orchestrating, locational orchestrating, situational orchestrating and being in the know. Nurses minimise risk by fostering a culture of safety, risk awareness, effective management and leadership. This study suggests that education and training regarding safety and leadership within the perioperative workplace is essential as Orchestrating contributes to promoting safety. Effective management structures and support systems are essential in promoting a culture of safety in perioperative setting.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness

Title	“Excuse me:” teaching interns to speak up.
Author (s), year of publication	O’Connor, P., Byrne, D., O’Dea, A., McVeigh, T. P., & Kerin, M. J. (2013).
Study location	An academic teaching hospital affiliated with a local university; University Hospital Galway
Aim of the study	The aim of the training program was threefold, as follows: 1. To demonstrate that speaking up is important for patient safety and quality of care 2. To show interns that attending physicians want them to speak up despite any possible discomfort 3. To provide the interns with techniques for speaking up on the basis of strategies used in aviation
Methods	Descriptive study of the design, conduct and evaluation of a training intervention based on the Crew Resource Management model designed to encourage interns to speak up.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	110 interns from the West Northwest intern training network in the Republic of Ireland
Intervention (type and duration of intervention if applicable)	Training based on Crew Resource Management designed to encourage interns to speak up. Participation in the training program took 90 minutes. Training was constructed around filmed stories of attending physicians describing situations in which, when they were interns, their communication and assertiveness skills were challenged, and their reflections on what they could have done better. The training was evaluated during two time periods, January 2012–March 2012 and November 2012–January 2013. Evaluations were carried out pretraining, posttraining, and with a control group.
Comparator (if any)	A control group of interns who had not attended the training with the same level of experience as the posttraining group of interns.
Outcome measures	First three levels of Kirkpatrick’s training evaluation hierarchy: (1) reactions; (2) knowledge; and (3) behavior.
key reported outcomes	Feedback from participants was positive. There was a significant increase in knowledge as a result of the training, and some evidence to support a shift in attitudes in the desirable direction relating to the need to speak up to seniors. No effect of the training was found on behavior. A significant effect of the training on knowledge was found between the posttraining group and the pretraining and control groups. The willingness to share examples of poor performance is an important part of building a good safety culture. Listening to the stories of attendings describing and reflecting on a situation in which they struggled is a powerful teaching method for training interns in the communication and assertiveness skills that are critical to their job.
Categorization based on the	Intervention study (Education and training intervention)

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

MMS framework (Vincent et al., 2014)	

Title	A mixed-methods examination of the nature and frequency of medical error among junior doctors
Author (s), year of publication	O'Connor, P., Lydon, S., Mongan, O., Connolly, F., Mcloughlin, A., McVicker, L., & Byrne, D. (2019)
Study location	Five Irish hospitals.
Aim of the study	To examining the experience and perceptions of junior doctors about medical errors to which they either made or contributed.
Methods	A mixed methods design consisting of an error survey and critical incident technique (CIT) interviews.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	A total of 201 out of 332 interns (60.5%) responded to the survey and 28 critical incident technique (CIT) interviews were conducted (Of the 32 scenarios collected, four scenarios were discarded)
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Risk to patients associated with each error scenario Contributing factors to error scenarios
key reported outcomes	Results of this paper showed that a total of 201 out of 332 (60.5%) respondents to the survey reported making an error that 'played on their mind'. 'Individual factors' were the most commonly identified group of factors (188/201; 93.5%), with 'high workload' (145/201; 72.1%) the most commonly identified contributory factor. Of the 28 CIT interviews which met the criteria for analysis, 'situational factors' (team, staff, task characteristics, and service user factors) were the most commonly identified group of contributory factors (24/28; 85.7%). A total of eight of the interviews were judged by subject matter experts (n=8) to be of medium risk to patients, and 20 to be of high-risk to patients. A significantly larger proportion of high-risk scenarios were attributed to 'local working conditions' than the medium-risk scenarios. Of the errors identified in the interview, the majority were identified as being of high risk to patients and the others as medium risk. Authors concluded that there is a need to prepare junior doctors to manage, and cope with, medical error and to ensure that healthcare professionals are adequately supported throughout their careers.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Title	A longitudinal and multicentre study of burnout and error in Irish junior doctors
Author (s), year of publication	O'Connor, P., Lydon, S., O'Dea, A., Hehir, L., Offiah, G., Vellinga, A., & Byrne, D. (2017)
Study location	A multicentre study including junior doctors from five national intern training networks
Aim of the study	To measure burnout in a population of junior doctors in Ireland and identify if: levels of burnout are similar to US medical residents; there is a change in the pattern of burnout during the first year of postgraduate clinical practice; and burnout is associated with self- reported error.
Methods	A survey study using the Maslach Burnout Inventory – Human Services Survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Of 601 junior doctors eligible to participate,172 (28.6%) from 5 training networks completed the survey.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	Authors comparted burnout level among junior doctors in Ireland to burnout level among US medical residents, 4 month responses to survey vs 6 month responses to survey.
Outcome measures	• Burnout level among junior doctors in Ireland. • Demographic Characteristics

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

	• Whether the doctors had made a medical error in that caused them anxiety
key reported outcomes	Irish junior doctors at time 2 were more burned out than a sample of US medical residents (72.6% and 60.3% burned out, respectively; p=0.001). There was a significant increase in emotional exhaustion from time 1 to time 2 (p=0.007). The association between burnout and error was significant at time 2 only (p=0.03). At time 2, of those respondents who were burned out, 81/122 (66.4%) reported making an error. A total of 22/46 (47.8%) of the junior doctors who were not burned out at time 2 reported an error.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Title	Surgical checklists: the human factor
Author (s), year of publication	O'Connor, P., Reddin, C., O'Sullivan, M., O'Duffy, F., & Keogh, I. (2013)
Study location	One Irish hospital.
Aim of the study	To examine attitudes towards an adaptation of the WHO surgical checklist as it has been implemented in an Irish hospital.
Methods	Mixed methods. 14 semi- structured interviews were conducted with theatre personnel regarding their attitudes towards, and levels of compliance with, a checklist. Based upon the interviews, a 27-item questionnaire was developed and distribute to all theatre personnel in an Irish hospital.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	14 members of theatre staff participated in the interviews and 107 theatre staff responded to the survey.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	• Attitudes towards hospital norms on the use of checklists • Impact of the checklist on safety and teamwork • Support of the checklist from specific groups • Intent to initiate the checklist • Difference between the hospital surgical checklist and the WHO surgical checklist • Barriers to the use of checklists
key reported outcomes	Findings in this paper demonstrated that, particularly for nurses, the overall attitudes towards the effect of the checklist on safety and teamworking were positive. There was a lack of rigour with which the checklist was being applied. Nurses were significantly more sensitive to the barriers to the use of the checklist than anaesthetists or surgeons. Barriers to use of the checklist included lack of time, signature requirement and assertiveness of staff. Additionally, often the timing of when the checklist is carried out. Moreover, anaesthetists were not as positively disposed to the surgical checklist as surgeons and nurse. This finding was attributed to the tendency for the checklist to be completed during a period of high workload for the anaesthetists, resulting in a lack of engagement with the process. Authors concluded that in order to improve the rigour with which the surgical checklist is applied, there is a need for: the involvement of all members of the theatre team in the checklist process, demonstrated support for the checklist from senior personnel, on-going education and training, and barriers to the implementation of the checklist to be addressed.
Categorization based on the MMS framework (Vincent et al., 2014)	Reliability of safety critical processes

Title	The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals—a retrospective record review study
Author (s), year of publication	Rafter, N., Hickey, A., Conroy, R. M., Condell, S., O'Connor, P., Vaughan, D., ... & Williams, D. J. (2017)
Study location	Eight acute public hospitals across the Republic of Ireland
Aim of the study	To assess the frequency and nature of adverse events in Irish hospitals.
Methods	A two-stage retrospective record review study of patient charts with nurse reviewers screening for triggers that may identify an adverse event followed by physician reviewers determining the presence of adverse events in trigger positive charts.
Study populations (e.g. healthcare workers group, type	A total of 1574 fully reviewed charts from eight acute public Irish hospitals.

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

of patients group, total number of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The prevalence of adverse events in admissions was 12.2% with an incidence of 10.3 events per 100 admissions. Over 70% of events were considered preventable. Adverse events were higher in admissions associated with an anesthetic code indicating a surgical procedure had likely occurred. Overall there was no significant difference in the incidence of adverse events between specialties. Two-thirds were rated as having a mild-to-moderate impact on the patient, 9.9% causing permanent impairment and 6.7% contributing to death. A mean of 6.1 added bed days was attributed to events, representing an expenditure of €5550 per event. The adverse event rate varied substantially (8.6%–17.0%) when applying different published adverse event eligibility criteria.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Title	Measuring and benchmarking safety culture: application of the safety attitudes questionnaire to an acute medical admissions unit.
Author (s), year of publication	Relihan, E., Glynn, S., Daly, D., Silke, B., & Ryder, S. (2009).
Study location	An acute medical admissions unit (AMAU) of a teaching hospital
Aim of the study	To assess the safety culture in an acute medical admissions unit (AMAU) of a teaching hospital in order to benchmark results against international data and guide a unit-based, integrated, risk management strategy.
Methods	Cross-sectional study using safety attitudes questionnaire (SAQ), a 30-item questionnaire that measures staff perceptions of safety culture. Data was collected during a 3-week period in June 2008.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Fifty-five of 92 staff targeted completed the survey, including doctors, nurses, healthcare assistants (HCAs) and allied healthcare professionals (AHPs).
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Safety culture
key reported outcomes	When compared against an international benchmark, the AMAU scored significantly higher for four of the six safety domains. The difference between nurse manager scores and the overall mean for the study group was statistically significant for the domains of 'teamwork climate' (<0.05) and 'safety climate' ($p<0.01$). HCAs scored significantly lower relative to staff overall with regard to 'working conditions' ($p<0.05$) and 'perceptions of management' ($p<0.01$). The SAQ was successfully applied to an AMAU setting giving a valuable insight into staff issues of concern across the safety spectrum: employee and environmental safety, clinical risk management and medication safety.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness

Title	Burnout syndrome among non-consultant hospital doctors in Ireland: relationship with self-reported patient care
Author (s), year of publication	Sulaiman, C. F. C., Henn, P., Smith, S., & O'Tuathaigh, C. M. (2017).
Study location	All teaching hospitals affiliated with University College Cork.
Aim of the study	The study examined the prevalence of burnout syndrome among Irish NCHDs and its association with self-reported medical error and poor quality of patient care.
Methods	A cross-sectional quantitative survey-based design.
Study populations (e.g. healthcare workers group, type	265 non-consultant hospital doctors (NCHDs)

(1) Past Harm; Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) Reliability; Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) Sensitivity to operations; Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) Anticipation and preparedness; Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) Integration and learning; Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

of patients group, total number of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Self-reported measures of burn out and poor quality of patient care
key reported outcomes	Prevalence of burnout among physicians (n = 265) was 26.4%. There was a significant gender difference for EE and DP, but none for PA. A positive weak correlation was observed between emotional exhaustion and depersonalization with medical error or poor patient care. A negative association was reported between personal achievement and medical error and reduced quality of patient care. Burnout syndrome is associated with self- reported medical error and quality of care in this sample population.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Title	Using co-design to develop a collective leadership intervention for healthcare teams to improve safety culture.
Author (s), year of publication	Ward, M. E., De Brún, A., Beirne, D., Conway, C., Cunningham, U., English, A., ... & McAuliffe, E. (2018).
Study location	11 hospitals working with four Community Healthcare Organisation (CHO) partners and an academic partner.
Aim of the study	This paper addresses the gap on how to do co-design in practice by delineating the approach taken in the co-design of a collective leadership intervention to improve healthcare team performance and patient safety culture. Authors aimed to design an intervention that was grounded in the real-world experience of healthcare staff and in their contextual reality through a co-design process, whereby all co-design team members have an equal voice and role in prioritising and designing content.
Methods	Co-design approach to develop a collective leadership intervention for healthcare teams to improve safety culture.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	21 healthcare staff, patient representatives and advocates, and health systems researchers.
Intervention (type and duration of intervention if applicable)	The intervention; a 'toolkit' of one-hour interventions to introduce Collective Leadership to healthcare teams with the aim of improving Safety Culture. It was co-designed over the course of six 3- hour workshops.
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Taking a co-design approach to developing the collective leadership was extremely beneficial in informing the development of the intervention and the different components of the Co-Lead toolkit. Co-design has great potential as a methodology for understanding health systems and for enhancing research outputs and potentially, implementation success.
Categorization based on the MMS framework (Vincent et al., 2014)	Pre-intervention study

Title	The co-design, implementation and evaluation of a serious board game 'PlayDecide patient safety' to educate junior doctors about patient safety and the importance of reporting safety concerns
Author (s), year of publication	Ward, M., Shé, É. N., De Brún, A., Korpos, C., Hamza, M., Burke, E., ... & McAuliffe, E. (2019)
Study location	Two large urban acute teaching hospitals in Ireland.
Aim of the study	The aim of the study was to co-design and implement an embedded learning intervention – a serious board game – to educate junior doctors about patient safety and the importance of reporting safety concerns, while at the same time shaping a culture of responsiveness from senior medical staff.
Methods	A learning intervention was co-designed and implemented. A paper-based questionnaire on 'Safety

(1) **Past Harm;** Has patient care been safe in the past? rates of past harm to patients, both physical and psychological.
(2) **Reliability;** Are clinical systems and processes reliable? the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
(3) **Sensitivity to operations;** Is care safe today? This is the information and capacity to monitor safety on an hourly or daily basis.
(4) **Anticipation and preparedness;** Will care be safe in the future? the ability to anticipate, and be prepared for, problems and threats to safety
(5) **Integration and learning;** Are we responding and improving? The capacity of an organisation to detect, analyse, integrate, respond and improve from, safety information

	Concerns' was developed and administered to assess pre-and post-playing the game reporting behaviour. Dissemination workshops were held with senior clinicians to promote more inclusive leadership behaviours and responsiveness to junior doctors raising of safety concerns from senior clinicians.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	The PPS game was played with the interns in groups of 4–6 on 3rd November 2015. 57 junior doctors in hospital A, 44 junior doctors in hospital B participated in the game
Intervention (type and duration of intervention if applicable)	Over three workshops this educational intervention, serious game based on the PlayDecide framework, aimed to educate junior doctors about patient safety and the importance of reporting safety concerns. The game consists of five different types of cards: story, white, information, challenge and issue cards.
Comparator (if any)	-
Outcome measures	Education impact of the PlayDecide game Impact of the PlayDecide game on reporting patient safety concerns
key reported outcomes	The PlayDecide game proved to be a valuable patient safety educational tool and proved effective in encouraging deep discussion on patient safety. There was a significant change in the reporting behaviour of junior doctors in one of the hospitals following the intervention. In both hospitals, junior doctors identified contributory factors to incidents which included collaboration and teamwork, communication and interpersonal skills and management.
Categorization based on the MMS framework (Vincent et al., 2014)	Intervention study (Education and training intervention)

Appendix 3
Additional file 1 (Search strategy)

Advanced google search

#	Search terms		Total search yield	Potentially relevant records / full text review	Included
1	"Measuring safety"	AND "Ireland"	n=94	n=9	
2		AND "Irish hospitals"	n=77	n=9	
3		AND "Irish healthcare"	n=79	n=3	
4	"Monitoring safety"	AND "Ireland"	n=90	n=3	
5		AND "Irish hospitals"	n=4	n=0	
6		AND "Irish healthcare"	n=7	n=0	
7	"Measurement of safety"	AND "Ireland"	n=19	n=0	
8		AND "Irish hospitals"	n=5	n=1	
9		AND "Irish healthcare"	n=10	n=0	
Total=			N=385	N=25	N=5

MEDLINE

Search strategy	Total search yield	Potentially relevant records / full text review	Included
1. exp patient safety/ 2. safe*2.ti,ab. 3. exp medical errors/ 4. (medica* adj1 error*1).ti,ab. 5. (adverse adj1 event*1).ti,ab. 6. (sentinel adj1 event*1).ti,ab. 7. (patient adj1 safety adj1 incident*1).ti,ab. 8. (patient adj1 harm*).ti,ab. 9. (healthcare adj1 quality).ti,ab. 10. (quality adj1 care).ti,ab. 11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 12. measur*.ti,ab. 13. monitor*.ti,ab. 14. assess*.ti,ab. 15. evaluat*.ti,ab. 16. 12 or 13 or 14 or 15 17. exp hospital/ 18. hospital*1.ti,ab. 19. exp secondary care/ 20. (secondary adj1 care).ti,ab. 21. exp tertiary healthcare/ 22. 17 or 18 or 19 or 20 or 21 23. exp ireland/ 24. irish.ti,ab. 25. 23 or 24 26. 11 and 16 and 22 and 25	226	2	0

CINAHL

Search strategy	Total	Potentially	Included

	search yield	relevant records / full text review	
S27 S12 AND S18 AND S22 AND S26 S26 S23 OR S24 S24 TI irish OR AB irish S23 TI ireland OR AB ireland S22 S19 OR S20 OR S21 S21 TI "tertiary care" OR AB "tertiary care" S20 TI "secondary care" OR AB "secondary care" S19 TI hospital* OR AB hospital* S18 S13 OR S14 OR S15 OR S16 OR S17 S17 TI evaluat* OR AB evaluat* S16 TI assess* OR AB assess* S15 TI manag* OR AB manag* S14 TI monitor* OR AB monitor* S13 TI measur* OR AB measur* S12 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 S11 TI "quality *care" OR AB "quality *care" S10 TI "healthcare quality" OR AB "healthcare quality" S9 TI "iatrogenic disease" OR AB "iatrogenic disease" S8 TI "patient harm" OR AB "patient harm" S7 TI "patient safety incident" OR AB "patient safety incident" S6 TI "sentinel event" OR AB "sentinel event" S5 TI "adverse event" OR AB "adverse event" S4 TI "risk management" OR AB "risk management" S3 TI "medica* error*" OR AB "medica* error*" S2 TI safe* OR AB safe* S1 TI "patient safety" OR AB "patient safety"	197	15	0

OAIster

#	Search terms			Total search yield	Potentially relevant records / full text review	Included
1	“Measuring safety”	AND	"Ireland"	n=2	n=0	n=0
2			"Irish hospitals"	n=0	n=0	n=0
3			"Irish healthcare"	n=0	n=0	n=0
4	“Monitoring safety”	AND	"Ireland"	n=0	n=0	n=0
5			"Irish hospitals"	n=0	n=0	n=0
6			"Irish healthcare"	n=0	n=0	n=0
7	“Measurement of safety”	AND	"Ireland"	n=0	n=0	n=0
8			"Irish hospitals"	n=0	n=0	n=0
9			"Irish healthcare"	n=0	n=0	n=0
Total=				N=2	N=0	N=0

WHO IRIS

#	Search terms	Total search yield	Potentially relevant records / full text review	Included
1	Title contains: Measuring safety	17	2	0
2	Title contains: Monitoring safety	12	0	0
3	Title contains: Measurement of safety	17	2	0

Google scholar

#	Search terms		Total search yield	Potentially relevant records / full text review	Included
1	“Measuring safety”	"Ireland"	n= first 100 hits	n=1	
2		"Irish hospitals"	n=8	n=1	
3		"Irish healthcare"	n=9	n=1	
4	“Monitoring safety”	"Ireland"	n= first 100 hits	n=2	
5		"Irish hospitals"	n=4	n=0	
6		"Irish healthcare"	n=2	n=0	
7	“Measurement of safety”	"Ireland"	n=0	n=0	
8		"Irish hospitals"	n=4	n=0	
9		"Irish healthcare"	n=4	n=0	
total			N=231	N=5	N=0

Lenus (the Irish health research repository)

#	Search terms	Total search yield	Potentially relevant records / full text review	Included
1	(Measuring safety [Title/Abstract])	97	0	0
2	(Monitoring safety [Title/Abstract])	60	3	0
3	(Measurement of safety [Title/Abstract])	97	0	0

HSE

#	Search terms	Total search yield	Potentially relevant records / full text review	Included
1	Measuring safety	n= first 100 hits	6	0
2	Monitoring safety	n= first 100 hits	1	0
3	Measurement of safety	n= first 100 hits	3	1

Department of Health

#	Search terms	Total search yield	Potentially relevant records / full text review	Included
1	Measuring safety	9	0	0
2	Monitoring safety	4	0	0
3	Measurement of safety	9	0	0

HIQA

#	Search terms	Total search yield	Potentially relevant records / full text review	Included
1	Measuring safety	22	7	0
2	Monitoring safety	39	2	0
3	Measurement of safety	317	3	0

Appendix 4
Additional File 2

Document analysis

1. Harm- have we been safe in the past?
2. Reliability of safety critical processes
3. Sensitivity to operations- are we safe today?
4. Anticipation and preparedness- will we be safe in the future?
5. Integration and learning- are we responding and improving?

Measure	Dimension
1st document: Patient Safety Strategy 2019-2024	
P6. a National Clinical Guideline for a National Early Warning Score (NEWS)	2
P6. Annual National Patient Experience Survey.	4
P8. working with and learning from patients to design, deliver, evaluate and improve care.	3
P8. embed a culture of learning and improvement that is compassionate, just, fair and open	4
P8. increased emphasis on proactively identifying risks	4
P8. reduce patient harm, with particular focus on the most common causes of harm.	1
P8.use information from various sources to provide intelligence that will help us recognise when things go wrong, learn from and support good practice and measure, monitor and recognise improvements in patient safety	5
P8. embed a culture of patient safety improvement through effective leadership and governance	4
P8. patients are supported with the knowledge, skills and supports that they need to take responsibility for improving their own safety in partnership with staff.	3
P8. patients, families, carers and advocates are listened to and actively involved in making our services safer.	3
P11. patients are fully informed and engaged in decisions about their care and are facilitated to best support their own safety.	3
P11. empower patients to contribute to the safety of health and social care services. This will include their involvement as partners in key governance structures and processes.	3
P11. National Care Experience Programme to listen to and act on the voice of patients.	3
P11. training and information needs of patients, families, carers, patient representatives and advocates to enable them to contribute to preventing harm and improving patient safety	3
P11. embed a culture where we acknowledge when things go wrong, offer meaningful apologies, and act to put things right	5
P.13 assess, plan and manage workforce and resource requirements, using risk based prioritisation, to ensure safe systems of work and safe staffing levels that support improvements to patient safety.	4
P.13 ensure that staff are effectively listened to, communicated with and are fully involved and engaged in the planning and delivery of the services they provide and that they are supported and facilitated to raise safety concerns and improve patient safety.	3
P.13 enhance the capacity and capability of health and social care services and staff to improve patient safety by designing and delivering safety information and training to include patient safety and reliability science, systems thinking, audit, quality improvement methodologies, change management, human factors and multidisciplinary team working for safety.	5
P.13 promote behaviours that support a culture of safety, this will include strategies that enhance situational awareness, for example ‘safety pauses’ for teams.	3
P.13 coordination, networking, sharing and learning for patient safety amongst patient safety leaders, staff, health care providers and external agencies	5
P.13 support staff in reporting and learning from incidents and implement strategies to enhance and improve incident reporting and reviews.	1,5
P.13 measure the culture of patient safety across health and social care services and identify and implement actions to address identified deficits.	4
P15. Key strategic and policy decisions taken by management teams will be routinely risk assessed so that unintended consequences that might impact on patient safety are avoided.	4
P15. systems to continuously improve the quality and analysis of patient safety data and intelligence to allow us assess risks to patient safety	4
P15. quality and timeliness of incident reviews and ensure that learning from the review of	5

incidents is optimised	
P15. formal processes for the communication of risk in line with the organisation's accountability arrangements.	5
P15. integrate patient safety information and data to allow us to analyse the reliability of health and social care processes	2
P15. proactively identify areas of risk to patient safety,	4
P15. and learn from where things go wrong and from examples of good practice in a way that will inform safety improvement programmes.	5
P15. publish data in relation to patient safety across the health and social care system.	5
P15. put in place resourcing for the full implementation of National Clinical Guidelines	4
P15. strengthen clinical audit structures and processes	2
P17. develop implementation plans and prioritise initiatives to address these and other emerging priorities for patient safety improvement as part of our annual and multi annual planning process over the course of the Strategy's lifetime	5
P17. constantly monitor and review patient safety risks and will prioritise other patient safety and improvement initiatives where this is required.	4
P19. develop and enhance local and national suites of key patient safety indicators	1
P19. develop, consolidate and continuously improve patient safety surveillance and reporting systems at every level of the health and social care service.	1
P19. use a range of information sources and methods of presenting data, including incident and risk data, quality and safety metrics for clinical service,	5
P19. assessments against national standards,	1
P19. patient engagement, staff engagement,	3
P19. claims,	1
P19. complaints,	1
P19. incident reviews,	1
P19. clinical audit,	1
P19. regulatory reports,	1
P19. mortality reviews,	1
P19. and research to support these patient safety surveillance and reporting systems.	5
P19. publish reports in relation to our performance in patient safety and we will recognise and highlight achievements in patient safety improvement.	5
P19. measure compliance with the National Standards for Safer, Better Healthcare	1
P19. support patient safety research and publish and act on the results	5
P19. develop and enhance technology solutions, including eHealth, to improve access to and reliability of information to measure and improve patient safety.	5
P21. align staff skilled in quality and patient safety with patient safety initiatives	4
P21. comprehensive communications programme and supporting awareness campaign to engage support for patient safety amongst the public and health and social care staff and to disseminate learning and good practices.	5
2nd Document: Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance	
P17. A national network of patient advocates who will work in partnership with healthcare organisations and other key players to improve patient safety should be identified, supported and developed through appropriate training programmes; the network should also, where appropriate, have strong links with international/worldwide initiatives.	3
P18. Provision should be made for patient and family involvement in research activities such as measuring patient contribution to bad outcomes, factors that rescue patients from provider error, and factors that mitigate the harm caused by errors.	5
P52. A confidential web-based national clinical incident reporting system, STARSWeb	1
P52. A very important objective for Clinical Indemnity Scheme (CIS) is sharing of learning to support patient safety. This is done in a variety of ways: as claims are closed, they are subjected to analysis in order to capture any learning from them. Feedback is provided to the individual enterprise and any generic lessons are fed back into the system through workshops, seminars, the Clinical Indemnity Scheme (CIS) website or newsletter	5
P56. patient forums and expert patient groups in engagement in service design, planning and evaluation	3
P.153. Clinical audit	2
3rd document: Key Performance Indicator Metadata 2021	

P64. Rate of new cases of hospital acquired Staphylococcus aureus bloodstream infection	1
P65. Rate of new cases of hospital associated C. difficile infection	1
P66. % of acute hospitals implementing the requirements for screening of patients with Carbapenemase Producing Enterobacterales (CPE) guidelines	2
P67. % of acute hospitals implementing the national policy on restricted antimicrobial agents	2
P69. Rate of medication incidents as reported to NIMS per 1,000 beds	1
P70. % of hospitals implementing Irish National Early Warning System (INEWS) in all clinical areas of acute hospitals (as per 2019 definition)	2
P72. % of hospitals implementing The Irish Paediatric Early Warning System (PEWS)	2
P74. % of hospitals that have completed a self-assessment against all 53 essential elements of the National Standards for Safer, Better Healthcare	2
P75. % of acute hospitals that have completed and published monthly hospital patient safety indicator reports	2
P83. % of maternity units / hospitals with full implementation of Irish Maternity Early Warning System (IMEWS) (as per 2019 definition)	2
P85. % of all hospitals implementing IMEWS (as per 2019 definition)	2
P87. % of maternity hospitals/units that have completed and published monthly Maternity Safety Statements	2
P88. % of Hospital Groups that have discussed a quality and safety agenda with NWIHP on a bi/quarterly/monthly basis in line with the frequency stipulated by NWIHP	2
P116. No. of new cases of CPE (Carbapenemase Producing Enterobacterales)	1
P117. Rate of venous thromboembolism (VTE, blood clots) associated with hospitalisation	1
4th Document: National Standards for the Conduct of Reviews of Patient Safety Incidents 2017	
P6. Standard 1 Service providers support a culture of patient safety that promotes trust, openness, empathy and respect in the review of patient safety incidents.	4
P21. Standard 1.5 Service providers promote a culture of welcoming feedback, compliments, complaints and concerns in relation to conducting reviews of patient safety incidents. This information is used effectively to improve safety and promote learning throughout the service.	5
P6. Standard 2 Service providers have formal governance structures in place service-wide for assuring timely and effective reviews of patient safety incidents.	2
P22. Standard 2.1 Governance structures are in place which ensure the service effectively reviews patient safety incidents, minimises the risk of harm to service users and implements actions and learning from reviews of patient safety incidents.	2
P22. Standard 2.2 Governance structures promote patient safety as a collective goal within the service to support the timely and effective review of patient safety incidents, including adherence to due process and fair procedure.	2
P22. Standard 2.3 Service providers have integrated corporate and clinical governance structures which define roles, accountability and responsibilities throughout the service for conducting reviews of patient safety incidents.	2
P22. Standard 2.4 Service providers demonstrate visible leadership in promoting a just culture of openness, quality and safety in the review of patient safety incidents through: allocation of resources and training	4
and monitoring and evaluation processes.	2
P22. Standard 2.5 Service providers have a standardised approach to the conduct of reviews of patient safety incidents service-wide in the following areas: reporting and escalation process, arrangements for feedback, staff skills and experience, workforce planning, including capacity building and protected time, implementation of recommendations from reviews, sharing the learning for improvement.	2
P23. Standard 2.6 Governance structures are in place to assess service-wide performance and proactively monitor, analyse (including historical and trend analysis) and respond to information relevant to the review of patient safety incidents. This information includes:	4
audits, including clinical audits	2
surveys, including experience surveys and patient safety culture surveys	4
complaints, compliments and concerns	1
findings from risk assessments	4
legal claims	1
findings and recommendations from local, national and international reviews and investigations.	5
P23. Standard 2.8 Service providers have governance structures in place for positive and	5

cooperative relationships with other agencies, as appropriate, to support the effective review of patient safety incidents; this includes procedures on information sharing and interagency working.	
P6. Standard 3 Service providers have clear lines of accountability in place service-wide for the conduct of reviews of patient safety incidents.	2
P6. Standard 4 Service providers implement a service-wide system to monitor and evaluate the effectiveness of reviews of patient safety incidents.	2
P25. Standard 4.1 Service providers monitor the conduct of reviews of patient safety incidents on a monthly basis in adherence with relevant national policy, standards and guidelines.	2
P25. Standard 4.2 Service providers publish an annual overview report on the conduct of reviews of patient safety incidents. This should include adherence to time frames for reviews and how actions and recommendations from reviews are being implemented in the service.	5
P25. Standard 4.3 Service providers evaluate the systems for monitoring the effectiveness of the conduct of reviews of patient safety incidents on an annual basis.	2
P25. Standard 4.5 Service providers evaluate the findings of reviews of patient safety incidents and any actions required and share relevant learning locally and nationally to improve the quality and safety of the service.	5
P25. Standard 4.6 Service providers evaluate the incident review process and incident review reports to identify opportunities for improvement for implementation service- wide.	5
P25. Standard 4.7 Service providers, in consultation with service users and staff, develop and implement quality improvement programmes to actively improve services based on the learning from reviews of patient safety incidents. These programmes are evaluated annually.	5
P6. Standard 5 Service providers have effective information governance structures in place service-wide for the management of information related to reviews of patient safety incidents.	2
P26 Standard 5.5 There is an annual evaluation of the service's record management practices and systems for information related to the review of patient safety incidents.	2
P6. Standard 6 Service users and their families are actively engaged with as part of the review of patient safety incidents, and their views are listened to, respected and responded to in a timely manner.	3
P29. Standard 6.4 Service users and their families are facilitated to provide feedback on their experience of the review process. Where areas for improvement are identified, the service provider takes action to address the issues raised.	5
P6. Standard 7 Service users and families involved in a patient safety incident are appointed a service-user liaison to facilitate communication with the incident management/review team and access to support.	3
P7. Standard 10 Service providers establish a standing incident management team to oversee the management and review of patient safety incidents.	2
P7. Standard 15 Service providers ensure a preliminary assessment of the patient safety incident takes place, and the decision on the appropriate level of review required is clearly documented.	2
P7. Standard 17 Reviews of patient safety incidents are conducted in a timely manner, in line with the service's policy and procedures.	2
P7. Standard 19 Service providers implement the recommendations and actions from patient safety incident-review reports.	5
P8: Standard 20 Service providers have structures in place to actively share the learning from reviews of patient safety incidents service-wide.	5
P.48 Standard 20.3 Service providers actively promote discussion on the learning from reviews of patient safety incidents to promote a positive safety culture service-wide.	3
P48. Standard 20.6 Service providers work in partnership with external bodies, as appropriate, to share the learning from reviews of patient safety incidents.	5
5th Document: The Incident Management Framework 2020	
P17. identifying areas where incidents are likely to occur and putting in place systems to prevent or reduce the likelihood of the risk of their occurrence.	4
P17. service's risk management and quality improvement processes are informed by information from a variety of sources such as but not limited to incidents, complaints, claims management, coroner's reports, and regulatory inspection	5
P17. The Quality and Safety Committee or equivalent has a key role in promoting, monitoring and sharing learning from the services' quality and safety processes.	5

P20. It is the responsibility of the staff member identifying the incident to report the incident either by completion of the appropriate National Incident Report Form (NIRF) or direct entry to NIMS if available	1
P20. All maternal deaths must also be reported to the NWIHP within 48 hours of occurrence.	1
P22. Category 1 incidents must be referred to the Serious Incident Management Team (SIMT)	2
P23. Systems Analysis: A structured process that aims to identify what happened, how and why it happened, what can be done to reduce the risk of recurrence and make services safer.	5
P23. After Action Review (AAR): This is a structured facilitated discussion of an event, the outcome of which enables the individuals involved in the event to understand why the outcome differed from that which was expected and what learning can be identified to assist improvement	5
P28. Systems for monitoring the progression of reviews should be established to ensure that it is completed within timeframes	2
P31. Sharing Learning from the Review Report : At a minimum, services must arrange to have final reports discussed at the relevant Committee, for example, the Quality and Safety Committee. This is to ensure that any learning identified can be shared internal to the service for the purpose of patient safety and quality improvement.	5
P31. Consideration should also be given to the completion of a learning summary which sets out a brief description of the background to the incident and the learning adduced. Such summaries can then be shared with services beyond the particular service/organisation within which the incident occurred	5
P31. Publication of the Review Report: Publication in this regard means putting the report in the public domain. Reports relating to service user incidents are personal to the service user and their relevant person(s) and as such are not generally published. If there is a request for such a report to be published, this request should be discussed with the Hospital Group CEO, CHO CO or equivalent senior manager.	5
P32. Look Back Reviews: A Look Back Review is a process that is initiated where it has been determined that a number of people have been exposed to a specific hazard. The process seeks to identify if any of those exposed to the hazard have been harmed and what needs to be done to ameliorate the harm.	1
P33. Cross service reviews: Due to the manner in which care is delivered, incidents may cross organisational/care boundaries, for example, pre-hospital/hospital care, hospital/community care, inter-hospital transfers, mental health/acute care, etc.	1
P33. external reviews/investigations e.g. An Garda Síochána	1
P33. Reviews relating to Multi-Incident Events: Multi-incident events may arise where a cluster of similar incidents are identified by the service or concerns are received by a service from members of the public relating to an aspect of service provision. Clusters of concerns may in particular arise in the aftermath of the public reporting of an incident(s).	1
P35. It is recommended that rather than monitor action plans for individual reviews, that action plans developed are interfaced with the relevant service improvement plan with implementation monitored via these.	5
P35. In cases where monitoring of implementation is being done through the service improvement plan, a record should be kept of the actions in the service improvement plan which relate to the implementation of recommendations in a particular review report	2
P35. A monitoring process must be in place to track the completion of actions and where there is evidence that actions are behind schedule, appropriate corrective action must be taken to address this.	2
P35. At a minimum, progress on implementation of actions from Category 1 incidents must be reported to the relevant committee e.g. Quality and Safety Committee on a quarterly basis.	5
P35. Reports relating to aggregate analysis of data from NIMS and thematic learning should be collated over specific timeframes to assist and inform the wider service improvement programmes.	5
P35. Services should have in place systems to verify implementation and monitor the effectiveness of improvement strategies which aim to improve the safety and quality of services. The use of audit and monitoring should be central to this and should occur both at the unit level and organisational level through the relevant committee e.g. Quality and Safety Committee.	2
P35. Services are required to publish an annual overview report in relation to incident reporting and management. This should include detail of incidents reported by type, speciality,	5

and severity, compliance with key performance indicators relating to incident management and detail on how the actions and recommendations from reviews are being implemented in the service to improve safety.	
6th documents: National Standards for Safer Better Healthcare	
P20. Standard 1.1.1 Proactive and systematic identification of service users' collective needs and preferences.	4
P20. Standard 1.1.7 Feedback from service users being used to continuously improve the experience for all service users.	5
P34. Standard 1.8.3 Complaints procedures that identify the expectations of service users making complaints and ensure that these expectations are taken into account and addressed throughout the process.	5
P42. Standard 2.1.2 Use of National Clinical Guidelines and nationally agreed protocols, care bundles and care pathways where available.	2
P42. Standard 2.1.3 Regular reviews of National Clinical Guidelines to determine what is relevant to the care and treatment provided and taking steps to address any identified gaps to ensure guidelines are implemented.	1
P42. Standard 2.1.4 A clearly documented risk assessment when services are unable to fully implement National Clinical Guidelines and appropriate action taken to ensure the quality and safety of services.	4
P52. Standard 2.6.4 Regular review of the services provided and evidence that the defined model of service can be delivered safely.	2
P53. Standard 2.6.5 Ongoing assessment of the volumes and casemix of their service users to ensure services are provided to sufficient numbers of service users to maintain the skills and competencies of clinical teams based on best available evidence or advice from the relevant professional and expert bodies.	4
P53. Standard 2.6.6 Management of available resources, including the workforce, to meet legislative requirements, and to deliver the defined model of service safely and sustainably at all times.	4
P54. Standard 2.7.9 The proactive identification of risks associated with changes to the physical environment where care is delivered and evaluation of identified risks and necessary action to eliminate or minimise such risks.	4
P56. Standard 2.8.1 Use of relevant national performance indicators and benchmarks, where they exist, to monitor and evaluate the quality and safety of the care and its outcomes.	1
P56. 2.8.5 Monitoring and evaluation of performance by developing and implementing clinical and non-clinical audits	1
and implementing improvements based on the findings.	5
P56. 2.8.8 Clinical governance arrangements that ensure findings from clinical audits are reported and monitored effectively.	5
P62. 3.1.1 Proactive monitoring, analysis and response to information relevant to the provision of safe services. This information includes: patient-safety incidents complaints, concerns and compliments, findings from risk assessments, legal claims, audits, satisfaction surveys, findings and recommendations from national and international reviews and investigations, casemix, activity and performance data.	4
P64. Standard 3.2 Service providers monitor and learn from information relevant to the provision of safe services and actively promote learning both internally and externally.	5
P66. Standard 3.3 Service providers effectively identify, manage, respond to and report on patient-safety incidents.	1
P66. Standard 3.3.7 Evaluation of the effectiveness of the arrangements for identifying, managing, responding to and reporting on patient-safety incidents.	2
P72. 3.6.2 Clear articulation of the elements of a patient-safety culture and specific arrangements that actively promote this culture through a mission statement, service design, code of conduct, allocation of resources and training, development and evaluation processes.	4
P74. 3.7.2 A patient-safety improvement programme based on assessed local needs and priorities and national and international initiatives. This programme incorporates specific evidence-based interventions that are proportionate to the context, nature and scale of the service provided.	5
P86. Standard 5.1 Service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare.	2
P88. Standard 5.2 Service providers have formalised governance arrangements for assuring	2

the delivery of high quality, safe and reliable healthcare.	
P96. 5.6.4 Regular review and identification of areas for improvement in the culture of the service, which incorporates feedback from service users and the workforce.	5
P100. 5.8.7 Proactive approach to learning from findings and recommendations from national and international reviews and investigations.	5
P112. Standard 6.1 Service providers plan, organise and manage their workforce to achieve the service objectives for high quality, safe and reliable healthcare.	4
P116. Standard 6.3.5 A training, educational and development programme with a specific focus on patient safety, communication and person-centred care, which has clear objectives and which is tailored to specific members of the workforce to develop competencies in order to ensure the delivery of high quality safe care.	5
P116. 6.4.5 Monitoring, management and development of the performance of the workforce, at individual and team level, including the evaluation of service users' feedback and taking action to address identified areas for improvement.	5
P124. 7.1.3 Consultation with key stakeholders including service users, policy makers and their workforce regarding the allocation of resources to achieve the best quality and safety outcomes for service users.	4
P126. 7.2.2 Regular evaluation and management of the efficiency and cost- effectiveness of services and technologies. This evaluation and management uses best available evidence to maximise quality and safety and to inform investment and disinvestment decisions.	4

Appendix 5
Supplementary material 1: Search strategy

Medline (OVID) Search strategy

1	exp patient safety/
2	safe*2.mp.
3	exp medical errors/
4	((healthcare or health care) adj error*1).mp.
5	(human* adj1 error*1).mp.
6	((incident* or voluntary) adj1 report*).mp.
7	(medical adj3 error*1).mp.
8	(adverse adj3 event*1).mp.
9	(sentinel adj3 event*1).mp.
10	exp patient harm/
11	((preventable or avoidable or unnecessary) adj3 harm).mp.
12	(patient adj3 harm).mp.
13	exp iatrogenic disease/
14	(iatrogenic adj disease*).mp.
15	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16	exp hospital/
17	hospital*1.mp.
18	exp secondary care/
19	(secondary adj1 (care or healthcare)).mp.
20	exp tertiary healthcare/
21	(tertiary adj1 (care or healthcare)).mp.
22	16 or 17 or 18 or 19 or 20 or 21
23	exp saudi arabia/
24	arab*3.mp.
25	saudi.mp.
26	23 or 24 or 25
27	15 and 22 and 26
28	limit 27 to (arabic or english)

Appendix Six
Supplementary material 2: Data charting forms of included studies

Paper number (PDF no.)	1 (1)
Title	Organisational empowerment and speaking up against unsafe practice: the case for newly qualified nurses in Saudi Arabia
Author (s), year of publication	Mansour Mansour, Maha Al-Madani, Abdelrahman Al-Anati, Aysar Jamama (2020)
Study location	Five publicly funded general hospitals in the Eastern Province of Saudi Arabia
Aim of the study	This study aimed to investigate perceptions of organisational empowerment and willingness to speak up against perceived unsafe practice among newly qualified nurses in Saudi Arabia.
Methods	cross-sectional survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	83 newly qualified nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The nurses reported moderate levels of both empowerment and willingness to speak up against unsafe practice. There was a statistically significant correlation between the participants' total structured empowerment score and their speaking up score. Willingness to speak up against potentially unsafe practice was also correlated with participants' perceived access to support at work. Authors suggested implementing practical strategies to help build and sustain newly qualified nurses' sense of work empowerment and assertiveness.
Categorization based on the MMS framework (Vincent et al., 2014)	Sensitivity to operations

Paper number (PDF no.)	2 (2)
Title	An evaluation of Datix implementation for incident reporting at Johns Hopkins Aramco Healthcare
Author (s), year of publication	Hayat Mushcab, David Bunting, Saeed Yami, Ali Abandi and Catherine Hunt (2020)
Study location	Johns Hopkins Aramco Healthcare (JHAH) Dhahran, Saudi Arabia
Aim of the study	This study aims to evaluate incident reporting at the Johns Hopkins Aramco Healthcare (JHAH) since the implementation of Datix and the staff's behavior towards incident reporting.
Methods	A prospective, mixed methods study using quantitative and qualitative methods
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	respondents to the main questionnaire (responses, n=377). Three questionnaires were developed in this study. A main questionnaire that was sent to all JHAH staff, and two sub-groups that were identified through the software's serve. The first of these were users who had never logged into the system (1516 employees) and the second was a group of the top 100 super-users of the system. These two sub-groups received follow-up questionnaire to understand the reasons behind their behaviour.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	
key reported outcomes	Incident reporting increased in 2017 and 2018 by 51% and 57%, respectively, using Datix compared with the previously implemented software. This study shows the influence of different incident reporting systems/software on reporting rates.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm (e.g. investing in user-friendly software to encourage healthcare workers to report, hence measuring and monitoring is improved)

Paper number (PDF no.)	3 (23)
Title	Knowledge, attitudes, and perception on patient safety among intern nurses at hemodialysis unit
Author (s), year of publication	Farhan F Alshammari, Soheir Tawfeek Ahamed, Salwa Abd El Gawad Sallam, Eddieson A Pasay-an (2020)
Study location	the hospital hemodialysis units in the Hail Region, Kingdom of Saudi Arabia
Aim of the study	This study aims to determine the differences in knowledge, attitude, and perception from interns' demographic information and correlates between knowledge, attitudes, and perception on patient safety.
Methods	A quantitative comparative-correlational study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	118 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Positive results of knowledge, attitudes, and perception of the nurse interns suggest a continuous improvement of the nursing intern program for patient safety. Furthermore, the knowledge translation to attitude and perception is a good indication that nurses can adapt patient safety practices in their future actual practice.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness

Paper number (PDF no.)	4 (25)
Title	Perceptions of Patient Safety Culture among Physicians and Nurses in a Tertiary Hospital in Southwestern Saudi Arabia
Author (s), year of publication	Abdullah A. Alsabaani (2020)
Study location	a tertiary hospital which is located in the southwestern part of the Kingdom of Saudi Arabia
Aim of the study	To explore physicians and nurses' overall atti- tudes and perceptions towards patient safety culture and to evaluate any differences in their cultures.
Methods	cross-sectional study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	369 medical staff (physicians and nurses) working in a tertiary hospital for at least six months
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using the HSPSC
key reported outcomes	perceptions regarding "teamwork within units", "organizational learning-continuous improvement" and "feedback and communication" were good. However, other patient safety dimensions need to be improved. Overall, nurses' perceptions are significantly better than physicians' perceptions. Authors suggest that capacity-building programs should focus on improving patient safety culture among health care providers in general and among physicians in particular.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	5 (27)
Title	Data on healthcare perceptions about system risk factors associated with patient safety from the Ministry of Health hospitals in Hail Region of Saudi Arabia
Author (s), year of publication	Fares Alshammari1, Hamoud Fahad Alshammari, Bandar Alsaedi, Rafat Zreiq & Fahad D. Algahtan (2021)
Study location	Three hospitals located in Hail city i.e. King Khalid Hospital, Hail General Hospital and Maternity and Children's Hospital
Aim of the study	The objectives of the present study are (i) to investigate the perceptions of nurses regarding system risk factors that undermine MEs, (ii) to rank the system risk factors and (iii) to assess differences among characteristics of the study sample in relation to the system risk factors.

Methods	A cross-sectional survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	450 nurses, only 246 questionnaires contained complete information.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	System risk factors associated with patient safety
key reported outcomes	Eight out of twelve factors tested were perceived as threatening factors of the patient safety that are: 'Shortage of medical staff', 'Poor design of the hospital structure', 'Long working hours', 'Overcrowding of patients', 'Poor coordination between hospital departments, 'Punitive and blaming environment, 'Lack of clinical practice standards' and, 'Poor financial incentives. Authors suggest there's an urgent need to plan corrective actions to improve patient safety issues.
Categorization based on the MMS framework (Vincent et al., 2014)	Sensitivity to operations

Paper number (PDF no.)	6 (28)
Title	Nurses burnout, resilience and its association with safety culture: a cross sectional study
Author (s), year of publication	Mohammed A. Majrabi, Abd Alhadi Hasan and Nofaa Alasmee (2021)
Study location	Jazan hospital
Aim of the study	The purpose of this study was to assess burnout, resilience and the association with safety culture in nurses working in mental health institutions in Jazan government Hospital.
Methods	A cross-sectional survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	119 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	The Safety Attitude Questionnaire was used to measure employee attitudes towards safety culture
key reported outcomes	The results of this study showed that 45.6% of the participants experienced a high level of emotional exhaustion, 36.5% reported a high level of depersonalisation and 15.9% reported high personal achievement. Authors believe that high level of burnout and its dimensions have a negative effect on patient safety and resilience. It is particularly important to assess burnout among mental health nurses, resilience and its association with safety culture. Authors suggest that the paper provides policymakers with evidence as how best to reduce burnout among nurses delivering mental health care in Saudi Arabia.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (include safety culture assessment using SAQ)

Paper number (PDF no.)	7 (30)
Title	Conceptualization of a Patient Safety Management Model as Practical Approach toward Benchmarking and Improving Healthcare Outcomes
Author (s), year of publication	Bahjat Al-Awa1, Isabelle Devreux, Agnes Jacquerye, Abeer Alhazmi1, Hussam AlBaz1, Hamed Habib and Osama Rayes (2012)
Study location	King Abdulaziz University Hospital (KAUH)
Aim of the study	To study the effectiveness of a patient safety model on patient safety indicators when implemented in a university hospital.
Methods	A task force constituted by various patient safety experts was established to design a practical concept of patient safety management based on a nine steps model and applied by all hospital departments. Patient safety indicators (780) were monitored over a four years period and the model's effectiveness was analyzed on 40 selected indicators.
Study populations (e.g. healthcare workers group, type of patients group, total number	-

of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	patient safety management model
Comparator (if any)	-
Outcome measures	Patient Safety Practices (PSP) and Patient Safety Indicators (PSI)
key reported outcomes	The implementation of a patient safety management model provided in the paper was found to be effective in improving patient safety practices (PSP) as well as patient safety indicators (PSIs) and finally patient outcomes.
Categorization based on the MMS framework (Vincent et al., 2014)	(An intervention study) Authors designed a patient safety model and used quantitative analysis to evaluate the model effectiveness on patient safety indicators after implementation in a university hospital.

Paper number (PDF no.)	8 (32)
Title	Assessment of patient safety culture in tertiary health care settings in Taif City, Saudi Arabia
Author (s), year of publication	Dalia El-Sayed Desouky, Atheer Alraqi, Rabeah Alsofyani, Najla Alghamdi (2019)
Study location	Al-Hada general hospital in Taif city, Saudi Arabia
Aim of the study	The purpose of this study is to evaluate the culture of patient safety in Saudi hospitals and to improve patient safety and quality of care through implementation of safety systems and creating a culture of safety.
Methods	cross-sectional study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	300 health professionals including nurses, technicians, managers and medical staff.
Intervention (type and duration of intervention if applicable)	
Comparator (if any)	-
Outcome measures	PSC using the HSPSC
key reported outcomes	Most of the participants had positive responses about communication, feedback about errors, and the procedure and system at preventing errors, however they reported that there are still many patient safety problems in hospital units. The staffing level in hospital units was not enough but there was good cooperation between hospital units, and they reported that the supervisor/manager has an important role in improving patient safety. Authors stated there's a need for increasing attention to patient safety and efforts to improve the performance and quality of service.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	9 (33)
Title	Patient safety culture of nurses in public and private hospitals in northwestern Saudi Arabia
Author (s), year of publication	Mohammed Hamdan Alshammari (2019)
Study location	Four government hospitals and three private hospitals.
Aim of the study	The study aimed to a) demographic profile of the participants as to gender, nationality, position, area of assignment, provision of direct care, educational attainment, total years in the hospital and in the unit of current assignment, number of work hours in a week, total years of experience and the classification of the hospital the participants are currently employed; b) what are the perceived patient safety culture of the participants when grouped according to the hospital classification either as private or government hospital.
Methods	cross-sectional study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	441 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	
Outcome measures	PSC using HSPSC
key reported outcomes	there was no significant difference between the responses of the participants from public and private hospitals except for two composites which are the 9th composite (Teamwork Across Units)

	and 11th composite (Handoff and Transitions) having a p value of 0.899 and 0.989, respectively. The author suggest it is clear that there are differences in some aspects of hospital guidelines between private and public hospitals. The difference in management and operational strategies between these two different institutions affects how their processes flow, thus affecting patient care provisions and safety as well. Although, private and public hospitals in Saudi Arabia follow the same guidelines on patient safety culture. The author found that nurses are aware of patient safety standards regardless of the classification of their hospital.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	10 (36)
Title	Missing chances to learn: a case study of barriers to near-miss reporting in a hospital
Author (s), year of publication	Safa ElKhider and Barbara M. Savage (2019)
Study location	
Aim of the study	the purpose of this paper is to identify the barriers of near miss (NM) reporting among healthcare workers in a governmental hospital in Saudi Arabia.
Methods	Exploratory case study using a mixed methods design, composed of a survey, followed by a set of semi-structured interviews
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	nurses (n = 129), technicians (n = 16) and doctors (n = 14) total= 159 responses to the survey. Three interviews were conducted as well to provide a more in-depth understanding of some responses.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The paper shows that the main barrier to reporting NMs in the hospital is a fear of professional and departmental consequences. Differences between employee groups are evident in their perceptions, special attention should be given to that when developing a programme to improve reporting. These findings show that a focus on NMs in particular is lacking in Saudi Arabia, despite the valuable learning opportunities they may hold. Authors suggest that better understanding of these factors is likely to help hospital leaders in addressing the barriers identified, so that the potential of NM reports can be maximized to improve hospital systems.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	11(38)
Title	Personal Preference and Perceived Barriers toward Disclosure and Report of Incident Errors among Healthcare Personnel
Author (s), year of publication	Shereen Ragab Dorgham and Lobna Khamis Mohamed (2012)
Study location	The study was conducted at two hospitals' namely; King Fahd Hospital of the University (KFHU) in Saudi Arabia and El-Behara Hospitals in Egypt in Intensive Care Units (ICUs) and surgical department.
Aim of the study	To assess the personal preference and perceived barriers toward disclosure and report of incident errors among healthcare personnel
Methods	A descriptive cross-sectional design
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	155 health care professionals (physicians and registered nurses).
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The paper demonstrated underreporting of adverse events by both nurses and physicians due to administrative barrier which considered as a major barrier. Majority of total sample preferred to disclose errors with near miss, followed those who don't prefer to disclose any errors then those preferred to disclose errors with minor harm. Furthermore, the majorities of participants did not prefer to disclose errors for patients or their families and did not prefer to report errors for colleges,

	head nurses or chief executive officer. Based on the results of the study, authors suggest that there's a need to improve healthcare professionals' education, training, and practice "about disclosure". Furthermore, health care organisations should establish non-punitive policies of error reporting and implement full disclosure policies.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	12 (39)
Title	Culture of Safety among Nurses in a Tertiary Teaching Hospital in Saudi Arabia
Author (s), year of publication	Hisham Aljadhey, Basmah Al-Babtain, Mansour Adam Mahmoud, Sinna Alaqeel and Yusuf Ahmed (2016)
Study location	King Khaled University Hospital in Riyadh, Saudi Arabia.
Aim of the study	To assess the culture of safety among nurses in a tertiary teaching hospital in Saudi Arabia.
Methods	A cross-sectional survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	492 nurses, only 418 complete ones were returned
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Culture of Safety using SAQ
key reported outcomes	Job satisfaction was perceived as the most common dimension of culture of safety among nurse participants, followed by working conditions, and safety, and teamwork. Stress recognition, and perception of management ranked as the least common dimensions of safety culture among study subjects. A significant difference in mean score was found between males and females for both working conditions and teamwork. Significant differences were also observed in terms of job satisfaction dimension scores in terms of years of work experience. A significant difference was also observed in terms of stress recognition dimension scores and years of work experience. The authors recommend that efforts are needed from healthcare authorities to increase nurses' perception of management and stress recognition in order to improve safety culture among nurses in Saudi Arabia.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	13 (40)
Title	Assessment of patient safety culture: a comparative case study between physicians and nurses
Author (s), year of publication	Ahmed Mohamed Elsheikh, Mohammed Abdullah AlShareef, Bassem Salah Saleh and Muhammad Abdullah Yassin El-Tawansi (2017)
Study location	Security Forces Hospital, Makkah, Saudi Arabia
Aim of the study	This study compares responses of physicians and nurses to patient safety culture assessment
Methods	Cross sectional survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	623 (336 nurses, 174 physicians, 9 pharmacists, and 104 technicians).
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	
Outcome measures	PSC using HSPSC
key reported outcomes	Composite-level results show values below minimum positive in "Staffing" and "Non-Punitive response to error" to have decreased values in nursing answers than physician ones. The average

	percentage positive concerning “staffing” items is below the average percentage positive of database hospitals; in nursing, it decreases more; it shows a low positive response regarding enough staff, work hours, and crisis mode; the last item shows a more negative response. The average percentage positive concerning “No punitive Response to Error” is below average positive of database hospitals; in nursing, it decreases more, with a low positive response concerning feeling responsible for mistakes. The authors stated that the results of the patient safety culture assessment in August 2015 can be concluded as follows: 80% of clinical staff feels that their mistakes are held against them, 83% feel like the person is written up, and 92% feel that mistakes are kept in their personnel file.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	14 (43)
Title	Impact of night shift rotations on nursing performance and patient safety: A cross-sectional study
Author (s), year of publication	Abdalkarem F. Alsharari, Fuad H. Abuadas, Mohammed N. Hakami, Adel A. Darraj, Magbool W. Hakami (2021)
Study location	public hospitals in multiple regions of Saudi Arabia
Aim of the study	aims to explore the impact of night shiftwork rotations on nurses' physiological status, work performance and patient safety concerns among nurses in public hospitals.
Methods	A descriptive predictive correlational design using a self-administered questionnaire
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	1,256 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Results of this paper showed that a large proportion of nurses on night shiftwork faced patient safety issues (85.7%) and physiological consequences (93.6%). Authors recommended counselling sessions and programmes to support at-risk nurses.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (the ability to be prepared for problems and threats to safety)

Paper number (PDF no.)	15 (46)
Title	Do Health Care Providers Pay Attention to Sharing Hospital Patient Safety Incidents Through Social Media in Saudi Arabia?
Author (s), year of publication	Turki Alanzi and Alhanouf Alfuraikh (2020)
Study location	Target population included all health care providers who showed interest in health care quality in Saudi Arabia.
Aim of the study	The aim of this study was to find out if health care providers in Saudi Arabia used social media to share the safety incidents that occurred in hospitals.
Methods	A survey study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	we distributed a survey to 450 health care providers in Saudi Arabia. The response rate was 33.55%, and (151 respondents) answered the questionnaire survey. The health care providers that responded to the survey were medical doctors (MD) and resident nurses (RN)
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	this research showed that most health care providers in Saudi Arabia considered that safety incidents that occur in hos- pitals should not be shared through social media because they affect the policies and privacy of hospitals, patients, and personnel. However, most of the respondents believed that social media could contribute to improving the quality of patient attention and thought that WhatsApp and Twitter could be the most useful social media for these purposes.
Categorization based on the MMS framework (Vincent et	Integration and learning (means/channels to share information about patient safety)

al., 2014)	

Paper number (PDF no.)	16 (47)
Title	The association between self-reported workload and perceptions of patient safety culture: A study of intensive care unit nurses (2021)
Author (s), year of publication	Yaseen Mohammed A. Alrabae, Ahmad E. Aboshaiqah, Regie B. Tumala
Study location	two hospitals in Riyadh, Saudi Arabia.
Aim of the study	This study aimed to examine the association between workload and patient safety culture (PSC) among intensive care unit (ICU) nurses.
Methods	Descriptive correlational design.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	380 ICU nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Includes a PSC assessment using HSPSC
key reported outcomes	The results showed that ICU nurses have high positive perceptions in the following PSC subscales: teamwork within units, organisational learning–continuous improvement, frequency of events reported, feedback and communication about error, management support for patient safety, teamwork across units, supervisor/manager expectations and actions promoting patient safety, handoffs and transitions, non-punitive response to errors, staffing and overall perceptions of patient safety. However, the participants collectively considered the overall grade on patient safety as (poor). The participants had high mean scores in physical demand, effort, mental demand and overall workload. A statistically significant variability existed in the mean scores of the PSC subscales and workload of ICU nurses. The overall workload was significantly and negatively associated with the PSC perceptions of ICU nurses. Authors found that ICU nurses experienced high overall workload, physical demand, effort and mental demand and that influenced the poor grade of their overall perceived PSC.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipant and preparedness (includes a safety culture assessment and whether workload has an effect)

Paper number (PDF no.)	17 (49)
Title	Top four types of sentinel events in Saudi Arabia during the period 2016–19
Author (s), year of publication	Nasser Altalhi, Haifa Alnaimi, Mafaten Chaouali, Falaa Alahmari, Noor Alabdulkareem, And Tareef Alaama (2021)
Study location	Ministry of Health (MOH) and private hospitals, Saudi Arabia
Aim of the study	The purpose of this study was to review the most common SEs reported by the MOH and private hospitals between the years 2016 and 2019 to assess the patterns and identify risk areas and the common root causes of these events in order to promote country-wide learning and support services that can improve patient safety.
Methods	retrospective descriptive study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Public and private hospitals in SA.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	727 sentinel events (SEs)reported, 38.4% unexpected patient death, 19.4% maternal death, 11.7% unexpected loss of limb or function and 9.9% retained instruments or sponge. Common root causes were related to policies and procedures, guidelines, miscommunication between health-care facilities, shortage of staff and lack of competencies. Based on these results, the authors suggest that efforts should focus on improving the care of deteriorating patients in general wards, ICU

	(Intensive Care Units) admission/discharge criteria and maternal, child and surgical safety. The results also highlighted the problem of underreporting of SEs, which needs to be addressed and improved. The authors also recommended linking data sources such as claims and patient complaints databases and electronic medical records to the national reporting system must also be considered to ensure an optimal estimation of the number of events.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	18 (50)
Title	Assessment of patient safety challenges and electronic occurrence variance reporting (e-OVR) barriers facing physicians and nurses in the emergency department: a cross sectional study
Author (s), year of publication	Ahmed I. Albarrak, Ammar S. Almansour, Ali A. Alzahrani, Abdulaziz H. Almalki, Abdulrahman A. Alshehri and Rafiuddin Mohammed (2020)
Study location	King Khalid University Hospital (KKUH) in Riyadh, Saudi Arabia
Aim of the study	the study aimed to determine the challenges faced by clinicians in maintaining patient safety in emergency departments, in addition to assessing the barriers experienced by health professionals in using e-OVR in Saudi Arabia.
Methods	cross-sectional study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	197 (48 physicians and 149 nurses) in the emergency department (ED) at King Khalid University Hospital (KKUH).
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Findings of the study revealed the following statistics: Only (39%) of participants thought that there was enough staff to handle work in the ED. Roughly half (48%) of participants spoke up when something negatively affected patient safety, and (61%) admitted that they sometimes missed important patient care information during shift changes. Two-thirds (66%) of the participants reported experiencing violence. Regarding e-OVR, (31%) of participants found reporting to be time consuming. Most (85%) participants agreed that e-OVR training regarding knowledge and skills was sufficient. Physicians reported lower knowledge levels regarding how to access (46%) and how to use (44%) e-OVR compared to nurses (98 and 95%, respectively). Less than a quarter of the staff did not receive timely feedback after reporting. Regarding overall satisfaction with e-OVR, only (25%) of physicians were generally satisfied compared to nearly half (52%) of nurses. Although patient safety is well emphasized in clinical practice, especially in the ED, many factors hinder patient safety. Authors believe more awareness is needed to eliminate violence and to emphasize the needs of additional staff in the ED. Electronic reporting and documentation of incidents should be well supported by continuous staff training, help, and feedback.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	19 (51)
Title	Patients' knowledge, awareness, and attitude regarding patient safety at a teaching hospital, Riyadh, Saudi Arabia
Author (s), year of publication	Abdullah A. Alnasser, Ibraheem A. Aldeeri, Waleed M. Aljamal, Khalid A. Sharahili, Yousef A. Alturki (2020)
Study location	King Khalid University Hospital, Riyadh, Saudi Arabia.
Aim of the study	The primary objective was to investigate the baseline status of patients' awareness, knowledge, and attitudes to patient safety. The secondary objective was to determine factors that influence patients' knowledge regarding patient safety
Methods	cross-sectional study
Study populations (e.g. healthcare workers group, type of patients group, total number	410 patients at King Khalid University Hospital, Riyadh, Saudi Arabia

of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Findings of the study revealed the following key statistics: Among the respondents who are taking drugs, (21.6%) do not have any knowledge about the side effects of their drugs, and (47.8%) of patients said that their physicians do not tell them the side effects of their prescribed drugs. Whereas (20.7%) of patients claimed that they experienced a medical error, and (66.3%) did not report the errors. The reason was not knowing how to report or to whom in (54.4%) of the patients. In regards of infection control, (47%) of the participants misunderstood means to prevent the spread of the infections and how it could be transmitted. The authors suggest that patients' knowledge about patient safety need to be improved. They recommend educating the patients by providing training programs and also recommended further studies to be conducted.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm AND Sensitivity to operations

Paper number (PDF no.)	20 (52)
Title	Policies vs Practice of Medical Error Disclosure at Teaching Hospital in Saudi Arabia
Author (s), year of publication	Reem Al Madani, Saja A Al-Rayes, Arwa Alumran (2020)
Study location	several departments at King Fahad Hospital of the University
Aim of the study	The objective of this study was to examine factors impacting the awareness of hospital policies and programs and their impact on the actual disclosure of medical errors.
Methods	cross-sectional study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	206 physicians
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Findings from this study showed that the majority of participants were not aware of policies and programs related to disclosure, nor they had disclosed a medical error to patients. Position level and gender were statistically significant in relation to awareness. Physicians demonstrated a low awareness rate of the hospital policies and programs regarding disclosure practice. The authors suggest that efforts of hospital leaders need to be made to communicate, train and educate providers about their policies to promote disclosure practice.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	21 (54)
Title	Staying ahead of the curve: Navigating changes and maintaining gains in patient safety culture - a mixed- methods study
Author (s), year of publication	Maher Abdelraheim Titi, Maram Mohammed Baksh, Beena Zubairi, Rawia Ahmad Mustafa Abdalla, Faisal Abdullah Alsaif, Yasser S Amer Diana Jamal, Fadi El-Jardali (2021)
Study location	a tertiary care teaching multisite hospital in Riyadh, Saudi Arabia.

Aim of the study	This study examines how the results of the Hospital Survey on Patient Safety Culture changed between 2012 and 2019 and identifies organisational factors affecting these changes.
Methods	Mixed method, quantitative surveys of staff and qualitative interviews with hospital leadership.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	One thousand hospital staff participated in the survey. Thirty-one executive board members and directors and four focus groups of front-liners were qualitatively interviewed.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	In this study, comparing the results revealed a general positive trend in scores from 2012 to 2019. The areas of strength included teamwork within and across units, organisational learning, managerial support, overall perception of safety and feedback and communication about error. Non- punitive response to error, staffing and communication and openness consistently remain the lowest-scoring composites. Interview results showed that organisational changes may have influenced participants responses to some survey composites. The authors suggest that effective quality improvement initiatives can lead to visible changes in the patient safety culture in a hospital, and consistent leadership commitment and support can maintain these improvements.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	22 (55)
Title	Examining the Influence of Workplace Incivility on Nurses' Patient Safety Competence
Author (s), year of publication	Nahed Alquwez (2020)
Study location	two acute healthcare facilities in Saudi Arabia
Aim of the study	This study assessed clinical nurses' workplace incivility experiences and determined the effects of workplace incivility experiences on nurses' patient safety competence.
Methods	quantitative survey study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	261 clinical nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Findings of the study revealed the following key scores: The highest mean score was recorded for patient or visitor incivility, whereas the lowest score was recorded for supervisor incivility. Regarding patient safety competence, the dimension "communicating effectively" received the highest mean score, whereas "working in teams with other health professionals" was rated the lowest. General and nurse incivilities had multivariate effects on the six dimensions of patient safety competence. The author believes that nurses' experiences of uncivil acts from nurses and from general incivility negatively impact nurses' patient safety competence.
Categorization based on the MMS framework (Vincent et al., 2014)	Sensitivity to operations

Paper number (PDF no.)	23 (57)
Title	Clinical practitioners' perception of the dimensions of patient safety culture in a government hospital: A one-sample correlational survey
Author (s), year of publication	Atallah Alenezi, Ramon Perley M. Pandaan, Joseph U. Almazan,| Isabelita N. Pandaan, Franklyn S. Casison, Jonas Preposi Cruz (2019)
Study location	A general hospital in the central region of Saudi Arabia.
Aim of the study	To assess the perceptions of clinical practitioners regarding the different dimensions of patient safety culture in their hospital and examine the work- related predictors of patient safety culture

	perceptions.
Methods	Survey study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	181 healthcare practitioners
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	Findings of the PSC assessment showed that nine of the 12 dimensions measured were identified as patient safety culture weaknesses, including 'management support for patient safety' (49.2%), 'team- work across unit' (44.2%), 'frequency of events reporting' (43.1%), 'communication openness' (41.3%), 'overall perception of patient safety' (38.7%), 'supervisor/manager expectations and actions promoting patient safety' (32.9%), 'staffing' (23.7%), 'hospital handoffs and transitions' (19.6%) and 'non-punitive response to errors' (15.8%). None of the dimensions were identified as strengths by the respondents. The results of this study highlight there's urgent need to promote PSC of the hospital. Authors found that working hours per week and staff position were identified as significant predictors.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	24 (59)
Title	Fostering a healthcare sector quality and safety culture
Author (s), year of publication	Ricardo Santa, Silvio Borrero, Mario Ferrer, Daniela Gherissi (2018)
Study location	various hospitals and managerial positions at a national level in SA
Aim of the study	to identify the most important quality and safety culture drivers, and thus propose appropriate operational actions for Saudi Arabian hospital managers and for managers in healthcare institutions worldwide.
Methods	Quantitative data from questionnaires were analysed using structural equation modeling.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	417 respondents affiliated with Saudi Arabia hospitals
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The results of this study suggest that providing feedback about error (FAE) and ensuring effective communication are QSC's main drivers. The authors found that a non-punitive response to error (NPRE) must be better addressed in the healthcare sector to achieve a quality and safety culture (QSC).
Categorization based on the MMS framework (Vincent et al., 2014)	Integration and learning (focus on communication and feedback about error and avoiding punitive Reponses)

Paper number (PDF no.)	25 (60)
Title	Attitudes of doctors and nurses toward patient safety within emergency departments of two Saudi Arabian hospitals
Author (s), year of publication	Naif Alzahrani1, Russell Jones, and Mohamed E. Abdel-Latif (2018)

Study location	
Aim of the study	This study aimed to investigate doctors' and nurses' attitudes toward patient safety in the emergency departments (ED) of two Saudi hospitals.
Methods	cross-sectional survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	503 ED doctors and nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Attitude towards patient safety using SAQ
key reported outcomes	The mean score of each SAQ dimension was < 75%, indicating that nurses and doctors generally had less than a positive safety attitude. This was especially prominent with dimensions of stress recognition (58.1%) and perceptions of hospital management (56.9%). Furthermore, nurses reported significantly lower on the teamwork climate dimension than doctors, whereas doctors reported significantly lower on the hospital work conditions dimension than nurses. There was a significant negative correlation between the number of errors reported and teamwork climate, job satisfaction, and work conditions. The authors concluded that safety attitudes of doctors and nurses employed in EDs of Saudi hospitals are "less than positive and correlate with the number of reported errors" The authors recommend safety training interventions and management support as the most likely avenues to improve the safety attitudes and performance within Saudi ED's.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (Attitude towards safety assessment using SAQ)

Paper number (PDF no.)	26 (61)
Title	Nurses' Perceptions of Patient Safety Culture in Three Hospitals in Saudi Arabia
Author (s), year of publication	Nahed Alquwez, Jonas Preposi Cruz, Ahmed Mohammed Almoghairi, Raid Salman Al-otaibi, Khalid Obaid Almutairi, Jerico G. Alicante & Paolo C. Colet (2018)
Study location	Three general hospitals in the central region of Saudi Arabia
Aim of the study	To assess the present patient safety culture of three general hospitals in Saudi Arabia, as perceived by nurses.
Methods	descriptive, cross-sectional design using a self-reported questionnaire. The survey tool used was Hospital Survey of Patients' Safety Culture (HSOPSC) from October 2016 to April 2017
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	351 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	Findings of this PSC assessment showed that several aspects of patient safety culture should be improved, especially those related to the establishment of a nonpunitive culture. The authors suggest that a multidimensional network intervention targeting the different dimensions of patient safety culture and involving different organizational levels should be implemented to improve patient safety.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	27 (63)
Title	Prevalence and preventability of sentinel events in Saudi Arabia: analysis of reports from 2012 to 2015
Author (s), year of publication	Salem Al Wahabi, Fayssal Farahat and Ahmed Y. Bahloul (2017)

Study location	
Aim of the study	This study aimed to assess the pattern of sentinel events reported to Ministry of Health of Saudi Arabia from January 2012 to June 2015.
Methods	retrospective review
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	retrospective review of all events reported to the MOH from January 2012 to June 2015
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	There were 433 sentinel events (SEs): 58.2% were deaths, 14.8% were unexpected loss of a limb or a function, 7.4% major medication errors and 7.4% retained instruments or sponges. Among the reported events, 44% were associated with surgical interventions and most were classified as preventable (91.6%). Age 19-64 years was significantly associated with death as an outcome. Non-preventable sentinel events were significantly more likely among women than men. *Unavailability of policy and procedures and/ or failure to implement them (55%), and lack of proper communication (35%) and training (33%) were the main causes for the adverse events. The authors recommended that efforts should focus on enhancing the National Sentinel Events Reporting System, adopting criteria for effective reporting and ensuring availability and implementation of policies and procedures.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	28 (64)
Title	Improving patient safety culture in Saudi Arabia (2012–2015): trending, improvement and benchmarking
Author (s), year of publication	Khalid Alswat, Rawia Ahmad Mustafa Abdalla, Maher Abdelraheim Titi, Maram Bakash1, Faiza Mehmood, Beena Zubairi1, Diana Jamal and Fadi El-Jardali (2017)
Study location	The Medical City is a tertiary care teaching hospital with a capacity of 800 beds in Riyadh, Saudi Arabia.
Aim of the study	We aim to re-assess PSC in a large multi-site healthcare facility in Riyadh, Kingdom of Saudi Arabia
Methods	Survey study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Total of 2592 Administrator/Manager/Director 47 (1.9%) Physician 141 (5.6%) Specialist 61 (2.4%) Coordinator 10 (0.4%) Assistant/Aide 39 (1.6%) Pharmacist 36 (1.4%) Therapist 1 (0%) Registered Nurse 1969 (78.3%) Resident/PG/Intern 64 (2.5%) Assistant/Clerk/Secretary/Facilitator 28 (1.1%) Technician 52 (2.1%) Other, please specify: 67 (2.7%)
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	Assessment and monitoring trends of PSC shoed that areas of strength in 2015 included teamwork within units, and organizational learning—continuous improvement; areas requiring improvement included non-punitive response to error, and staffing. Comparing results to the 2012 survey revealed improvement on some areas but non-punitive response to error and Staffing remained the lowest scoring composites in 2015. Regression highlighted significant association between managerial support, organizational learning and feedback and improved survey outcomes.

	Comparison to international benchmarks revealed that the hospital is performing at or better than benchmark on several composites. Authors concluded that the Medical City has made significant progress on several of the patient safety culture composites despite still having areas requiring additional improvement, and patient safety culture outcomes are evidently linked to better performance on specific composites.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	29 (67)
Title	Mental health nurses' perceptions of patient safety culture in psychiatric settings
Author (s), year of publication	S.H. Hamaideh (2017)
Study location	Three Saudi Arabian psychiatric hospitals
Aim of the study	The aims of this study were to assess the perception of mental health nurses about patients' safety culture and to detect the factors which may affect patients' safety culture at psychiatric hospitals.
Methods	Survey study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	224 mental health nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	This PSC assessment showed the following scores: positive scores to patients' safety culture dimensions ranged between 13.4% and 81.2%. Two-thirds of mental health nurses perceived safety as excellent/very good, 20.5% perceived it as acceptable and 10.8% perceived it as poor/failing. Overall perception of safety correlated significantly with four dimensions and explained 32.6% of the variance. Frequency of events reported correlated significantly with six dimensions and explained 23.1% of the variance. Of the 12 dimensions of patients' safety culture, only one was strong, six within acceptable range and five were weak and need improvement. The authors recommend that healthcare managers and policymakers should encourage educational interventions and help to establish a reporting system that focus on improving systems, not on blaming individuals and encourage open communication among mental healthcare workers.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	30 (68)
Title	Assessment of patient safety measures in governmental hospitals in Al- Baha, Saudi Arabia
Author (s), year of publication	Mohamed Awadelkarim Mohamed Ibrahim, Osman Babiker Osman and Waled Amen Mohammed Ahmed (2019)
Study location	two governmental referral hospitals in Al-Baha region (Aqiq General Hospital and Prince Mashari Hospital)
Aim of the study	This study aimed to assess the application patient safety measures at governmental hospitals in Al-Baha region
Methods	descriptive cross-sectional study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if	115 healthcare providers (doctors and nurses)

applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The study showed that most of participants have previous training on patient safety and about (81.7%) of them had heard about global aims of patient safety. The level of application of patient safety at Al-Baha governmental hospitals was 106 (92.2%). The findings showed that there are no significant influencing factors on application of patient safety. the authors believe that the application of patient safety in Al-Baha governmental hospitals is very high, and there are no significant influencing factors for the application of patient safety measures in Al-Baha governmental hospitals.
Categorization based on the MMS framework (Vincent et al., 2014)	Reliability of safety critical processes

Paper number (PDF no.)	31 (69)
Title	Assessing Building Blocks for Patient Safety Culture - —a Quantitative Assessment of Saudi Arabia
Author (s), year of publication	Zeid Alrowely, Omar Ghazi Baker (2019)
Study location	Six different public hospitals from Arar city, Saudi Arabia (Arar Central Hospital, Arar Maternity and Children Hospital, Prince Abdul-Aziz Bin Musaad Hospital, and AlAmal Complex for Mental Health; Rafah Central Hospital in Rafah City, and Turaif General Hospital in Turaif City)
Aim of the study	The study analyses staffs' perception of a safety culture and their knowledge of safety measures in the hospitals of Saudi Arabia.
Methods	cross-sectional study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	503 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	This PSC assessment showed the following scores: The highest positive rating (81%) was received by both "people support one another in this unit" and "in this unit, people treat each other with respect." Supervisor/ manager expectations and actions promoting patient safety was rated neutrally (n = 283; 56%) which suggested a neutral response by participants. Organizational learning, along with continuous improvement, was positively rated (n = 406; 81%) with an average mean score of 3.93±0.61. The authors assessment of PSC in this paper suggest that participant nurses neither disagree nor agree on the level of patient safety culture in their hospital setting.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	32 (70)
Title	Attitudes of Doctors and Nurses toward Patient Safety within Emergency Departments of a Saudi Arabian Hospital: A Qualitative Study
Author (s), year of publication	Naif Alzahrani, Russell Jones and Mohamed E. Abdel-Latif (2019)
Study location	the emergency department of a Ministry of Health (MOH) hospital in Riyadh, Kingdom of Saudi Arabia
Aim of the study	aims to investigate and compare the patient safety attitudes of doctors and nurses in a Saudi hospital emergency department
Methods	qualitative research design via semi-structured interviews
Study populations (e.g.	5 Saudi doctors, 5 non-Saudi doctors, 3 Saudi nurses, and 7 non-Saudi nurses.

healthcare workers group, type of patients group, total number of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Findings of this study discovered that doctors and nurses held some similar safety attitudes; however, nurses reported issues with doctors with respect to their teamwork, communication, and patient safety attitudes. Moreover, authors identified several barriers to the patient safety climate, including limits to resources, teamwork, communication, and incident reporting. The findings provide one of the few research contributions to knowledge regarding the patient safety attitudes of Saudi and non-Saudi doctors and nurses and suggest the application of such knowledge would enhance positive patient outcomes in emergency departments.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (assessment of attitude towards safety)

Paper number (PDF no.)	33 (71)
Title	Patient safety culture as a quality indicator for a safe health system: Experience from Almadinah Almunawwarah, KSA
Author (s), year of publication	Mohamed S. Mahrous (2018)
Study location	King Fahad Hospital in Almadinah Almunawwarah, KSA
Aim of the study	This study aimed to evaluate the extent to which the culture supports patient safety at a hospital in KSA.
Methods	cross-section analytical observational study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	240 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	PSC assessment conducted in this papers showed that the greatest positive scores were obtained for teamwork within units, safety culture composites, feedback, communication about error, management expectations, actions promoting patient safety, organisational learning, and continuous improvement. However, none of these features achieved a positive score of 75% or more as an area of strength. The rest of the aspects were negatively ranked as areas for improvement, with the lowest scores obtained for non-punitive reaction to error, staffing, hospital handoff and transition, communication openness, and hospital management support for patient safety. Commitment to quality care as an outcome is certainly correlated with patient safety. There is a strong need to improve and promote applicable policies to improve the culture of patient safety in hospitals. The authors suggest the development of strong management competence to promote an environment of open consultation and administrative wisdom will contribute to improving patient safety culture.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	34 (74)
Title	Assessment of Patient Safety Culture in an Adult Oncology Department in Saudi Arabia
Author (s), year of publication	Waleed Alharbi, Jennifer Cleland and Zoe Morrison (2018)
Study location	The study setting was in the adult oncology department at a medical facility in Saudi Arabia

Aim of the study	to evaluate patient safety culture across different healthcare professionals from different countries of origin working in an adult oncology department in a medical facility in Saudi Arabia
Methods	cross-sectional survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	127 Medical doctors 21 (16.2%) Pharmacists 18 (13.8%) Nurses 88 (67.7%)
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	This PSC assessment found that 8 out of the 12 HSOPSC composites were considered areas for improvement (percent positivity < 50.0%). Significantly different mean scores were observed across the three professional groups in all 12 HSOPSC composites. doctors tended to rate patient safety culture significantly more positively than nurses or pharmacists. nurses scored significantly lower than pharmacists in the majority of HSOPSC composites. no significant differences in patient safety culture composite scores were observed between Saudi/Gulf Cooperation Council (GCC) and non- Saudi/GCC groups. Regression analysis showed that the frequency of reported events is predicted by feedback and communication about errors, and teamwork across units. Perception of patient safety is associated with respondents' profession and teamwork across units. This study brings to the fore the assumption that all healthcare professionals have a shared understanding of patient safety. Authors urged healthcare leaders and policy makers to look at patient safety culture at this granular level in their contexts and use this information to develop strategies and training to improve patient safety culture.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	35 (76)
Title	Learning from defects using a comprehensive management system for incident reports in critical care
Author (s), year of publication	Y. M. Arabi, S. M. Al Owais, K. Al-Attas, A. Alamry, K. Alzahrani, B. Baig, D. White, A. M. Deeb, H. D. Al-Dorzi, S. Haddad, H. M. Tamim, S. Taher (2016)
Study location	the Intensive Care Department in King Abdulaziz Medical City, Riyadh, Saudi Arabia
Aim of the study	To describe the experience of implementing a Comprehensive Management System (CMS) for incident reports in the ICU
Methods	
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	A total of 1719 incidents were studied
Intervention (type and duration of intervention if applicable)	Quality improvement project (CMS)
Comparator (if any)	A comparison of pre- and post-intervention (comprehensive management system)
Outcome measures	Authors compared the pre- and post-intervention periods for the impact on the number of incident reports, level of harm, time needed to close reports and reporting individuals
key reported outcomes	A physician-led multidisciplinary Incident Report Committee was created to review, analyse and manage the department incident reports. New protocols, policies and procedures, and other patient safety interventions were developed as a result. ICU- related incident reports increased from 20 to 36 incidents per 1000 patient days. After implementing the CMS, there was an increase in reporting 'no harm' from 14.2 to 28.1 incidents per 1000 patient days. There was a significant decrease in the time needed to close incident report after implementing the CMS (median of 70 days versus 13 days). A physician-led multidisciplinary CMS resulted in significant improvement

	in the output of the incident reporting system. This may be important to enhance the effectiveness of incident reporting systems in highlighting system defects, increasing learning opportunities and improving patient safety.
Categorization based on the MMS framework (Vincent et al., 2014)	(intervention study) assessing the impact of a Comprehensive Management System on rates of incident reports, level of harm, time needed to complete reports and reporting individuals

Paper number (PDF no.)	36 (77)
Title	Physicians' knowledge and practice towards medical error reporting: a cross-sectional hospital-based study in Saudi Arabia
Author (s), year of publication	E. Alsafi, S. Baharoon, A. Ahmed, H.H. Al-Jahdali, S. Al Zahrani and A. Al Sayyari (2014)
Study location	a tertiary care Ministry of Health hospital in Riyadh, the capital city of Saudi Arabia. Al-Iman General Hospital.
Aim of the study	
Methods	cross-sectional survey study, The questionnaire used in this study was developed and previously validated by the study group
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	107 physicians.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Findings showed that physicians tended not to report medical errors when no harm had occurred to patients. One-third of respondents feared punitive actions if they reported errors and only 56.4% felt that error reporting had led to positive changes in overall care. A majority of errors were related to late interventions and misdiagnosis. Authors also found that under-reporting of medical errors is common in the hospital. Moreover, physicians did not appreciate attempts to improve the system of error reporting and a blaming culture still prevailed.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	37 (78)
Title	Improvement Critical Care Patient Safety: Using Nursing Staff Development Strategies, At Saudi Arabia
Author (s), year of publication	Enas M. Bassuni & Magda M. Bayoumi (2015)
Study location	the intensive care units at General Mohail Hospital and National Mohail Hospital, King Khalid University, Saudi Arabia.
Aim of the study	This study aimed at using staff development strategies through implementing patient safety educational program that may minimize the medical errors and improve patient outcome in hospital.
Methods	quasi experimental design
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	50 nurses were engaged in the program
Intervention (type and duration	patient safety educational program

of intervention if applicable)	
Comparator (if any)	-
Outcome measures	-
key reported outcomes	This study found that improvements were observed in safety climate, teamwork climate, and nurse turnover rates on ICUs, nurses' total knowledge and attitude towards patent safety after implementing a safety program. Authors believe continuous educational program for ICUs nursing staff through organized in-service training is needed to increase their knowledge and skills about the importance of improving patient safety measure. They also believed that emphasis on effective collaborative system will also improve patient safety measures in ICUS.
Categorization based on the MMS framework (Vincent et al., 2014)	(intervention study) patient safety educational program

Paper number (PDF no.)	38 (79)
Title	Saudi Arabian ICU safety culture and nurses' attitudes
Author (s), year of publication	Abdulrahman S. Alayed, Helena Lööf, Unn-Britt Johansson (2014)
Study location	Six Saudi Arabian urban and teaching hospitals. The wards were adult ICUs with a minimum ten-bed capacity
Aim of the study	to examine nurses' attitudes towards safety culture in six Saudi Arabian intensive care units (ICUs).
Methods	descriptive, cross-sectional
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	216 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	
Outcome measures	Attitudes towards safety using SAQ-ICU
key reported outcomes	In this study, ICU nurse safety culture perceptions were low (mean 1⁄4 3.5 on a five- point Likert scale). This low score was consistent with recent findings found in Raftopoulos and Pavlakis' study in 2013. Another study conducted by Almutairi et al. (2013) found that 319 nurses, representing medical, surgical and pediatrics wards, had low safety-culture perceptions and all safety culture sub-domains in this study scored less than 75, which is the cut-off point for a positive safety score.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (assessing safety culture and nurses' attitude)

Paper number (PDF no.)	39 (80)
Title	Patient safety culture in a large teaching hospital in Riyadh: baseline assessment, comparative analysis and opportunities for improvement
Author (s), year of publication	Fadi El-Jardali, Farheen Sheikh, Nereo A Garcia, Diana Jamal and Ayman Abdo (2014)
Study location	A tertiary care university hospital, The hospital is composed of two sites, Site A which is large (800 beds) and Site B which is small (104 beds).
Aim of the study	The objective of this study was to conduct a baseline assessment of the patient safety culture in a large hospital in Riyadh, Kingdom of Saudi Arabia
Methods	cross sectional study
Study populations (e.g. healthcare workers group, type	Total of 2,572 Administration/Management 92 (3.6%)

of patients group, total number of participants in the study if applicable)	Attending/Staff physician 158 (6.1%) Dietician 46 (1.8%) Infection control practitioner/Coordinator/Nurse 13 (0.5%) Patient care assistant/Hospital aide/Care partner 45 (1.8%) Pharmacist 56 (2.2%) Physical, occupational, speech therapist 52 (2.0%) Physician assistant/Nurse practitioner 17 (0.7%) Registered nurse 1287 (50.1%) Resident physician/Physician in training 67 (2.6%) Respiratory therapist 10 (0.4%) Quality staff 23 (0.9%) Unit assistant/Clerk/Secretary 133 (5.2%) Technician (e.g., EKG, Lab, Radiology) 308 (12.0%) Other, please specify: 264 (10.3%)
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	This PSC assessment identified organizational learning and continuous improvement and teamwork within units as areas of strength whereas hospital non-punitive response to error, staffing, and communication openness as areas that require improvement.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	40 (82)
Title	Perceptions of clinical safety climate of the multicultural nursing workforce in Saudi Arabia: A cross-sectional survey
Author (s), year of publication	Adel F. Almutairi, Glenn Gardner, Alexandra McCarthy (2013)
Study location	King Abdul-Aziz Medical City in the Riyadh region (KAMC-R)
Aim of the study	The purpose of this study is to explore the safety climate perceptions of the multi- cultural nursing workforce, and to investigate the influence of diversity of the multicultural nursing workforce on clinical safety in a large tertiary hospital in Saudi Arabia.
Methods	A mixed-method case study (survey, interview and document analysis) was employed.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	319 registered nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	SC using Safety Climate Survey (SCS)
key reported outcomes	The results from this paper demonstrated that nurses' perceptions of the clinical safety climate was unsafe. No significant difference was found between the age groups, years of nursing experience and their perceptions of the safety climate in this context. A significant difference was observed between the national background categories of nurses and perceptions of safety climate. This study suggests that there is a need for a well-structured continuing education programme for nurses that aim to increase their cultural competence to enable them to provide high quality and clinically safe care. These findings have the potential to inform policy and practice related to cultural diversity in Saudi Arabia.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety climate assessment)

Paper number (PDF no.)	41 (83)
Title	Assessment of Nurses' Perceptions of Patient Safety Culture in a Saudi Arabia Hospital
Author (s), year of publication	Ahmad E. Aboshaiqah, Omar Ghazi Baker (2013)

Study location	a metropolitan public tertiary care hospital in the capital Riyadh, Kingdom of Saudi Arabia.
Aim of the study	The purpose of this research was to identify the factors that nurses perceive as major contributors to a culture of patient safety and examine the effects of these perceptions on nurses' participation and engagement in the patient safety culture.
Methods	A cross-sectional descriptive, correlational design
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	498 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	The majority of nurses perceived a positive patient safety culture. There were significant differences in nurses' perceptions of patient safety culture based on gender, age, years of experience, Arabic versus non-Arabic speaking, and length of shift. Recognizing such factors will help in encouraging nurse participation and engagement in the patient safety culture and determining ways to improve and maintain it. The results of this study suggest areas of strength and also areas needing improvement with regard to nurses' perceptions of safety culture on multiple units. These findings suggest that patient safety culture is an important issue that hospital management and leadership should focus on, ensuring that nurses are satisfied with their work and have the resources needed to perform patient care correctly and sufficiently. Results are expected to lead to the development of interventions aimed at improving patient safety.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	42 (85)
Title	The perception of safety culture among nurses in a tertiary hospital in Central Saudi Arabia
Author (s), year of publication	Noufa A Alonazi , Aisha A Alonazi, Elshazaly Saeed, Sarar Mohamed (2016)
Study location	Prince Sultan Military Medical City (PSMMC), a tertiary centre in Riyadh, Central Saudi Arabia
Aim of the study	The aim of this study is to explore perceptions of patient safety among nursing staff in a tertiary hospital in Central Saudi Arabia in different discipline units.
Methods	Survey study
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	224 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using modified version of HSPSC
key reported outcomes	The overall perception of patient safety among participants was (57.9%). The majority (74.1%) thought that the existing system is good at preventing errors and only one third indicated that they have patient safety problems. Most of the participants were happy with the existing patient safety culture including organizational learning/continuous improvement (95.5%), and errors feedback and communication (76.64%). In conclusion, this study showed that perception of patient safety was sub-optimal among nurses and there are several areas for improvement regarding safety culture.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	43 (86)
Title	The pattern of medical errors and litigation against doctors in Saudi Arabia
Author (s), year of publication	Jamal S. AlJarallah, Norah AlRowaiss (2013)

Study location	Medico-legal Committees (MLC) in the 12 regions of the Kingdom.
Aim of the study	The current study was designed to review the lawsuits against healthcare professionals by analyzing records of the cases dealt with by the Medico-legal Committees (MLC) in various provinces in Saudi Arabia, in order to determine the pattern of medical errors and litigations in the country.
Methods	A retrospective review of lawsuits against healthcare professionals dealt with by the Medical Violation Committee (MVC) (over 2 years) and the Medical Jurisprudence Committee (MJC) (over 1 years). A pre-designed data sheet was used to collect data from the records, which consisted of information on details of the cases, details on where the error had occurred, and details of the errors.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	642 cases from the records of Medical Violation Committee (MVC) and Medical Jurisprudence Committee (MJC) against healthcare professionals
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The review of records revealed 642 cases, most of which were from hospitals *Where?* run by the Ministry of Health (MOH). The operating room was where most of the errors (20.4%) had occurred, followed by the emergency room (18.1%). *By whom?* Surgery was at the top of the specialties (25.1%). Most of the deaths occurred in surgery and obstetrics (about 25% for each), followed by other medical specialties (17%). About half of the lawsuit cases studied (46.5%) involved *Type of patients?* patients belonging to a relatively young age group (20–50 years). This study demonstrated that most of the medical error litigations involved surgeons and obstetricians especially in MOH hospitals. Authors suggest that the process of litigations and documentation should be improved, and access to the records for research and education to be made easier. They also recommend more prospective field studies to be conducted.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	44 (87)
Title	Incident Reporting at a Tertiary Care Hospital in Saudi Arabia
Author (s), year of publication	Yaseen Arabi, Ahmed Alamry, Souzan M. Al Owais, Hasan Al-Dorzi, Seema Noushad, Saadi Taher (2012)
Study location	King Abdulaziz Medical City (KAMC) – Riyadh, An academic tertiary care center in Saudi Arabia
Aim of the study	This study aimed to examine the rates and categories of incident reports in an academic tertiary care center in Saudi Arabia both hospital-wide and in the intensive care unit (ICU)
Methods	This is a descriptive study of the paper-based incident reports registered at King Abdulaziz Medical City (KAMC) - Riyadh, between January 1 and December 31, 2008. Incident report rates were calculated as number of incident reports per 1000 patient days. The classifications (major categories) of the generated incident reports were also reviewed and the top 2 reported major categories were further analyzed into their respective minor categories. Each report was counted separately even if more than 1 report affected the same patient or individual.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if	During the study period, there were 38,171 hospital admissions accounting for 252,851 patient days. There were a total of 3041 incident reports from all hospital areas, of which 1464 occurred in the inpatient setting.

applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	A total of 3041 incident reports were submitted from all hospital areas; yielding a rate of 5.8 per 1000 patient days. Sixty-two incident reports were reported from the ICU, yielding a rate of 5.8 per 1000 patient days. The most frequent type of incident reports was procedural variances (37%), followed by behavior and communication incidents (34%), hazardous and safety incidents (9.5%), and medication errors (7.4%). In the ICU, the most frequently reported type of incidents was behavior and communication incidents (30.6%), followed by procedural variances (21%) and medication errors (13%). The study demonstrated that rates of incident reports at a tertiary care center in Saudi Arabia were low compared with reported international rates. The main categories of incident reports were related to procedural variances and behavior and communication incidents. Authors suggest that patient safety initiatives should focus primarily on these 2 domains. In addition, more prospective research is needed in this important area to further understand patient safety challenges and reporting practice and culture in the country.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	45 (88)
Title	Benchmarking the post-accreditation patient safety culture at King Abdulaziz University Hospital
Author (s), year of publication	Bahjat Al-Awa, Adnan Al Mazrooa, Osama Rayes, Taghreed El Hati, Isabelle Devreux, Khaled Al-Noury, Hamed Habib, Basem Salama El-Deek (2012)
Study location	King Abdulaziz University Hospital in Jeddah, Saudi Arabia
Aim of the study	The objective of this study was to evaluate the perception of the KAUH nursing staff about patient safety after the application of the Canadian accreditation pro- cess and the contributing factors that could explain any changes in the hospital's safety culture.
Methods	Cross-sectional retrospective and prospective design using a self-reported questionnaire. The survey tool assessed perceptions of patient safety culture after the application of the Canadian accreditation process and data was collected from January 1, 2006 to December 31, 2009. The survey results were matched with the international benchmarks from the Hospital Survey on Patient Safety Culture, 2005.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	605 nurses
Intervention (type and duration of intervention if applicable)	The Canadian accreditation process was conducted at KAUH during 2007 and 2008. Throughout the process, the hospital was exposed to a challenging self-assessment of present standards, meeting the required standards and data collection. This included many different clinical indicators
Comparator (if any)	The survey results were matched with the international benchmarks from the Hospital Survey on Patient Safety Culture, 2005
Outcome measures	PSC using HSPSC
key reported outcomes	The comparison between the percentages of nurses at King Abdulaziz University Hospital (KAUH) and those at international hospitals who answered "Agree" and "Strongly agree" showed a post-accreditation improved perception of the culture of patient safety. Accreditation has an overall statistically significant improvement in the perception of the culture of patient safety. The authors strongly recommend that for further improvement in patient outcomes, investigators should evaluate more indicators and conduct further unbiased assessments of the impact of accreditation on patient safety culture as perceived by the nursing staff. The assessments presented in this study should be repeated on a yearly basis in the hospital, using the survey format presented in this study and altered to meet any new strategic changes in our hospital environment.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	46 (89)

Title	Measuring Patient Safety Culture in Riyadh's Hospitals: A Comparison between Public and Private Hospitals
Author (s), year of publication	Talal A. Al-Ahmadi (2009)
Study location	Nine public hospitals and two private hospitals
Aim of the study	The aim of this research was to explore the perceptions of Riyadh hospitals' staff on patient safety and error reporting and to identify factors that influence the levels of frequency of events reported.
Methods	Cross-sectional design using a self-reported questionnaire. The survey tool was the Hospital Survey on Patient Safety Culture (HSPSC) data was collected carried out was carried out during May-August, 2008.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	1224 hospital staff. The majority of the respondents (82.4%) work in public hospitals. Most of the respondents were nurses (63.7%), followed by physicians (8.8%) technicians (8.1%) and dieticians (0.4%).
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	Areas that need improvement in Riyadh hospitals include handoffs and transitions, communication openness, staffing and non-punitive response to error. Results of this study show a tendency for under reporting of errors whether harmful to patients or not. Frequency of events reporting varied according to hospital type and staff position. Regression analysis indicated that event reporting is influenced by six variables in Riyadh hospitals: feedback and communication about error, staff position (nurse), teamwork across units, non- punitive response to error, supervisor/managers expectations and actions promoting patient safety, and type of hospital. Author believe that healthcare organizations should reduce the fear of blame culture and create a climate of open communication and continuous learning.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	47 (90)
Title	Factors affecting nurses' perceptions of patient safety
Author (s), year of publication	Ari Mwachofi, Stephen L. Walston and Badran A. Al-Omar (2011)
Study location	Five Hospitals (two private, two public and one military hospital) in Riyadh, Kingdom of Saudi Arabia (KSA).
Aim of the study	This paper aims to examine socioeconomic and organizational/system factors affecting patient safety and quality perceptions.
Methods	Cross-sectional survey design using a self-reported questionnaire. The survey aimed to assess demographic information, managerial support perceptions, implementing and integrating information technology views.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	566 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Factors that improve patient safety and the likelihood that nurses use their own facility include: fewer visible errors; ability to communicate suggestions; information technology support and training; and a confidential error reporting system. Nurses are important communicators; especially about hospital safety and quality. The research informs leaders about areas that need considering and improving. Findings indicate that system factors, including functional feedback,

	suggestions, and error reporting significantly affect patient safety improvements. Likewise, nurse education to operate their information systems has positive effects. Healthcare leaders need to understand factors that affect patient safety perceptions when creating a patient safety culture.
Categorization based on the MMS framework (Vincent et al., 2014)	Sensitivity to operations

Paper number (PDF no.)	48 (91)
Title	Physicians' Attitudes Toward Reporting Medical Errors: An Observational Study at a General Hospital in Saudi Arabia
Author (s), year of publication	Eiman Alsafi, Salim A. Bahroon, Hani Tamim, Hamdan H. Al-Jahdali Saeed Alzahrani, Abdullah Al Sayyari (2011)
Study location	Al-Iman General Hospital, a tertiary care hospital, Riyadh, Saudi Arabia
Aim of the study	This cross-sectional survey study aims to assess the medical error reporting practice among physicians in Al-Iman General Hospital, Riyadh, Saudi Arabia. The study also aims to identify the factors that hinder or enhance physicians' reporting of medical errors.
Methods	Descriptive cross-sectional design using a self-reported questionnaire. The survey tool was developed by the study group to address demographic details, as well as attitudes, practice, and views on medical error reporting.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	107 physicians
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The physicians in this study were likely to disclose errors made by a colleague only if the error resulted in a severe damage to the patient, and as such, medical errors go underreported for a variety of reasons. Considering these factors when adopting programs to enhance patients' safety is important. The burden in promoting such practice is on physicians and health care institutions and administrators. Health care institutions should adopt a program that enhances and promotes error reporting. This should entail involvement of patients, transparency, confidentiality, and no blame culture.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	49 (93)
Title	Factors affecting the climate of hospital patient safety: A study of hospitals in Saudi Arabia
Author (s), year of publication	Stephen L. Walston, Badran A. Al-Omar, Faisal A. Al-Mutari (2010)
Study location	Four types of hospitals in Riyadh, Saudi Arabia (Ministry of Health, Private, Military, Teaching)
Aim of the study	To describe three organizational dimensions that influence hospital patient safety climate, also showing and discussing differences between organizational types
Methods	Cross-sectional survey design using a self-reported questionnaire. The survey tool was used to measure respondents' patient safety perceptions and to ascertain the respondents' personal characteristics and was developed after reviewing pertinent patient safety and climate literature.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if	496 healthcare professionals. Physician (30%) nurses (26.6) pharmacists (9.3) technicians and other specialists (34%)

applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The paper provides a unique Saudi Arabian hospital perspective and suggests that three dimensions influence the patient safety climate. *Management support, a proper reporting system and adequate resources* were found to influence the hospital patient safety climate. Major changes including hospital privatization and healthcare insurance systems may have significant effects on hospital organizational climates. Hospital managers are encouraged to improve these critical dimensions to positively develop their patient safety climate. Hospitals that address these issues are likely to provide better and safer patient care.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (examining three dimensions related to the safety climate)

Paper number (PDF no.)	50 (94)
Title	Which medical error to disclose to patients and by whom? Public preference and perceptions of norm and current practice
Author (s), year of publication	Muhammad M Hammami, Sahar Attalah, Mohammad Al Qadire (2010)
Study location	The outpatient's clinics of King Faisal Specialist Hospital and Research Center (KFSH&RC) a tertiary care hospital in Saudi Arabia
Aim of the study	The aim of this study was to obtain empirical evidence on public views on disclosure of ME in the outpatient's setting at a tertiary care hospital in Saudi Arabia. We examined preference, perception of norm, and perception of current practice on two topics, which ME to be disclosed and who to disclose ME
Methods	Descriptive cross-sectional design using a self-reported questionnaire. Two sets of three questionnaires were used to address personal preference, perception of norm (what is appropriate in general/should be done), and perception of current practice at the King Faisal Specialist Hospital and Research Center regarding which medical error is disclosed to patients (set one) and by whom (set two). The questionnaires were developed by the authors in Arabic language based on a literature review, and data was collected from November 2007 to March 2009.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	902 patients attending the outpatient's clinics
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The authors conclude that: 1) there is a considerable diversity in preferences and perceptions of norm and current practice among respondents regarding which ME to be disclosed and by whom, 2) Distributions of preference and perception of norm were similar but significantly different from the distribution of perception of current practice, 3) most respondents preferred to be informed of ME and by at-fault physician, and 4) one third of respondents preferred to be informed of near-miss ME, with a higher percentage among females, older, and healthy individuals.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	51 (95)
Title	Assessment of patient safety culture in Saudi Arabian hospitals
Author (s), year of publication	H A Alahmadi (2010)
Study location	Nine public and four private hospitals in Riyadh, including military, academic, specialist and Ministry of Health hospitals.
Aim of the study	The purpose of this study to evaluate the extent to which the culture supports patient safety at Saudi hospitals.
Methods	
Study populations (e.g.	1224 health professionals including (nurses, technicians, managers and medical staff)

healthcare workers group, type of patients group, total number of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	Results showed the overall patient safety grade was rated as excellent or very good by 60% of respondents, acceptable by 33% and failing or poor by 7%. More than half of respondents thought that managers overlook safety problems that happen over and over. Areas of strength for most hospitals were organisational learning/ continuous improvement, teamwork within units, feedback and communication about errors. Areas with potential for improvement for most hospitals were under- reporting of events, non-punitive response to error, staffing, teamwork across hospital units. The study revealed that leadership is a critical element to the effectiveness of patient safety initiatives. Author suggested that in order for healthcare organisations to create a culture of safety and improvement, they must eliminate fear of blame and create a climate of open communication and continuous learning.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	52 (99)
Title	The impact of accreditation on patient safety and quality of care indicators at king Abdulaziz University Hospital in Saudi Arabia
Author (s), year of publication	Al-Awa, B., De Wever A., Almazrooa, A., Habib, H., al-Noury, K., El Deek, B., El Hati T., & Devreux, I. (2011)
Study location	King Abdulaziz University Hospital, An acute care teaching hospital in Saudi Arabia.
Aim of the study	The study aimed to determine if the accreditation process has a positive impact on patient safety and quality of care.
Methods	A 4-year retrospective and prospective study design was used. A total of 119 performance indicators were collected through various processes and were transformed into 81 patient safety and quality indicators. The 81 indicators were collected over the period from January 2006 to December 2009 (pre-accreditation: January to December 2006; accreditation period: January 2007 to December 2008)
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	81 performance indicators- no patient of healthcare professionals sampled. January to December 2006; accreditation period was January 2007 to December 2008).
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Indicators included: Mortality - 15 indicators Healthcare Associated Infections (HAI) - 26 indicators Medication use - 5 indicators Blood utilization - 2 indicators Surgery/Invasive procedures - 7 indicators Cardiopulmonary resuscitation - 8 indicators Adverse events - 18 indicators
key reported outcomes	With the strong support of Hospital Management, the Canadian accreditation process conducted at King Abdulaziz University Hospital has had a positive impact on the quality of care and patient safety indicators tackled in this study, i.e., mortality, healthcare-associated infections, blood transfusion reactions, surgery/invasive procedures, CPR codes and adverse events.
Categorization based on the MMS framework (Vincent et al., 2014)	(intervention study) to track changes in quality and PS indicators before and after the accreditation

Paper number (PDF no.)	53 (100)
Title	A survey of hospital healthcare professionals' perceptions toward patient safety culture in Saudi Arabia
Author (s), year of publication	Farhan Alshammari, Eddieson Pasay-an , Mohammad Alboliteeh, Mohammed Hamdan

	Alshammari, Tantut Susanto, Sandro Villareal, Maria Charito Laarni Indonto, Ferdinand Gonzales (2019)
Study location	all hospitals within Hail Region, Kingdom of Saudi Arabia
Aim of the study	The present study investigates the perceptions of healthcare professionals toward patient safety culture in hospitals throughout Hail Region, Kingdom of Saudi Arabia.
Methods	descriptive cross-sectional survey
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	255 hospital staff comprising (nurses, physicians, and administrators/managers)
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	PSC using HSPSC
key reported outcomes	Healthcare professionals have an affirmative view toward patient safety culture aspects, and positive relationships were found between the patient safety dimensions and study participants' profile. The findings presented herein suggest that healthcare professionals affirm the practice of patient safety culture. However, further research is required to continuously appraise the significance of healthcare-based quality indicators. Overall, the assessment results suggest a platform for better intervention and transformation procedures targeting the promotion of patient safety culture.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	54 (103) Note: papers 54 and 56 used the same dataset and therefore treated as one paper
Title	The impact of accreditation on patient safety and quality of care as perceived by nursing staff in a University Hospital in Saudi Arabia.
Author (s), year of publication	B. Al-Awa B, A. Al-Mazrooa, H.S. Habib, O. Rayes, K. Al-Noury, T. Elhati, B. El-Deek, & I. Devreux (2010)
Study location	One larger sized governmental hospital in Saudi Arabia
Aim of the study	To evaluate the perception of King Abdul-Aziz University Hospital (KAUH) nursing staff on the quality of patients care and patients safety after application of the Canadian accreditation and its contributing factors that can explain changes, if any.
Methods	Cross-sectional survey design was conducted pre and post accreditation using a self-reported questionnaire. The survey tool assessed perceptions on quality of patient care and patient safety and data was collected before and after the accreditation process.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	675 nurses
Intervention (type and duration of intervention if applicable)	The Canadian accreditation process was conducted in KAUH during the period 2006-2008. The hospital was exposed to challenging self-assessment of present standards, meeting required standards and data collection which included many different clinical indicators. The hospital met the accreditation requirements successfully.
Comparator (if any)	-
Outcome measures	Improvement in perceptions on quality of patient care and patient safety (assessed by the four clinical indicators comprising the survey components).
key reported outcomes	Accreditation has an overall statistically highly significant perceived improvement on quality of patient care and patient safety. The researchers discovered that the approach of accreditation organizations was not exhausted and that the true value of accreditation may lie in its ability to generate discussion and stimulate change in general. The researchers strongly recommend that in order to further improve the patient outcomes, evaluate more indicators and further confirm the unbiased assessment of the impact of accreditation on the quality of patient care and patient safety as perceived by the nursing staff, the study presented in this research should repeated on a yearly basis in the hospital with evaluation of the survey format made and altered to meet any new

	strategic changes in the hospital environment.
Categorization based on the MMS framework (Vincent et al., 2014)	(intervention study) evaluate staff perception before and after the accreditation using a five-points Likert scale.

Paper number (PDF no.)	55 (105)
Title	Health professional perspectives of patient safety issues in intensive care units in Saudi Arabia
Author (s), year of publication	Adel Al Malki, Ruth Endacott, & Kelli Innes (2018)
Study location	The ICUs of two major teaching hospitals in Saudi Arabia
Aim of the study	To examine attitudes to patient safety in two Intensive Care Units (ICU) from the perspective of healthcare professionals in Saudi Arabia.
Methods	Descriptive cross-sectional design using a self-reported questionnaire. The survey tool was the Safety Attitude Questionnaire-Intensive Care Unit (SAQ-ICU) and data was collected throughout November and December 2015
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	106 nurses, 15 respiratory therapists, and 23 physicians
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Attitudes towards safety using SAQ-ICU
key reported outcomes	There are significant challenges for safety culture in this study. Findings were that healthcare professionals had a negative attitude towards patient safety according to all six safety domains. Key issues identified were job satisfaction, stress recognition, collaboration and communication, staffing levels, training and education and resources and guidelines. Managers may need to review and consider policies relating to safety culture including workforce planning, leadership and patient centred care. Further research into this global health priority is required to contribute to improving patient safety in ICUs.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (it examined safety attitude towards safety)

Paper number (PDF no.)	56 (106) papers 54 and 56 used the same dataset and therefore treated as one paper Note: the title of this paper no.56 doesn't reflect the content of the paper, it uses the same dataset and results from paper no.54, however, paper no.52 is about changes in indicators per and post accreditation)
Title	Comparison of patient safety and quality of care indicators between pre and post accreditation periods in King Abdulaziz University Hospital
Author (s), year of publication	Al-Awa, B., Jacquery, A., Almazrooa, A., Habib, H., al-Noury, K., El Deek, B., El Hati, T. & Devreux, I. (2011).
Study location	King Abdulaziz University Hospital
Aim of the study	To evaluate the perception of KAUH nursing staff on the quality of patients care and patients safety after the application of the accreditation process and its contributing factors that can explain changes, if any.
Methods	Cross-sectional survey design was conducted pre and post accreditation using a self-reported questionnaire. The survey tool was based on the National Patient Safety Goals and consisted of 4 major scales with 18 subscales. Data was collected before and after the accreditation process.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	675 nurses
Intervention (type and duration of intervention if applicable)	The Canadian accreditation process was conducted in KAUH during the period 2006-2008. The hospital was exposed to challenging self-assessment of present standards, meeting required standards and data collection which included many different clinical indicators. The hospital met the accreditation requirements successfully.
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Accreditation has an overall statistically highly significant perceived improvement on quality of patient care and patient safety. The researchers discovered that the approach of accreditation organizations was not exhausted and that the true value of accreditation may lie in its ability to generate discussion and stimulate change in general. The researchers strongly recommend that in

	order to further improve the patient outcomes, evaluate more indicators and further confirm the unbiased assessment of the impact of accreditation on the quality of patient care and patient safety as perceived by the nursing staff, the study presented in this research should repeated on a yearly basis in the hospital with evaluation of the survey format made and altered to meet any new strategic changes in the hospital environment.
Categorization based on the MMS framework (Vincent et al., 2014)	(intervention study) to evaluate nursing staff on the quality of patients care and patients safety after the application of the accreditation process using a five points Likert Scale.

Paper number (PDF no.)	57 (108)
Title	Exploring the Perceptions of the patient safety Culture
Author (s), year of publication	Dr. Sana Al Mahmoud1, Fatimah Al Shakhs, Weam Al Fayez, Dr. Ayaz Ahmad (2020)
Study location	Healthcare providers and patients in Eastern Region of Saudi Arabia.
Aim of the study	The main aim of this study is to understand the perceptions of the patient safety culture in Saudi hospitals by the healthcare providers and the patients, and to explore the discrepancy between them.
Methods	Cross-sectional survey design using two self-reported questionnaires; one for the healthcare providers and the second for the patients. The healthcare provider's survey tool was a customized version of the Patient Safety Culture survey provided by the Agency for Healthcare Research and Quality; the average mean of the positive answers were compared to the average mean of the positive answers to the same dimension in AHRQ database of the Hospital Survey on Patient Safety Culture (HSOPSC). The patient's questionnaire was constructed by using items from several literatures which has been customized to fit the purpose of the study and local customs. Data was collected from 04 October to 24 October 2018.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	195 healthcare providers (including the staff working in the following area: Physician- Medical, Nurse, Radiology, Pharmacy, Laboratory, Anaesthesiology, Rehabilitation, Dietitian, Administration- Management, and Other areas) and 584 patients.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	Included assessment of PSC using HSPSC
key reported outcomes	The overall positive grade on patient safety culture in the healthcare organizations as perceived by the healthcare providers was (74%) The results of this study are highly matched with a study conducted in 13 hospitals in Riyadh, Saudi Arabia, where the area highly perceived as positive were organizational learning/ continuous improvement, teamwork within units, feedback and communication about errors. While the areas received low positive responses were underreporting of events, non-punitive response to error, staffing and teamwork across hospital units. Both studies highlighted numerous opportunities to improve the underreporting of events and building non-punitive response to errors culture, which relies mainly on healthcare leadership and management support due to the extensive amount of efforts and resources needed to achieve better patient safety culture.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipant and preparedness (safety culture assessment)

Paper number (PDF no.)	58 (110)
Title	The COVID-19 outbreak in Saudi Arabia and the impact on patient safety incident reports: An empirical study among the medical facilities of Qassim health cluster
Author (s), year of publication	Sultan Al-Shaya, Ayed Al-Reshidi, Majeda Farajat & Aliaa Elnefiely (2021)
Study location	19 hospitals and 3 specialised centers of the Qassim Health Cluster (QHC)
Aim of the study	This study aimed to provide empirical evidence on how the COVID-19 outbreak impacted patient safety incident reports (PSIRs) among the Qassim Health Cluster (QHC) in Saudi Arabia.
Methods	Descriptive retrospective review of patient safety incident reports (PSIRs) pre and post COVID-19. The survey tool was based on the National Patient Safety Goals and consisted of 4 major scales with 18 subscales. Data was collected during a COVID-19 period (March 2, 2020to July 31, 2020) and was compared to a pre-COVID-19 period (March 2, 2019 to July 31, 2019).
Study populations (e.g. healthcare workers group, type of patients group, total number	23,481 inpatient patient safety incident reports from 22 medical facilities between COVID-19 period (March–July 2020) and a comparable pre-COVID-19 period (March–July 2019).

of participants in the study if applicable)	
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	In the COVID-19 period: inpatient admissions have significantly dropped by one-fourth, and the median score of PSIRs significantly increased to 30.6/100 inpatients. Nevertheless, there were no changes in PSIRs harm level. The top five areas of reporting were related to: patient care, medication, infection control, staff, and facility maintenance. Furthermore, there were no significant differences in the frequency rate of PSIRs by facility bed capacity. The significant increase in PSIRs at COVID-19 time can be perceived as a positive outcome. Our view considers both the COVID-19 crisis and future health crises. The lessons learned here should be employed to promote sustainable preparedness and responses to subsequent crises.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	59 (121)
Title	Attitude of Academic Ambulatory Nurses toward Patient Safety Culture in Saudi Arabia
Author (s), year of publication	Nazik M.A. Zakari (2011)
Study location	Four ambulatory academic departments which included medical, surgical, obstetrics/gynecological, and pediatric in Riyadh.
Aim of the study	This study was designed to examine nursing attitudes toward patient safety culture in an academic ambulatory healthcare organization.
Methods	descriptive cross-sectional correlational study. Full version of the Safety Attitude Questionnaire Ambulatory version (SAQ-A) which was developed to to assess the attitude of health providers in an ambulatory setting.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	221 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	Safety attitude towards safety using SAQ-A
Outcome measures	-
key reported outcomes	Highest positive attitudes were toward job satisfaction and work experience followed by working conditions and the quality of the work environment and its logistical support. However, the lowest positive attitude was toward the quality of collaboration between personnel and the proactive organizational commitment to safety. Authors suggest that enhancing these two aspects may promote the safety culture in this health setting and conducting PSC assessment will be the first step towards identifying barriers faced by nurses to provide safe patient care.
Categorization based on the MMS framework (Vincent et al., 2014)	Anticipation and preparedness (safety culture assessment)

Paper number (PDF no.)	60 (122)
Title	To Report or not: The Dilemma of Reporting Medical Errors among Physicians
Author (s), year of publication	Saleh M. Aldaqal, Munaser S. Al-Amoodi (2014)
Study location	King Abdulaziz University Hospital
Aim of the study	The study aimed to investigate the attitude of physicians towards reporting their ME, and to evaluate their knowledge on reporting. Furthermore, the study aimed to find the aspects behind physicians' practice of reporting and/or concealing their errors. The study also focused on investigating the possible appropriate actions to be taken following reporting of errors in the hope of reducing their re- occurrence.
Methods	cross-sectional descriptive survey study. The study team developed a questionnaire that was

	designed to measure knowledge and evaluate the attitude and practice of physicians on reporting medical errors.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	169 physicians (Consultants, Specialists, and Residents)
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Results of this study showed that reporting was significantly higher among consultants. There was (n=81) 48% confessed committing ME, of which 35% (n=59) had reported it. The majority of participants 81% (n=137) consider reporting medical errors an ethical issue. The authors concluded that there is an agreement amongst physicians that reporting ME is an ethical issue. The authors recommend that reinforcement of reporting medical errors and reducing medical errors can be achieved by implementing strict guidelines, training personnel efficiently and using the experience of professionals in their appropriate fields.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	61 (123)
Title	Improving Occurrence Variance Reporting System through Implementing an Educational Program for Staff at King Saud Hospital Unaizah, Al –Qassim, KSA
Author (s), year of publication	Ayed Awadh AlReshidi (2014)
Study location	King Saud Hospital. A tertiary care hospital in Unaizah, Al –Qassim, KSA.
Aim of the study	To improve Occurrence Variance Reporting System at King Saud Hospital, Al –Qassim
Methods	A quasi-experimental research design.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	Retrospective analysis of all OVRs submitted to quality and clinical risk management department. The incidents submitted to quality and clinical risk management department are any incident occurring in any hospital department, regardless whether the incident resulted in sentinel event or not.
Intervention (type and duration of intervention if applicable)	The study took 3.5 years and included several phases: Phase I: was 6 months before the educational program and during this phase a pretest was completed to assess the status of OVR reporting system Phase II (planning): took two months in which an improvement team was built. This team was responsible for the analysis of the problem of OVR under reporting and generating possible solutions for improving the system o Phase III (implementation): took 4.5 months, during this phase routine meetings were conducted on every Monday at 9:00 AM followed by a risk management and patient safety walk rounds in designated units/departments according to the prepared schedule prior to the meeting. Phase IV (evaluation of improvement): through which the improvement in the OVR system was monitored. This evaluation was done on 3 phases: 1- Post-test: In the first 6 months immediately after the education OVR trending and analysis were done 2- Follow up 1: OVR trending and analysis were done one year after implementation of the program 3- Follow up 2: for continuous monitoring of the OVR reporting system, OVR trending and analysis were done two years after the educational program to monitor the retention.
Comparator (if any)	-
Outcome measures	Trends in use of OVR system
key reported outcomes	Findings in this study revealed that the occurrence variance reporting system improved significantly after the implementation of an educational program on OVR to hospital staff and administrators. The author recommendations included: Continues monthly and quarterly

	monitoring and gathering of data to maintain the performance, Continuous education, Rewards and commendations to be given for the highest reporting department.
Categorization based on the MMS framework (Vincent et al., 2014)	Intervention study (educational program to improve incident reporting)

Paper number (PDF no.)	62 (124)
Title	Medical errors in Saudi Arabia: understanding the pattern and associated financial cost
Author (s), year of publication	M.H. Alshammari, Dinesh P. Mital (2016)
Study location	
Aim of the study	To determine the pattern of medical errors claims and associated financial cost in Saudi Arabia from the 2012 medical jurisprudence committee (MJC) report.
Methods	A descriptive analysis of the MJC report was performed. The report published by MOH and detailed the MJC performance during the year 2012
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	medical errors claims in Saudi Arabia during the during the year 2012.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Findings of this study revealed that medical record claims continued to rise throughout the report period. The highest rate of claims was observed in obstetrics/gynaecology and in private sector. 45.78% of death cases were compensated an amount of 100,000–500,000 SR and 53.65% of disability cases were compensated an amount of 1,000–50,000 SR. This paper demonstrated that the rate of medical error claims is rising in Saudi Arabia, as the number of claims had increased by 16.82% in 2009 when compared to 2008. In 2010 the number of claims also had increased by 14.11% in comparison to the number of claims in 2009. Authors recommended that further studies are needed to investigate causes and establish preventive measures.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	63 (125)
Title	Barriers of Reporting Errors among Nurses in a Tertiary Hospital
Author (s), year of publication	Maram Ahmed Banakhar, Amjad Ibrahim Tambosi, Shrooq Al-Ameen Asiri, Yosra Badr Banjar and Yomna Ashraf Essa (2017)
Study location	One tertiary hospital in Jeddah, Saudi Arabia
Aim of the study	This study aimed to identify barriers of reporting errors at one tertiary hospital in Saudi Arabia from the perspective of nurses themselves.
Methods	descriptive cross-sectional survey study. Authors used an adapted questionnaire from another study titled "*Barriers and strategies of reporting medical errors in public hospitals in Riyadh city: A survey-study*" conducted by Alduaiset al. (2014)
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	84 nurses
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The results of the study discovered that lack of time and complexity of works were the main barriers for nurses to report incidents within the hospital. The authors concluded that this study

	was conducted only in one teaching hospital and with small sample size and recommended further research is needed to identify the barriers of reporting errors in nursing practice across different healthcare organizations, considering large sample size.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	64 (126)
Title	Status of medical liability claims in Saudi Arabia
Author (s), year of publication	Abdulhamid Samarkandi (2006)
Study location	The National Medico-Legal Committee (MLC) under the authority of the MOH in Saudi Arabia
Aim of the study	to evaluate the magnitude and underlying factors of the problem (medical liability claims) in Saudi Arabia.
Methods	A retrospective analysis of the official records of Medico- Legal malpractice claims over the period (1999-2003). The incidence among different medical specialties, location, and final resolution of each claim were identified.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	The data, gathered from all the medico-legal subcommittees (6 subcommittees over 1999-2001) and upgraded to eight subcommittees thereafter during 2002-2003) covering the various health care regions in the Kingdom of Saudi Arabia, included all claims against all medical specialties.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Results revealed an increasing trend in the total number of claims over the study period, with a sharp increase in the transition between (2001-2002). In relation to claims, obstetrical practice took the lead with 27%, followed by general surgery and subspecialties, represented by 17% each, internal medicine 13%, while pediatrics represented 10% of claims; the fewest claims were in dentistry with 2.5%. The majority of claims were referred to Ministry of Health and private sectors medical facilities. The author recommends that adherence to standards of medical practice is by far the best approach to avoid or reduce the incidence of litigation. The author stated that “The number of cases included in this study does not represent the total number of litigations against different special- ties because there were other cases that were investigated at a lower level and were not included”.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	65 (127)
Title	Medical liability litigation in Saudi Arabia
Author (s), year of publication	Abdulhamid Hassan Al-Saeed (2010)
Study location	the Legal Health Organization (LHO) in Saudi Arabia, in which the author is an active member in Riyadh region.
Aim of the study	to evaluate the magnitude and underlying factors of the problem (medical liability litigation) in Saudi Arabia.
Methods	Annual reports covering the period from (1999–2008) were statistically analysed.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	The data were collected from the official annual reports of Legal Health Organization; the data received were raw figures demonstrates a census of all claims presented to different committees covering the Kingdom of Saudi Arabia
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	Data analysis showed an escalating trend for the total number of claims over the study period. Distribution of final verdicts among different clinical specialities showed that obstetrics takes the

	lead with a mean percentage of 25.5% followed by the practice of general surgery with a mean percentage of 13.8%. number of final verdicts with accusation along the studied period were the highest in the Ministry of Health sector with a mean number of 216.8 claims, followed by the private sector with a mean number of 197.3 claims. The author suggested that Adherence to the standards of medical practice is by far to the best approach to avoid and reduce the incidence of litigation.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Paper number (PDF no.)	66 (128)
Title	Studying Medical Errors among Hospital-Staff at Saudi Health Providers
Author (s), year of publication	Khalid Saad Al-Saleh and Mohamed Zaki Ramadan (2012)
Study location	16 hospitals from three different regions in Saudi Arabia.
Aim of the study	The study was designed to evaluate the relationship between sleep deprivation, performance, and the number of occupational errors and patient errors, and to measure systemic and individual factors that contribute to medical errors and compliance rates at different hospitals
Methods	A cross-sectional survey study. The survey used was adapted from four studies
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	932 medical staff.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-
key reported outcomes	The results of the study indicated that heavy workload and lack of education/experience were significantly higher than other reasons of having medical errors. Education and continuous training, adjustment in work schedule and less working hours in night shifts and throughout the week significantly affected rates of medical errors. Authors found that hospitals that offered and encouraged their medical staffs to have training programs and up-to date workshops related to their specialties decreased their errors significantly when compared to the hospitals that did not offer nor encourage their employees to have such types of training programs.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm (focus of survey was on reporting errors)

Paper number (PDF no.)	67 (129)
Title	Medical liability: The dilemma of litigations
Author (s), year of publication	Ahmed A. Alsaddique (2004)
Study location	The main medico-legal committee (MLC) of the Ministry of Health (MOH), Riyadh, Kingdom of Saudi Arabia
Aim of the study	The author purpose was to determine the pattern of medical errors claims
Methods	The data of the cases submitted to the Medico-legal committee of the Ministry of Health, Riyadh, Kingdom of Saudi Arabia from various parts of the country for the period (1999-2003) were examined and analysed. Data was provided by the main medico-legal committee (MLC) of the Ministry of Health (MOH), Riyadh, Kingdom of Saudi Arabia.
Study populations (e.g. healthcare workers group, type of patients group, total number of participants in the study if applicable)	A total of 2223 cases were referred to the different committees over the past 4-years for considerations.
Intervention (type and duration of intervention if applicable)	-
Comparator (if any)	-
Outcome measures	-

key reported outcomes	Similar to results of the studies that investigated the litigations, obstetrics led the way in being the most litigation prone medical specialty. Surgery was in the second place followed by internal medicine pediatrics in the fourth place in order of frequency. The other specialties are somewhere in between. The least number of malpractice lawsuits were filed against the dental profession.
Categorization based on the MMS framework (Vincent et al., 2014)	Past harm

Appendix 7
Supplemental Material 3
Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	2,3
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	3
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	N/A
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	4
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	3
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Supplementary material 1
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	4
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	5
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if	N/A

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
		appropriate).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	5,6
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	Figure 1
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	Table 3
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	Supplemental material 2
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	6-9
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	9-13
Limitations	20	Discuss the limitations of the scoping review process.	10
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	13
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	14

Appendix : Additional file 1 (Search strategy)

Advanced google search

#	Search terms		Total search yield	Potentially relevant records / full text review	Included
1	"Measuring safety"	AND "Saudi Arabia"	n=18	n=3	
2		AND "Saudi hospitals"	n=80	n=14	
3		AND "Saudi healthcare"	n=90	n=3	
4	"Monitoring safety"	AND "Saudi Arabia"	n=120	n=1	
5		AND "Saudi hospitals"	n=70	n=1	
6		AND "Saudi healthcare"	n=60	n=5	
7	"Measurement of safety"	AND "Saudi Arabia"	n=93	n=1	
8		AND "Saudi hospitals"	n=70	n=2	
9		AND "Saudi healthcare"	n=70	n=2	
Total=			N=671	N=32	N=3

MEDLINE

Search strategy	Total search yield	Potentially relevant records / full text review	Included
1. exp patient safety/ 2. safe*2.ti,ab. 3. exp medical errors/ 4. (medica* adj1 error*1).ti,ab. 5. (adverse adj1 event*1).ti,ab. 6. (sentinel adj1 event*1).ti,ab. 7. (patient adj1 safety adj1 incident*1).ti,ab. 8. (patient adj1 harm*).ti,ab. 9. (healthcare adj1 quality).ti,ab. 10. (quality adj1 care).ti,ab. 11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 12. measur*.ti,ab. 13. monitor*.ti,ab. 14. assess*.ti,ab. 15. evaluat*.ti,ab. 16. 12 or 13 or 14 or 15 17. exp hospital/ 18. hospital*1.ti,ab. 19. exp secondary care/ 20. (secondary adj1 care).ti,ab. 21. exp tertiary healthcare/ 22. 17 or 18 or 19 or 20 or 21 23. exp saudi arabia/ 24. exp middle east/ 25. arab*3.ti,ab. 26. 23 or 24 or 25 27. 11 and 16 and 22 and 26	1043	2	0

CINAHL

Search strategy	Total search yield	Potentially relevant records / full text review	Included
S27 S12 AND S18 AND S22 AND S26 S26 S23 OR S24 OR S25 S25 TI arab* OR AB arab* S24 TI "middle east" OR AB "middle east" S23 TI saudi* OR AB saudi* S22 S19 OR S20 OR S21 S21 TI "tertiary care" OR AB "tertiary care" S20 TI "secondary care" OR AB "secondary care" S19 TI hospital* OR AB hospital* S18 S13 OR S14 OR S15 OR S16 OR S17 S17 TI evaluat* OR AB evaluat* S16 TI assess* OR AB assess* S15 TI manag* OR AB manag* S14 TI monitor* OR AB monitor* S13 TI measur* OR AB measur* S12 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 S11 TI "quality *care" OR AB "quality *care" S10 TI "healthcare quality" OR AB "healthcare quality" S9 TI "iatrogenic disease" OR AB "iatrogenic disease" S8 TI "patient harm" OR AB "patient harm" S7 TI "patient safety incident" OR AB "patient safety incident" S6 TI "sentinel event" OR AB "sentinel event" S5 TI "adverse event" OR AB "adverse event" S4 TI "risk management" OR AB "risk management" S3 TI "medica* error*" OR AB "medica* error*" S2 TI safe* OR AB safe* S1 TI "patient safety" OR AB "patient safety"	189	1	0

OAIster

#	Search terms			Total search yield	Potentially relevant records / full text review	Included
1	ti: “Measuring safety”	AND	“Saudi Arabia”	n=18	n=2	n=0
2			“Saudi hospitals”	n=6	n=0	n=0
3			“Saudi healthcare”	n=2	n=0	n=0
4	ti: “Monitoring safety”	AND	“Saudi Arabia”	n=8	n=0	n=0
5			“Saudi hospitals”	n=3	n=1	n=0
6			“Saudi healthcare”	n=4	n=0	n=0
7	ti: “Measurement of safety”	AND	“Saudi Arabia”	n=18	n=1	n=0
8			“Saudi hospitals”	n=6	n=0	n=0
9			“Saudi healthcare”	n=2	n=0	n=0
Total=				N=67	N=4	N=0

IMEMR

#	Search terms	Total search yield	Potentially relevant records / full text review	Included
1	(Measuring safety [Title/Abstract])	2	0	0
2	(Monitoring safety [Title/Abstract])	1	0	0
3	(Monitoring safety [Title/Abstract])	0	0	0

WHO IRIS

#	Search terms	Total search yield	Potentially relevant records / full text review	Included
1	Title contains: Measuring safety	4	4	1
2	Title contains: Monitoring safety	16	1	0
3	Title contains: Measurement of safety	17	3	1

Google scholar

#	Search terms		Total search yield	Potentially relevant records / full text review	Included
1	"Measuring safety"	"Saudi Arabia"	n= first 100 hits	n=2	
2		"Saudi hospitals"	n=15	n=0	
3		"Saudi healthcare"	n=4	n=0	
4	"Monitoring safety"	"Saudi Arabia"	n= first 100 hits	n=0	
5		"Saudi hospitals"	n=2	n=0	
6		"Saudi healthcare"	n=2	n=0	
7	"Measurement of safety"	"Saudi Arabia"	n=63	n=1	
8		"Saudi hospitals"	n=4	n=0	
9		"Saudi healthcare"	n=0	n=0	
total			N=290	N=3	N=0

Appendix : Additional File 2

Document analysis

1. Harm- have we been safe in the past?
2. Reliability of safety critical processes
3. Sensitivity to operations- are we safe today?
4. Anticipation and preparedness- will we be safe in the future?
5. Integration and learning- are we responding and improving?

Measure	Dimension
Quality and Patient Safety Measures in King Faisal Specialist Hospital and Research Centre (KFSH&RC) (2015)	
Hand hygiene audit	2
Number of patient falls that result in injury	1
Number of hospital acquired pressure injuries	1
Department of Quality and Safety at King Fahd Hospital of the University (KFHU) Annual Report (2015)	
P10. Conducted a patient record review	1
P11. Tracer activities- assessed compliance with standards by 'tracing' the care experiences that a patient had received to assess standards compliance	2
P12. Leadership safety walk arounds- leaders go to the wards/units and talk to front line staff about safety.	3
P13. Monitoring of KPIs (e.g. patient falls).	1
P14. Use of occurrence variance reporting system in order to monitor any event or circumstance not consistent with the standard routine operations of the hospital.	2
P15. Conducted environmental safety monitoring to measure the effectiveness of safety protocols against agreed standards of high quality and safety	2
P109. Collect adverse event reports.	1
P109. Analyse adverse event reports	5
CBAHI National Hospital Standards 3rd edition (2015)	
P17. Accreditation survey- a broad assessment using multiple methods of data collection (e.g. observations, interviews, document review) in order to determine the hospital's compliance and performance. Three days, if failed must develop a corrective action plan. Planned and random surveys	2
P32. Reporting of sentinel events	1
P33. Learning from sentinel events using root cause analysis to re-design processes and systems.	5
P48. Inspections of medical supplies and devices	2
P48. Reporting of adverse events with medical devices	2
P55 Conduct staff satisfaction surveys.	1
P61 Conduct monthly morbidity and mortality meetings to review relevant cases, and;	1
P61 make recommendations for actions for improvement based on M and M meetings	5
P61 Medical record review committee monitors the documentation in medical records for quality, completeness, and timeliness.	2
P61 Medical record review committee makes recommendations for improvement as required	5
P63. Utilization committee assesses the appropriateness of care, e.g. quality of care	2
P63 Utilization committee make recommendations for actions for improvement	5
P64. Operating room, tissue, pharmacy and therapeutic committee monitors performance.	2
P64. Operating room, tissue, pharmacy and therapeutic committee makes improvements in the relevant areas.	5
P64. Cardiopulmonary resuscitation committee reviews all codes.	2
P64. Cardiopulmonary resuscitation committee identifies actions for improvement.	5
P75 Regular evaluation of the activities and outcomes of the rapid response teams (team that responds to a rapidly deteriorating patient outside ICU).	2
P88/89. Analysis of indicators such as mortality rates, healthcare associated infections, patient satisfaction, adverse events, medication errors, sentinel events, patient complaints.	1,5
P88/89. The hospital monitors its performance through regular data collection	2
P88/89. Regularly collected data is used to make improvements.	5

P.90 Systematic process is used to identify and analyse potential risks for severity and likelihood of occurrence e.g. use of proactive approaches such as failure mode and effects analysis	4
P103. The hospital collates trended data on patient complaints.	4
P103. The hospital takes a QI and strategic actions based on trended data on patient complaints.	1
P180. The hospital has a system to monitor the completeness of medical records.	2
P184. There is continuous surveillance of healthcare associated infections.	2
P185 Results of surveillance of healthcare associated infections are integrated into QI programme.	5
P192. Compliance with hand hygiene is regularly monitored.	2
P199 Monitor and evaluate adverse drug events.	1
P212. The hospital conducts analysis of all adverse drug reactions.	1
P212. Hospital collects data on significant and potential medication errors	1
P212. Hospital conducts root-cause analysis for significant and potential medication errors, and uses this data to change practices	5
P212. Healthcare professionals receive feedback on medication errors and near misses.	5
P227 System for reporting adverse blood donation events.	1
P227 System for monitoring adverse blood donation events.	3
P239 Safety committee conducts quarterly and as needed safety tours to identify risks and hazards related to facilities and physical plant and evaluates staff knowledge.	3