Evaluating Hospitals' Responses to Patient Safety Events

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PREFACE

Funding

This thesis was supported by a University of Ottawa tuition scholarship awarded to Hassan Mahmoud upon admission to the PhD program (2018–2022).

Ethical Considerations

This thesis includes three studies. The first study, a systematic review, was exempt from Research Ethics Board approval as it involved only analysis of existing literature and did not involve human participants.

The second and third studies involved surveys of healthcare leaders and experts in quality and safety. These studies received ethics approval from the Research Ethics Board at The Ottawa Hospital prior to data collection. All participants were provided with detailed information about the study and gave informed consent electronically before participation.

Participation in the surveys was voluntary and confidentiality was strictly maintained. All data were de-identified and securely stored. Results were reported in aggregate to protect the identities of individual respondents.

Author Contributions

Under the supervision of my thesis supervisor, Dr. Alan Forster, I, Hassan Mahmoud, am the guarantor of this doctoral research project. I have led all aspects of the thesis, including the formulation of research questions, study design, data collection, data analysis, interpretation of results, manuscript development, and the writing of the full thesis.

The Thesis Advisory Committee—composed of Dr. Kednapa Thavorn and Dr. Sunita Mulpuru—was assembled in collaboration with my supervisor and members were selected for their expertise in patient safety, health systems, and quality improvement. The committee provided guidance and reviewed the design and execution of the studies, offering critical feedback throughout the research process.

Three manuscripts were prepared for publication as part of this thesis (presented in Chapters 2–4). I served as the lead and corresponding author on these papers, two of which have been published as research articles, the third awaits submission to a journal.

Throughout the course of this work, I also sought expert input and methodological guidance, including consultation with patient safety experts.

The supervisor, committee members, and co-authors reviewed the manuscripts included in this thesis and provided constructive comments that contributed significantly to the refinement of this work.

ABSTRACT

Adverse events—defined as unintended harm associated with the delivery of healthcare—can result in prolonged hospitalization, disability, or death of a patient. While most Canadians receive safe care, thousands of hospital-acquired adverse events still occur annually, nearly half of which might be preventable, imposing a significant economic burden. To mitigate this, patient safety learning systems (PSLSs) have been developed to promote learning from incidents and prevent recurrence. These systems offer critical insights into how and why harm occurs at the organizational level, but they face limitations to their implementation and evaluation.

More than two decades have passed since the landmark report "To Err is Human" was published, but patient harm during hospitalization remains prevalent. This might be due to barriers to implementing a PSLS or to the biased evaluations that obscure the areas needing improvement. The overarching aim of this doctoral thesis was to address key evidence gaps relevant to strengthening a hospital's response to safety events and lay a foundation for future evaluation studies.

The first of three studies synthesized current evidence on the barriers and enablers to implementing the PSLS through a systematic review and meta-synthesis. The barriers identified included inadequate organizational support, resource shortages, lack of training, weak safety culture, lack of accountability, punitive environments, complex systems, and lack of feedback. Enablers included continuous training, leadership as role models, balanced accountability, anonymous reporting, user-friendly platforms, well-structured analysis teams, and evidence of improvement.

The second study applied this evidence to develop a comprehensive, evidence-based self-assessment tool for PSLSs. Designed for use by hospitals, health systems, and researchers, the tool assesses the full spectrum of activities following safety events, helping organizations identify areas for improvement and enabling researchers to evaluate the effectiveness of a PSLS.

The third study used this tool to evaluate PSLS capabilities in a sample of large, reputable general and university hospitals in Ontario. It identified critical areas of improvement for decision-makers and provided insight into practical PSLS challenges.

Overall, this thesis has direct implications for improving PSLS-related policies and practices, and indirectly contributes to enhancing hospital safety culture by addressing barriers to implementation and integrating safety learning into daily routines.

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I would like to express my deepest gratitude to my esteemed supervisor, Dr. Alan J Forster, for his unwavering support, invaluable guidance, and profound wisdom throughout the journey of completing this PhD thesis. Dr. Forster, your mentorship has been instrumental in shaping not only the academic trajectory of this work but also my growth as a researcher and individual. Your insightful feedback, encouragement, and patience have been truly invaluable, and I am profoundly grateful for the privilege of receiving your tutelage.

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To my beloved family, words cannot express the depth of my gratitude for your unwavering love, encouragement, and support throughout this challenging yet rewarding journey. Your constant belief in me has been my source of strength, and I am profoundly grateful for your sacrifices, understanding, and constant encouragement. This achievement is as much yours as it is mine, and I am forever indebted to you for believing in me even when I doubted myself.

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CHAPTER 1

Introduction

Patient safety is defined as the prevention of healthcare-associated errors and adverse events occurring with patients, and involves coordinating efforts to minimize risks, ensuring proper healthcare practices, and promoting a culture of safety within medical institutions [1]. Patient safety is a critical priority in global healthcare practice. This is because adverse events related to safety significantly compromise patient outcomes, place strain on healthcare systems, and erode the trust of the public [2,3]. Adverse events are unintentional and unfavourable injuries that were caused by medical management (rather than the underlying condition) as well as those that prolonged hospitalization, inflicted a disability at the time of discharge, or both [1]. They can manifest as clinical signs or symptoms, including complications of an underlying disease, any new illness, or the deterioration of existing disease detected clinically or by laboratory assessment [4]. There is a wide range of sources through which adverse events can be identified; these sources vary in accuracy and include patient charts, incident reports, electronic database records, interviews of clinical staff, and examination of patients. Studies have estimated that 3% to 17% of hospitalized patients experience adverse events, with 35% to 50% of those events being preventable [5]. This corresponds to about 185,000 out of the 2.5 million inpatients in Canadian hospitals every year being involved in adverse incidents, 70,000 of which are preventable [2]. This rate of adverse events was estimated to have placed an extra burden of more than a billion Canadian dollars on the Canadian economy in 2010 [6]. However, only 1% to 10% of adverse events are reported, so the real burden of these incidents is likely to

be much greater [7]. In recognition of these challenges, the Institute of Medicine (USA) in 2000 published its report "To Err is Human: Building a Safer Health System". This landmark report focused on the importance of learning from mistakes, and in doing so, ushered in a new era of patient safety [8,9]. The report recommended the creation of patient safety learning systems (PSLSs) as one response to this problem. A PSLS, according to the Canadian Patient Safety Institute (CPSI), is intended to "capture patient safety concerns, hazards and/or incidents and are meant to trigger action, facilitate communication, response, learning and improvement" [10]. As a result of the Institute of Medicine's recommendation, PSLSs were adopted by healthcare organizations worldwide as a structured approach to reporting, analyzing, and learning from safety incidents. However, the potential of a PSLS to transform patient safety outcomes remains unfulfilled due to a lack of critical implementation and evaluation [5,11,12].

Many factors such as inadequate safety culture, fear of blame, and limited resources have been extensively documented in PSLS research as barriers to effective reporting of adverse safety events [13,14]. Therefore, a barrier is defined as anything that prevents or suppresses an individual from reporting [15], obstructs the process of incident analysis, or interferes with hospital learning.

The literature underscores the need for strengthening a safety culture in which healthcare-providing personnel feel safe to report incidents without fear of retribution. However, beyond these cultural factors, PSLS data is slow to translate into actionable insights for organizational learning [5,16]. A growing body of evidence highlights that although many institutions have adopted PSLS frameworks, their implementation often focuses on incident reporting rather than the iterative learning and quality-improvement

processes that minimize the chance future errors will occur [5,16]. As an example, Vincent and Amalberti argued in 2016 that many PSLS frameworks prioritize event documentation and classification, yet fail to translate these insights into systemic changes that enhance patient safety [17]. Later, Wears and Sutcliffe similarly emphasized that tangible safety improvements require iterative learning cycles, organizational shifts in culture, and proactive risk management, all of which are frequently underdeveloped in PSLS implementation [18].

The absence of standardized tools for evaluating the effectiveness of a PSLS and fear of damage to reputation further exacerbates these challenges, leading to inconsistent implementation and limited transparency across a healthcare organization, respectively [8,19]. In Ontario hospitals, for instance, variations in PSLS capabilities highlight the need for improved approaches to enhancing organizational learning after an incident. Also, the results from observations and walkthroughs demonstrate that hospital reports on staff compliance with safety guidelines were not as transparent as they could be [5,10,20].

This thesis critically examines how the three intersective domains of implementation science, organizational learning, and patient safety combine to influence the range of patient safety outcomes that occur in a clinical setting. Rooted within a foundational framework presented by the Patient Safety and Incident Management Toolkit (PSIMT) courtesy of the CPSI, this thesis presents an urgent call to bridge the knowledge gap between implementation and impact on patient safety. While the literature is dominated by descriptive metrics, such as incident-reporting rates and the categories of events reported, it often misses the highly systemic and organizational dynamics that either support or hinder effective learning from those incidents. Also, numerous studies explored the barriers and

facilitators associated with PSLSs. However, there remain a limited number of studies that comprehensively integrate these factors and systematically prioritize them to enhance PSLS management and effectiveness [21].

Furthermore, the general absence of a common methodology to assess PSLSs makes conducting consistent evaluations of their effectiveness across diverse healthcare settings difficult, which in turn limits the possibilities for benchmarking improvements, best practices, and meaningful system-wide change.

By addressing these gaps, this thesis contributes to advancing PSLS research and practice in three key ways. First, a comprehensive systematic review identifies the organizational barriers and facilitators that influence the effectiveness of a PSLS, these facilitators are identified as any factor that supports incident reporting, analysis, and learning by providing indirect or inconspicuous support, steering, or oversight [15]. Second, a survey instrument is developed and validated that can be applied by a hospital to assess the extent to which they overcome these barriers and identify the areas in the PSLS that need improvement. Third, the current state of PSLS implementation is evaluated in Ontario hospitals, providing actionable insights into their capability to foster a culture of safety and learning.

STAGES OF THE PATIENT SAFETY LEARNING SYSTEM

To be able to identify the factors for improvement in a PSLS, it is important to understand the main steps of that system and the elements that are essential for its success in preventing incidents from reoccurring.

The main steps in any PSLS are structured reporting, collation of reports, analysis and learning from these reported incidents (Figure 1) [22]. Structured reporting, also known as the detection stage, includes discovery of the incident to be reported followed by submission of data about this incident into the reporting system. In this first stage, the reporting individual typically completes a form describing the type of incident according to given reporting criteria; these forms might feature check boxes and space for entering a description of the event using free text [23]. The second stage usually involves collation and analysis of these submitted data alongside further investigations to identify the contributing factors [24]. In the third stage, learning from incidents starts by considering all the information generated from previous stages to lead to a change in understanding or practice. The fourth and final stage involves feedback, which starts during the second and third stages and helps to improve the quality of reporting and confidence in that particular organizational learning system [25].

PSLSs are applied all over the world, such as Australia's Advanced Incident Management System (AIMS), Canada's CPSI reporting system, and the Patient Safety Organization Program under the Agency for Healthcare Research and Quality (AHRQ) in the US. Despite structural and implementation variations, the systems share one common purpose: to create an active learning environment for preventing harm to patients and improving healthcare safety [26].

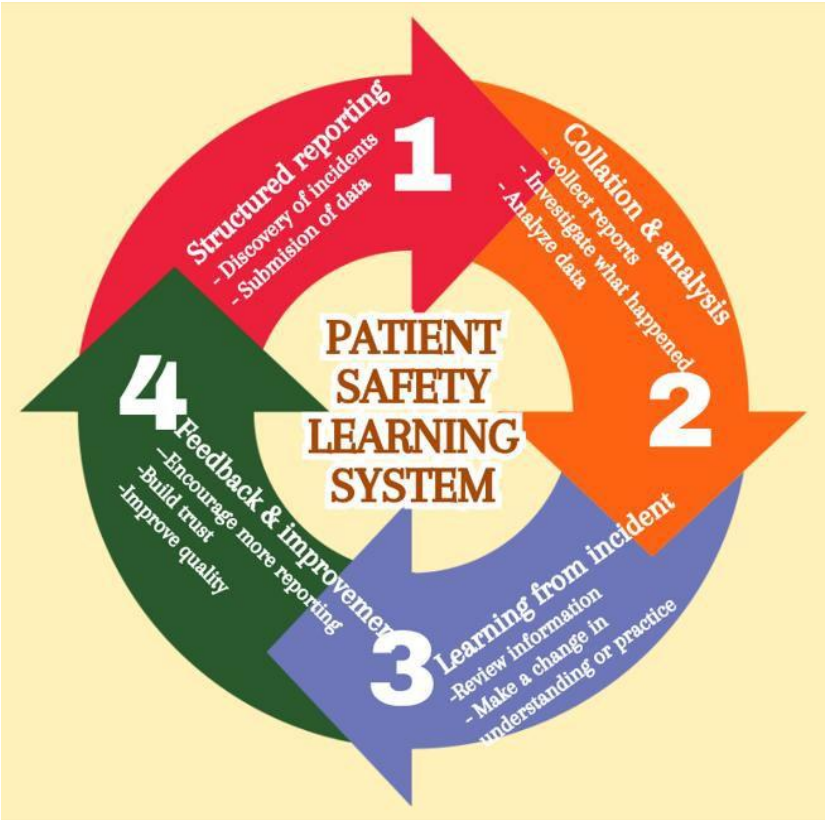

Figure 1. The four main steps of the PSLS.

EVOLUTION OF PATIENT SAFETY LEARNING SYSTEMS

Over the past two decades, patient safety has evolved as a global healthcare priority from a culture of blame to one of learning from mistakes. PSLSs have evolved from simple incident-reporting tools into comprehensive frameworks that foster continuous learning, transparency, and systemic change in patient safety practices [27]. Here, we chart the history of the PSLS to the present day.

Early Efforts and the Rise of Structured Reporting (2000–2010)

The publication of *To Err is Human* (2000) by the Institute of Medicine marked a seminal point, exposing the shocking frequency of preventable medical errors and stimulating the creation of national reporting systems [8], such as the UK's NRLS and Canada's CPSI, both in 2003 [2,28]. Initially, these systems were passive repositories for data, and mechanisms for providing feedback were lacking. A pervading fear of blame led to chronic underreporting, with estimates as low as 1–10% of incidents being reported [29,30].

Widening the Lens Beyond Reporting to Learning and Culture (2010–2020)

The decade of the 2010s marked a shift in paradigm from reporting-focused systems to building a culture of learning and prevention. International frameworks from organizations such as the WHO supported non-punitive reporting environments [31]. In the US, the Patient Safety and Quality Improvement Act of 2005 led to the creation of patient safety organizations, which provided a legally protected space for healthcare providers to report safety events confidentially [32]. During this period, advances in electronic health records and artificial intelligence (AI) enabled risk monitoring in real time [33]. However, challenges persisted, including an inconsistency of standards for reporting, a lack of standardized evaluation tools, and difficulties in translating incident data into actionable safety improvements [34].

Contemporary Developments (2020–Present) and the Future of PSLSs

The COVID-19 pandemic tested the resilience of PSLSs, prompting rapid adaptations to capture pandemic-related safety concerns, such as shortages of personal protective equipment and disruptions to care [35]. Current trends emphasize proactive risk

management through AI-driven analytics and global data sharing to benchmark best practices [36,37]. Looking ahead, PSLSs will increasingly integrate technology and promote a "just culture" that frames errors as learning opportunities rather than individual failings, enhancing system-wide patient safety efforts [38].

NATIONAL AND GLOBAL PSLS APPROACHES AND THEIR ECONOMIC IMPACT

Canada

The report by the Canadian Institute for Health Information, 2022, revealed a decrease in avoidable adverse events: surgical site infections and medication-related harm. National efforts have included the creation of the CPSI and its management tool, and the National System for Incident Reporting. All have contributed to better incident reporting, safety culture, and learning strategies. Because preventing just 1% of adverse events has been estimated to save approximately $100 million annually, there is an economic as well as patient benefit to interventions aimed at patient safety [2,39,40].

United States

In the US, implementation of the Patient Safety and Quality Improvement Act (PSQIA, 2005) and the AHRQ Patient Safety Indicators led to a 21% reduction in hospital-acquired conditions between 2010 and 2015, which translates to estimated savings of $28 billion [41]. Thus, these initiatives significantly reduced the economic burden of adverse events, which was approximately $17.1 billion in 2008, demonstrating the cost-effectiveness of implementing a PSLS [41,42].

European Union

The EU's initiatives on patient safety, led by the European Union Network for Patient Safety and Quality of Care, has resulted in better safety outcomes across its member states. For example, Denmark and the Netherlands instituted national reporting systems, which have led to a reduction in adverse event rates and associated costs. In 2014, adverse events across the EU accounted for approximately €21 billion in direct costs, accounting for 1.5% of the EU's total expenditure on healthcare [43]. Although there has been some improvement, variable implementation of PSLSs and the lack of standardized policies across member states make it difficult to scale up these economic benefits more widely [44].

United Kingdom

One such well-known system was the National Reporting and Learning System (NRLS). It was established in 2003 by NHS England for the National Health Service (NHS) in the UK to recognize and study incidents of patient safety, such as adverse events and near misses. NRLS was a voluntary, confidential reporting system by which healthcare professionals reported incidents, causative factors, and patient outcomes. By applying standardized data collection and trend analysis, the NRLS identified systemic risks and informed national safety policy. Enhancing a culture of safety was one of its key strengths, as it promoted open discussion of errors without punitive consequences. The NRLS facilitated the collection of large amounts of data for comparison across healthcare settings. The 2019 NHS Patient Safety Strategy further strengthened learning from safety-related events, and medicines safety and infection control has significantly improved as a result [26]. Although the NRLS facilitated cost reduction [45], the financial burden of adverse events was

significant, accounting for annual staffing costs equivalent to 2,000 general practitioners or 3,500 hospital nurses [46]. There were limitations in the NRLS, which included underreporting due to fear of being blamed, data quality issues resulting from inconsistent reporting, lack of engagement of frontline workers, and delays in giving feedback to the relevant healthcare organization. In order to overcome these limitations, the NRLS was gradually phased out by NHS England and replaced by the Learn from Patient Safety Events (LFPSE) service. This transition aimed to enhance patient safety reporting by providing a more efficient platform. The LFPSE system improves data collection by making it centralized ensuring standardized data entry and real-time analysis. It also enhances accessibility, making it easier for healthcare professionals and organizations to report incidents while offering more precise categorization to provide deeper insights. These advancements are expected to contribute to a stronger culture of learning and continuous improvement in patient care. Between 2022 and 2023, healthcare organizations across the UK transitioned to LFPSE, marking a significant step forward in modernizing patient safety management.

International Context

The WHO has highlighted the global economic consequences of unsafe care practices, stating that medication errors alone cost an estimated $42 billion annually, nearly 1% of global health expenditure [47]. High-income countries have reported significant success in reducing the number of adverse events and thereby costs, whereas resource constraints, underreporting, and weak safety cultures persist in low- and middle-income countries. The WHO Global Patient Safety Action Plan 2021–2030 stresses that globally, there is an

increasing need for context-specific strategies to improve PSLS effectiveness, especially in resource-limited countries [48].

SURVEY TOOLS FOR EVALUATING A PSLS

Developing a survey tool to assess the effectiveness of a PSLS requires robust validation that it consistently and repeatedly measures the intended outcomes. Assessment of the survey tool typically involves three key areas: reliability, validity, and standardization. These are important because they allow the tool to provide reliable, valid, and consistent results in various settings and populations.

Reliability herein refers to the consistency and stability of the survey instrument in measuring exactly the same constructs uniformly across various settings and at different points in time [49]. There are various types of reliability that an assessment might include. Internal consistency is a measure of reliability that examines whether items on the survey are associated with others and if they are actually testing for the same thing; it can be assessed using Cronbach's alpha value. Test–retest reliability checks the instrument for consistent results at different times on the same population. Inter-rater reliability determines whether different examiners rate and score answers the same way, which is necessary if numerous individuals are going to be administering or grading the survey [50].

Validity testing ascertains if the survey tool indeed measures what it is intended to measure, that results will be effective and useful for the PSLS. If validity is weak, a survey result will not reflect the true status of the system being evaluated [51]. There are several types of validity tests that can be used to assess PSLS survey tools, including content

validity that ensures all necessary elements of a PSLS are addressed by the instrument. Construct validity is concerned with whether the tool actually measures the theoretical constructs that it was intended to measure, for example, attitudes toward reporting safety incidents, and can be assessed using methods such as factor analysis. Criterion-related validity looks at the outcomes from the survey against an external criterion, for example, actual reported safety events, and assesses how well the instrument measures compared to real results. Face validity ensures that the questions are relevant to the respondents and easy to comprehend, promoting participation as well as quality of response [52].

Standardizing a survey entails its uniform administration so that is comparable across contexts and populations. This is important as standardization boosts the replicability and comparability of outcomes such that it is easier to compare PSLS practices across different hospitals or geographical locations [53]. There are numerous aspects of standardization that are important for a survey to function. They range from uniform wording and formatting, which helps to maximize the clarity and minimize the ambiguity of questions. Standard response scales such as Likert scales improve the consistency of responses. Furthermore, standardized administration procedures ensure that respondents are neither given different instructions nor exposed to different survey conditions, thereby eliminating additional variation in responses. Finally, benchmarking capability allows healthcare organizations to compare their PSLS practices with others and achieve improvement in those areas [50].

Late in 2020 (after the start of our study), the WHO developed its own self-assessment tool to help healthcare organizations evaluate their PSLS. The tool is organized into six large components: Environment for Reporting; Reporting Rules and Content; Analysis and Investigation; Governance; Action and Learning; and Patient and Family Engagement.

Each factor has specific items that can be assessed by an organization to determine their strengths and weaknesses. Responses are recorded on a Likert scale, on which the respondent rates their agreement with statements, which enables data to be collected and analyzed in a standardized manner. Although the tool is grounded in established principles of patient safety and expert consensus, specific psychometric evaluations (such as statistical analyses to determine validity and reliability) are not detailed in the WHO's technical report [31]. The Hospital Survey on Patient Safety Culture (HSOPSC), developed by the AHRQ, is another widely used tool designed to assess a number of aspects of patient safety culture—defined as shared values, beliefs, norms, and procedures related to patient safety among members of an organization [54,55]—including teamwork, error reporting, and leadership support for safety [56]. The main strengths of HSOPSC are its comprehensive scope, high psychometric quality, and its widespread use such that the results of a hospital can be compared with those of national or international counterparts. However, the instrument is not PSLS specific and its sheer length risks respondent fatigue, which jeopardizes response rates and data validity. Furthermore, it is not focused on PSLS practice [56].

CONCEPTUAL FRAMEWORK

Development of the Patient Safety Incident Management Toolkit

In 2014, the CPSI and the main health sector partners formed the National Patient Safety Consortium. The consortium announced a national call to action on patient safety, involving more than 50 healthcare organizations across Canada. These organizations represented governments, healthcare professionals, patients and families, regulators, enforcement agencies, and national and provincial agencies and associations [57]; each shared their experience and knowledge. One outcome of this initiative was a strategy for managing patient safety incidents. These incidents can be any unintended circumstances caused by healthcare that either did harm to the patient (an "adverse event") or might have led to patient harm (a "near miss"). They are not caused by the medical condition for which the patient is being treated [58]. Reporting systems are designed to capture patient safety concerns, hazards and incidents, and are meant to induce action and facilitate communication, response, learning, and improvement. Establishing a reporting system and processes to support it, including identifying and spreading learning, is foundational to patient safety and incident management and essential to advancing a culture of patient safety [19].

In order to create an incident management system, a toolkit that includes the strategies and resources to manage incidents effectively and keep patients safe was developed. The toolkit places much emphasis on the needs and concerns of patients and their families through proper engagement throughout the incident management process [19]. Figure 2 shows the workflow of the patient safety incident management toolkit (PSIMT), which was derived from the best available evidence and expert advice. This toolkit is intended for use

by those responsible for managing patient safety, quality improvement, risk management, and staff training in any healthcare setting, and might help to address the barriers to a successful PSLS [59].

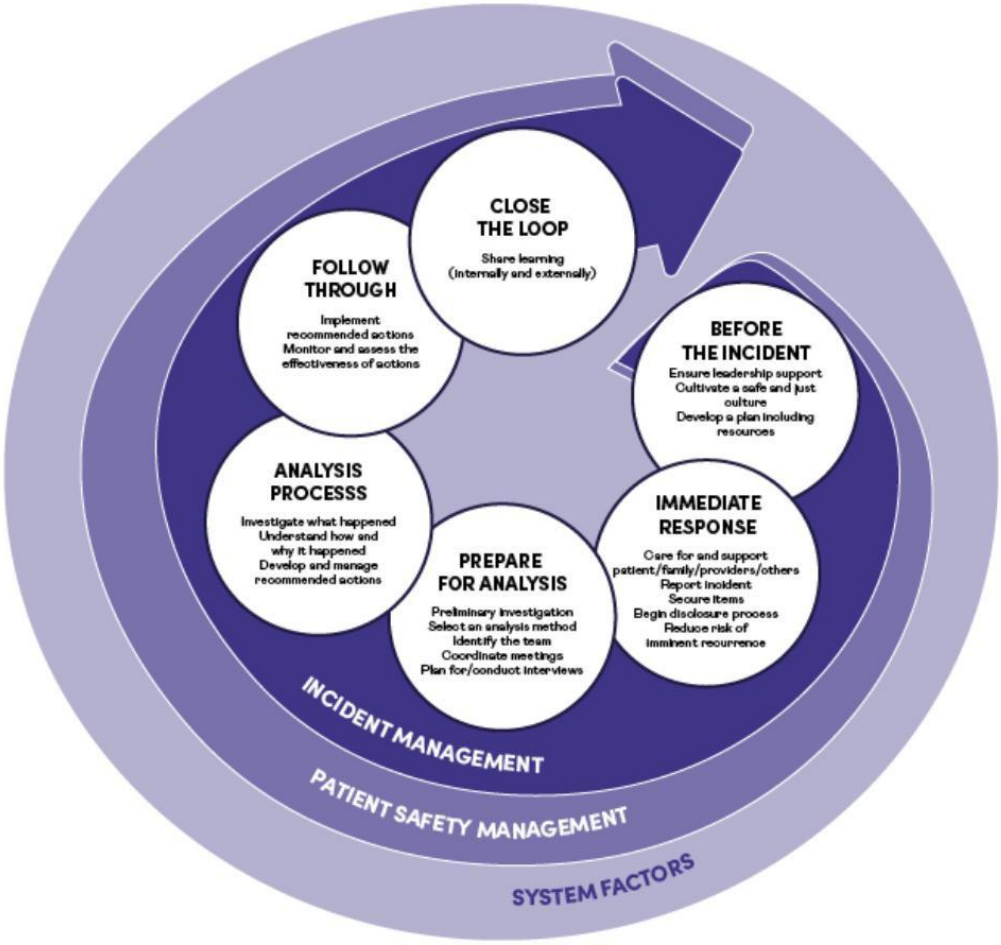

Figure 2. Visual representation of the toolkit. Reproduced from [59] with permission; copyright Healthcare Excellence Canada.

Components of the PSIMT

Incident management

Incident management (Figure 2, dark purple) provides guidance and ensures readiness of the system to respond to an incident related to patient safety. This component deals with the period before an incident, explaining how to make the environment suitable for incident reporting, analysis and learning. It also guides the immediate response by detailing the process of identifying the incident and reporting it. This is followed by disclosure of what error has happened and to whom, then preparation for analysis and the analysis itself. Follow-through includes implementation and follow-up of recommendations. Finally, closing the loop involves sending feedback to the reporter(s) and sharing learning internally with other workers within the organization or externally with other healthcare settings [59,60].

Patient safety management

Patient safety management (Figure 2, medium purple) refers to improving the ability to anticipate incidents and prevent their occurrence (i.e., plan, anticipate, and monitor for responding to expected and unexpected safety issues) so that current and future safety is considered [59,60].

System factors

All determinants of patient safety and its management at different system levels internally and externally must be considered. These factors (Figure 2, light purple) could be related to legislation, policies, culture, people, processes, or resources [59].

The Patient Safety Incident Management Toolkit As the Framework for This Study

Although it was developed based on strong methods and is provided by a reputable organization, a number of other frameworks were reviewed (discussed later) to ensure the most appropriate framework for this study was selected. All of those frameworks possessed different strengths in addressing patient safety and incident management. However, the PSIMT model was chosen due to its comprehensiveness, adaptability, and alignment with our objectives to improve patient safety. The PSIMT was developed in 2012 and revised in 2017 to provide a guide to healthcare organizations on the effective management, reporting and learning from patient safety incidents. It is a structured and systematic approach that encompasses not only reporting but also analysis, response, and preventive measures [59].

Comprehensive and holistic approach

The structure of the PSIMT is particularly appropriate for this study because, as discussed later, it is all-encompassing. Unlike other approaches that are mainly intended for identifying risk or documenting incidents, the PSIMT encompasses the whole PSLS process: proactive strategies for avoiding incidents, detection systems for identifying adverse events, and learning processes to lower subsequent risk. Such a holistic approach ensures comprehensive coverage of the patient safety landscape and supports the present study's intention to examine both incident prevention and systemic learning in improving the safety of care [61].

Adaptability across healthcare settings

Another key factor in choosing the PSIMT is its flexibility in application across diverse healthcare environments. Whereas many frameworks are tailored to specific healthcare settings, the PSIMT's adaptability makes it suitable in various organizational contexts, from large hospitals to smaller clinics and long-term care facilities. This broad applicability is crucial for ensuring the generalizability of the findings across different healthcare settings, which enhances the relevance and practical utility of the study's outcomes [23].

Emphasis on incident reporting and learning

This toolkit not only guides the implementation of effective reporting systems but also emphasizes the necessity of root-cause analyses and post-incident reviews to identify the underlying causes of adverse events [59].

Conforming to the international goals of patient safety

The PSIMT shares its key underpinnings with major international patient safety frameworks and priorities, including those of the WHO and the Institute of Medicine. These are centered on issues of communication, a culture of safety, and prevention of error—all themes of the PSIMT. This commonality strengthens the relevance and effectiveness of the toolkit in supporting the global goals of improvement in healthcare safety through enhanced communication, leadership, and clinical practices [62].

Evidence of success

Evidence that supports its effectiveness in changing patient safety knowledge, attitudes, and behaviors increases the validity for its selection for this study. Research has demonstrated that health institutions applying the PSIMT reduced their rates of medical errors, surgical complications, and nosocomial infections [80]. Reducing the incidence of these infections makes patients safer and saves money, thus making an evidence-based case for how a PSLS can lower the rate of an adverse event and the associated economic burdens [63].

Comparison with Other Frameworks

Although the High Reliability Organization (HRO) model, the Swiss Cheese model, the Reason's Human Error model, the Theoretical Domains Framework (TDF), and the Consolidated Framework for Implementation Research (CFIR) model are also widely used, they tend to focus on narrower aspects of patient safety. For example, the HRO model focuses on operational reliability and minimization of process variability, but less so on incident management [64]. The Swiss Cheese model and the Reason's Human Error model only provide theoretical views on accident occurrence but lack a structured, practical approach to accident management, unlike the PSIMT [65,66]. The TDF focuses on barriers and facilitators to behavior change at both the individual and organizational levels, which is helpful but does not include a direct focus on incident reporting, analysis, and system-wide learning [67]. In turn, the CFIR is designed to assess the contexts for implementation and guide strategies of intervention; it is more applicable for evaluating implementation processes than managing adverse patient safety incidents and learning from them [68].

By contrast, the PSIMT offers a comprehensive and structured framework specifically tailored to the systematic management of safety incidents and is therefore more aligned with the objectives of our research [59].

KEY GAPS

High Rates of Adverse Events Despite PSLS Implementation

Although evidence exists that adverse event rates are significantly lowered by PSLSs (see the section NATIONAL AND GLOBAL PSLS APPROACHES AND THEIR ECONOMIC IMPACT), there are also instances in which they are not. Studies have shown that adverse event rates, which could be reduced, are still high even in hospitals with an established PSLS. For example, a systematic review by Panagioti et al. found that patient safety interventions, including reporting systems, have had only limited success in significantly reducing harm rates in healthcare settings [3]. This can be attributed to underreporting and ineffective learning. Some studies indicate that underreporting of incidents leads to missed opportunities for the system to reduce adverse events. A study by Vincent et al. in 2013 found that many adverse events are unreported, resulting in repeated errors and failures to implement preventive measures [16]. The high rates of adverse events can also be attributed to the failure of the PSLS to translate reported incidents into meaningful policy and procedural changes. Macrae reported that many healthcare organizations struggle to convert incident reporting into actionable learning and improvement [69]. Lack of system standardization also plays a major role as many hospitals and healthcare organizations use different reporting criteria, formats, frameworks, and definitions, making it difficult to compare data across institutions [5]. Another study demonstrated that healthcare organizations that implement

comprehensive learning frameworks, for example, fostering a culture of transparency or blame-free environments, providing adequate training, or ensuring robust feedback mechanisms, observed a 22.41% increase in overall event-reporting rates, indicating enhanced engagement of staff with safety protocols [70].

Lack of Standardized Survey Tools and Related Transparency Issues

The lack of standardized tools that survey the performance of a PSLS is a significant barrier to rational improvement of patient safety in healthcare organizations [71]. Studies have indicated that existing surveys vary greatly in their format, questions, and scales of response, and therefore the results from different healthcare organizations are not comparable. The majority of tools focus on specific areas such as incident reporting or safety culture but do not provide a complete assessment of PSLS implementation and effect [72]. Furthermore, although some instruments have high internal consistency, comprehensive psychometric testing involving construct validity, face validity, and inter-rater reliability is often lacking [73]. Another discrepancy lies in the underrepresentation of certain stakeholder groups, including patients and families whose interests are most often excluded from an assessment of a PSLS [74]. Also, frontline providers' comments on reporting systems lack appropriate representation across the majority of system processes, leaving the potential for mismatches between an organization's ratings and true-site challenges [75]. Moreover, the majority of studies on PSLS-assessing instruments have been carried out in high-income countries, skewing the longitudinal and cross-cultural comparisons of the literature [76]. Without access to a standardized measure, organizations are unable to compare their performance, identify gaps, and assess change over time.

This issue is compounded by fears of blame and damage to professional reputations, which discourage transparent reporting of system performance to external bodies and limits open discussions about safety incidents [77]. In 2016, Macrae noted that healthcare organizations, especially in competitive settings, might prioritize maintaining their public image over candid disclosure, leading to underreporting and missed opportunities for learning [69]. To minimize that, there was a need for structured self-evaluation and internal audits as a powerful strategy for discovering deficiencies in safety, fostering reflection, and facilitating a culture of continuous improvement without dependence on external pressures [78,79]. That is only likely to be achieved if true organizational dedication to transparency and learning exists, as opposed to simple regulatory compliance.

THESIS OBJECTIVES

The central goal of this thesis is to provide comprehensive and up-to-date information about the use of a PSLS for improving patient safety in hospitals. The wider aim of providing such information is to assist policy makers, healthcare providers, and healthcare system researchers in making decisions about the use of PSLSs.

This goal will be achieved by meeting three key objectives, summarized here:

Objective 1: Describe the barriers and facilitators perceived to affect the PSLS in hospitals.

Objective 2: Develop a survey instrument to assess an organization's approach to learning from self-reported safety-related events.

Objective 3: Assess PSLS practices as described by executives in general hospitals within a publicly funded health system.

METHODOLOGIES OF THE STUDIES IN THIS THESIS

This thesis comprises three studies tailored to achieving each of our objectives, namely, "Barriers and facilitators to improving patient safety learning systems, a systematic review of qualitative studies and meta-synthesis", "Development of a survey to support assessment of safety learning systems", and finally "Quality leaders' survey of their patient safety learning system capability". This section provides a detailed description of the design of these studies and the methodologies involved in their execution.

Objective 1: Describe the Barriers and Facilitators Perceived to Affect the PSLS in Hospitals

In this section we describe the detailed methodology for addressing our first objective.

- ***Research question****: What are the key barriers and facilitators perceived by healthcare professionals that impact the effectiveness of the PSLS in hospitals?*

Study design: systematic review and meta-synthesis

We used systematic review and meta-synthesis techniques [80] for evaluating published and unpublished studies that have assessed PSLSs in order to identify the factors perceived to improve the effectiveness of a PSLS in a hospital setting. The protocol follows the adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement for qualitative and quantitative studies [81,82]. The systematic review and meta-synthesis followed the steps outlined in Figure 3 [83]. The quality assessment was critically appraised according to the Critical Appraisal Skills Program (CASP) for qualitative studies. CASP was used to ensure rigorous quality assessment as its checklist provides a structured and transparent approach to evaluating qualitative studies,

guaranteeing that only methodologically sound researches were included in the survey [84]. This helps to minimize the risk of bias and enhances the credibility of findings. CASP is a standardized tool, so we can systematically compare studies based on their methodological strengths and weaknesses. This consistency is particularly valuable for meta-synthesis, where diverse qualitative findings are integrated to generate higher-order interpretations [85]. CASP encourages critical reflection on aspects such as researcher bias, ethical considerations and data rigor, which are crucial in qualitative research. This improves the trustworthiness of the synthesis by ensuring that findings are contextually grounded and methodologically sound [86]. It also helps reviewers systematically assess whether studies meet minimum quality thresholds, preventing the inclusion of poorly conducted research that could weaken the reliability of the overall synthesis [87]. CASP strengthens the interpretative process by evaluating studies for their design, data collection methods, and analytical process [88].

Data was extracted with the data extraction tool for qualitative data of the Joanna Briggs Institute (JBI) [89,90]. We selected this tool as it provides a systematic, standardized and context-sensitive approach to capturing key study elements, ensuring consistency and rigor in the data synthesis [91]. Its structured format facilitates thematic analysis and meta-synthesis, allowing for deeper insights into qualitative findings while maintaining transparency and replicability [85]. Moreover, the JBI's methodology is widely recognized in evidence-based healthcare research and endorsed by organizations such as Cochrane and the WHO, enhancing the credibility and robustness of our systematic review [92].

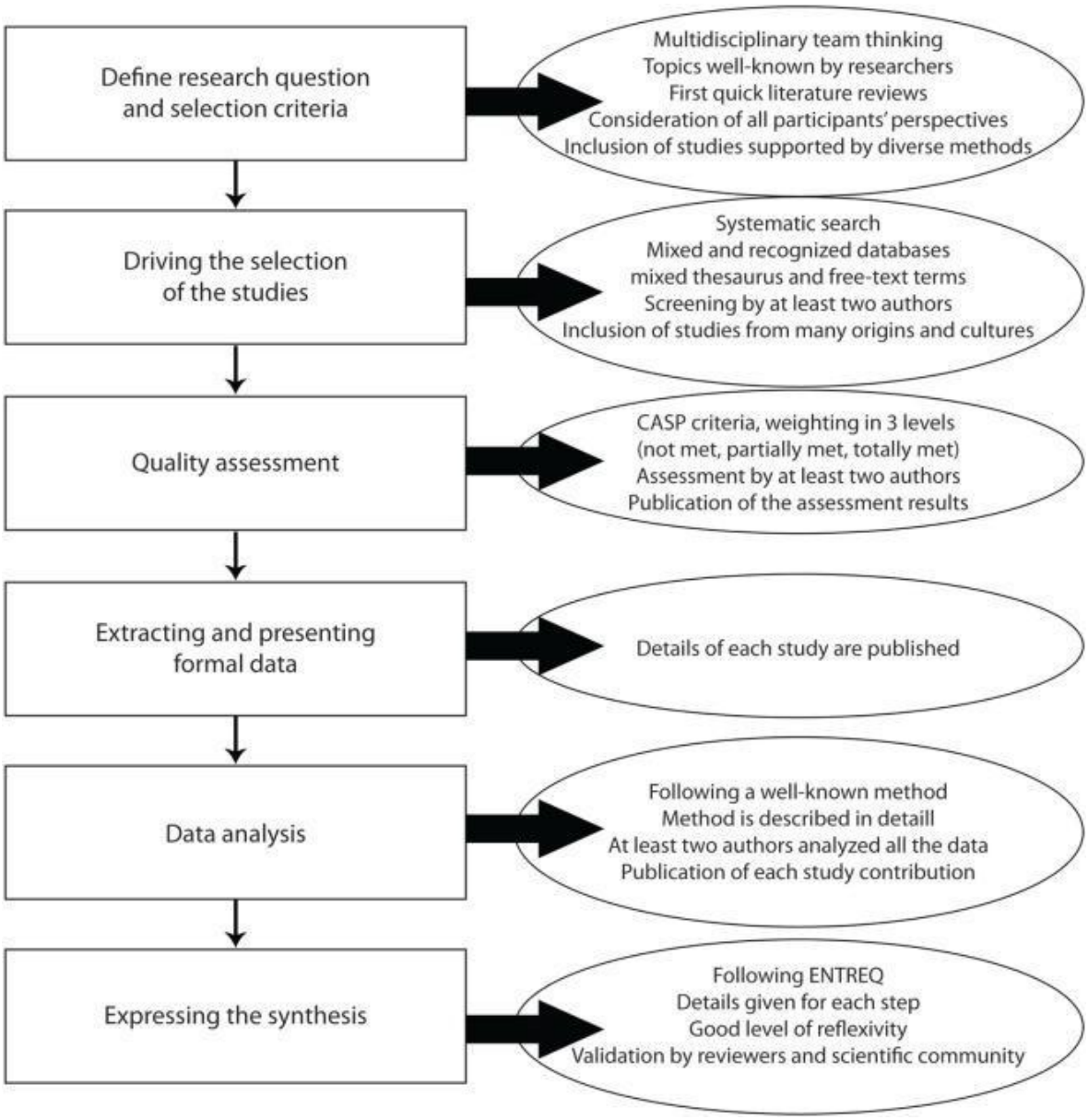

Figure 3. Schematic description of the systematic review and meta-synthesis for qualitative studies. Reproduced from [83], licensed under CC BY 4.0.

Eligibility criteria

We used the PICO approach (suited to qualitative systematic reviews and meta-synthesis) for selecting our primary studies. Table 1 provides a summary of the qualitative research tool PICoS (Problem, Interest, Context, and the study design) [93].

Table 1. The PICoS (problem, intervention, context, and the study design) of the systematic review.

Problem (P)	The continuous occurrence of patient safety incidents and the factors perceived to be responsible for ineffective PSLSs.
Interest (I)	Understanding the factors that are perceived to improve effectiveness of the PSLS's response to safety incidents.
Context (Co)	General or specialized hospitals.
Studies (S)	All related qualitative studies (phenomenology, ethnography, grounded theory, and case studies) assessed for eligibility.

Problem. The perceived low effectiveness of PSLSs in hospitals can be attributed to two issues: the continuous occurrence of safety incidents and the incomplete understanding of the factors responsible.

Interest. All qualitative studies that assessed the factors thought to improve the effectiveness of a PSLS were included. Such studies include evaluations of factors related to patients, healthcare workers, and/or processes that improve the hospital's PSLS.

Context. We are interested in factors predisposing to improvement or deterioration of safety learning systems in general and specialized hospitals. These hospitals can be academic health facilities or community-based entities. They can be general hospitals providing medical services including admission of all types of patients who have acute illnesses needing relatively short-term care, or they can be specialized hospitals and centers receiving patients referred from general hospitals to provide more specialized care.

Types of studies. Only qualitative studies defined primarily as "an inductive process of organizing data into categories and identifying patterns (relationships) among categories" were included. These studies might have been phenomenological, ethnographical, grounded

theory, or case studies [94]. No demographic or geographic restriction was placed on sample participants or study setting, as it is good practice to be as inclusive as possible in a meta-synthesis [95].

Furthermore, only studies written in English were included in this systematic review.

Exclusion criteria

We excluded studies that were not performed in hospitals, studies evaluating a particular incident such as surgical errors, or assessing the effectiveness of the safety learning system, and studies that investigate the criteria and trends of reporting incidents.

Search strategy

A librarian experienced in searching databases at University of Ottawa library was consulted to develop a primary search strategy that was piloted on the Medline (Ovid) database. Then the search strategy was used to include EMBASE (Ovid), CINAHL, Scopus, and Web of Science. We manually searched Google Scholar, Grey Literature Reports, the CPSI, and the WHO for unpublished studies.

The keywords used for the searches included "incident reporting system", "patient safety learning system", "safety incidents", "prevention strategies", "system improvement", "influencing factors", "barriers", "facilitators", "improvement factors", "general hospital", and "specialized hospital".

Study screening and selection. The titles, abstracts and full texts of the selected studies were reviewed by two independent researchers to identify studies that potentially meet the inclusion criteria outlined above. The Covidence systematic review software (2020, Veritas Health Innovation) was used to facilitate the title, abstract and full-text screening processes. After importing references and the inclusion/exclusion criteria into Covidence, two independent reviewers screened the titles of the included studies according to the eligibility criteria. Conflicts between those two reviewers were resolved through discussion with a third reviewer. The same procedures were utilized for abstract screening. After abstract screening, the full texts of these potentially eligible studies were retrieved and independently assessed for eligibility by two reviewers. Again, disagreements over the eligibility of a particular study were resolved by the third reviewer.

Assessment of methodological quality. Two independent reviewers assessed the methodological validity of the screened papers that will be selected for retrieval using the qualitative assessment tool: Critical Appraisal Skills Programme (CASP) Qualitative Checklist. Disagreements between the two reviewers were referred to a third reviewer.

Data extraction. After studies were screened and selected, key information from those studies were extracted into Excel (Microsoft) for further analysis. We used the qualitative assessment and review instrument (QARI) for qualitative data extraction from the JBI [88]. We used the tool to extract 1) study characteristics such as authors, year of publication, and journal title; 2) the methods of the study, including study design, purpose, and/or research questions; 3) participant characteristics, country in which the study was conducted, setting, population, and sample size if applicable; 4) the data analysis; and 5) the conclusions and

comments from the reviewers. Two reviewers independently performed data extraction. The authors of the reviewed papers were to be contacted in case details of their studies were missing.

Data synthesis. The central process in our meta-synthesis was a directed analysis that included data identification and counting, sorting them by themes derived from the PSIMT, and examining these data to generate a set of main findings.

We also provided a narrative synthesis of the findings for understanding better the identified improvement factors. An improvement factor for a PSLS can be either a facilitator or a remover of a barrier. The narrative synthesis was structured by describing the studies and the themes mentioned above. The results are presented in tables, figures and graphs as appropriate with a corresponding discussion.

Conclusion

We anticipated that the review would provide a detailed summary of factors perceived to be effective in improving a PSLS, with subsequent reduction in the occurrence of hospital-acquired safety events. It was also expected that the study would evaluate these improvement factors according to the frequency of their reporting in the reviewed literature and that it might guide future research on this topic.

Objective 2: Develop a Survey Instrument to Assess an Organization's Approach to Learning from Self-Reported Safety Events

- ***Research question:*** *How can a survey instrument be developed and validated to assess an organization's approach to learning from self-reported safety events?*

Study design: survey development

Step 1: Identify candidate questions and their response variables (standardization). Based on the results of the systematic review, which collected its data from national and international research, we developed a list of factors (barriers and facilitators) that impact the effectiveness of the PSLS; these factors were translated into the items of the questionnaire.

The items were grouped under domains that represent the subthemes identified in the systematic review and rephrased into questions. Standardized responses to item questions took the form of a modified Likert scale (strongly agree, agree, partially agree, disagree, strongly disagree) to assess more nuanced attitudes by allowing respondents to express degrees of agreement rather than being limited to absolute categories. Traditional Likert scales with fewer response options might not capture subtleties in opinion, especially in areas such as quality improvement, where attitudes and experiences fall along a continuum rather than being positive or negative. By including "partially agree," respondents can indicate when they agree with some part of a statement but also have exceptions or reservations. This is particularly useful for patient safety surveys, where processes may be perceived as being partially effective but still require improvement [96]. The literature showed that researchers had used this modification with the aim of adjusting the scales to

better reflect the subjective interpretations of respondents, thereby improving the reliability and validity of the collected data [97].

Step 2: Input from methodology experts (pre-testing). Our goal was to develop a comprehensible and parsimonious set of questions with high face validity. We put particular emphasis on face validity in our study to ensure that the survey instrument is clear, relevant, and simple to understand for respondents. Since we are assessing the real-world practice of the PSLS, it was critical that healthcare professionals could easily understand the questions and identify their relevance to real reporting. Furthermore, a well-designed and straightforward survey draws more responses, reduces misinterpretations, and improves response accuracy. By first establishing face validity, we guaranteed that the tool was simple to apply and consistent with users' perceptions, thus establishing a good foundation for further extensive validity tests in future research.

Co-investigators were asked to review the questions to determine if their understanding of the questions met our goals. Reviewers were asked, for each question, whether we should accept the question as is, modify the question to enhance its comprehension or validity, or exclude the question. We resolved differences of opinion between co-investigators by consensus. The questionnaire was modified according to the pretesting results.

Step 3: Questionnaire testing in a representative sample of respondents (clinical sensibility and internal consistency). A cover letter was developed to communicate the rationale of the study, our objectives, why potential respondents were selected, and the estimated time needed to complete the questionnaire. The letter gave affirmation that the recipient's participation is confidential, anonymous, and imperative to the success of the study.

This step was concerned with measuring the clinical sensibility (necessity and clarity) of the questionnaire by seeking input from quality and safety (Q&S) managers and leaders at The Ottawa Hospital. The target population was all the Q&S experts employed at the hospital as nurses, physicians, and so forth, and with a role in managing patient safety events.

Participants were asked to answer the clinical sensibility check questions. These questions were developed based on prior work by Karen et al. [98] to assess the question's perceived utility and comprehensibility. We determined that questions should be modified or removed if more than 20% of respondents selected "no" to either "clear" or "necessary".

Simultaneously, the data needed for assessing the internal consistency was collected from the same participants. All participants were required to answer the entire questionnaire. Three follow-up emails were sent to the participants two weeks apart as reminders to answer the questionnaire. The survey was distributed by email using the hospital's internal network, which facilitated tracking of completion rates and analysis.

Data synthesis

After the questions were formulated by the main researcher in the first step, step 2 took place in which data was generated through pretesting. Four co-investigators provided feedback on each question. Any disagreements were resolved through discussion to reach consensus.

In the third step of the study, data was collected from the returned questionnaires. Two groups of data were generated: the first group was concerned with the clinical sensibility testing and according to their answers for each question, we determined the action to be taken (modify the question, keep it as is, remove it). The second group of data was used to test for internal consistency of the questions using the Cronbach's alpha score. This score ranges from 0 to 1; the closer it is to 1 the higher the internal consistency of the questions [99]. The results of this process were used to modify the questionnaire and finalize it.

Limitations

Patients and families were not involved in developing our PSLS self-assessment tool because the tool's focus is on organizational learning from safety events. This necessitates feedback from healthcare professionals who are familiar with reporting mechanisms and institutional safety culture. Although patient and family engagement is critical to broader safety initiatives, they are not privy to the internal reporting processes that are being evaluated here [100]. Furthermore, validated tools already exist to formally and separately assess patients' perspectives on safety, for example, the Patient Measure of Safety (PMOS) [101].

In conclusion, we developed a survey tool that after preliminary testing was deemed valid and reliable. This survey instrument helps to identify and prioritize perceived barriers and facilitators of the PSLS in hospitals. This tool can either be used by institutions, in an anonymous and confidential manner to enhance the transparency of the collected data, or used externally as a standardized tool to audit healthcare settings.

Objective 3: Assess PSLS Practices As Described by Executives in General Hospitals within a Publicly Funded Health System

- ***Research question:*** *What insights can be provided to decision-makers in Ontario regarding the strengths and challenges of the PSLS in their hospitals, considering the identified barriers and facilitators?*

Study design

A descriptive, cross-sectional survey was conducted using a pre-validated online structured questionnaire. The survey is reported in accordance with the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [102].

Sample selection

The quality or safety director, manager, or leaders in each of the selected hospitals were invited.

Settings

Only general hospitals with more than 100 beds and more than 10 ICU beds were selected.

Data collection

Survey questionnaire. A previously developed evidence-based structured questionnaire was used to assess various aspects such as awareness and utilization of the PSLS, reporting and analysis practices, integration of patient safety information, and barriers to implementation.

Data collection process. The survey questionnaire was administered electronically to the participants in the selected hospitals. A clear explanation of the study's purpose was provided to participants and confidentiality of their responses was pledged.

Data analysis

Descriptive analysis. The demographic data from the survey was analyzed descriptively using frequencies and percentages. We prioritized the PSLS-related barriers and facilitators in Ontario hospitals using median, mode, standard deviation, frequency, and percentage.

Inferential statistics. Chi-squared values were calculated to compare responses at the domain level and at the total questionnaire level for professional role, years of experience of the participant, and number of beds in the participating hospital.

We aimed for high transparency by ensuring confidentiality and anonymity of the data provided.

Ethical considerations

Participants were provided with detailed information about the study and their rights. Voluntary participation and the ability to withdraw from the study at any time was assured. All data collected is kept confidential and stored securely, and the results will be reported in an aggregated manner to maintain anonymity. The study protocol and survey

questionnaire were submitted and approved by the relevant Research Ethics Board prior to data collection.

Limitations

Sampling techniques. Obtained by purposive sampling, the sample might not be representative, affecting the generality of the results. Also, those who agreed to participate might have different characteristics or motivations compared to those who did not, affecting the study's validity.

Self-reported data. The survey relies on self-reported data, which might be subject to recall bias or social desirability.

Generality. Although efforts were made to select a diverse sample of hospitals, the findings might not be general to other healthcare settings or regions.

Conclusion

Ranking of the obstacles to the PSLS in Ontario hospitals was determined by self-ranking by Q&S experts who worked in those hospitals. The approach allowed the principal challenges to be determined directly from experts with firsthand experience of using and managing the PSLS. By ranking these obstacles in systematic order, the study aimed to highlight those most significant to useful learning in patient safety, presenting valuable insights for interventions and policy reform.

THESIS ORGANIZATION

This thesis is arranged into an article format, in accordance with the University of Ottawa doctoral thesis guidelines. A brief overview of each chapter is provided below:

- Chapter 1 provides an introduction to the topic and a rationale for the thesis.

- Chapter 2 represents the first study of the thesis, titled "Barriers and facilitators to improving patient safety learning systems: a systematic review of qualitative studies and meta-synthesis". A version of this chapter is published in *BMJ Open Quality*.

- Chapter 3 represents the second study of the thesis, titled "Development of a survey to support assessment of safety learning systems". A version of this chapter is published in *BMJ Open Quality*.

- Chapter 4 represents the third study of this thesis, titled "Quality leaders' survey of their patient safety learning system capability". A version of this chapter is in preparation for submission to a peer-reviewed journal.

- Chapter 5 provides a summary of the key findings from the studies presented in Chapters 2–4 and discusses the implications of the research in this thesis.

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CHAPTER 2

Barriers and facilitators to improving patient safety learning systems: a systematic review of qualitative studies and meta-synthesis

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Preface

This chapter details the rationale and planned methodology for a systematic review and meta-synthesis aimed to summarize the barriers and facilitators perceived by hospital staff and physicians to influence the reporting, analysis, learning and feedback within patient safety learning systems in hospitals.

Author Contributions

Hassan A. Mahmoud was responsible for the whole research at its different stages (protocol development, planning, screening of primary studies, extraction and analysis of data, writing, editing and publication. Alan J. Forster was the research supervisor responsible for planning, supervision, and revision of the final manuscript. Sunita Mulpuru, Kednapa Thavorn, and Daniel McIsaac participated in developing the protocol, revising and approving the analysis, writing the manuscript and revising each iteration of the manuscript. Amr A. Mahmoud and Mohamed A. Abdelrazek participated in the screening of primary studies, data extraction and analysis and in revising the manuscript.

ABSTRACT

Background: The implementation and continuous improvement of patient safety learning systems (PSLSs) is a principal strategy for mitigating preventable harm to patients. Although substantial efforts have sought to improve these systems, there is a need to more comprehensively understand critical success factors. This study aims to summarize the barriers and facilitators perceived by hospital staff and physicians to influence the reporting, analysis, learning, and feedback within PSLSs in hospitals.

Methods: We performed a systematic review and meta-synthesis by searching MEDLINE (Ovid), EMBASE (Ovid), CINAHL, Scopus, and Web of Science. We included English-language manuscripts of qualitative studies evaluating effectiveness of the PSLS and excluded studies evaluating specific individual adverse events, such as systems for tracking only medication side effects. We followed the Joanna Briggs Institute's methodology for qualitative systematic reviews.

Results: We extracted data from 22 studies, after screening 2475 against inclusion/exclusion criteria. The included studies focused on reporting aspects of the PSLS; however, there were important barriers and facilitators across the analysis, learning, and feedback phases. We identified the following barriers for effective use of a PSLS: inadequate organizational support with shortage of resources, lack of training, weak safety culture, lack of accountability, defective policies, blame and a punitive environment, complex system, lack of experience, and lack of feedback. We identified the following enabling factors: continuous training, a balance between accountability and responsibility, leaders as role models, anonymous reporting, user-friendly systems, well-structured analysis teams, and tangible improvement.

Conclusion: Multiple barriers and facilitators to the uptake of PSLSs exist. These factors should be considered by decision makers seeking to enhance the impact of a PSLS.

Keywords: Adverse events, barriers, facilitators, improvement factors, meta-synthesis, patient safety learning systems, systematic reviews.

BACKGROUND

Patient safety learning systems (PSLSs) support healthcare staff in documenting patient safety events and concerns, facilitate immediate corrective actions including communication, and promote the learning and improvement required to prevent future similar occurrences [1]. The use of PSLSs involves four related and sequential efforts [2]: 1) structured reporting, 2) collation of data, 3) analysis, and 4) learning from the reported incident [3]. In their 1999 report, the Institute of Medicine strongly recommended the use of incident reporting as a means to improve patient safety.

The success of PSLSs in improving patient safety is debatable [4], as errors and adverse events occur in all healthcare settings. It is also important to note that using the percentage of reported incidents as a measure of improvement after implementation of a PSLS might be unreliable as the true number of incidents (the denominator) is unknown because of underreporting [4]. Although there are no published reports demonstrating a reduction in the numbers of adverse events, many studies have evaluated the adoption of PSLSs [5]. These studies identified factors associated with improving the use of PSLSs, but tended to focus on the reporting of events rather than the factors improving the downstream actions of analysis and learning. As these later steps are the actions that will lead to improved safety, it is important that they are addressed in efforts to improve a PSLS [1]. To address this potential gap, we conducted a systematic review to identify the perceived barriers and facilitators for effective adoption of PSLSs in hospital settings. We assessed factors related to all phases of a PSLS, not just the reporting of events. A full description of all aspects of PSLSs will help design future studies, support our understanding of ways to

improve the effectiveness of PSLSs, and enable hospitals and health systems to assess their own efforts. To guide our qualitative evaluation, we meta-characterized factors based on the Patient Safety Toolkit developed by the Canadian Patient Safety Institute (CPSI; Figure 1) [6].

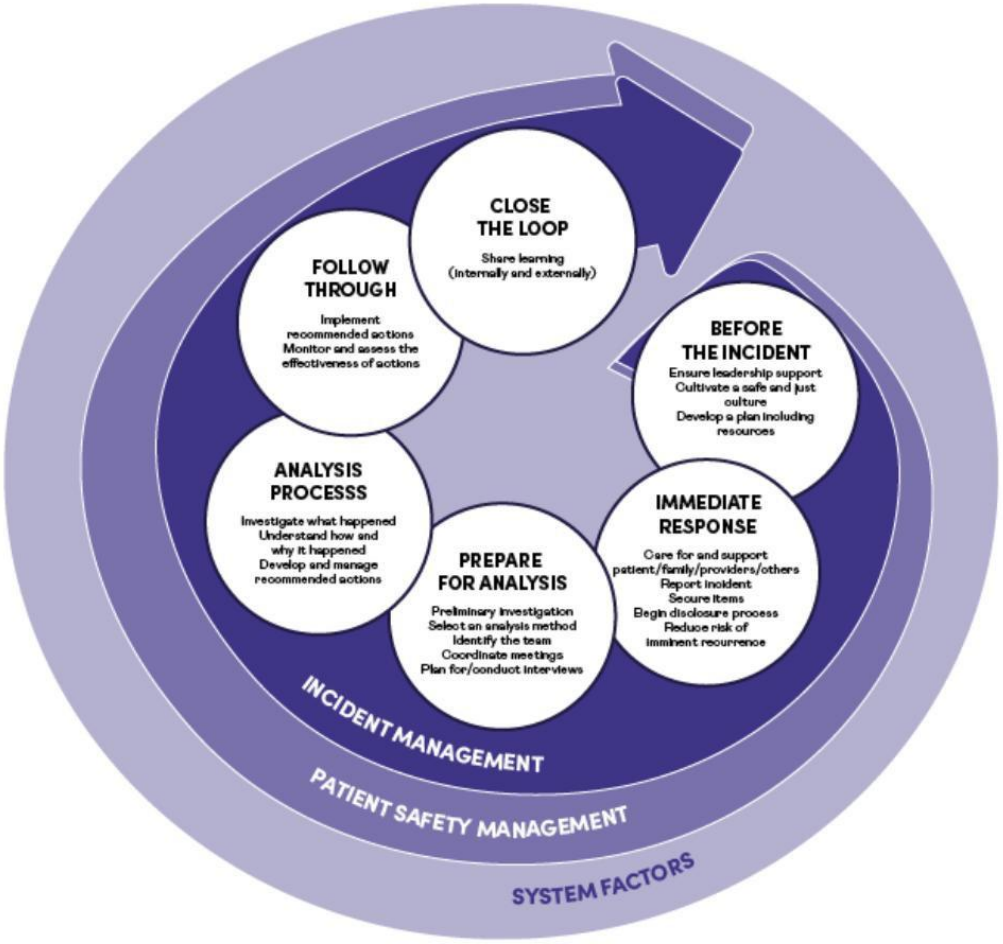

Figure 1. The steps of the CPSI's Patient Safety Management Toolkit. Reproduced from [6] with permission; copyright Healthcare Excellence Canada.

METHODS

To synthesize the large array of qualitative findings in the literature, we first identified an overarching conceptual framework for safety reporting and response. We then mapped the factors related to the barriers and facilitators to this framework. This inductive approach resulted in the development of emerging themes. A protocol was registered a priori (CRD42021220504) [7].

Search Strategy

An experienced medical librarian (Lindsey Sikora, University of Ottawa) was consulted to develop a search strategy. The strategy was piloted in MEDLINE (Ovid), and then translated to include EMBASE (Ovid), CINAHL, Scopus, and Web of Science. We manually searched Google Scholar, Grey Literature Reports, the CPSI, and the World Health Organization (WHO) for unpublished studies. The multifield search query we used in our study is shown in the Supplementary Information.

We used the PICO approach (suited to qualitative systematic reviews and meta-synthesis) for selecting our primary studies [8]. The participants in these studies were healthcare professionals and quality and safety experts. According to the criteria discussed below, we included qualitative studies that investigated the problem of the continuous occurrence of patient safety incidents and the factors perceived to be responsible for ineffective PSLSs.

Inclusion Criteria

Studies published in English and discussing the perceived barriers and/or facilitators to the use of PSLSs in hospitals were included. No restrictions on the type of incidents, demographic or geographic areas, sampling, or type of participant were applied.

Exclusion Criteria

We excluded studies that evaluated the effectiveness of PSLSs, those focused on a single incident and those examining the effect of a specific factor on PSLSs. Studies investigating the criteria for reporting incidents and the trends in doing so were also excluded.

Study Screening and Selection

Two reviewers (H.A.M. and M.A.A.) independently screened the titles, abstracts and full text (in that sequence) of citations using Covidence software [9]. Any disagreement between the two reviewers was resolved by discussion with a third reviewer (A.A.M.).

Data Extraction

Data were extracted into an Excel spreadsheet for analysis, including the following data points: study characteristics (authors, year of publication, journal); methodology (design, research purpose and/or questions, method of analysis); participant characteristics; country in which the study took place; setting; population descriptors; sample size; barriers, facilitators and conclusions reported. We used the qualitative assessment and review instrument (QARI) for the qualitative data extraction tool from the Joanna Briggs Institute (Supplementary Information) [10]. Data were extracted by one reviewer (H.A.M.), and the

second (M.A.A.) verified the extracted data. Disagreements were resolved through discussion with a third reviewer (A.A.M.).

Assessment of Methodological Quality

The purpose of assessing methodological quality for qualitative research is to describe the overall robustness and validity of the findings. It is not to be used to weight results or support the exclusion of studies as it is possible to find important themes from research with relatively weak designs. We therefore assessed quality using the Critical Appraisal Skills Programme (CASP) Qualitative Checklist (Supplementary Information) by two independent reviewers (H.A.M. and M.A.A.), and any disagreement was resolved through discussion with a third researcher (A.A.M.). However, this process did not lead to any studies being excluded from the analysis.

Guiding Framework

The Patient Safety Toolkit [6] is derived from the best available evidence and expert advice, and can be tailored to any healthcare setting. As such, we thought it might help us identify barriers to the success of a PSLS, and used it as a framework for summarizing our findings. This framework is comprehensive in that as well as including the four steps of PSLSs, it describes other aspects expected to influence the effectiveness of such systems, for example, those "before the incident", which include the organizational culture that encourages reporting and the support from the leadership. The incident management domain within the tool was used to develop our themes and subthemes.

Data Synthesis

Two reviewers (H.A.M. and M.A.A.) reviewed all articles to retrieve data describing the participants, study characteristics, and perceived barriers and facilitators. Directed analysis was done including identification and classification of extracted factors (barriers and/or facilitators), and assigning factors to themes and subthemes according to the CPSI Patient Safety Toolkit. These data were entered into separate spreadsheets. The results from the two reviewers were compared and differences were resolved by consensus with a third reviewer (A.A.M.). We then counted the number of factors identified within each subtheme to inform our narrative synthesis. After removing duplicates, these factors were analyzed and merged, and new definitions were developed. In the present report, the resulting synthesized factors are narrated and tabulated as a set of main findings [11].

RESULTS

Study Inclusion

A total of 3507 studies were identified from searched databases on February 1, 2021, leaving 2475 studies for title and abstract screening after removal of 1032 duplicates (Figure 2). Of these, 2352 studies were excluded according to the following criteria: the language was not English, they were review articles, or they had different study designs or outcomes. After assessment of the full texts, a further 101 articles were excluded: different study design (70 articles), different outcome (13), full text was not found (seven), different intervention (four) or setting (three), specific incident type (two), different indication (one), and conference report (one). After this exclusion process, we included 22 full-text articles.

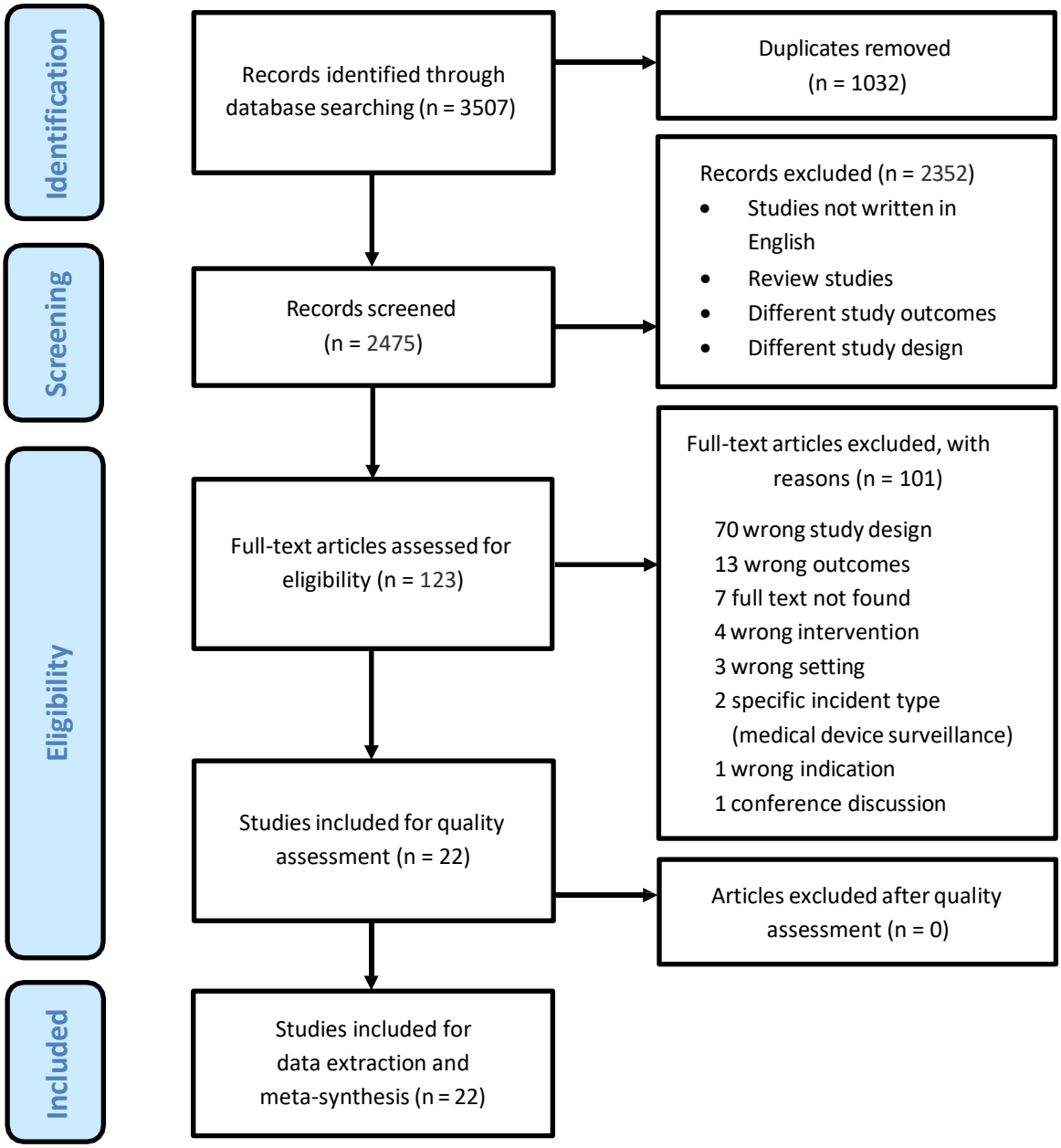

Figure 2. PRISMA 2020 flow diagram.

Study Characteristics

All studies included were published in 2010–2021, except for three [12–14]. Five were conducted in England [13,15–18], two in Australia [12,14], Canada [19,20], the USA [21,22], Brazil [23,24], and Iran [25,26], and one in the Netherlands [27], UAE [28], Sweden [29], Turkey [30], Qatar [31], and South Korea [32]. One included study was multinational [33]. All studies had been granted ethical approval.

No data were provided regarding the sex, age, or work experience of any of the participants. Participants in the 22 included studies were 781 healthcare professionals including 359 nurses from different medical, intensive care and surgical departments, 190 physicians, 49 pharmacists, 42 quality and safety managers, and five allied health professionals. The professions of the remaining 136 participants were not mentioned in three of the studies [17,23,24]. Studies were conducted in intensive care units [12], teaching hospitals [15,20,23,30,34], university hospitals [25], tertiary hospitals [22,31,32], large general public or community hospitals [13,14,17–19,24,29,31], and children's hospitals [21]; one of the studies involved participants from 111 hospitals [26].

In relation to sampling, eight studies used a purposive sampling technique [14,15,18,21,28–30,33]; two studies used purposive sampling and snowball sampling [20,31]; four studies used invitation letters [22,24,25,34]; the researchers of one study sought out their acquaintances by posting advertisements and using snowball sampling techniques [32]; one study used posters and nurse leader appeal in selecting their participants [12]; one study involved all nurses until saturation occurred [23]; four studies did not clearly describe their sampling methods [16,17,19,26].

Assessment of Methodological Quality

All of the included studies clearly described how they were conducted, but eight articles failed to clarify the researchers' relationships to the participants (Table 1) [12,13,19,20,22,23,29,31]. In relation to sampling, 11 of the 22 studies carried a risk of selection bias (the researchers selected their participants) and/or a risk of non-representative sampling [12,16,18,19,21–23,25,26,31,32]. One study included only less-experienced residents [22]. Two studies did not report how data saturation was defined or achieved [16,22]. There was no weight to specific questions nor a scoring system for the CASP Qualitative Checklist. As qualitative studies, we included all primary studies regardless of the quality of their methodology, as even methodologically sound studies can be poorly interpreted thereby offering insufficient insight in a particular topic; conversely, studies of lower quality may provide new insights. This heterogeneity contributed to the interpretation of the overall findings [35].

Summary of Study Findings

We extracted 375 reported factors from the 22 studies, all of which were either unequivocal or credible based on the participants' verbatim transcripts and researcher experience.

Six themes and 16 subthemes were developed based on the Patient Safety Toolkit and are outlined below and in Table 2. Factors under the theme "immediate response" were the most cited as perceived barriers to improving PSLSs, cited 170 times out of 375 reported

factors (45.3%). Its subthemes "reporting the incident", "secure items for confidentiality" and "care for reporter" were cited 98, 41 and 31 times, respectively. The theme "factors before the incident" was cited 134 times (35.7%) and included subthemes "training" (46 citations), "organizational and leadership support" (39), "cultivate just and safe culture" (28), and "availability of resources" (21). Other factors were reported less frequently; however, this does not necessarily indicate lesser importance, as all of the included studies were more focused on reporting procedures of the PSLS and less on the subsequent steps.

Table 1. A summary of the overall methodological quality of the included studies.

First author and year	Clear research aim?	Appropriate qualitative methodology?	Appropriate design?	Appropriate recruitment strategy to address the aim?	Appropriate method of data collection?	Researcher–participant relationship considered?	Ethical issues considered?	Rigorous data analysis?	Clear findings?	Valuable results?
Alqubaisi 2016	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anderson 2013	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Burns 2018	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Carlfjord 2018	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Elder 2008	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Hartnell 2012	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No
Hashemi 2012	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Hewitt 2017	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Howell 2017	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Kingston 2011	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Kingston 2004	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Lee 2018	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Martowirono 2012	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
McArdle 2003	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Nicolini 2011	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mirbaha 2015	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Siman 2017	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Soydemir 2017	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Stewart 2020	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Szymusiak 2020	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes
Varallo 2018	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Williams 2013	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes

Table 2. Identified themes and subthemes based on the CPSI safety tool kit, and their percentages.

Theme	Subtheme	Subtheme domain	Frequency	% of total	% within theme
Before the incident			134	35.7	
	Training		46		34.3
	Organizational and leadership support		39		29.1
	Just and safe culture		28		20.9
	Availability of resources		21		15.7
Immediate response			170	45.3	
	Care for reporter		31		18.2
	Confidentiality		41		24.1
	Reporting the incident		98		57.6
		User friendly	37		37.8*
		External and internal influencers	32		32.7*
		Incident characteristics	29		29.6*
Prepare for analysis			12	3.2	
	Preliminary investigation		5		41.7
	Appropriate analysis methods		0		
	Identify team		6		50.0
	Interview plan		1		8.3

Table 2 ***(continued)*****.** Identified themes and subthemes based on the CPSI safety tool kit, and their percentages.

Theme	Subtheme	Subtheme domain	Frequency	% of total	% within theme
Analysis process			12	3.2	
	Investigate what happened		5		41.7
	Understand why and how happened		1		8.3
	Develop and manage recommendations		6		50.0
Follow through			16	4.3	
	Implement		11		68.8
	Follow and assess		5		31.3
Close the loop			31	8.3	
	Share learn internally and externally		31		100
Total			375		

*The percentage of reported factors versus total number under the subtheme "reporting the incident".

Theme 1: Before the Incident (n=134)

Subtheme 1.1: Training

Training was examined by 16 studies [13–15,19–26,28,30,32–34], which identified a "lack of training"—of both reporters and managers—as a major barrier (46 of 134 responses, 34.3%). Facilitators included planning for and implementation of continuous training, which should be effectively communicated to staff and managers.

Subtheme 1.2: Organizational and leadership support

Factors related to organizational and leadership support were mentioned 39 times (29.1%) and included: lack of accountability that would make staff feel more responsible; ineffective reporting systems [19,20,24,25,33]; lack of definitions, policies or standards [14,18,19,21,26,32]; poor communication [19,26]; negative responses to reporting by leaders [13,18,22,26,30–32,34]; lack of authority [25] and role models [32]. Related facilitators included: incentives and initiatives to report more [31]; professional accountability and supportive atmospheres [19,20,25,28,29,33]; writing and dissemination of a guiding manual; increased confidentiality and security of the reporting process [14]; motivating staff to report through the display of posters [34]; eliminating blame by seniors or doctors [29,30].

Subtheme 1.3: Cultivate a just and safe culture

This subtheme was cited 28 times (20.9%). Barriers included a blaming and punitive culture [14,18,21–23,25,32]; an attitude of the administration for personalizing errors [30,34]; a lack of awareness about safety culture, which subsequently fostered a lack of responsibility and undervaluing the reporting system [14,30]; a defective culture unwilling to accept responsibility for errors [25]; a culture of low expectations, for example, "Well they’re in a hospital and things happen." [22]. Facilitators included balancing the need for responsibility and accountability [15]; building trust in a nonpunitive system by supporting the reporters, promoting peer reporting, anonymous reporting to an independent body [20,29,31]; belief that this promotes patient protection [19]; stimulating role of superiors [34].

***Subtheme 1.4:** Availability of resources*

Reported 21 times (15.7%), this subtheme comprised the following barriers: manual reporting systems or defective electronic systems that can be time consuming [18]; shortage of time and equipment for reporting [14–16,18,19,21,22,25,26,29,32]. Facilitators included carrying a pocket-size plasticized card that outlines the reporting process [34]; electronic systems together with human and financial resources [18,28,29]; the option of faster reporting processes (e.g., telephone reporting) [14].

Theme 2: Immediate Response to the Incident (n=170)

Subtheme 2.1: Reporting the incident

Factors in this subtheme were reported 98 times (57.6%) and were classified further into three categories: "user friendly" (reported 37 times, 37.8%), "external and internal reporter influencers" (32 times, 32.7%), and "incident related factors" (29 times, 29.6%).

Under the "user friendly" category, participants reported the following barriers: complex systems and forms asking for unnecessary data [13,14,16,18,19,22,24,28–30,33,34]; poor quality of the incident report [15]; reporting is time consuming [12,16,19,25,29,32,34]; limited access to forms [29]; the extra work burden on the reporter [19,32,34]; duplication of work being registered in patient files and in the PSLS or re-reporting by other staff [18,22,24]. Facilitators included profession-specific forms [14,18]; forms that balance the amount of information requested with time [18,19,29,34].

A second category is "internal and external influencers to report", which included the following barriers: juniors are afraid to report seniors' errors; seniors preventing juniors

from reporting; the norm that doctors never report but nurses should [12,18,20,28]; avoiding reports that might cause internal disputes [12,18,19,22,25,28,32]; negative attitudes to reporting (e.g., it is "a waste of time") [29,32,34]; reporting yields a feeling of failure [12]; the perception that reporting brings no personal benefit [12,19,25]; non-mandatory reporting [19,20,25]; a lack of perceived ability to report or that staff either do not think of reporting [34] or consider errors a normal part of daily events [30]. Facilitators included a belief in learning from errors [20], that this benefits patients [19,25] and showing commitment to adhering to policies [19].

A third category, "incident related factors", includes "seriousness of incidents regarding impact, consequences, severity and frequency", that is, the more serious incidents are more likely to be reported, whereas near misses are perceived to have less chance of being reported [12,18–25,29,30,32–34]; no clear cause for the error [24]. The facilitators included: focusing on reporting serious prioritized incidents, which allows better analysis and management [18,29]; errors with serious consequences and high frequency of occurrence influence reporting [25,32].

Subtheme 2.2: Care for and support for reporter

This subtheme was mentioned 31 times (18.2%) in the primary studies, 25 of which described barriers, including: "reporters feel worse, guilt, shame, uncertainty, disloyal to colleagues and emotionally charged"; a lack of a supporting managers [12,13,18,21,22,24,30,32,34]; the feeling that reporting the error might cause loss of honor, respect, reputation and dignity along with perceived incompetence [19–21,25]; inappropriate responses by managers [21,25]. Six facilitators included protecting reporters against legal and non-legal actions [14,19].

Subtheme 2.3: Confidentiality

This subtheme was reported 41 times (24.1%) and some barriers were directly related to "breach of confidentiality that might cause loss of reputation, career, relationships, friendships, and respect" [12,13,15,16,19,20,28,30]; "fear of blame or punishment or legal action" [12,13,16,19,20,22,25,26,29,30,34]; "lack of anonymity and lack of trust in system confidentiality" [18–20,22,25,32]; "fear of economic losses" [25]. Confidentiality and anonymous reporting to independent bodies have been repeatedly reported as positive system influencers [18,21,31,34].

Theme 3: Prepare for Analysis (n=12)

Subtheme 3.1: Preliminary investigation

Factors related to preliminary investigations were mentioned five times, always as barriers, such as lack of time and resources [15] and poor communication [18]. Furthermore, anonymity was cited as making information about the incident more difficult to obtain [17,32].

Subtheme 3.2: Identify team

Factors related to "identify team" were cited six times, and included the following barriers: lack of front-line engagement [15]; complex organizations, in which it is difficult to assemble the appropriate team [15,17]; lack of cooperation between units related to the incident [29]. Building fully representative teams was reported as an aspect that might improve PSLSs [31].

Subtheme 3.3: Plan for interview

In thinking about planning for incident-related interviews, participants only reported fearing loss of reputation as a barrier for participation [17].

Theme 4: Analysis Process (n=12)

Subtheme 4.1: Investigate what happened

One barrier and four facilitators were related to investigation: mass reporting might interfere with accurate analysis and capacity for learning [33]; "multidisciplinary meetings ensure equal and fair participation" [17]; applying tools and analytical approaches, avoiding analytical myopia [15,17], and to have open communication [40].

Subtheme 4.2: Understand why and how it happened

This subtheme was represented only by one facilitator of PSLSs: use of proper analysis tools [27].

Subtheme 4.3: Develop and manage recommendations

Factors in this subtheme were reported six times, including poor-quality recommendations such as "too much details or too simple" [24], contradictions with other change agendas and initiatives [26]. "Avoid giving undue attention to the report" [26] was reported as a facilitator.

Theme 5: Follow Through (n=16)

Subtheme 5.1: Implement

Reported 11 times, this subtheme includes a lack of effective measures that make tangible changes [22,24,29,34] and also time-consuming recommendations [29], difficult to implement recommendations [32], existence of plans that contradict recommendations [26]. Visible change was reported as a facilitator [18].

Subtheme 5.2: Follow and assess

Factors in this subtheme were reported five times, four of which were facilitators. Two of these were the use of risk-assessment tools to prioritize actions for follow-up [14] and formal (e.g., targets, audits and score cards) and informal (keeping to meeting agenda, management oversight, risk-officer spot-checks) performance management for evaluating changes [15]. Only one barrier was reported under this subtheme: data processing does not reflect the real number of reports due to underreporting [23].

Theme 6: Close the Loop (n=31)

This theme was reported 31 times (8.3%) and includes only one subtheme "share learning internally and externally". The barriers are lack of or defective feedback resulting in erosion of trust in the system [12–14,16,22,24,26,28,32,34]. Facilitators include: feedback mechanisms that motivate reporting [15,18,19,29]; improving error-related communication from senior management to healthcare professionals [19]; to "definitely collect less data of better quality of learning and feedback"; to "share learning horizontally (with peers), and also for vertical accountability" [33]; transparency in sharing data [21]; the type and timing

of feedback depend on the severity of the incident or the degree of risk to the organization; individual and group feedback about action taken will increase trust in the system [14].

DISCUSSION

In this systematic review, we identified all PSLS barriers and facilitators reported in the literature. In those studies, recommendations were reported by participants encountering such barriers. The results also revealed the participants' perceptions of how these barriers might prevent improvement of the system. By including all the aforementioned factors and recommendations, managers and other decision makers have a wide range of options for taking innovative actions to improve their safety systems.

We included 22 primary studies. We sorted the reported factors (barriers and facilitators) into themes based on a framework derived from the CPSI Patient Safety Toolkit. Facilitators and barriers related to "before the incident" included the preparedness of a hospital to implement a PSLS through planning, training, assignment of resources, a well-established safety culture that focuses on systems not people and ensures top-level commitment and support, and well-developed policies and procedures. Related to "the immediate response", some studies recommended that hospitals support reporters emotionally and against legal action. Factors related to "analysis process" and "follow through" included having a well-trained multidisciplinary team to ensure high-quality investigations of safety incidents. Analysis should start with the selection of the most appropriate analytical approaches, followed by investigating the incident and development and implementation of smart recommendations that make tangible system changes. Factors related to "closing the loop" included providing timely feedback to reporters and sharing

results of the analysis internally with other departments as well as externally with other hospitals to facilitate learning on a wider scale.

Our results are consistent with other systematic review studies; however, we identified a gap in the research—the predominant focus is the reporting stage, leaving the subsequent stages of the learning system neglected. Vrbnjak et al. stated that "a non-blaming, non-punitive and non-fearful learning culture" is needed to encourage incident reporting. They grouped most of the system barriers into three main areas: the efficiency of the reporting system, management behavior, and staff education [36]. In 2015, Health Quality Ontario identified the barriers and facilitators of PSLSs, all of which are consistent with our results, including a non-accusatory environment, improving safety culture, training, enhanced transparency and effective feedback, role models (such as managers), protecting reporters, anonymous reporting, and clear operational policies. Barriers identified for other steps of PSLSs have been derived from the WHO guidelines and not primary studies [37]. Similar findings by other studies include a blame-free culture, clear guidelines on how and what to report, user-friendly systems, organizational support for data analysis to generate meaningful learning outcomes, and multiple mechanisms to provide feedback through routes to reporters and the wider community [6,37,38].

Gaps in the Research

It is important to note that identified barriers to the reporting stage are also pertinent to the three themes not addressed in 19 of our included studies [12–14,16,18–25,28,30–34,39]: "prepare for analysis", "analysis process", and "follow up". These include a lack of time, resources and training for analysis, and a lack of direct communication between responsible

departments. Under these circumstances, developing analysis teams is difficult, especially in complex organizations. Also, staff are unwilling to participate in these teams because they are afraid of losing reputation. The corresponding facilitator to these barriers is to bridge the gap in communication by holding regular meetings and structuring well-represented teams with front-line engagement and top-level commitment. A newly reported barrier was related to the anonymity of the system, making it difficult to clarify incidents for which data is missing. Modifying an electronic system to not accept incomplete reports was suggested to overcome this barrier [40]. It is also important to mention the problem of underreporting and its effect on the accuracy of data processing with subsequent failure of follow-up. This can be improved through audits, use of performance scorecards, and spot checks.

Participants did not reveal any barriers or facilitators under the "select appropriate analysis method" subtheme. This can be attributed to it being outside the scope of the included studies.

Strengths and Limitations

Our study is unique as it included a variety of safety incidents including medication- and device-related incidents. As it is more comprehensive than prior published studies, its results are more applicable to the common setting of a general hospital with a need to track all patient safety events. Our review included 22 primary studies with 781 participants, making it the largest published review on this topic, increasing the likelihood we have not omitted important published information. In addition, the participants represent different departments in hospitals, further increasing the general applicability of our findings.

Furthermore, the included studies were done in geographically and economically diverse countries, representing both the developed and the developing world. We included only qualitative studies that increased the likelihood that participants would express their concerns about the system, which was reflected in the number of perceived system barriers and facilitators. We ensured valid results by including studies with high-quality methodology. Although nine of the 22 studies involved relationships between the researchers and the participants with a risk of selection bias, no potential bias in their studies was reported [25].

One limitation of our study relates to the selection methods of the included studies. More than half of the included studies selected participants non-representative of the healthcare worker population, that is, either only doctors [13,16,34] or only nurses [12,21,25], or residents. This potentially limits the generality of each study's conclusions. However, taking the totality of findings across all studies and the consistency of the findings, we are confident our results are valid. Another limitation was an inability to perform subgroup analyses based on healthcare worker characteristics (e.g., age, sex, occupation and years of experience of the participants) as studies did not consistently provide that information. Given our findings, we do not feel this limits our conclusions.

Finally, this study is based on what hospital staff perceive as factors affecting PSLSs as opposed to actual quantifiable effects. This is a limitation of the existing knowledgebase that needs to be addressed in future studies.

CONCLUSION

Our review found that most studies on the effectiveness of PSLSs relate to aspects "before the incident" and the "immediate response". Themes related to investigations, follow-through, and "closing the loop" have received less attention, and it is likely that health systems have spent less time considering them. As it is these stages that lead to improvements in safety, it is not surprising that PSLSs have not achieved the desired success. We recommend that researchers, safety leaders, and health system policy makers focus more of their attention on these aspects of PSLSs.

Author Contributions

H.A.M. was responsible for the whole research at its different stages (protocol development, planning, screening of primary studies, extraction and analysis of data, writing, editing and publication. A.J.F. was the research supervisor responsible for planning, supervision, and revision of the final manuscript. S.M., K.T. and D.M. all participated in developing the protocol, revising and approving the analysis, writing the manuscript and revising the various iterations of the manuscript. A.A.M. and M.A.A. both participated in the screening of primary studies, data extraction and analysis and in revising the manuscript.

Competing Interests

The authors declare no competing interests.

Ethics and Dissemination

No formal ethical approval or consent were required as no primary data were collected.

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SUPPLEMENTARY INFORMATION

The multifield search query was: ((((TITLE-ABS-KEY(quality AND improvement*)) OR (TITLE-ABS-KEY(quality AND control*)) OR (TITLE-ABS-KEY(quality AND assurance*)) OR (TITLE-ABS-KEY(policy*)) OR (TITLE-ABS-KEY(program AND evaluation*))) OR ((TITLE-ABS-KEY(system AND improvement*)) OR (TITLE-ABS-KEY(influencing AND factors*)) OR (TITLE-ABS-KEY(barriers*)) OR (TITLE-ABS-KEY(facilitators*)) OR (TITLE-ABS-KEY(improvement AND factors*)))) AND ((TITLE-ABS-KEY(surveys* AND questionnaires*)) OR (TITLE-ABS-KEY(behavior*)) OR (TITLE-ABS-KEY(self AND concept*)) OR (TITLE-ABS-KEY(self AND concept*)) OR (TITLE-ABS-KEY(work AND experience*)) OR (TITLE-ABS-KEY(personal AND experience*)) OR (TITLE-ABS-KEY(experience*)) OR (TITLE-ABS-KEY(health AND personnel AND attitude*))) AND ((TITLE-ABS-KEY(safety AND incidents*)) OR ((TITLE-ABS-KEY(near AND miss*)) OR (TITLE-ABS-KEY(medication AND errors*)) OR (TITLE-ABS-KEY(medical AND errors*)) OR (TITLE-ABS-KEY(sentinel AND surveillance*)))) AND ((TITLE-ABS-KEY(incident AND reporting AND system*)) OR (TITLE-ABS-KEY(patient AND safety AND learning AND system*)) OR (TITLE-ABS-KEY(prevention AND strategies*)) OR ((TITLE-ABS-KEY(safety AND management*)) OR (TITLE-ABS-KEY(risk AND management*)) OR (TITLE-ABS-KEY(patient AND safety*)) OR (TITLE-ABS-KEY(adverse AND drug AND reaction AND reporting AND systems*))))) AND (TITLE-ABS-KEY(hospital*)).

JBI QARI Data Extraction Tool for Qualitative Research

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Study Description

Methodology

Method

Phenomena of interest

Setting

Geographical

Cultural

Participants

Data analysis

Authors conclusions

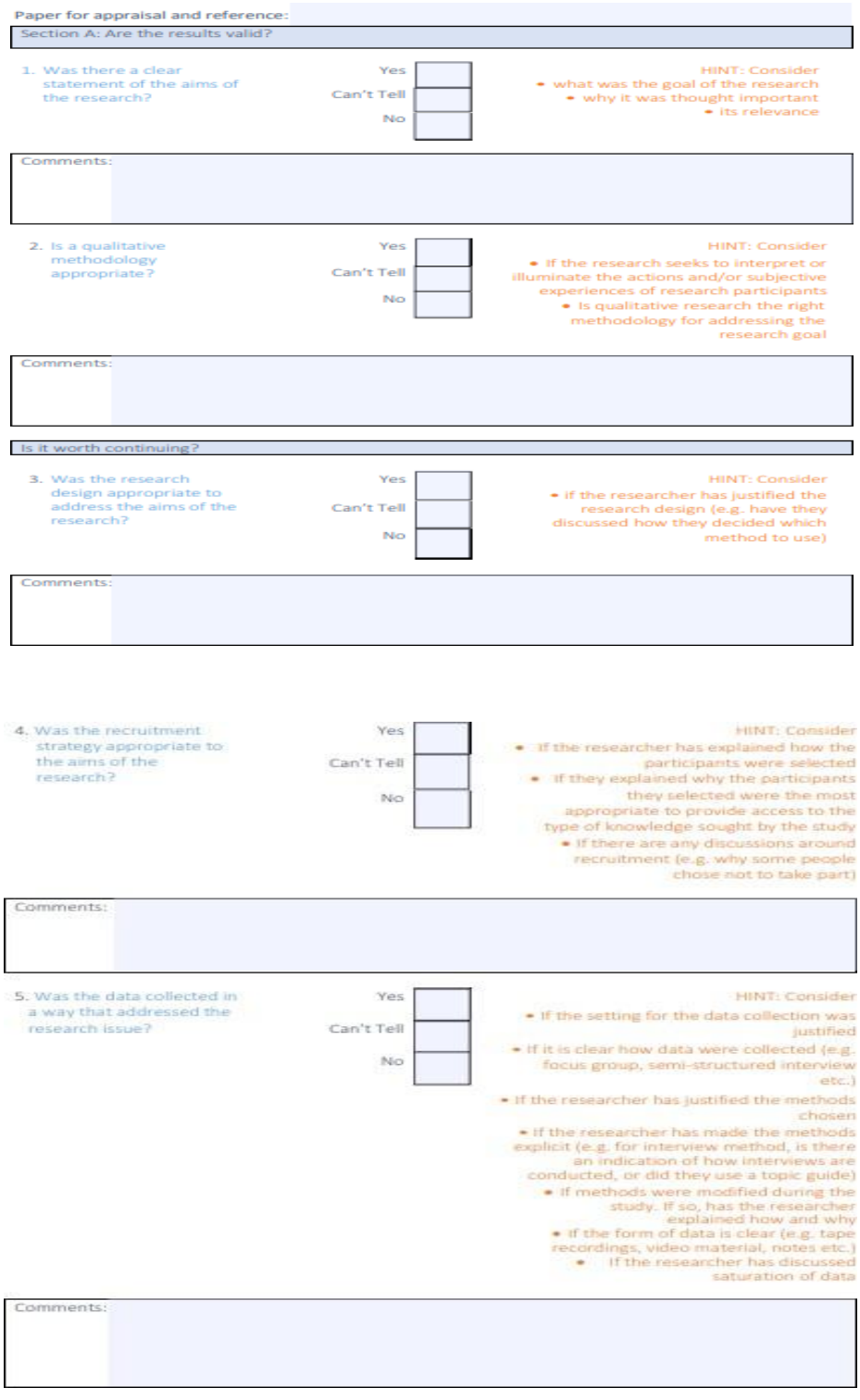
Comments

Complete Yes ☐ No ☐

Findings	Illustration form Publication (page number)	Evidence		
		Unequivocal	Credible	Unsupported

Extraction of findings complete Yes ☐ No ☐

CASP Qualitative Checklist



Paper for appraisal and reference:

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- If the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments:

4. Was the recruitment strategy appropriate to the aims of the research?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments:

5. Was the data collected in a way that addressed the research issue?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments:

6. Has the relationship between researcher and participants been adequately considered?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments:

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments:

8. Was the data analysis sufficiently rigorous?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments:

9. Is there a clear statement of findings?

Yes ☐
Can't Tell ☐
No ☐

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments:

Section C: Will the results help locally?

10. How valuable is the research?

HINT: Consider
- If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature
- If they identify new areas where research is necessary
- If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:

CHAPTER 3

Development of a survey to support assessment of safety learning systems

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Preface

This chapter details the rationale and planned methodology for development of a self-assessment survey tool aimed to assess an organization's approach to learning from safety events.

Author Contributions

Hassan A. Mahmoud was involved in the design and implementation of the study, data analysis, writing and interpretation of the study. Alan J. Forster was the research supervisor responsible for planning, supervision, and revision of the final manuscript. Sunita Mulpuru was involved in pretesting step of the survey development, the analysis of the data, review of the article and revisions. Kednapa Thavorn was involved in the development of the

protocol, pretesting step of the study, revision and approval of the analysis, and revision of each iteration of the manuscript.

ABSTRACT

Background: Patient safety learning systems play a critical role in supporting safety culture in healthcare organizations. A lack of explicit standards leads to inconsistent implementation across organizations, causing uncertainty about their roles and impact. Organizations can address inconsistent implementation by using a self-assessment tool based on agreed-upon best practices. Therefore, we aimed to create a survey instrument to assess an organization's approach to learning from safety events.

Methods: The foundation for this work was a recent systematic review that defined features associated with the performance of a safety learning system. We organized these features into themes and rephrased them into questions (items). Face validity was checked, which included independent pre-testing to ensure comprehensibility and parsimony. It also included clinical sensibility testing in which a representative sample of leaders in quality at a large teaching hospital (The Ottawa Hospital) answered two questions to judge each item for clarity and necessity. If more than 20% of respondents judged a question unclear or unnecessary, we modified or removed that question accordingly. Finally, we checked the internal consistency of the questionnaire using Cronbach's alpha.

Results: We initially developed a 47-item questionnaire based on a prior systematic review. Pre-testing resulted in the modification of 15 of the questions; two were removed, and two questions were added to ensure comprehensiveness and relevance. Face validity was assessed through yes/no responses, with over 80% of respondents confirming the clarity and 85% the necessity of each question, leading to the retention of all 47 questions. Data collected from the five-point responses (strongly disagree to strongly agree) for each

question were used to assess the questionnaire's internal consistency. The Cronbach's alpha was 0.94, indicating high internal consistency.

Conclusion: This self-assessment questionnaire is evidence-based and upon preliminary testing is deemed valid, comprehensible, and reliable. Future work should assess the range of survey responses in a large sample of respondents from different hospitals.

Keywords: Barriers, clinical sensibility, facilitators, patient safety learning systems, pre-testing, self-assessment questionnaires.

BACKGROUND

Many healthcare systems and accrediting bodies require institutions to implement a patient safety learning system (PSLS) [1,2] to track patient safety incidents, the learnings arising from them, and completion of actions to mitigate or prevent similar events in the future [3]. A PSLS typically includes a digital platform and associated policies and procedures to support reporting, investigating, learning, and improving following an unsafe act and/or patient harm. The premise underlying PSLSs is that errors and harmful events might re-occur if predisposing factors are not addressed [4]. They also contribute to a culture of safety by creating the expectation that events are followed and acted upon in a fair and transparent manner [5,6].

Although most hospitals and accrediting bodies have adopted and promoted the use of PSLSs, their value is a subject of debate [7]. Indeed, multiple failures in their implementation and use could be detrimental; for example, failure to report events, investigate and learn from them, and, most importantly, failure to act to prevent them [8,9,10]. We recently performed a systematic review to identify the features associated with effective use of PSLSs [11]. These features were classified according to the stages of the PSLS derived from the Patient Safety and Incident Management Toolkit [12]. Most of included literature focuses on the reporting and feedback of incidents; event analysis and mechanisms to support learning were less prominent [11]. That literature might reflect actual practice in which organizations spend more time collecting data rather than developing action plans for improving [13]. Furthermore, we documented the variability in the PSLS factors evaluated, which likely reflects an underlying inconsistency in how organizations implemented their PSLS [11]. Thus, it seems plausible that the effectiveness

of PSLSs might result from a combination of local factors [10], in addition to generic factors. These generic factors include cultural factors (e.g., lack of safety culture), educational factors (e.g., lack of training on the PSLS and statistical analysis), governing and regulatory bodies (e.g., legislation that supports reporting and protects reporters) [11,14]. To deepen our understanding of the impact of a PSLS, a unified approach is crucial for evaluating the complete range of activities required after a safety event. Currently, there is a notable paucity of validated and reliable tools for hospitals to self-assess the effectiveness of their PSLS at various stages [15]. This highlights the urgent need to create a high-quality, evidence-based, standardized survey tool specifically designed for evaluating a PSLS.

This chapter outlines the creation of such a tool and was intended for diverse applications, whether by individual hospitals, entire health systems, or researchers. With this tool, hospitals and health systems can pinpoint areas of their PSLS needing enhancement, while researchers can assess the effectiveness of PSLS programs across the board.

METHODS

Overview

Our work consisted of three steps (Figure 1). First, based on our previous systematic review, we developed questions pertaining to the specific barriers and facilitators of PSLS effectiveness. Next, patient safety and methodologic experts (A.J.F., D.M., S.M., K.T.) reviewed the questions for their comprehensibility and perceived importance. Third, we tested the questions on a representative sample of staff members responsible for aspects of

patient safety at a single teaching hospital in Ottawa, Ontario, Canada (The Ottawa Hospital). The Research Ethics Board at The Ottawa Hospital [OHSN-REB number: 20210441-01H (2658)] approved the protocol. Patient and public involvement was outside of the scope of this study.

Step 1: Establishing Candidate Questions and Their Response Variables

We developed the questionnaire using findings from our systematic review, which identified 68 factors associated with PSLSs [11]. We organized the questions into the same domains and sub-domains used in the review, which were derived from the Canadian Patient Safety Institute's Patient Safety and Incident Management Toolkit [12].

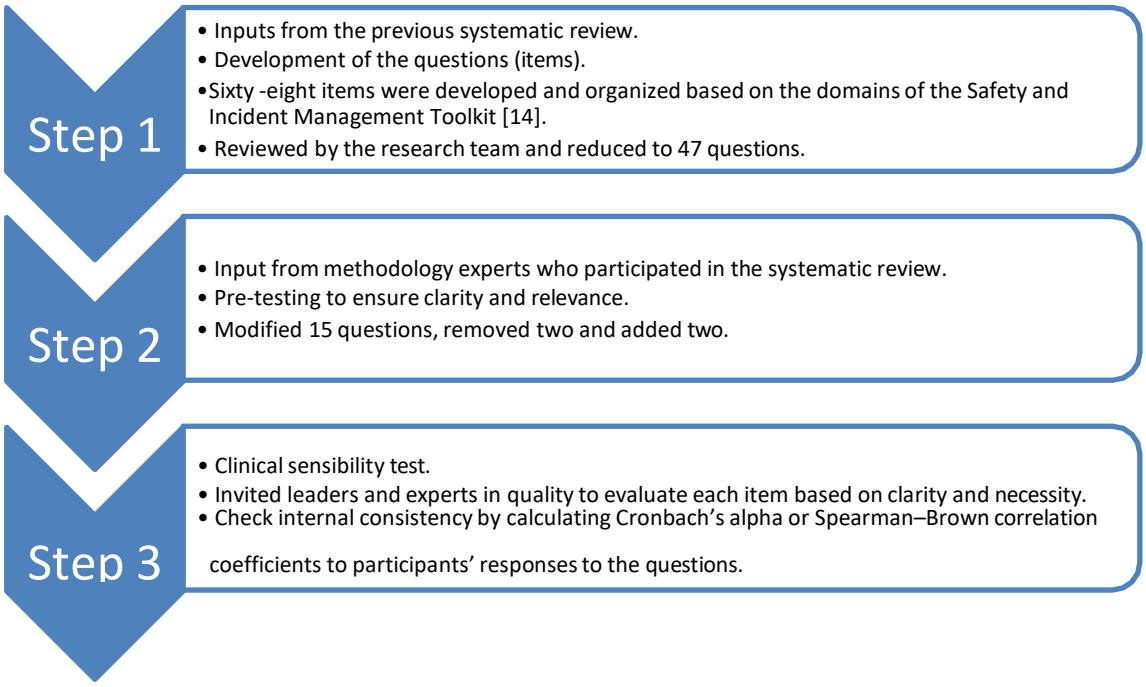

Figure 1. Flow chart showing the steps taken to develop and validate the questionnaire.

We used an iterative approach to develop the questionnaire, carefully refining questions to eliminate redundancy. To that end, we collected different questions that evaluate same area or process in the PSLS together, then formulated single comprehensive statements to address them. This process reduced the initial 68 statements to 47 questions for evaluation. We chose a five-point response scale (strongly disagree, disagree, partially agree, agree, strongly agree) to allow accurate PSLS assessment and to help participants better understand the questions' intent.

Step 2: Input from Methodology Experts (Pre-testing)

To ensure the clarity and relevance of the questions together with their response variables, we invited three health services researchers who participated in the systematic review to assess them independently. Using an online tool, each reviewer provided feedback on the relevance and clarity of every question. To simplify their input, they indicated whether the question should be included in the final survey tool using the following responses: "no", "uncertain", "yes, with modification" or "yes, as is". The reviewers were asked to ground their responses such that "no" meant no relevance or poor clarity, and "yes" meant high relevance and clarity. If two reviewers or more rated the relevance of a statement "no", the statement was removed from the draft. If the reviewer rated "yes, with modification" they were asked to suggest new wording for consideration by the research team. If two or more rated "uncertain", they were contacted for clarification and the sentence was edited. The research team met to discuss the feedback and make changes accordingly. We also asked the researchers to determine the target group—either quality and safety (Q&S) managers and leaders or frontline workers—for each question to ensure precise and accurate results.

Step 3: Questionnaire testing in a representative sample of respondents (clinical sensibility and internal consistency)

This step assessed the necessity, clarity, and the internal consistency of the questionnaire by seeking input from Q&S managers and leaders at The Ottawa Hospital. We identified all the Q&S experts employed at the hospital as nurses, physicians, and so forth, and with a role in managing patient safety events, and invited them to participate in the study (N=56). All participants were expected to be aware of the Q&S management activities at the hospital and were required to answer the entire questionnaire. We sent all participants a letter detailing our study objectives and emphasized that their participation was voluntary, anonymous, and would not impact their employment. Three follow-up emails were sent two weeks apart to the participants as reminders to answer the questionnaire. Participants were not compensated for answering the questionnaire. The survey (LimeSurvey) was distributed using the hospital's internal network, which facilitated tracking of completion rates and analysis.

We asked the experts to answer each survey question about the hospital by selecting one response. These data were used to measure the internal consistency of the questionnaire rather than evaluating the hospital's PSLS. They were also asked to answer the two clinical sensibility check questions ("Do you find the question easy to understand (clear)?" and "Do you think this question is important (necessary)?") by choosing either "yes" or "no" for each question. We developed these two questions (based on prior work by Karen et al. [16]) to assess the question's perceived utility and comprehensibility. We determined that questions should be modified or removed if more than 20% of respondents selected "no" for "clear" or "necessary", respectively. We determined this threshold based on experts' and

researchers' feedback to strike a balance between addressing potential issues and avoiding unnecessary changes that could impact the validity of the survey results.

Statistical Analysis

We report the frequencies and descriptive statistics for all questions in the survey. We assessed the internal consistency for the whole questionnaire and at the domain level using the Cronbach's alpha coefficient. This is a test that measures the internal consistency, or reliability, of a set of survey items. We used this statistic to help determine whether a collection of items consistently measures the same underlying concept [17]. It quantifies the level of agreement on a standardized 0 to 1 scale. It is also important to note that Cronbach's alpha underestimates the reliability of domains having two questions; for those we used the Spearman–Brown correlation coefficient [18]. For both tests, we considered values of 0.7 or greater to be reliable [18]. All statistical analysis was conducted using Microsoft Excel version 16.

RESULTS

Step 1

From the 68 factors identified in a previous systematic review [11], we developed a questionnaire consisting of 47 statements. These questions were organized within the domains and subdomains of the Patient Safety and Incident Management Tool Kit (Figure 2) [12].

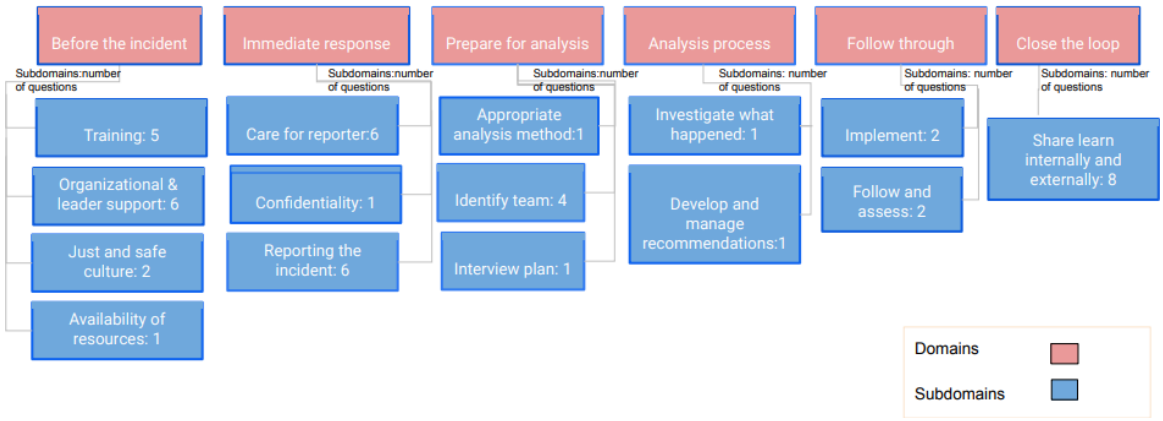

Figure 2. The domains, subdomains and the number of questions under each subdomain.

We also thought it important to know the number of years of experience and place of work as these might affect our interpretation of the answers and subsequently the development of the recommendations. Accordingly, we added "Section A: Demographics" to the questionnaire (Table 1).

Step 2

Based on the feedback from the three researchers all the questionnaire items were relevant. Clarity assessment resulted in the following modification of the questionnaire: 15 questions were edited, four of which were rated "uncertain" by two of the researchers and 11 were rated "yes (with modification)" by one or more; two questions were removed; two questions were added. The reviewers also reported that all 47 questions were appropriate to be answered by the Q&S managers and leaders, whereas frontline workers could only answer 30 of these questions (Table 1). At the end of this step, there were 47 statements in the questionnaire in addition to four demographic questions that all participants were required to answer.

Step 3

Of the 56 employees who have a role in managing patient safety events at The Ottawa Hospital, we received complete responses from 20 (36%), whereas 19 (34%) provided incomplete responses, and 17 (30%) did not participate in the study. We considered only the "complete responders" as our respondents. Respondents were doctors (n=11; 55%), nurses (n=3; 15%), engineers (n=2; 10%), pharmacists (n=1; 5%), physiotherapists (n=1; 5%), and quality coordinators (n=2; 10%). Their years of experience in Q&S varied between 1 and 25 years, with an average of 4.35 years (SD=4.72).

Regarding clarity and necessity, no question exceeded the threshold of 20% negative responses, thus all were adjudged clear and necessary (Table 1). Two questions received low scores (<90%) for clarity: "I must report the same incident using different approaches. (e.g., patient files, nursing reporting system, safety department)" was rated "unclear" by only three participants, whereas the second question "The management has a defined communication approach to share learning externally" was rated "unclear" by four participants. The two questions that received the lowest scores for necessity were "Management ensures analysis teams are composed of representative expertise" and "The management has a defined communication approach to share learning internally". Both were reported "unnecessary" by three participants.

Table 1. The PSLS self-assessment questionnaire and participants' assessment of questions' clarity and importance, and the percentage of their rating for the PSLS in The Ottawa Hospital (N=20).

Section A: Demographics	1. Institution 2. Position title (quality and safety role) 3. What is your professional designation? 4. Years of experience			
Section B: Domains	Questions/responses**	Comprehension = clear? Yes, n (%)	Importance = necessary? Yes, n (%)	No. respondents that partially agree, agree, strongly agree (%). N=20
a. Before the incident	5. I received training on our patient SLS at least once during my employment.	19 (95)	20 (100)	N/A
	6. It should be my responsibility to undergo re-training on the SLS periodically.	18 (90)	19 (95)	18 (90)
	7. My training on reporting and/or analyzing incidents was effective in preparing to fulfill my responsibilities.	18 (90)	20 (100)	16 (80)
	8. Training material describes how to classify safety events in terms of their severity and recurrence risk.	19 (95)	20 (100)	16 (80)
	9. The training plan for SLS is well-developed, monitored and tailored to each member of staff according to their role in the system.	19 (95)	19 (95)	12 (60)
	10. I have access to all policies and procedures related to the SLS.	19 (95)	19 (95)	15 (75)
	11. The policies and procedures related to the SLS are easy to understand.	20 (100)	20 (100)	15 (75)
	12. I am recognized positively for reporting safety events by my supervisor or leader.	20 (100)	19 (95)	19 (95)
	13. Hospital leadership provides rewards and incentives to encourage safety event reporting.	20 (100)	19 (95)	11 (55)
	14. The reporting system prevents individuals from being unfairly blamed for making errors.	20 (100)	19 (95)	15 (75)
	*15. Managers regularly review and update system related policies and procedures.	19 (95)	20 (100)	19 (95)
	16. I believe reporting incidents is my responsibility as it will lead to preventing future events.	19 (95)	19 (95)	20 (100)
	17. The SLS is integrated in everyday work to ensure high compliance.	19 (95)	19 (95)	14 (70)
	*18. Management allocates sufficient resources for reporting, analysis and investigating incidents.	20 (100)	20 (100)	17 (85)
b. Immediate response	19. I must report the same incident using different approaches (e.g., patient files, nursing reporting system, safety department).	17 (85)	18 (90)	17 (85)
	20. Reporting incidents have never caused troubles with my colleagues and is viewed favorably within my unit's culture.	20 (100)	20 (100)	15 (75)

Table 1 ***(continued)*****.** The PSLS self-assessment questionnaire and participants' assessment of questions' clarity and importance, and the percentage of their rating for the PSLS in The Ottawa Hospital (N=20).

Section B: Domains	Questions/responses**	Comprehension = clear? Yes, n (%)	Importance = necessary? Yes, n (%)	No. respondents that partially agree, agree, strongly agree (%). N=20
b. Immediate response *(cont'd.)*	*21. Managers and leaders have the authority to support reporters.	19 (95)	18 (90)	18 (90)
	22. Policies and protocols support the non-punitive reporting environment.	19 (95)	19 (95)	20 (100)
	23. There are policies and protocols to protect reporters against legal and non-legal actions.	19 (95)	19 (95)	14 (70)
	24. The hospital requires reporting to an independent body to avoid blaming and enhance fair analysis.	18 (90)	18 (90)	14 (70)
	25. I have no concern about confidentiality when I complete the incident report forms.	20 (100)	20 (100)	19 (95)
	26. All staff have access to an electronic system for reporting safety events.	19 (95)	19 (95)	8 (40)
	27. I have alternative reporting options to enhance efficiency, such as telephone reporting, manual and electronic reporting.	19 (95)	18 (90)	19 (95)
	28. Incident review forms are self-explanatory and time efficient to complete.	20 (100)	20 (100)	18 (90)
	29. I understand that Incident reporting is the responsibility of the person who witnessed the event and should not be delegated.	19 (95)	18 (90)	12 (60)
	30. Incident reporting is mandatory.	20 (100)	19 (95)	11 (55)
	*31. The hospital has a list of prioritized incidents to be reported.	19 (95)	19 (95)	20 (100)
c. Prepare for analysis	*32. The investigation team uses appropriate analysis tools to describe the findings of the review.	18 (90)	19 (95)	15 (75)
	*33. Management ensures engagement of the front-line workers in the investigation team.	18 (90)	18 (90)	14 (70)
	*34. Management ensures analysis teams are composed of representative expertise.	18 (90)	17 (85)	17 (85)
	*35. There are well trained investigation experts participating in each team.	18 (90)	19 (95)	13 (65)
	*36. The incident investigating team ensures equal and fair multidisciplinary participation.	19 (95)	18 (90)	11 (55)
	37. Staff and management are capable in performing incident investigation.	20 (100)	19 (95)	13 (65)
d. Analysis process	*38. Interviewers investigating the incidents consider and confirm the confidentiality of the interviewees.	19 (95)	19 (95)	17 (85)
	*39. Recommendations are professionally developed.	18 (90)	18 (90)	16 (80)

Table 1 ***(continued)*****.** The PSLS self-assessment questionnaire and participants' assessment of questions' clarity and importance, and the percentage of their rating for the PSLS in The Ottawa Hospital (N=20).

Section B: Domains	Questions/responses**	Comprehension = clear? Yes, n (%)	Importance = necessary? Yes, n (%)	No. respondents that partially agree, agree, strongly agree (%). N=20
e. Follow through	*40. Implementation of recommendations is well monitored.	18 (90)	19 (95)	18 (90)
	41. I observe enhancements to safety based on previously reported incidents.	20 (100)	20 (100)	18 (90)
	*42. Management evaluates compliance with recommended safety enhancements using formal (e.g., audits, and score cards) methods.	20 (100)	19 (95)	17 (85)
	*43. Management evaluates compliance with recommended safety enhancements using informal (e.g., risk officer spot check) methods.	18 (90)	19 (95)	17 (85)
f. Close the loop	44. I can track the processing of my reported incidents.	20 (100)	19 (95)	17 (85)
	45. People receive feedback on their reported events.	20 (100)	20 (100)	12 (60)
	46. There are regular communications between senior management and frontline staff with respect to values, expectations, and the results of learning from incident reporting.	19 (95)	19 (95)	15 (75)
	*47. There are regular communications between senior management and quality leaders with respect to values, expectations, and the results of learning from incident reporting.	18 (90)	18 (90)	11 (55)
	*48. The management has a defined communication approach to share learning internally.	19 (95)	17 (85)	15 (75)
	*49. The management has a defined communication approach to share learning externally.	16 (80)	18 (90)	10 (50)
	50. There is transparency in data sharing about the findings of reviews.	19 (95)	20 (100)	14 (70)
	51. Serious and high-risk incidents have their own feedback route.	20 (100)	19 (95)	19 (95)

* Questions assigned only for Q&S leaders and managers to answer.
** Each question has a five-point scale as response variables (strongly disagree, disagree, partially agree, agree, strongly agree) evaluating the PSLS. In step 3, each participant was asked to evaluate each question based on the clarity and necessity using either a yes or no response.

To obtain a more accurate measure of the internal consistency and reliability of the questionnaire, and to mitigate the effect of low participation, we used Cronbach's alpha statistics [19]. This mainly depends on measuring the correlation between the responses of

each participant. We measured the correlation between all the participants' responses (strongly disagree–strongly agree) to all the questions, and measured it separately for the responses within each domain.

Based on the participants' responses to the 47 statements in the questionnaire, Cronbach's alpha was calculated to be 0.94. The Cronbach's alpha coefficients for each domain were as follows: domain A "before the incident", 0.77; domain B "immediate response", 0.77; domain C "prepare for analysis", 0.61; domain E "follow through", 0.92; domain F "close the loop", 0.88. For domain D "analysis process", which has only two questions, we found it more reliable to calculate the Spearman–Brown reliability coefficient, which was 0.89. This indicates excellent agreement.

Table 1 also shows the percentages of the participants who agreed (total "partially agree", "agree" and "strongly agree" responses) on each question based on the status of their PSLS in the hospital. The questions "All staff have access to an electronic system for reporting safety events" and "The management has a defined communication approach to share learning externally" received the two lowest agreement scores (40% and 50%, respectively).

The percentages of combined "disagree" and "strongly disagree" scores were also calculated at the domain level. Domains C ("prepare for analysis") and F ("close the loop") received the highest disagreement scores (30.8% and 29.4%, respectively), compared to domains A ("before the incident", 20.8%), B ("immediate response", 21.2%), D ("analysis process", 17.5%), and E ("follow through", 12.5%).

In conclusion, Step 3 confirmed the high reliability and validity of the 47 questions and did not result in the removal or modification of any.

DISCUSSION

We systematically developed a survey to assess institutional PSLSs. The tool builds upon a previous systematic review of PSLS outcome factors, and was refined with input from experts in patient safety and quality, ensuring comprehension, face validity, and internal consistency. The study had three steps. Initially, we developed the survey's questions and their corresponding response options, culminating in a draft of 47 questions. During the second phase, experienced researchers who were also involved in the systematic review conducted a pre-test. This led to the elimination of two questions, the revision of 15, and the introduction of two new ones. Additionally, to reduce bias, it was determined that 17 questions focused on PSLS management should be exclusively answered by Q&S experts and leaders, while the rest could be addressed by both Q&S professionals and other staff members involved in the study. The final phase involved clinical sensibility testing—evaluating the clarity and necessity of the questions—by Q&S experts at The Ottawa Hospital. Despite receiving the lowest scores in these areas, four questions (numbers 15, 30, 44, and 45) were retained by the research team because their approval ratings exceeded the 80% benchmark set for inclusion.

Four demographic questions were also added. The first three questions "Institution", "Position title", and "What is your professional designation?" can help to direct improvement efforts to the right hospital department, while the fourth question "Years of experience" can help to determine the inclusion of participants based on their experience,

which might affect their answers. Finally, the questionnaire was tested for internal consistency using the participants' evaluation of their PSLS; a Cronbach's alpha score of 0.94 indicated high reliability.

Although this study did not intend to evaluate the hospital's PSLS, we grouped the responses of the participants' opinions into either "agree" or "disagree" and only present the percentage agreement in Table 1 for simpler reporting. It is also important to mention that improving the PSLS is a continuous process; therefore, decision makers can work on any of the system areas even those with high agreed percentages. We also wish to highlight that the domains "prepare for analysis" and "closing the loop" received the highest totals of "disagree" or "strongly disagree" scores.

This study's unique strength lies in the rigorous steps taken to develop the survey. To ensure the accuracy of the collected data, we followed the methods of Karen et al. [16] for face validity checks, based our questions on evidence from a systematic review, and piloted the survey at a large, reputable hospital. This pilot allowed us to assess the applicability, clarity, and necessity of all items. Finally, we incorporated feedback from both PSLS experts and experienced Q&S professionals working within the PSLS at The Ottawa Hospital.

Our newly developed questionnaire has many points in common with a 44-item self-assessment tool developed by the World Health Organization (WHO) in 2020 [20]. That tool was developed based on feedback from international experts in PSLSs. Both questionnaires use similar rating scales and cover many of the same major topics, including safety culture, leadership support, training, analysis and investigation, blame-free culture, availability of resources, feedback, and the internal and external sharing of learning. On the

other hand, our questionnaire was rigorously developed to enhance accuracy and clarity. We carefully formulated the questions to ensure understanding across diverse participant backgrounds. The questions were organized into domains to focus improvement efforts. We divided participants into two groups for obtaining tailored, precise results. To ensure practicality and relevance, we incorporated feedback from Q&S leaders working directly within a large accredited hospital's PSLS. Finally, demographic data will inform recommendations, allowing us to target improvements for specific departments or groups of employees.

Another study developed and validated an online questionnaire survey to test recently graduated doctors' knowledge and experience of patient safety and incident reporting, and assessed related attitudes and behaviors [21]. It was developed based on previously published questionnaires for medical students and nurses. It included 21 questions that partly overlap with our questionnaire including the principles of patient safety in their hospitals, their views on local reporting, training, the reporting stage, blame-free environment, involvement in incident discussions and one question on feedback. Our questionnaire has more items to assess feedback in addition to detailed evaluation of the management role and the analysis process [21]. Our questionnaire was tested for validity and reliability to ensure highly precise data collection. Being based on a systematic review, our collected data and subsequent recommendations are more generalizable and applicable.

The strengths of this study include the testing of face validity of the questionnaire. A group of experienced health services researchers who are experts in patient safety reviewed and gave feedback on each item to ensure it is fit for purpose. The questionnaire was evaluated again in the clinical sensibility test by experts in the field. Finally, internal

consistency was found to be high. Therefore, we are highly confident that no irrelevant questions were included and that all critical topics were covered. In addition, our questionnaire was based on a systematic review study that included 22 primary research studies conducted worldwide. It collected the views of a range of healthcare professionals on the barriers and facilitators of PSLSs. This would be reflected on the generalizability of our results. Being standardized might aid the comparison of PSLS performances between different hospitals.

All the safety experts, leaders, and managers at The Ottawa Hospital were invited to participate in the internal consistency assessment; however, the response rate was low at 36%. Domain C had the lowest Cronbach's alpha score (0.61), which can be explained by the low number of questions (six) known to affect the accuracy of the test; however, the result is still close to the lower reliability limit. Everyone rating the hospital's PSLS were experts in Q&S and might be concerned for the reputation of their hospital, so the possibility of bias in their responses exists. However, generalizability of the questionnaire is not expected to be affected as questions were based on the result of a systematic review that included studies from around the world. Furthermore, testing the questionnaire for clarity, necessity, and reliability depended mainly on participants' general knowledge on Q&S. However, despite this theoretical consideration, further testing in a large sample of participants from multiple settings is required.

CONCLUSION

This PSLS self-assessment questionnaire is an evidence-based tool that preliminary testing deems valid and reliable. The questionnaire created and evaluated in this study provides a

reliable means for healthcare providers to self-assess their PSLS. Using this questionnaire within a larger sample of respondents from different institutions will be required to further assess the survey psychometric properties as well as determine possible differences in PSLS practices.

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Author Contributions

The corresponding author was responsible for the whole research at its different stages (protocol development, planning, survey development, data collection and analysis, writing of the manuscript, editing, and publication). A.J.F. is the research supervisor responsible for planning, supervision, and revision of the final manuscript. All authors participated in development of the protocol, revision and approval of the analysis, writing the manuscript, and revision of each iteration of the manuscript; they also participated in the pretesting step of survey development.

Competing Interests

The authors declare no competing interests.

Ethics

The Research Ethics Board at The Ottawa Hospital (OHSN-REB Number: 20210441-01H (2658)) approved the protocol.

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Post-publication addendum to the methodological discussion: item-deleted Cronbach's alpha analysis

INTRODUCTION

Item-deleted Cronbach's alpha analysis serves a dual purpose in survey development—it can be used both to increase reliability and to reduce redundancy within measurement instruments. To increase consistency, researchers examine how the overall Cronbach's alpha value changes if individual items are removed; items whose deletion substantially raises the alpha value might be poorly aligned with the construct and can be revised or excluded to improve internal consistency [1]. Conversely, if alpha values are already very high (e.g., >0.90), the same analysis can help identify items that repeat similar content and therefore exaggerate the reliability estimate [2]. In this way, item-deleted analysis helps balance measurement precision ensuring that each item strengthens the scale's reliability without duplicating content unnecessarily [3,4]. In Chapter 3, the Cronbach's alpha score for the overall instrument was 0.94, Although such a high score indicates excellent internal reliability, it can also suggest that several items within the instrument are redundant—measuring similar or overlapping aspects of the same underlying constructs [1,2].

RESULTS AND ANALYSIS

An item-deleted Cronbach's alpha analysis was conducted to assess potential redundancy within the 47-item survey designed to measure multiple domains of organizational learning from self-reported incidents. Microsoft Excel was used to conduct an iterative item-deleted Cronbach's alpha analysis on data collected for testing the internal consistency of the

survey tool, as described in Chapter 3. Each item was systematically removed in turn, and the overall Cronbach's alpha value was recalculated after each deletion to assess the impact of individual items on the scale's reliability. The analysis produced values of alpha ranging between 0.919 and 0.946 (Supplementary Table 1), with an overall value of approximately 0.94.

The item-deletion results showed minimal variation across items, with no significant decrease or increase in alpha when any single item was removed. Deleting item 37 "Staff and management are capable in performing incident investigation." caused the biggest increase in alpha score to 0.946, although this change was marginal. Deleting item 7 "My training on reporting and/or analyzing incidents was effective in preparing to fulfill my responsibilities." resulted in the lowest alpha score (0.919).

DISCUSSION

The stability of alpha across all items might imply that the instrument's high reliability is not derived from any single item but rather from strong inter-item correlations across the entire set. In psychometric terms, this pattern can indicate that items share similar meaning or wording, contributing to item redundancy [3]. While internal homogeneity is desirable, excessive overlap among items can inflate Cronbach's alpha artificially and obscure the distinctiveness of each domain [4].

In Chapter 3, when internal consistency was examined within each domain, the Cronbach's alpha coefficients were 0.77 for domain A (Before the incident), 0.77 for domain B (Immediate response), 0.61 for domain C (Prepare for analysis), 0.92 for domain E (Follow through), and 0.88 for domain F (Close the loop). For domain D (Analysis

process), which contained only two items, a Spearman–Brown coefficient of 0.89 was calculated, which indicates strong internal consistency [5].

Because domains C and D are conceptually linked, with both having few items and domain C a low alpha score of 0.61, a combined reliability assessment was conducted, yielding a Cronbach's alpha value of 0.77, which demonstrates satisfactory reliability without suggesting excessive redundancy.

A comparison between the overall alpha (0.94) and the domain-level alpha values provides insight into the survey's structure. The markedly higher overall alpha value indicates that combining items from multiple domains increases internal correlation, not necessarily because all items measure the same construct, but due to shared variance and conceptual overlap across domains. This is a common phenomenon in multidimensional surveys, where items from related domains can inadvertently reflect similar organizational processes or attitudes [6]. For example, items assessing ―follow through‖ and ―closing the loop‖ might both tap into post-incident accountability, creating statistical redundancy even if they are conceptually distinct.

Interpretation and Implications

The high overall Cronbach's alpha score suggests that the instrument performs well in terms of reliability but also underscores the need to evaluate whether all items are necessary. Redundant items can inflate internal consistency without enhancing construct validity [2]. This redundancy might reduce respondent engagement and increase response burden while adding little to measurement precision. In the present analysis, the negligible changes in Cronbach's alpha upon deletion of a single item indicate that the removal of any

individual item from the instrument would have minimal impact on the overall consistency of the scale. This approach was appropriate for exploring the source of the very high Cronbach's alpha value and is particularly suitable for evaluating newly developed questionnaires with limited available data, small sample sizes, and reliance on simple statistical measures. Based on the findings of this study, it is recommended that all items of the tool are retained. For future studies, researchers need to consider conducting higher-level construct validation such as exploratory and confirmatory factor analyses to address the limitations of the item-deletion alpha test. These could further help to distinguish conceptually distinct domains from redundant content [7].

Strengths and Limitations

The use of item-deleted Cronbach's alpha analysis is particularly valuable in identifying redundancy in complex, multi-domain surveys. Its simplicity and diagnostic clarity make it an essential preliminary step in psychometric evaluation [1]. However, the method assumes uni-dimensionality and equal item contributions, which limits its interpretive precision with multidimensional tools [4]. Therefore, the present findings should be integrated with additional evidence of validity, such as factor analysis and content review, to confirm whether redundancy is due to true conceptual overlap or measurement design.

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SUPPLEMENTARY INFORMATION

Supplementary Table 1. Items of the PSLS self-assessment questionnaire and corresponding item-deleted Cronbach's alpha scores based on responses from quality and safety leaders at The Ottawa Hospital (N = 20). Questions are written in full in Table 1 of Chapter 3. Questions 1–5 do not have Likert-scale answers and are therefore not represented here.

Q. No.	Question deleted	Item deleted Cronbach's alpha score
6	It should be my responsibility to undergo re-training on the SLS periodically.	0.941109163
7	My training on reporting and/or analyzing incidents was effective in preparing to f	0.919400856
8	Training material describes how to classify safety events in terms of their severity	0.939181081
9	I have access to all policies and procedures related to the SLS.	0.941299147
10	The policies and procedures related to the SLS are easy to understand.	0.938007781
11	I am recognized positively for reporting safety events by my supervisor or leader.	0.94036914
12	Hospital leadership provides rewards and incentives to encourage safety event rep	0.939483546
13	The reporting system prevents individuals from being unfairly blamed for making	0.940207221
14	I believe reporting incidents is my responsibility as it will lead to preventing future	0.940712134
15	Managers regularly review and update system related policies and procedures.	0.942501096
16	The training plan for SLS is well-developed, monitored and tailored to each staff ac	0.942475592
17	The SLS is integrated in everyday work to ensure high compliance.	0.94151838
18	Management allocates sufficient resources for reporting, analysis and investigatin	0.939558956
19	All staff have access to an electronic system for reporting safety events.	0.940828252
20	I have alternative reporting options to enhance efficiency, such as telephone repo	0.941441965
21	Incident review forms are self-explanatory and time efficient to complete.	0.940611929
22	I have no concern about confidentiality when I complete the incident report forms	0.940028868
23	I must report the same incident using different approaches.(e.g Patient files, nursi	0.940041442
24	I understand that Incident reporting is the responsibility of the person who witnes	0.941010517
25	Reporting incidents has never caused troubles with my colleagues and is viewed fa	0.942002921
26	Managers and leaders have the authority to support reporters.	0.940960407
27	Policies and protocols support the non-punitive reporting environment.	0.940651514
28	Incident reporting is mandatory.	0.940783799
29	The hospital has a list of prioritized incidents to be reported.	0.939484855
30	There are policies and protocols to protect reporters against legal and non-legal ac	0.942378708
31	The hospital requires reporting to an independent body to avoid blaming and enha	0.939929894
32	Staff and management are capable in performing incident investigation.	0.946375791
33	Management ensures engagement of the front-line workers in the investigation te	0.940169811
34	Management ensures analysis teams are composed of representative expertise.	0.93867335
35	The incident investigating team ensures equal and fair multidisciplinary participati	0.939876831
36	There are well trained investigation experts participating in each team.	0.940664926
37	The investigation team uses appropriate analysis tools to describe the findings of t	0.938008951
38	Interviewers investigating the incidents consider and confirm the confidentiality o	0.93862858
39	Recommendations are professionally developed.	0.938229552
40	I observe enhancements to safety based on previously reported incidents.	0.938492255
41	Implementation of recommendations is well monitored.	0.938039764
42	Management evaluates compliance with recommended safety enhancements usin	0.938232715
43	Management evaluates compliance with recommended safety enhancements usin	0.937864936
44	I can track the processing of my reported incidents.	0.940263438
45	People receive feedback on their reported events.	0.939509571
46	There are regular communications between senior management and frontline staf	0.937276485
47	There are regular communications between senior management and quality leade	0.94080864
48	The management has a defined communication approach to share learning interna	0.939389721
49	The management has a defined communication approach to share learning extern	0.939380339
50	There is transparency in data sharing about the findings of reviews.	0.938866295
51	Serious and high-risk incidents have their own feedback route.	0.940002771

CHAPTER 4

Quality leaders' survey of their patient safety learning system capability

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A version of this chapter is in preparation for submission to a journal.

Preface

This chapter presents a survey study in which we used the questionnaire developed in Chapter 3. The aim of this study was to assess patient safety learning system practices as described by executives in general hospitals within a publicly funded health system.

Author Contributions

Hassan A. Mahmoud was involved in the design and implementation of the study, statistical analysis, writing, and interpretation of the study. Alan J. Forster was the supervisor and was involved in the design, implementation, and review of the manuscript. Kednapa Thavorn was involved in the analysis, review, and revision of the manuscript. Sunita Mulpuru was involved in the design of the study, review, and revision of the manuscript.

ABSTRACT

Background: The patient safety learning system (PSLS) is a crucial component of healthcare systems that focuses on enhancing patient safety by promoting a culture of learning.

Objective: Assess PSLS practices as described by executives in general hospitals within a publicly funded health system.

Methods: We conducted a cross-sectional online survey across 42 teaching and non-teaching hospitals in Ontario, Canada, each with ≥100 ward beds and ≥10 ICU beds. One quality or safety executive from each hospital participated. Three analytical approaches were applied: (1) grouping "partially agree" with positive responses ("agree"/"strongly agree"), (2) grouping it with suboptimal responses ("disagree"/"strongly disagree"), and (3) neutralizing it using the net positive percentage. Results were examined across two cut-off points (25% and 40%) to assess interpretive impact. Findings from the primary approach were used to report the perceived PSLS performance among quality and safety experts.

Results: Thirty hospitals (71%) responded to our survey. Of these, 25 (83%) showed suboptimal overall PSLS performance, with the "follow through" and "close the loop" domains rated suboptimal by 80% and 97% of respondents, respectively. The most suboptimally rated item was the lack of leadership reward structures for reporting (83%), followed by insufficient retraining (77%). Comparison of the three analytical approaches showed no difference between the primary and tertiary analyses, while the secondary approach—where "partially agree" responses were grouped positively—substantially reduced the number of items identified for improvement.

Conclusions: Our survey demonstrated that safety executives in a publicly funded health system consistently perceived several opportunities to improve their PSLS practices. Ineffective PSLS practices might reflect a failure to prioritize safety by health system leaders and could help to explain why safety is not improving.

Keywords: Barriers, patient safety learning systems, publicly funded general hospitals, self-assessment surveys.

BACKGROUND

In the past two decades, improvement in patient safety has been limited despite considerable efforts. In fact, there are suggestions that safety has diminished [1,2]. Within a healthcare institution, the patient safety learning system (PSLS) is a strategy that focuses on enhancing patient safety, promoting a culture of learning from safety incidents and preventing such adverse events occurring [3]. A PSLS is a platform for reporting and analyzing incidents, near misses and safety concerns, and facilitates the dissemination of knowledge and best practices to improve patient safety [4]. It is possible that ineffective utilization of a PSLS contributes to failure to learn from incidents [5] and implement recommendations for improvement [6].

Understanding how learning processes take place after a safety incident and the ability to evaluate these processes are crucial for improving a PSLS [7]. Hence, considerable focus has been placed on studying the barriers and facilitators of these systems globally [8]. Healthcare organizations striving to make PSLSs more robust encourage a free flow of information, openness, and shared accountability. Legal systems and administrative policies have been developed to enable reporting of adverse events and the examination of probable causes without individuals fearing reprisals. For instance, the World Health Organization's (WHO) Global Patient Safety Action Plan 2021–2030 recognizes blame-free reporting as essential to help prevention of adverse events [9]. Despite this advisory and policy work, the effectiveness of PSLS implementation in practice is unknown.

To address this concern, we developed and validated an evidence-informed "PSLS assessment tool" [10,11], which organizations and health systems could use to identify opportunities to address their learning culture. In this present study, we used we

used the tool to evaluate patient safety leaders' perceptions of PSLS within a publicly funded health system. The findings will help identify organizational strengths and gaps in PSLS implementation, informing strategies to enhance learning from patient safety events and ultimately improve patient safety outcomes.

METHODS

Design

This descriptive, cross-sectional survey was conducted in March and April 2024 using an online questionnaire distributed using the website SurveyMonkey. We report the results of the survey in accordance with the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [12].

Selection/Inclusion Criteria

According to the Canadian Institute for Health Information [13], Ontario has a total of 140 hospitals. However, many of these are relatively small and, given their limited number of units, patient encounters, and reportable events, might lack dedicated personnel or software infrastructure to support a comprehensive PSLS. For this study, we intentionally selected the 42 hospitals having more than 10 intensive care unit (ICU) beds and 100 beds in total. This sampling strategy aligned with the study's objective to evaluate existing PSLS for potential weaknesses, as larger hospitals are more likely to have established systems and designated quality and safety (Q&S) executives capable of providing informed and accurate evaluations. We reached out to all hospitals that met the inclusion criteria.

We considered the hospitals as the unit of sampling and at least one representative purposefully selected to provide accurate evaluation of the PSLS was invited to represent their hospital.

The Executive Vice-President responsible for Quality at the Ottawa Hospital distributed an invitation letter, a URL to participate, and a consent form, by way of an email sent to the Q&S executive at the included hospitals. Both the Q&S director and the Q&S manager from each hospital were invited to participate in the survey, with the intent that either could represent their hospital in evaluating the PSLS, as both postholders have substantial experience and are deeply involved in their PSLS. If the invitee suggested that another employee with better awareness of the PSLS complete the survey, we asked that employee to participate instead. All participants held senior managerial Q&S positions, with experience in reporting and analyzing incidents, and were persons of contact for implementing the safety learning system in their hospital.

We chose to conduct our survey in Ontario hospitals as Ontario has a publicly funded single-hospital system service for approximately 14 million people. This allowed us to minimize potential confounding factors, such as variations in regulatory and funding frameworks, cultural differences, economic disparities, and position requirements, which might influence the study's outcomes.

Data Collection

An electronic-based self-administered online survey instrument was used to collect the data. An invitation letter was sent to the participants together with a URL to open the

survey and provide implied consent. The invitation letter contained information about the study, the confidentiality of data, the importance of the study and participation, and an estimate of the time needed to complete the survey. The data were collected over a period of eight weeks. Reminders were sent two and four weeks after the invitation letters were received. The estimated time to complete the questionnaire was 14 minutes.

The questionnaire was developed from two previous studies (Chapter 2 [10] and Chapter 3 [11]). It comprised four items for recording the demographic characteristics of the respondent (institution, position title/Q&S role, professional designation, and number of years of experience in a Q&S role) and 47 items grouped within six domains. These domains included: "before the incident" (1; items 5–18), "immediate response" (2; items 19–31), "prepare for analysis" (3; items 32–37), "analysis process" (4; items 38–39), "follow through" (5; items 40–43) and "close the loop" (6; items 44–51). Items 6–51 were rated on a five-point Likert scale from "strongly disagree" to "strongly agree"; question 5 was a yes/no choice.

A unique identifier was assigned to each participating hospital, and the data were kept strictly confidential. Only aggregated data are reported to ensure confidentiality of reporting institutions.

Data Analysis

All statistical analyses were done in Microsoft Excel and JASP (version 0.18.3) [14].

Data Preparation

Partially completed questionnaires were retained in the analysis. For each survey item, the number of respondents was reported, and percentages were calculated using the number of participants who answered that specific question as the denominator.

Responses were recorded on a five-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"). Prior to analysis, scores for the negatively worded item (Item 18) were reverse-coded to ensure that higher scores consistently reflected more favourable evaluations of the PSLS.

Domains 3 ("Prepare for Analysis") and 4 ("Analysis Process") were combined based on their conceptual overlap and the previously reported Cronbach's alpha value of 0.77 for the merged domain, compared to 0.61 for domain 3 alone. Combining the two enhanced internal consistency, increased the number of items to strengthen statistical power, and reduced measurement error by reflecting their closely related functions in practice.

Descriptive analysis

Respondent characteristics were summarized using descriptive statistics. Categorical variables were reported as frequencies and percentages. Distributions of responses for each PSLS assessment item were examined to describe participants' perceptions of PSLS implementation across hospitals.

Primary analysis

The primary analytical approach focused on identifying areas of potential improvement within the PSLS. Responses were dichotomized into:

- Suboptimal responses: strongly disagree, disagree, and partially agree
- Optimal responses: agree and strongly agree

The inclusion of "partially agree" responses within the suboptimal category was intended to provide a conservative assessment of PSLS performance. Given that respondents were quality and safety professionals evaluating systems within their own organizations, this approach was considered appropriate to minimize overly favourable interpretations and to support an improvement-oriented evaluation framework.

For each item, domain, and hospital, the proportion of suboptimal responses was calculated. Areas exceeding predefined cut-off points were classified as requiring improvement.

Secondary analysis

A secondary analysis was conducted to assess the influence of alternative response categorizations on study findings. In this approach, "partially agree" responses were grouped with the positive response categories:

- Suboptimal responses: strongly disagree and disagree
- Optimal responses: partially agree, agree, and strongly agree

The resulting proportions were compared with those obtained from the primary analysis to determine the extent to which classification of the "partially agree" category affected

interpretation.

Tertiary analysis

A third approach involved calculating the net positive percentages, defined as:

$$\text{Net Positive (\%)} = \frac{(\text{Agree} + \text{Strongly Agree})}{\text{Total Responses}} \times 100 - \frac{(\text{Disagree} + \text{Strongly Disagree})}{\text{Total Responses}} \times 100$$

This approach was conducted as a sensitivity analysis using net positive scores, a metric commonly applied in patient safety culture research. To facilitate comparison with the primary analysis, an equivalent threshold was established based on the distribution of responses across the five-point Likert scale. However, because net positive scores and suboptimal-response percentages are conceptually different measures, the tertiary analysis was intended to assess the robustness of findings rather than provide a directly equivalent classification of performance.

To enhance transparency and interpretability, complete response distributions for individual items were also presented, allowing readers to examine the full range of participant responses.

Cut-off point comparison

To evaluate the sensitivity of findings to different performance thresholds, two cut-off points were examined. Consistent with the recommendations of the AHRQ [15] and the cut-off points used in previous studies [16,17], thresholds of 25% and 40% were used to define suboptimal performance.

For the primary and secondary analyses, an item, domain, or hospital was classified as suboptimal when the proportion of suboptimal responses met or exceeded the specified

threshold. Results obtained using the two cut-off points were compared to assess their influence on identifying priority areas for improvement. For the tertiary analysis, an equivalent net-positive threshold corresponding to the 25% suboptimal-response criterion was calculated to facilitate comparison across analytical approaches.

Ethics

Ethical approval for the study was granted by the Research Ethics Board at The Ottawa Hospital.

RESULTS

Demographic Characteristics

A total of 30 hospitals responded of the 42 approached (71% response rate) and 35 questionnaires were returned. Of those questionnaires received, 33 had been completed and two were incomplete; questionnaires were not excluded because of missing data. Three hospitals returned two questionnaires each and one responded with three (the quality manager participated, the director initially delegated the task to a safety leader but later decided to complete the survey personally after receiving a reminder). In these four cases, only one response from each hospital was included (that of the respondent with the most experience and highest position).

The characteristics of the included respondents and their hospitals are shown in Table 1. We received 35 responses: 10 respondents were directors (all were included), 17 were managers (only 14 were included), and eight were leaders (only six were included). Only two participants did not report their professional background. Of those that did, 13 listed

nursing (46%). Ten responded with "other" (36%), which comprised one technician, one therapist, one quality manager, two healthcare administrators, one public health specialist, two risk specialists, one epidemiologist, and one engineer. We received responses from five doctors (18%). The mean experience was 14.33 years (4–29 years).

Table 1. Demographic characteristics of participants.

Profession	**Number**	**Percentage**
Doctor	5	17.9
Nurse	13	46.4
Other	10	35.7
Not answered	2	6.7*
Hospital type		
Teaching	6	20
Non-teaching	24	80
Number of hospital beds		
< 300	11	36.7
300–600	11	36.7
> 600	8	26.7
Participant's years of Q&S experience		
< 10	6	20
10–18	19	63.3
> 18	5	16.7

* Calculated from the total number of participants (30).

Questionnaire Completion Process

The time taken to complete the questionnaire was recorded, and none of the participants asked to change or edit their answers. The completion time ranged from 11 to 25 minutes, which aligned with expectations from our validation study. We did not receive any negative feedback regarding the clarity or necessity of the questions.

Descriptive Analysis

The proportion of suboptimal responses for each hospital was calculated and used at two cut-off points (≥25% and ≥40%) to determine whether a hospital, domain, or individual item was considered suboptimal (i.e., at or below the cut-off point; Figure 1).

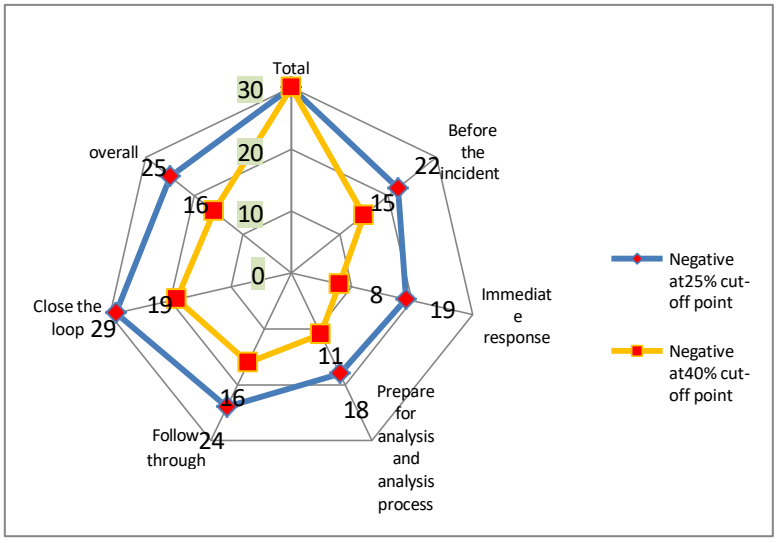

Figure 1. The number of hospitals that responded suboptimally for at least 25% and 40% of questions within a domain and overall.

At the 25% cut-off point, 83% of hospitals returned a suboptimal overall evaluation of their PSLS. When the more stringent 40% cut-off point was applied, 53% of hospitals remained within the suboptimal category.

Across domains, at the 25% cut-off point, the "Prepare for Analysis and Analysis Process" combined domain had the lowest proportion of suboptimal responses (60%), followed by Immediate Response (19, 63%), Before the Incident (22, 73%), Follow Through (24, 80%), and Close the Loop (96%). When the 40% threshold was applied, the Immediate Response domain showed the fewest suboptimal responses (8, 27%), while Close the Loop remained the most critical area (19, 63%).

As shown in Figure 2, at the 25% threshold, only seven hospitals (23%) were rated negatively, and at the 40% threshold, this dropped to a single hospital (3%). The domain-level results followed a similar trend, with Immediate Response garnering the least concern (20% at 25%, 0% at 40%), and other domains such as Close the Loop and Follow Through also showing notable reductions in negative ratings.

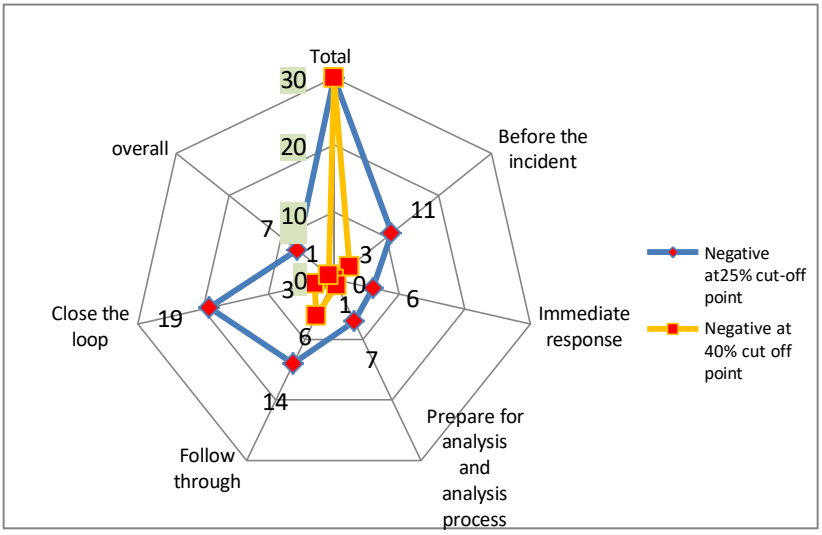

Figure 2. The number of hospitals that responded suboptimally according to the secondary analysis approach for at least 25% and 40% of questions within a domain and overall.

We also reported the frequency for each response category per item (see Supplementary Figure 1).

Using the tertiary analysis approach (net positive percentages; Figure 3), only six items across the entire questionnaire demonstrated negative net positive percentages (i.e., values below zero). However, this does not mean that those are the only suboptimal items because the net positive percentage combines both positive and negative proportions. To maintain consistency with the suboptimal item classification used in the primary analysis, a net positive cut-off point of approximately 63% or lower would correspond to the 25% suboptimal cut-off point in the primary approach (i.e., % positive – % negative = 25%; e.g., 62.5% – 37.5% = 25%).

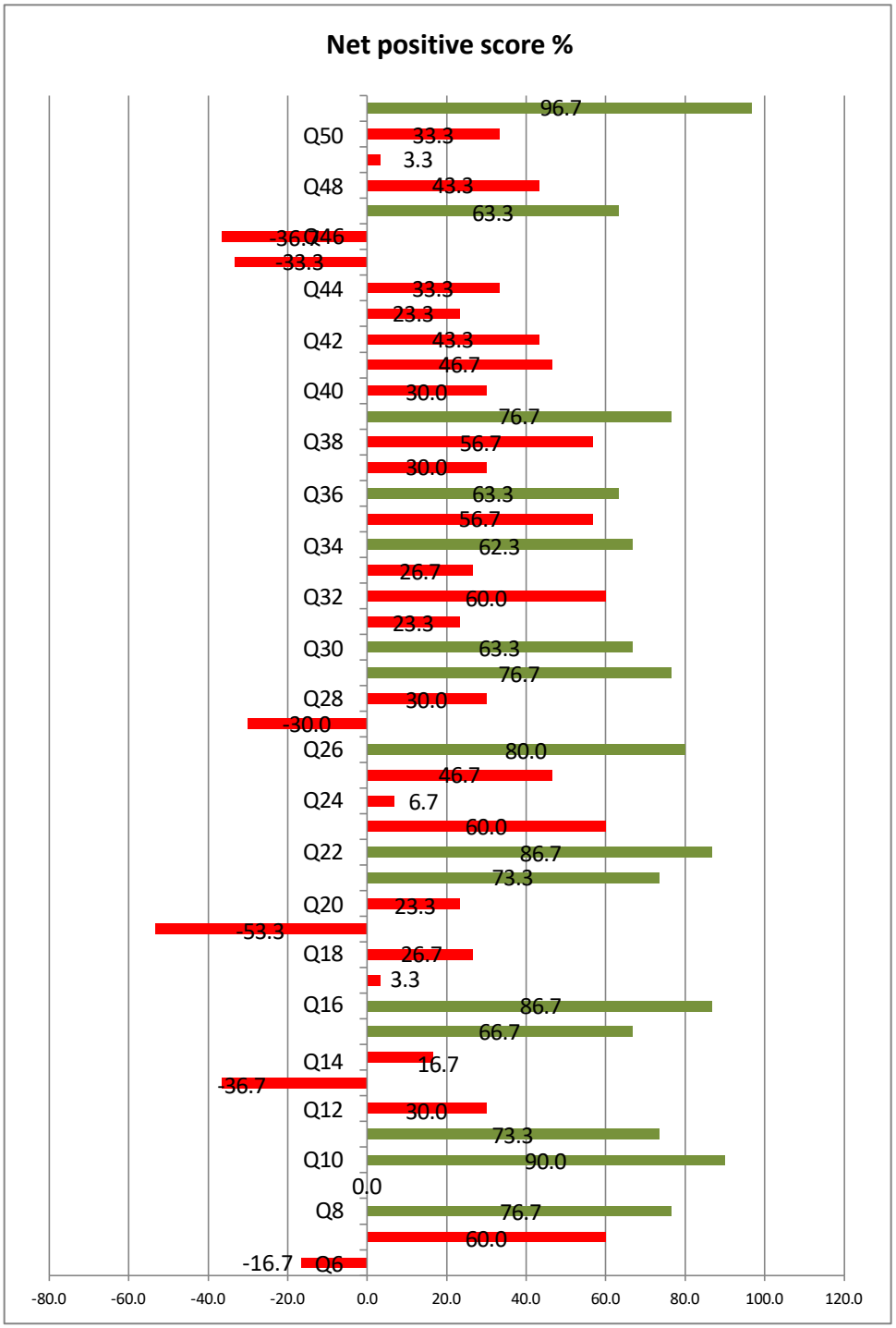

Figure 3. The net positive percentages of hospitals' responses to questions 6–51 categorized into positive or negative based on the primary study at 25% cut-off point. Questions are written in full in Supplementary Table 1. Questions 1–5 do not have Likert-scale answers and are therefore not represented here.

Effect of Varying Cut-Off Points (25% and 40%) across Primary, Secondary, and Tertiary Approaches

The number of items classified as suboptimal varied across analytical approaches. At the 25% cut-off point and the corresponding 63% threshold for the tertiary analysis, of the 33 items that were jointly identified as suboptimal in both the primary and tertiary analyses, 11 were also deemed suboptimal with the secondary approach. Applying the 40% cut-off point in the primary approach reduced the number of suboptimal items to 26, while only eight items remained suboptimal when the same threshold was applied to both the primary and secondary approaches (Table 2). Increasing the threshold from 25% to 40% reduced the number of items classified as suboptimal across approaches. These findings indicate that the classification of "partially agree" responses has a considerable influence on the identification of improvement priorities. Approaches that treated "partially agree" responses as favourable produced fewer items requiring action, whereas approaches that classified these responses as suboptimal or excluded them from positive ratings identified a greater number of opportunities for improvement.

Table 2. Comparison of high-scoring items across primary, secondary approaches at 25% and 40% cut-off points and reporting results from tertiary approach of analysis to the same items. Questions are written in full in Supplementary Table 1. Questions 1–5 do not have Likert-scale answers and are therefore not represented here.

Question No.	Primary %	Secondary %	≥25%	≥40%	Tertiary analysis
Q6.It should be my responsibility to und	77	40	yes	yes	-17
Q9.The training plan for SLS is well-deve	60	40	yes	yes	0
Q12.I am recognized positively for repor	50	20	yes (primary only)	yes (primary only)	30
Q13.Hospital leadership provides reward	83	53	yes	yes	-37
Q14.The reporting system prevents indiv	57	27	yes (primary only)	yes (primary only)	17
Q17.The SLS is integrated in everyday wo	60	37	yes	yes (primary only)	3
Q18.Management allocates sufficient res	53	20	yes (primary only)	yes (primary only)	27
Q19.I must report the same incident usin	80	73	yes	yes	-53
Q20.Reporting incidents have never caus	57	20	yes (primary only)	yes (primary only)	23
Q23.There are policies and protocols to p	33	7	yes (primary only)	No	60
Q24.The hospital requires reporting to a	53	40	yes	yes	7
Q25.I have no concern about confidentia	37	17	yes (primary only)	No	47
Q27.I have alternative reporting options	73	57	yes	yes	-30
Q28.Incident review forms are self-expla	50	20	yes (primary only)	yes (primary only)	30
Q30.Incident reporting is mandatory.	27	7	yes (primary only)	No	63
Q31.The hospital has a list of prioritized	50	27	yes	yes (primary only)	23
Q32.The investigation team uses approp	30	10	yes (primary only)	No	60
Q33.Management ensures engagement	50	23	yes (primary only)	yes (primary only)	27
Q34.Management ensures analysis team	30	3	yes (primary only)	No	62
Q35.There are well trained investigation	40	3	yes (primary only)	yes (primary only)	57
Q36.The incident investigating team ens	30	7	yes (primary only)	No	63
Q37.Staff and management are capable i	50	20	yes (primary only)	yes (primary only)	30
Q38.Interviewers investigating the incid	30	13	yes (primary only)	No	57
Q40.Implementation of recommendatio	50	20	yes (primary only)	yes (primary only)	30
Q41.I observe enhancements to safety b	40	13	yes (primary only)	yes (primary only)	47
Q42.Management evaluates compliance	40	17	yes (primary only)	yes (primary only)	43
Q43.Management evaluates compliance	50	23	yes (primary only)	yes (primary only)	23
Q44.I can track the processing of my repo	40	27	yes	yes (primary only)	33
Q45.People receive feedback on their re	87	47	yes	yes	-33
Q46.There are regular communications b	80	57	yes	yes	-37
Q48.The management has a defined com	47	10	yes (primary only)	yes (primary only)	43
Q49.The management has a defined com	73	23	yes (primary only)	yes (primary only)	3
Q50.There is transparency in data sharin	47	20	yes (primary only)	yes (primary only)	33

Notably, no item was highly rated as suboptimal in the secondary approach that was not already identified using the primary approach.

Question Score Analysis: the Highest Percentages of Suboptimal Responses

To better interpret the results, we classified the results from the primary analysis approach (shown in Figure 5) according to the subdomains of the Patient Safety Management Tool Kit [11] (Figure 4).

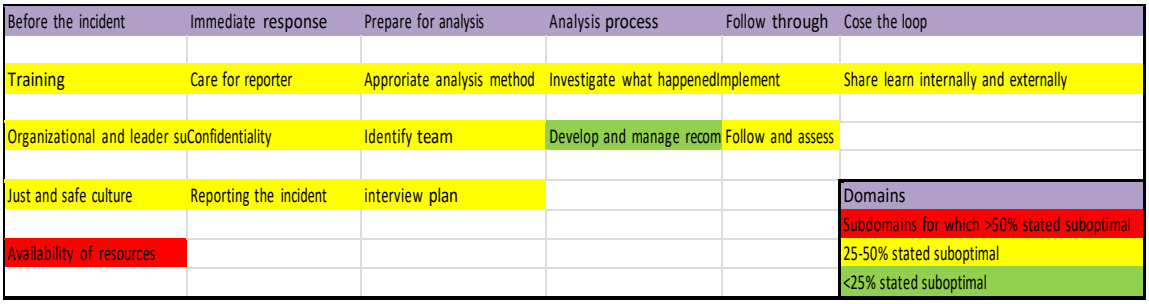

Figure 4. The percentages of suboptimal responses from participating hospitals on the subdomain level (the denominator is the total number of responses, positive and suboptimal, for the 30 hospitals) for the related questions [11].

Training

Within the training subdomain, questions 6 ("It should be my responsibility to undergo re-training on the PSLS periodically") and 9 ("Training plan is well-developed and monitored") returned the highest suboptimal responses at 77% and 60%, respectively. These items also remained the highest in the secondary analysis, each with 40% negative responses. Other training-related items demonstrated less than 25% negative responses in the secondary approach. Applying the 40% cut-off point did not significantly alter the interpretation of these findings.

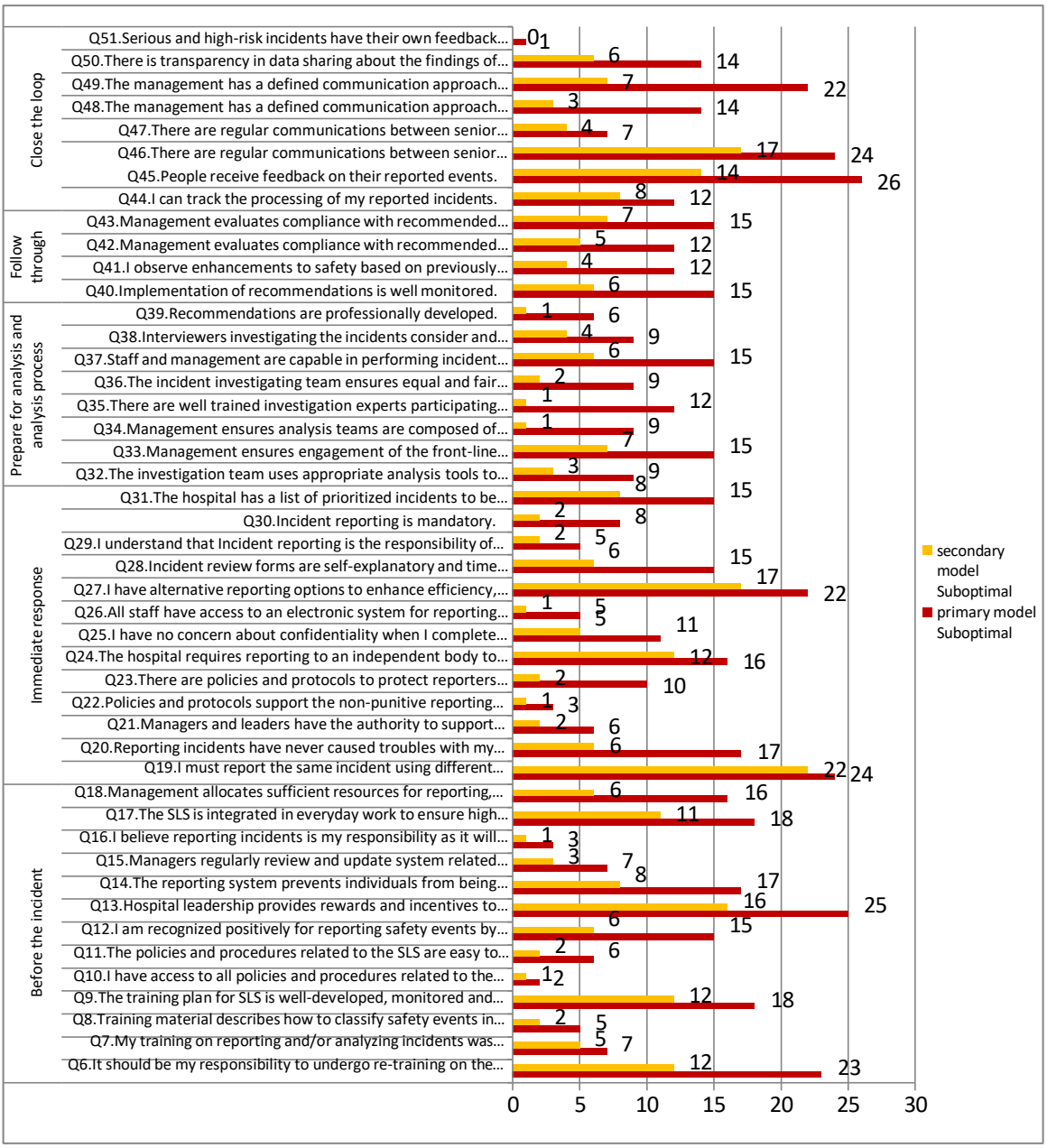

Figure 5. The frequency of hospitals' responses to questions 6–51 categorized into suboptimal responses (strongly disagree, disagree, partially agree) according to the primary analysis approach, compared to suboptimal responses (disagree and strongly disagree) of the secondary analysis. Questions are written in full in Supplementary Table 1. Questions 1–5 do not have Likert-scale answers and are therefore not represented here.

Organizational and leader support

Items assessing hospital policies and procedures demonstrated relatively low proportions of suboptimal and negative responses, remaining below the 25% cut-off point in both analytical approaches. However, items evaluating leadership behaviors related to fostering a supportive safety culture—specifically, preventing unfair blame and recognizing staff that report incidents—had higher suboptimal response rates of 57% and 50%, respectively, with corresponding negative responses of 27% and 20%. The highest suboptimal percentage within this subdomain was observed for question 13, which examined the role of leadership in providing rewards and incentives to reporters, to which 83% of respondents provided suboptimal responses compared to 53% negative responses in the secondary analysis.

Just and safe culture

For question 17, which evaluated the integration of the PSLS into routine organizational practice, 60% of respondents provided suboptimal responses, compared to 37% negative responses in the secondary analysis.

Availability of resources

Question 18 assessed whether management allocates sufficient resources for reporting, analyzing, and investigating incidents. Over half of the respondents (53%) provided suboptimal assessments according to the primary approach. Secondary analysis showed less than 25% negative responses to the same item.

Care for reporter

Question 19 ("I must report the same incident using different approaches") yielded one of the highest suboptimal response rates across the survey (80%), with a similarly elevated 73% negative response rate in the secondary approach. This suggests strong perceptions of inefficiency and redundancy toward reporting procedures. Questions 20 ("Reporting incidents have never caused troubles with my colleagues and is viewed favorably within my unit's culture") and 24 ("The hospital requires reporting to an independent body to avoid blaming and enhance fair analysis") also demonstrated high suboptimal response rates of 57% and 53%, compared to 20% and 40% negative responses, respectively. Other items in this subdomain received less concern, remaining below 35% in the primary approach and below 25% in the secondary approach.

Confidentiality and reporting the incident

The highest suboptimal response rates within this subdomain were reported for question 27 ("I have alternative reporting options to enhance efficiency, such as telephone reporting, manual and electronic reporting") at 73%, and 57% negative in the secondary approach. Question 28 ("Incident review forms are self-explanatory and time efficient to complete") showed 50% suboptimal versus 20% negative responses, whereas question 31 ("The hospital has a list of prioritized incidents to be reported") had 50% suboptimal and 27% negative responses. The other items in this subdomain recorded less than 30% suboptimal responses under both analytical approaches.

Preliminary investigation and appropriate analysis methods, investigation process, identify team and interview plan, develop and manage recommendations

The four subdomains demonstrated comparatively lower proportions of suboptimal responses than other domains. The items with the highest suboptimal percentages in the primary analysis were "Management ensures engagement of the front-line workers in the investigation team" (Q33) and "Staff and management are capable in performing incident investigation" (Q37), both with 50%, followed by "There are well-trained investigation experts participating in each team" (Q35) at 40%. In the secondary analysis, these items all dropped below the 25% threshold. All remaining items in these subdomains had suboptimal scores below 40% in the primary approach and below 25% in the secondary approach.

Implement, follow and assess

All items within this subdomain received 40% or more suboptimal responses, highlighting a perceived need for improvement. Specifically, "Implementation of recommendations is well monitored" (Q40) received 50%; "I observe enhancements to safety based on previously reported incidents" (Q41) received 40%; "Management evaluates compliance with recommended safety enhancements using formal (e.g., audits and scorecards) methods" (Q42) received 40%; and "Management evaluates compliance using informal (e.g., risk officer spot checks) methods" (Q43) received 50%. In the secondary analysis, these items maintained the highest negative percentages within the subdomain—20%, 13%, 17%, and 23%, respectively—though all fell below the 25% cut-off point.

Share learn internally and externally

Within this subdomain, six of the eight items were rated suboptimally by 40% or more of respondents in the primary approach. The two most critically viewed items were "People receive feedback on their reported events" (Q45) and "There are regular communications between senior management and frontline staff with respect to values, expectations, and the results of learning from incident reporting" (Q46), which recorded 87% and 80% suboptimal responses, respectively. Additionally, "The management has a defined communication approach to share learning externally" (Q49) showed 73%, and "There is transparency in data sharing about the findings of reviews" (Q50) received 47%, reinforcing concerns regarding the transparency of PSLS data sharing with external authorities. In the secondary analysis, these items remained the most negatively rated within the domain, although the proportions decreased to 47%, 57%, 23%, and 20%, respectively.

DISCUSSION

The aim of this study was to evaluate the perceptions of Q&S professionals toward the barriers and facilitators of the PSLS in hospitals in a publicly funded health system. It also compared the methodological implications of using different analytical approaches for handling Likert-scale data and applying variable cut-off points.

The results from the primary analysis approach were used to assess the PSLS, taking a conservative approach by combining "partially agree" responses with negative evaluations. This method offered a more cautious and improvement-focused view of the system's performance. Although the discussions on response scale grouping and cut-off points considered insights from all three analytical approaches, the primary approach served as the

foundation for the PSLS evaluation.

The findings from this approach highlighted significant gaps in how effective the PSLS implementation was perceived to be. In total, 83% of hospitals rated their evaluations as suboptimal, with particularly high percentages in the areas of "close the loop" (97%) and "follow through" (80%), pointing to deficiencies in feedback and corrective action processes. These results are consistent with earlier studies that identified follow-up and communication as ongoing challenges to the effectiveness of PSLS [18,19].

Item Evaluation

There were clear gaps in training and leadership support, as 77% of participants did not fully agree with their responsibility to regularly retrain, and 60% pointed out shortcomings in current training plans. Prior research has widely recognized ongoing education as crucial to maintaining a robust safety culture [20]. Leadership support was another significant issue, with 83% of respondents either disagreeing or only somewhat agreeing that there were reward systems for reporting incidents, and 57% felt that their PSLS did not prevent unfair blame. These results are consistent with existing literature that highlights the importance of leadership in creating non-punitive and transparent reporting environments [21]. Whereas policies related to the PSLS received mostly positive feedback (only 10% deemed them suboptimal), 33% of respondents still expressed concerns about potential legal or non-legal consequences. Resource limitations were also a significant issue, with 53% reporting insufficient support for incident reporting, analysis and investigation, which aligns with previous studies linking resource issues to poor PSLS performance [22]. Additionally, 80% of respondents were concerned about duplicated efforts, and 56% feared that reporting could lead to conflicts or breaches of confidentiality, underscoring the

ongoing issue of blame as a deterrent [21] and 53% emphasized the necessity of independent reporting mechanisms to ensure a fair unbiased analysis.

The combined domain of "prepare for analysis" and "analysis process" performed relatively well, but 50% of respondents noted limited engagement from frontline staff and inadequate analytical skills. Similarly, 40–50% identified weaknesses in the implementation and monitoring of recommendations. Communication between leadership and staff was identified as a significant weakness, with 80% rating it as suboptimal, which aligns with literature emphasizing the importance of open communication for effective learning systems [23].

The findings of this study are consistent with previous Canadian studies that identified insufficient leadership support, resource limitations, and weak feedback mechanisms as key barriers to the effectiveness of a PSLS [18,21]. Additionally, time constraints and duplication of work have been documented as major barriers to reporting adverse events in healthcare settings [24] as well as the need for improved frontline worker engagement and communication [22]. Our results also align with the organization for Economic Co-operation and Development OECD data from 2020–2021, which found that 33% of feedback systems were rated as suboptimal [25]; in comparison, our "close the loop" domain had a 50% suboptimal rating, indicating ongoing challenges with feedback. The variation in results between both studies might be influenced by differences in provincial representation or study methodologies; however, both numbers indicate the need for more robust mechanisms for feedback. Compared to data from 20 years ago [26], there has been a slight improvement in cultural barriers: fear of blame decreased from 72% to 57%. The highest suboptimal percentage in this subdomain pertained to the lack of integration of

safety learning systems into daily routines, with 60% of respondents highlighting this challenge. Furthermore, suboptimal perceptions of resource adequacy worsened from 28% to 53%. Although methodological differences between the studies limit a direct comparison, the findings suggest that progress in embedding safety practices and ensuring adequate resources remains uneven and warrants continued attention [26].

Overall, hospitals seem dedicated to formalizing PSLS policies but struggle to implement them effectively. To improve the reporting culture and the effectiveness of PSLS, it is essential to enhance leadership engagement, ensure adequate resources, and foster recognition and open communication through meetings, visible feedback, and staff acknowledgment.

Methodological Implications and Inferences from Observed Differences

Comparison of the primary, secondary, and tertiary analytical approaches demonstrated that PSLS evaluation is highly sensitive to how midpoint responses are treated. Although all three approaches were applied to the same dataset, the number of items classified as requiring improvement varied substantially. The primary approach, which classified "partially agree" responses as suboptimal, identified the greatest number of items requiring attention. In contrast, reclassifying midpoint responses as positive in the secondary approach resulted in considerably fewer items being identified. For instance, Q6 "responsibility to undergo SLS re-training" had a suboptimal score of 77%, which decreased to 40% in the secondary approach after reclassifying "partially agree" as a positive response, a decrease of 37%. Likewise, Q13 "leadership provides rewards for reporting" decreased from 83% to 53%, and Q45 "people receive feedback on reported events" decreased from 87% to 47%. In total, over 80% of items experienced reductions of

20–40 percentage points in suboptimal ratings between the approaches.

These findings suggest that the treatment of midpoint responses represents an important methodological decision rather than a purely statistical one that directly influences the identification of improvement priorities. The observed differences arise because each analytical approach reflects different assumptions regarding the meaning of a "partially agree" response. When partial agreement is interpreted as evidence of satisfactory performance, fewer deficiencies are identified. Conversely, when it is interpreted as an indication that optimal processes are not fully established, a greater number of opportunities for improvement become apparent.

For the purpose of evaluating patient safety learning systems, the primary approach appears to be the most appropriate. Unlike satisfaction surveys or organizational benchmarking exercises, PSLS assessments are intended to identify gaps in organizational learning processes and inform quality improvement efforts. From this perspective, classifying "partially agree" responses as suboptimal provides a more conservative and improvement-oriented assessment. This approach is particularly relevant because respondents were quality and safety professionals evaluating systems within their own organizations, creating the potential for favourable assessments. Treating partial agreement as evidence that a process is only partially implemented reduces the risk that important weaknesses are overlooked and aligns with the preventive principles underpinning patient safety practice.

The tertiary (net positive) approach produced findings that were generally more consistent with the primary approach than with the secondary approach. As net positive scores are widely used in patient safety culture research, this approach may be useful for comparisons with previous studies. However, because it excludes "partially agree" responses from both positive and negative classifications, it may obscure areas where implementation is incomplete or uncertain. Consequently, the tertiary approach may be better viewed as a sensitivity analysis rather than the preferred method for identifying priorities for improvement.

The secondary approach remains useful when the objective is benchmarking or summative evaluation, where a more restrictive definition of suboptimal performance may be desired. However, its tendency to classify partially favourable responses as positive may underestimate opportunities for system improvement. Importantly, despite differences in the number of items identified, the highest-ranked suboptimal items remained largely consistent across all three approaches, suggesting that the most critical PSLS weaknesses were robust to the analytical method used.

Management of the "Middle" Response Category

The handling of the "partially agree" option proved to be the single most influential methodological factor. When classified with suboptimal responses (primary approach), it amplified signals for improvement, identifying 33 suboptimal items at the 25% cut-off

point. Reclassifying it as positive (secondary approach) reduced this to 11 shared items at the same threshold. This sharp reduction indicates that "partially agree" responses likely reflect cautious or conditional agreement rather than full endorsement. The tertiary approach's near- or below-zero net positive scores for several items with high "partially agree" proportions (Figure 3 and Table 2) further suggest that this category operates as a transitional or neutral response rather than a clear indicator of satisfaction.

From a practical standpoint, the choice of grouping the middle response should depend on the analytic intent. For a formative evaluation, where identifying potential weaknesses is paramount, the primary approach, that is, treating "partially agree" as suboptimal, is more sensitive and better suited to quality improvement.

Regarding thresholds, the 25% cut-off point remains an effective early-warning indicator of suboptimal performance, whereas the exploratory 40% threshold helps to highlight only the most critical deficiencies. In the tertiary approach, a net positive threshold of approximately 63% or lower aligns with the 25% suboptimal cut-off, offering a comparable reference for overall interpretation.

Implications

This study constitutes a valid contribution to the methodological as well as practical understanding of PSLSs in publicly funded hospitals. This research introduces three comparative analytical approaches through differential handling of "partially agree" responses and differing cut-off points, showing how different analytical framing can significantly alter interpretations of patient safety data. The identification of a net positive threshold equating to a traditional 25% suboptimal cut-off point (approximately 63%)

provides a replicable approach to harmonizing categorical and sentiment-based analyses that can enhance the comparability and interpretability of future surveys. These methodological insights have broader generalizability beyond PSLS evaluation, offering a scalable means for refining Likert-based survey analytics within patient safety and healthcare quality research.

The findings of our survey in Ontario hospitals can offer valuable insights beyond the province, benefiting both national and international healthcare systems. Many barriers and facilitators of the PSLS, such as reporting challenges, fear of blame, and insufficient resources, are common across healthcare settings. By prioritizing these factors, our study can serve as a benchmark for comparison with other regions to guide improvements in their patient safety practices. Additionally, because our survey tool was developed based on a systematic review of global research, its methodology is expected to be scientifically sound and adaptable, allowing for replication in diverse healthcare contexts.

Our findings can guide interventional studies that test the effectiveness of specific strategies to address the high-priority gaps identified, such as in training, leadership support, or closing the feedback loop. Also, they emphasize the importance of exploring organizational and cultural determinants of PSLSs.

Moreover, as the survey was conducted in selected general Ontario hospitals, future studies could be expanded in scope by including smaller or specialized hospitals, community-based facilities, or long-term care settings to assess whether similar needs persist across different healthcare contexts and allow to increase generalizability of the findings.

Another important implication for future research is that we provide a foundation for mixed-method or qualitative follow-up research to delve deeper into why certain areas (e.g., resource availability, reporting culture) continue to be perceived as problematic. Understanding the barriers in more depth might inform tailored interventions. Finally, future studies should seek to validate these findings in broader healthcare contexts, including smaller hospitals, specialized care facilities, community-based organizations, and long-term care settings. Expanding the application of the PSLS assessment tool across diverse healthcare environments would strengthen the generalizability of the findings and support the development of benchmarking frameworks, performance dashboards, and other tools that facilitate ongoing monitoring and improvement of patient safety learning systems at local, provincial, national, and international levels.

Strengths and Limitations

The criteria for selecting hospitals are a major strength of this study. We included a variety of teaching and non-teaching hospitals, each with over 100 beds and at least 10 ICU beds, all part of a health system recognized for its strong commitment to patient safety and the implementation of PSLS [27-30]. These hospitals are expected to have well-developed safety-learning systems, making any shortcomings identified in the study particularly alarming compared to a less-established systems. The study achieved a 71% response rate, which supports the validity of the findings. Participants were senior positions involved in patient safety, ensuring that their responses were informed and credible. Their diverse managerial backgrounds, with an average of 15 years of experience in quality and safety, further enhanced the reliability and generalizability of the results. Participants were likely motivated to enhance their PSLS, which might positively influence the accuracy of the

data. Lastly, following the CHERRIES checklist ensured methodological rigor, transparency, and reduced bias in recruitment, responses, and data management.

While self-reporting enhances transparency and reflects internal accountability, it also introduces potential limitations. Our data may be subject to social desirability or recall bias, and concerns about punishment, blame, or hospital reputation could have influenced responses. To minimize these effects, we emphasized confidentiality and anonymity throughout the survey. The study did not include all Ontario hospitals, nor smaller or out-of-province institutions, which, while controlling for variations in legislation, funding, and culture, may limit the generalizability of findings to smaller or remote hospitals. Including only one participant per hospital, exclusively in patient safety executives, ensured informed responses but may have restricted perspectives across disciplines. Involving frontline workers could have provided a more comprehensive view of PSLS practice but might have reduced assessment precision. Likewise, patients and public members were excluded to avoid heterogeneity from differing backgrounds and experiences. The inferential analysis was exploratory, constrained by the sample size and lack of representation from multiple disciplines. Future studies should conduct post hoc analyses, with larger and more diverse samples, to enhance statistical power and produce more robust, generalizable conclusions.

CONCLUSION

This study demonstrates that the effectiveness of a PSLS depends not only on its structure but also on how its performance is measured and interpreted. The integration of multiple analytical approaches enhances understanding of response sensitivity, while identifying tangible barriers to learning from safety events.

Although policies and frameworks for patient safety learning exist, the leaders' reporting was significantly suboptimal, particularly in the domains of leadership support, training, resource allocation, and feedback mechanisms. The high percentage of suboptimal evaluations, particularly in the "closing the loop" and "follow through" domains, emphasize the need for enhanced communication strategies, leadership-driven engagement, and systematic follow-up on implementing recommendations.

Author Contributions

H.A.M. was primarily responsible for conducting the study, including data collection, data analysis, development of the discussion, and drafting the manuscript. A.F.J., in collaboration with K.T. and S.M., contributed to the design and planning of the study, supervised its progress, and provided critical review and feedback throughout the writing process. The list of participants was jointly developed by H.A.M. and A.J.F., and the invitation letters and consent forms were distributed by A.J.F. All authors reviewed and approved the final version of the manuscript.

Competing Interests

The authors declare no competing interests.

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SUPPLEMENTARY INFORMATION

Supplementary Table 1. The five-point scale questions of the survey classified by domains. The frequencies of the "suboptimal", "agree" and "strongly agree" responses are shown for each question on the level of the selected Ontario hospitals.

Domains	Subdomains	Questions/responses*	Suboptimal responses	Agree	Strongly agree
a. Before the incident	Training	5. I received training on our PSLS at least once during my employment.*	NA	NA	NA
		6. It should be my responsibility to undergo re-training on the PSLS periodically.	23	4	3
		7. My training on reporting and/or analyzing incidents was effective in preparing to fulfill my responsibilities.	7	18	5
		8. Training material describes how to classify safety events in terms of their severity and recurrence risk.	5	14	11
		9. The training plan for PSLS is well-developed, monitored and tailored to each member of staff according to their role in the system.	18	10	2
	Organizational and leadership support	10. I have access to all policies and procedures related to the PSLS.	2	12	16
		11. The policies and procedures related to the PSLS are easy to understand.	6	15	9
		12. I am recognized positively for reporting safety events by my supervisor or leader.	15	5	10
		13. Hospital leadership provides rewards and incentives to encourage safety event reporting.	25	3	2
		14. The reporting system prevents individuals from being unfairly blamed for making errors.	17	9	4
		15. Managers regularly review and update system related policies and procedures.	7	13	10

	Just and safety culture	16. I believe reporting incidents is my responsibility as it will lead to preventing future events.	3	9	18
		17- The PSLS is integrated in everyday work to ensure high compliance.	18	7	5
	Availability of resources	18. Management allocates sufficient resources for reporting, analysis and investigating incidents.	16	9	5
b. Immediate response	Care for reporters	19. I must report the same incident using different approaches (e.g., patient files, nursing reporting system, safety department).	24	6	0
		20. Reporting incidents have never caused troubles with my colleagues and is viewed favorably within my unit's culture.	17	4	9
		21. Managers and leaders have the authority to support reporters.	6	16	8
		22. Policies and protocols support the non-punitive reporting environment.	3	14	13
		23. There are policies and protocols to protect reporters against legal and non-legal actions.	10	15	5
		24. The hospital requires reporting to an independent body to avoid blaming and enhance fair analysis.	16	11	3
	Confidentiality	25. I have no concern about confidentiality when I complete the incident report forms.	11	12	7
	Reporting the incident	26. All staff have access to an electronic system for reporting safety events.	5	13	12
		27. I have alternative reporting options to enhance efficiency, such as telephone reporting, manual and electronic reporting.	22	6	2
		28. Incident review forms are self-explanatory and time efficient to complete.	15	12	3
		29. I understand that Incident reporting is the responsibility of the person who witnessed the event	5	11	14

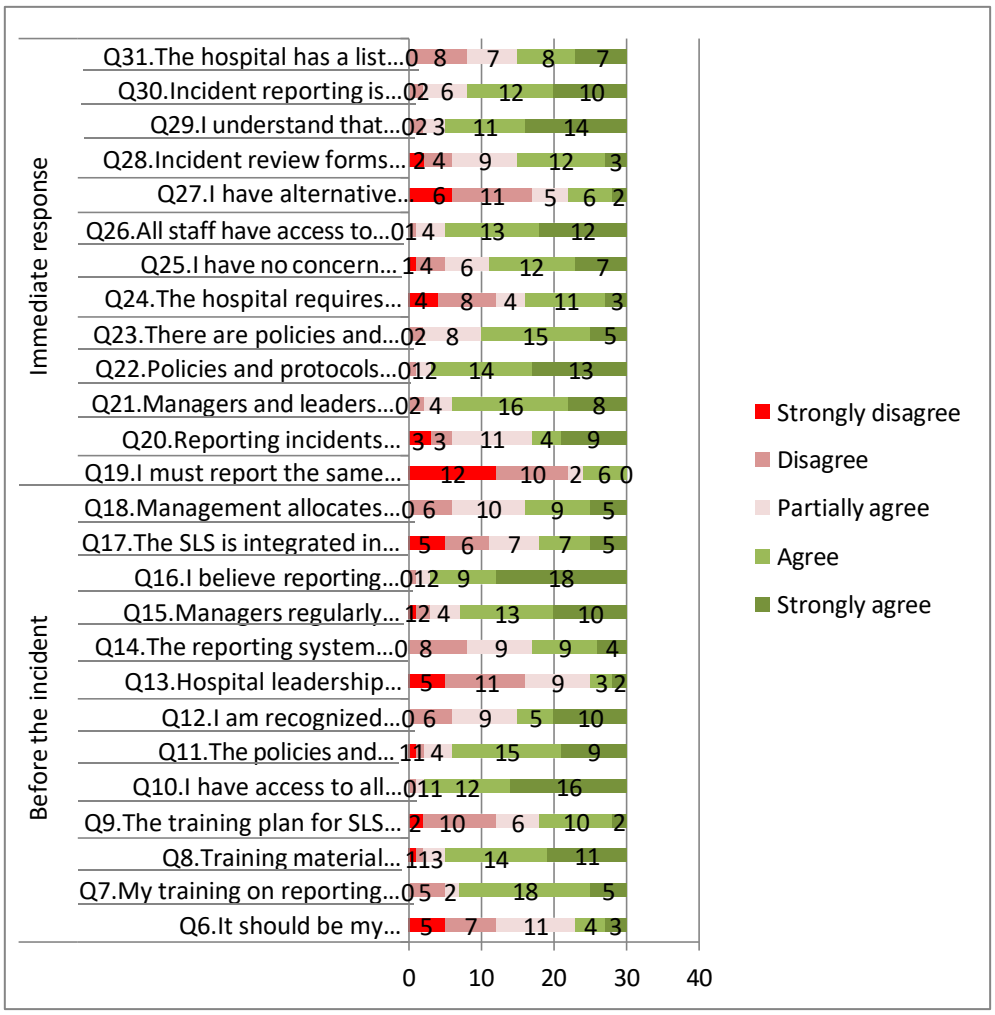
		and should not be delegated.			
		30. Incident reporting is mandatory.	8	12	10
		31. The hospital has a list of prioritized incidents to be reported.	15	8	7
c. Prepare for analysis	Preliminary investigation and appropriate analysis methods	32. The investigation team uses appropriate analysis tools to describe the findings of the review.	9	15	6
	Identify team and interview plan	33. Management ensures engagement of the front-line workers in the investigation team.	15	12	3
		34. Management ensures analysis teams are composed of representative expertise.	9	16	5
		35. There are well trained investigation experts participating in each team.	12	9	9
		36. The incident investigating team ensures equal and fair multidisciplinary participation.	9	16	5
		37. Staff and management are capable in performing incident investigation.	15	13	2
d. Analysis process	Investigation process	38. Interviewers investigating the incidents consider and confirm the confidentiality of the interviewees.	9	16	5
	Develop and manage recommendations	39. Recommendations are professionally developed.	6	16	8
e. Follow through	implement	40. Implementation of recommendations is well monitored.	15	10	5
		41. I observe enhancements to safety based on previously reported incidents.	12	12	6
	Follow and assess	42. Management evaluates compliance with recommended safety enhancements using formal	12	12	6

		(e.g., audits, and score cards) methods.			
		43. Management evaluates compliance with recommended safety enhancements using informal (e.g., risk officer spot check) methods.	15	9	5
f. Close the loop	Share learn internally and externally	44. I can track the processing of my reported incidents.	12	7	11
		45. People receive feedback on their reported events.	26	3	1
		46. There are regular communications between senior management and frontline staff with respect to values, expectations, and the results of learning from incident reporting.	24	5	1
		47. There are regular communications between senior management and quality leaders with respect to values, expectations, and the results of learning from incident reporting.	7	19	4
		48. The management has a defined communication approach to share learning internally.	14	15	1
		49. The management has a defined communication approach to share learning externally.	22	7	1
		50. There is transparency in data sharing about the findings of reviews.	14	15	1
		51. Serious and high-risk incidents have their own feedback route.	1	16	13

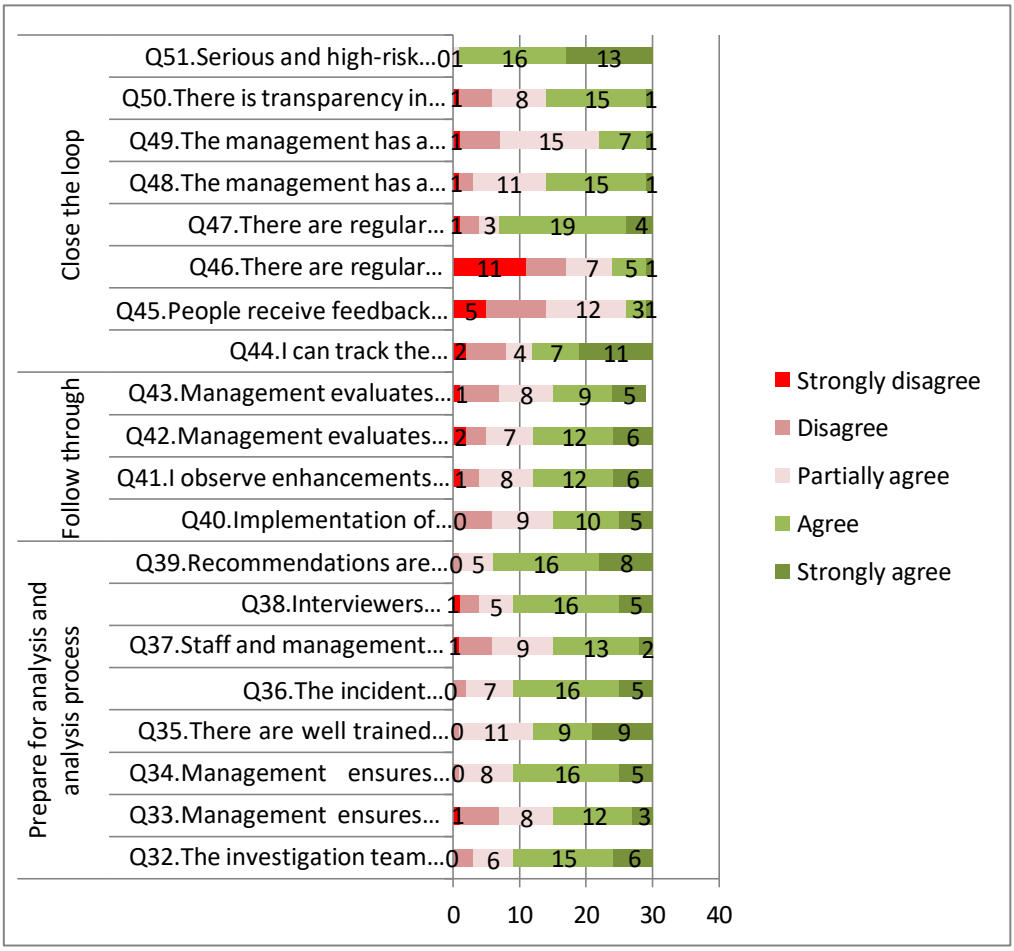
* Response variables for this question are yes/no items, total number = 30.

** Strongly disagree=1, disagree=2, partially agree=3, agree=4 and strongly agree =5.

Supplementary figure 1. The number of hospitals distributed over the different response categories for each item of the questionnaire. No threshold for reporting was used. Questions are written in full in Supplementary Table 1. Questions 1–5 do not have Likert-scale answers and are therefore not represented here.



Supplementary Figure 1 (*continued*). The number of hospitals distributed over the different response categories for each item of the questionnaire. No threshold for reporting was used. Questions are written in full in Supplementary Table 1. Questions 1–5 do not have Likert-scale answers and are therefore not represented here.



CHAPTER 5

Discussion

This thesis adopts a methodological design that integrates both the development of a standardized self-assessment instrument for evaluating Patient Safety Learning Systems (PSLSs) and its empirical testing in Ontario hospitals to assess its psychometric properties and applicability in real-world healthcare settings. The central goal of this thesis was to develop a tool for assessing PSLSs using comprehensive and up-to-date evidence from recent studies on factors that facilitate or hinder their effectiveness. This tool aims to provide insights into healthcare systems to support policymakers, healthcare providers, and researchers in making informed decisions to strengthen PSLSs and ultimately enhance patient safety.

This discussion chapter synthesizes the findings from three interrelated studies aimed at identifying barriers and facilitators of a PSLS, developing a survey tool that can be used as a standardized self-assessment questionnaire for evaluating practices within the PSLSs in Canadian as well as international hospital settings. The introduction to the thesis (Chapter 1) presented a comprehensive literature review on PSLSs, highlighting the challenges associated with their implementation. It described the ongoing efforts to integrate PSLSs into healthcare settings and illustrated the persistently high rates of adverse events, which point to significant gaps in the effectiveness and adoption of the system [1]. Studies have tended to focus on the reporting of events rather than the factors improving the downstream actions of analysis and learning [2]. I surmised, and it is supported by others, that this might reflect actual practice by which organizations spend more time

collecting data rather than developing action plans for improving [3]. Chapter 1 also presented the research objectives that each corresponded to one of the three studies comprising my thesis. In Chapter 2, I present my first study which used systematic review and meta-synthesis techniques [4] for evaluating factors identified in published and unpublished studies perceived to affect the safety learning system in hospital settings. The results from this study directly informed and were incorporated into the second study (Chapter 3) in which I described our methodology for developing a self-assessment survey tool to evaluate the PSLS [5]. The tool was tested for face validity and internal consistency, which are suitable for preliminary evaluation of a newly developed tool. Before considering its broader application, further testing is essential and is discussed in this chapter alongside key implications for practice, policy, and future research. This tool served as the cornerstone for implementing the third study (Chapter 4), in which I surveyed quality and safety (Q&S) leaders within a large publicly administered health system to assess their perceptions of a voluntary reporting system and to test the tool's response scale and different cut-off points.

SUMMARY OF METHODOLOGIES AND KEY FINDINGS FROM CHAPTERS 2–4

Barriers and Facilitators of the Patient Safety Learning System

The first study (Chapter 2) systematically reviewed 22 studies, extracting 375 factors influencing the effectiveness of patient safety learning systems (PSLSs) in hospitals [4]. Using the Patient Safety Management Toolkit [6], six themes and 16 subthemes were developed, with "immediate response" emerging as the most cited barrier, particularly around incident reporting, confidentiality, and emotional support for reporters. Key

challenges included fear of blame, lack of psychological safety, and insufficient confidentiality mechanisms deterring incident reporting [7-10]. The "before the incident" theme emphasized the importance of training, leadership support, safety culture, and adequate resources in fostering proactive safety practices [11]. Less frequently cited but equally important factors—such as multidisciplinary analysis, effective follow-up, and timely feedback—were found critical for ensuring learning and system improvement. Overall, the study highlighted the need for strong leadership, just culture, and structured feedback processes to enhance PSLS effectiveness and learning across healthcare organizations.

Development of a Valid and Reliable PSLS Survey Tool

The development of the survey tool followed three structured steps. **Step one** involved retrieving the 68 items developed from the systematic review and refining them through iterative meetings between two researchers to reduce redundancy and improve clarity. Items measuring similar aspects of the system were merged and rephrased into clear, concise questions [5]. This process, conducted over several iterative sessions, reduced the number of items from 68 to 47. Specifically, the number of items under the "Before the Incident" domain decreased from 21 to 14, "Immediate Response" from 19 to 13, "Prepare for Analysis" from 10 to 6, "Follow Through" from 6 to 4, and "Close the Loop" from 10 to 8, whereas "Analysis Process" remained unchanged. **Step two** focused on ensuring the clarity and relevance of questions and their response variables. Three health service researchers with substantial Q&S expertise, who also participated in the systematic review, independently evaluated the items using an Excel-based feedback form. This was a purposive expert panel, chosen for their familiarity with the study and experience in

evaluating PSLSs, rather than a representative sample. Although this approach provided expert insight, limitations included the small number of participants, reduced diversity, and potential bias arising from the reviewers' prior involvement in the systematic review, which might have limited generalizability. **Step three** involved piloting the finalized tool using LimeSurvey, with 56 participants invited and 20 completing the survey. Seventeen participants provided partial responses, which were excluded from the analysis. Including partial responses could have biased the clarity and necessity ratings and compromised the validity indices, as each item would have been rated by a different number of respondents. All completed responses were analyzed for clarity, necessity, and internal consistency, with items receiving more than 20% negative ratings considered for removal. As none met this criterion, all 47 items were retained.

In the original peer-reviewed article, we described the second step of the study and how the participating researchers rated every survey item. In retrospect, we recognize that the description of their criteria for rating might have been confusing. For clarity, we reiterate the process: reviewers were requested to anchor their response such that "no" would indicate the item was not relevant, and "yes" would indicate high relevance and clarity. If two or more reviewers scored an item "no," that item was excluded from the draft. If a reviewer selected "yes, with modification," it indicated that the item was relevant but unclear. In these cases, reviewers were invited to supply an alternative text for the research team to deliberate on. This led to the cancelling of two questions, the revision of 15, and the introduction of two new ones. Additionally, to improve the accuracy of the collected data, it was determined through formal consensus among the three researchers that 17 questions focusing on the managerial aspects of PSLS management (which could

fall outside the scope of work for some staff) should be answered exclusively by Q&S experts and leaders, whereas the remaining questions could be completed by Q&S professionals and other participating staff members alike. Finally, the questionnaire's internal consistency was tested using participants' evaluations of their PSLS at The Ottawa Hospital, yielding a high Cronbach's alpha value of 0.94. An item-deletion analysis was conducted and showed no significant reduction in alpha score when any single item was removed, indicating relative overall coherence of the instrument. This finding suggests that all items contribute meaningfully to the construct being measured and that the very high reliability score can be attributed to the close interrelationship among the survey domains.

Quality Leaders' Survey of Their Safety Learning System Capability

The third study of this thesis (Chapter 4) explored Q&S experts' opinions on the barriers within the PSLS in their hospitals in Ontario. Overall and based on the primary approach of analysis, 33 out of 47 questions (67%) received a suboptimal response, that is, at least 25% of respondents rated their opinions as strongly disagree, disagree, or partially agree. The highest proportions of suboptimal responses were received for the following questions: "People receive feedback on reported events" (26/30, 87%), "Hospital leadership provides rewards and incentives to encourage safety reporting" (25/30, 83%), and "Regular communications with respect to values, expectations, and learning" (24/30, 80%). The lowest proportions of suboptimal responses were returned for the following questions: "Serious and high-risk incidents have their own feedback route" (1/30, 3%), "I have access to all policies and procedures related to the PSLS" (2/30, 7%), and "I believe incident reporting is my responsibility" (3/30, 10%). The lowest proportion of negative perceptions by PSLS domain was in "analysis of events" for which 15% had negative perceptions.

It is also important to note that over 83% of hospitals perceived their PSLS to have significant gaps. Within domains, 97% and 80% of respondents, respectively, had a negative perception of their ability to close the loop and follow through with actions.

In addition, the comparison of different analytical approaches in this thesis highlights important methodological considerations in PSLS measurement and interpretation. The primary, secondary, and tertiary analytical approaches produced variations in the classification of items requiring improvement, demonstrating how methodological choices can influence organizational assessment outcomes. The treatment of the mid-point response ―partially agree‖ and the application of varying cut-off thresholds (25%, 40%, and the equivalent 63% net-positive score) significantly influenced interpretation of the results. Grouping ―partially agree with negative responses in the primary approach produced the most conservative findings, identifying 33 suboptimal items, a broader range of potentially suboptimal areas, which may be preferable in safety-sensitive environments where early identification of weaknesses is prioritized over restrictive classification. In contrast, the secondary approach provided narrower classifications that reduce false positive identification but risk overlooking emerging concerns. Reclassifying it as positive in the secondary approach reduced the number of identified suboptimal items to 11; however, these items corresponded to the highest-ranked suboptimal items identified in the primary approach. When a corresponding cut-off point was applied to the tertiary approach, which neutralized the midpoint and applied the 63% threshold, the resulting list of priority items showed strong alignment with the findings generated by the primary approach. This suggests that although analytical methods may differ statistically, they can converge conceptually in identifying major areas requiring attention.

TOWARD A BROADER UNDERSTANDING: MERGING FINDINGS FOR A HOLISTIC VIEW

Both the first and third studies explored the barriers and facilitators of the PSLS, each from a distinct perspective. The first study identified these factors globally through a systematic review, prioritizing them based on the frequency at which they are reported in published research. By contrast, the third study focused on Ontario hospitals, surveying Q&S experts to determine the most pressing challenges in their local context. Findings from the third study revealed that 83% of participants evaluated their PSLS suboptimally. Notably, the survey items evaluated in the third study had been developed in the second study, which built upon insights from the systematic review conducted in the first. Differences in how challenges within a PSLS are perceived can be attributed to factors such as cultural context, economic conditions, education, and professional experience.

An overall theme arising from the published literature and confirmed by the opinion of Ontario leaders was that inadequate training remains a significant barrier to effective incident reporting in healthcare settings. Both studies demonstrated a perception that insufficient education plays a role in how safety events are reported, with a notable lack of continuous training for both frontline staff and management. These findings align with previous research emphasizing that ongoing education is critical for fostering a culture of safety and improving reporting behaviors [12,13]. Another key issue identified in both studies is the lack of leadership management support. Participants in our survey opined that leadership often fails to encourage reporting, provide rewards, or prevent a punitive response when incidents are reported. This corresponds with findings from other studies that show strong leadership engagement to be essential for establishing a positive reporting

culture, as healthcare professionals are more likely to report incidents if they feel supported by management [14-17]. The challenge of creating a just and safe culture also emerged as a common theme. Both the first and third studies found that many healthcare professionals perceive incident reporting as a process tied to personal blame rather than a system for learning and improvement. This fear-driven culture discourages reporting and has been identified as a critical factor in the underreporting of patient safety incidents [18,19].

Resource adequacy emerged as a recurring factor influencing PSLS performance across both the literature and Ontario survey findings. Participants identified limitations related to staffing, time, infrastructure, and technological support as barriers affecting reporting, analysis, and follow-through activities. These findings suggest that organizational capacity and resource availability represent important measurable dimensions within PSLS evaluation frameworks [7,11,13,20-26].

Confidentiality concerns and fear of repercussions also emerged as major barriers. Many leaders demonstrated a lack of confidence in their system's ability to protect against legal consequences, loss of professional reputation, or punitive action from leadership. This fear is well-documented in other studies, which emphasize the importance of anonymous reporting and clear policies for protecting reporters from negative consequences [11,27].

This thesis highlights the importance of analyzing reported incidents and following up on recommendations, development and implementation, and identifies them as areas for improvement.

The included systematic review identified a shortage in research assessing incident analysis, development and implementation of recommendations and the follow-up on these

recommendations. To address this problem, we aligned our results with these areas, ensuring more comprehensive coverage of the different stages of the system. This was attained by applying the identified barriers for "before the incident" and "immediate response" to the three themes not addressed in the primary included studies: "prepare for analysis", "analysis process", and "follow up". We found that these barriers are pertinent to the missed subdomains and include a lack of time, resources and training for analysis, and a lack of direct communication between the departments responsible. Under these circumstances, developing analysis teams is difficult. Also, staff are unwilling to participate in these teams for fear of losing reputation. The corresponding facilitators to these barriers are to bridge the gap in communication by holding regular meetings and structuring well-represented teams with front-line engagement and top-level commitment.

Engagement of front-line workers, use of appropriate analysis tools, and capability of staff to investigate incidents are expected to improve the analysis and consequently the development of recommendations. Our third study reported that the monitoring of recommendations needs improvement in Ontario hospitals. That improvement should be tangible to reporters, with strong follow-up and monitoring measures in place.

This shortfall critically undermines the effectiveness of PSLSs, as the primary objective of these systems is to foster continuous improvement in patient safety through the application of learned insights. When there is a defective analysis, or recommendations are not well developed or wrongly executed, the same errors are likely to recur, perpetuating preventable harm and eroding trust in the healthcare system. The WHO has emphasized that incident reporting systems are only effective if they lead to actual improvements in patient safety. The WHO cautions that without the implementation of corrective actions, reporting systems can fail to achieve sustainable risk reduction and safety enhancements

[12]. A study conducted at a Swedish university hospital sought to identify the mechanisms behind successful implementation of recommendations from incident investigations. The findings showed that merely generating recommendations is insufficient; active efforts to implement these recommendations are crucial for achieving tangible safety improvements [13].

Both studies reported a system lack in providing feedback after incidents are reported. This aligns with existing literature, which confirms that timely and meaningful feedback is essential to maintaining trust in the reporting system and encouraging participation [28,29].

KEY GAPS AND THE CONTRIBUTION OF THIS THESIS

As reported in Chapter 1, key gaps in the field of PSLSs include the continued high rates of adverse events despite PSLS adoption, the scarcity of evidence-based studies (systematic reviews) that identify factors that might hinder the effectiveness of the PSLS, the focus of literature on reporting rather than the subsequent steps of the system, the lack of standardized and empirically informed tools capable of assessing PSLS performance in a structured and reproducible manner across healthcare settings. The three studies presented here directly or indirectly addressed these gaps: the first study systematically identified and categorized key barriers and facilitators influencing PSLS performance, establishing an evidence-based foundation for evaluation; it emphasized the importance of different steps of the system for the cycle of learning to complete, and this was reflected on the survey tool developed.

Building on these findings, the second study developed a domain-structured self-

assessment survey intended to measure organizational PSLS practices in a standardized way. The survey was constructed directly from factors identified in the systematic review and organized across multiple stages of the learning system, thereby addressing the absence of structured measurement instruments in the field. Preliminary psychometric evaluation demonstrated strong face validity and high internal consistency, supporting the coherence of the proposed domains while also highlighting the need for further construct validation and reliability testing in larger and more diverse samples. Importantly, this study contributes to the field by shifting the focus from measuring isolated patient safety outcomes toward measuring the organizational systems responsible for detecting, analyzing, learning from, and responding to safety events.

The third study applied this instrument within Ontario hospitals to examine how PSLS performance can be interpreted using different analytical approaches and cut-off thresholds. The findings demonstrated that the classification of midpoint responses and the choice of threshold substantially influence the number of items identified as requiring improvement. However, the primary and tertiary analytical approaches identified highly similar priority areas when corresponding cut-off points were applied, suggesting that more conservative analytical approaches may provide a precautionary advantage in patient safety research by identifying a broader range of potential system weaknesses. These findings allow us to contribute methodologically to the field by illustrating how analytical decisions influence PSLS evaluation and interpretation.

METHODOLOGICAL CHALLENGES IN PSLS MEASUREMENT

Assessing the effectiveness of PSLSs continues to pose methodological difficulties, given

their multidimensional nature and their operation within complex organizational contexts. Unlike clinical outcomes that can often be measured directly, PSLS effectiveness depends on multiple interrelated domains, including reporting accessibility, leadership support, feedback processes, training, organizational learning, confidentiality, and safety culture. Previous studies have similarly described PSLSs as complex sociotechnical systems involving interconnected organizational, cultural, and governance-related processes rather than isolated reporting mechanisms alone [28,30-32]. Many of these constructs are inherently subjective, relying on staff perceptions and organizational behaviors that cannot be directly observed or quantified through a single indicator. Moreover, the lack of universally accepted gold standards for evaluating PSLSs contributes to significant variation in how healthcare organizations define, implement, and assess their safety learning activities [33,34]. Differences in organizational structure, governance models, reporting practices, and institutional resources further complicate efforts to compare systems across hospitals and health systems [31,35].

A further challenge lies in distinguishing between the measurements of patient safety itself and the measurement of systems designed to support patient safety learning. While PSLSs ultimately aim to reduce patient harm, improvements in patient outcomes are shaped by numerous external clinical and organizational factors that extend beyond the reporting system alone. Consequently, evaluating a PSLS requires measuring whether the system effectively supports reporting, analysis, feedback, learning, and organizational response rather than measuring patient outcomes alone. This distinction is increasingly recognized in the literature, which suggests that adverse event rates alone may not adequately reflect the maturity, responsiveness, or learning capacity of organizational safety systems [30,36]. It is possible for a healthcare organization to exhibit robust reporting and learning mechanisms

even while contending with persistent, system-wide safety issues. As such, the evaluation of PSLSs demands methodologies that account for organizational learning capacity, governance frameworks, and system functionality alongside conventional safety metrics [28,37].

Safety culture and organizational learning also present important methodological challenges because they are heavily influenced by institutional context, professional role, leadership practices, and interpersonal dynamics. Perceptions of blame, fairness, openness, and psychological safety may differ substantially across departments and professional groups, making standardized measurement difficult [38,39]. Similar challenges have been reported in studies evaluating safety culture instruments, where contextual variation and subjective interpretation can affect reliability and comparability between institutions [37,39]. Many of the barriers identified in this thesis, including communication difficulties, inconsistent feedback processes, leadership engagement, and reporting reluctance, reflect broader governance and organizational learning challenges commonly observed in large and complex institutions rather than issues unique to healthcare settings alone [30,32,35].

PSYCHOMETRIC CONSIDERATIONS AND FUTURE VALIDATION OF THE DEVELOPED TOOL

Although the tool has undergone face validation and demonstrated strong internal consistency, it is not yet fully ready for widespread application. A deeper understanding of the various approaches to testing validity and reliability is necessary to comprehensively evaluate its current stage of development.

Face validity reflects the extent to which our tool appears, on the surface, to measure

what it is intended to measure. It is typically evaluated through expert judgment rather than statistical analysis. In developing the PSLS survey, face validity was established through iterative review by Q&S professionals and patient safety experts who assessed each item for clarity and relevance. This process suggests that the questions were understandable and contextually appropriate for the target respondents. The main strength of this approach lies in its ease of application, its ability to enhance user acceptance, and its credibility. However, as a subjective measure, it does not provide empirical evidence of accuracy and might overlook deeper conceptual gaps that only emerge through quantitative validation [40-42].

Content validity was partially addressed by systematically mapping survey items to the six PSLS domains identified through the meta-synthesis study and subsequent expert review [43]. This process helped ensure that the instrument captured multiple dimensions of PSLS functioning, including reporting, analysis, feedback, and organizational learning. Nevertheless, the relatively small number of experts and participants from a single healthcare system may limit the broader generalizability of the findings [40,44].

Establishing criterion validity for PSLS instruments remains particularly challenging because no universally accepted external benchmark for organizational safety learning currently exists [43,45]. Unlike clinical outcomes that can often be compared against objective standards, PSLS effectiveness involves organizational processes, perceptions, governance structures, and learning activities that are difficult to measure directly. Furthermore, external indicators such as adverse event rates or safety culture surveys may themselves be influenced by multiple confounding organizational and clinical factors, limiting their suitability as gold-standard comparators [46,47].

Construct validity represents another important challenge in PSLS measurement. Because PSLSs are inherently multidimensional systems involving organizational culture, leadership, reporting behaviors, communication, and learning processes, establishing whether survey items accurately reflect the intended theoretical domains requires rigorous statistical evaluation [46,47]. In this thesis, construct validity was preliminarily supported by high internal consistency (Cronbach's $\alpha = 0.94$), suggesting that the survey items coherently measured related aspects of PSLS performance. However, such a high alpha value may also indicate overlap or redundancy among closely related domains, emphasizing the need for additional construct validation [48]. Future studies should therefore apply exploratory and confirmatory factor analysis across larger and more diverse samples to determine whether the proposed domain structure remains stable across institutions and professional groups.

Reliability tests are also essential to confirm the stability of the newly developed PSLS tool, each with distinct advantages and limitations. Inter-rater reliability assesses the level of agreement among different raters, ensuring consistency across hospitals or professional groups. It provides strong evidence of scoring objectivity and tool clarity [49] but can be influenced by variations in rater training, interpretation, or institutional context, potentially lowering agreement even if the instrument is robust. Test–retest reliability, which involves administering the tool twice over a short interval, measures temporal stability and helps determine if responses are consistent over time [41]. Although straightforward, this method can be affected by recall bias or actual organizational changes between tests, thus confounding reliability estimates. Longitudinal reliability, which is a measure of a tool's stability over months or years, or post-intervention changes, extends this concept by evaluating consistency across repeated applications in evolving contexts. It provides insight

into long-term dependability and sensitivity to change but is resource-intensive, time-consuming, and vulnerable to participant attrition or system-level shifts that obscure reliability pattern [50].

Based on the aforementioned methods, conducting further psychometric evaluation of the newly developed tool is required before using it on a wider scale; future studies on PSLS survey tools should include several complementary methods. Construct validity can be established through exploratory and confirmatory factor analysis across diverse hospitals to confirm that items align with theoretical PSLS domains. Test–retest reliability should be evaluated by re-administering the survey after 2–4 weeks to the same participants and calculating intra-class correlation coefficients (ICCs) to assess response stability over time. Longitudinal reliability would track changes in PSLS scores before and after safety interventions, providing evidence of responsiveness and sensitivity to change. Finally, inter-rater reliability should be examined by comparing ratings from multiple respondents within the same institution (e.g., quality leaders vs. frontline workers) using ICCs to ensure consistent interpretation of survey items between raters and settings. Future studies should include a greater sample size to allow for construct validity and, inter-rater reliability testing with raters from different disciplines in each participating hospital as well as from a diverse range of hospitals that vary in size, type, and region to ensure both within- and between-institution consistency and generalizability.

VARIED STAKEHOLDER PERSPECTIVES

Excluding patients, families, and small hospitals from our research may introduce limitations regarding inclusivity and the scope of learning. A focus on large, general and tertiary-care hospitals with mature PSLS infrastructures might strengthen a study's internal validity. These institutions provide data from experienced Q&S teams whose assessments of such complex systems are expected to be both accurate and appropriate to the research scope [51]. These larger facilities typically employ dedicated patient safety officers, maintain integrated electronic reporting platforms, and adhere to standardized protocols, which collectively enhance the reliability and comparability of findings [52]. Moreover, directing this research toward well-resourced environments enables the evaluation of established safety cultures and advanced feedback mechanisms. This approach might yield a clearer picture of system performance and potential improvement areas, while minimizing confounding variables like resource scarcity or partial system implementation often encountered in smaller healthcare settings. Furthermore, exclusion of broader coordinating bodies, such as the Ontario Surgical Quality Improvement Network (OSQIN), allowed this investigation to concentrate specifically on hospital-level PSLS implementation. This narrower focus was designed to generate more precise insights into frontline operations and leadership practices [53]. This method reduced potential confounding from broader system initiatives.

Furthermore, smaller and rural hospitals frequently encounter distinct barriers, including constrained staffing, technology, and training resources, that differentially influence the implementation of PSLS compared to larger institutions [54]. Overlooking these settings may lead to an overestimation of overall system performance and an

underrepresentation of the challenges related to scalability and equity in safety learning [55]. Similarly, failing to include patient and family input overlooks crucial experiential knowledge that can reveal communication gaps, cultural barriers, and missed opportunities to learn from harmful events [56]. Additionally, excluding higher-level coordinating centers may restrict insights into cross-hospital learning, benchmarking efforts, and the integration of related policies [57,58].

PRACTICAL RECOMMENDATIONS AND CONCLUSIONS BASED ON FINDINGS

The findings from this research highlight several organizational and methodological factors that influence how PSLS effectiveness can be evaluated within healthcare settings. Rather than focusing solely on improving patient safety outcomes directly, the findings emphasize the importance of measuring the structures, processes, and organizational conditions that support safety learning within healthcare organizations.

Organizational Infrastructure and Governance

An effective PSLS is a foundation for improving patient safety; it goes beyond systematic reporting to ensure accessibility (easy to use), completeness (captures all event types), non-punitive nature (encourages honest reporting), timely feedback, and system-wide learning integration [59]. Across the studies, reporting accessibility, ease of use, confidentiality, and clarity of reporting procedures emerged as important dimensions influencing perceptions of PSLS effectiveness. The findings suggest that these characteristics should be conceptualized as measurable organizational constructs within PSLS evaluation frameworks.

The studies also identified confidentiality and fear of repercussions as important

determinants of reporting engagement [3]. Perceptions of psychological safety, anonymity, and trust in reporting processes were consistently associated with willingness to participate in safety reporting and learning activities. In addition, leadership support emerged as an important organizational factor influencing PSLS performance [60]. Leadership engagement affected multiple domains simultaneously, including reporting culture, communication, resource allocation, staff participation, and follow-through on recommendations, making it difficult to operationalize as a single construct. Nevertheless, the findings suggest that governance-related characteristics, such as formal reporting policies, accountability structures, leadership participation in safety review processes, and existence of feedback mechanisms, represent important measurable indicators of PSLS functioning.

Resource adequacy also emerged as an important dimension influencing PSLS performance [2,61]. Participants frequently identified limitations related to staffing, protected time, infrastructure, and training capacity as barriers affecting reporting, analysis, and follow-through activities. These findings suggest that organizational capacity should be incorporated into PSLS evaluation frameworks, not solely in financial terms, but as measurable organizational characteristics influencing the ability of institutions to sustain safety learning processes.

Organizational Learning and Feedback Processes

A major finding across the studies was the perceived weakness of feedback and follow-through mechanisms within PSLSs. These findings reinforce the importance of evaluating not only whether incidents are reported, but also whether organizations demonstrate evidence of analysis, communication, implementation of recommendations, and

organizational learning following reported events [2,62].

The studies suggest that feedback processes, dissemination of lessons learned, and monitoring of recommendations represent measurable indicators of PSLS maturity. However, evaluating organizational learning remains methodologically challenging because learning processes are often indirect, multidimensional, and influenced by broader institutional culture and governance structures.

Training also emerged as a recurring factor influencing perceptions of PSLS effectiveness across both the systematic review and the Ontario survey findings [63,64]. Rather than being viewed solely as an operational intervention, training should be considered a measurable component of PSLS performance. Important indicators may include the availability of training programs, frequency of educational activities, and staff perceptions regarding preparedness to participate in reporting and learning processes.

Safety culture is defined as shared values, beliefs, attitudes, and behaviors within an organization that determine how safety is prioritized, managed, and improved [65]. Just culture is a component of safety culture that focuses on accountability and fairness, ensuring that individuals are not punished for human errors, but are held accountable for reckless or negligent behaviors [66]. Measuring safety culture remains conceptually challenging because perceptions of blame, fairness, openness, and psychological safety may differ substantially between individuals, professions, and institutions. Despite these challenges, the findings indicate that perceptions of non-punitive reporting and psychological safety remain important measurable domains influencing participation in reporting and organizational learning activities.

The findings also highlight transparency and communication as important organizational dimensions influencing perceptions of PSLS effectiveness [67,68]. In particular, participants emphasized the importance of clear communication regarding incident analysis, feedback processes, and follow-up activities. These findings suggest that transparency-related constructs, such as openness of communication, clarity of reporting processes, and perceived fairness of analysis procedures, may represent important domains for future PSLS measurement frameworks.

FUTURE DIRECTIONS IN PSLS MEASUREMENT AND EVALUATION

The next steps for advancing the field of PSLSs should prioritize the development of standardized and empirically validated measurement approaches. A recent scoping review highlighted substantial heterogeneity among existing PSLS evaluation tools and limited comparability across healthcare settings, reinforcing the need for methodological standardization [69]. Establishing standardized PSLS frameworks and evaluation approaches across healthcare organizations could improve benchmarking, facilitate cross-institutional learning, and support more consistent interpretation of organizational safety learning practices [57]. Future research should also focus on methodological harmonization, including clearer guidance regarding analytical approaches, treatment of midpoint responses, selection of cut-off thresholds, and interpretation of domain-level performance. As demonstrated in this thesis, analytical decisions can substantially influence the number of items identified as requiring improvement, even when overall patterns remain conceptually similar.

Further psychometric evaluation of the newly developed survey tool is also required before broader implementation. Although preliminary testing demonstrated strong face validity and internal consistency, additional validation studies should examine construct validity, inter-rater reliability, test–retest reliability, and longitudinal responsiveness across larger and more diverse healthcare settings. Future studies should evaluate whether the proposed domains remain stable across institutions, professional groups, and healthcare systems, while also assessing the survey's suitability for longitudinal monitoring and benchmarking purposes. Replication in other jurisdictions and countries would further clarify the generalizability of the findings and determine whether the identified challenges are specific to Ontario hospitals or reflect broader organizational issues affecting PSLSs internationally.

Expanding PSLS evaluation across diverse healthcare contexts remains equally important. Smaller hospitals, rural institutions, and other underrepresented healthcare settings may experience different organizational and structural barriers affecting PSLS implementation and evaluation [70]. In addition, future studies should further explore how patients and families can contribute to PSLS evaluation and organizational learning processes. Their perspectives may provide important insights into communication, transparency, and follow-up practices that are not fully captured through organizational self-assessment alone [70]. Similarly, additional research is needed to better evaluate downstream PSLS functions, including incident analysis, implementation of recommendations, monitoring of corrective actions, and dissemination of lessons learned, as these stages remain comparatively underexplored in the literature despite representing essential components of organizational learning.

Governance and leadership structures also remain important determinants of PSLS

effectiveness. Previous studies have demonstrated that leadership engagement influences reporting culture, staff participation, and organizational learning processes [71,72]. The AHRQ similarly emphasizes the importance of leadership support in maintaining reporting systems, protecting reporters, and integrating safety learning into organizational priorities [73]. However, future work should move beyond broad discussions of leadership principles toward identifying measurable governance structures and organizational practices associated with stronger PSLS performance. Examples may include the presence of dedicated PSLS committees, frequency of safety review meetings, existence of formal feedback mechanisms to reporters, and monitoring of recommendation implementation rates.

Despite the complexity of healthcare systems and the barriers affecting PSLS implementation, some Canadian initiatives illustrate the potential value of structured reporting, benchmarking, and longitudinal feedback processes. One example is the ONSQIN, a provincial quality-improvement initiative focused on surgical care [74]. Although ONSQIN is not a comprehensive PSLS, it demonstrates how standardized data collection, benchmarking, and continuous performance feedback can support organizational learning and system improvement over time [75]. Such initiatives may help inform the future development of broader PSLS evaluation frameworks that integrate learning, feedback, benchmarking, and continuous organizational improvement mechanisms. Future research should include representatives from such networks to strengthen generalizability and link local PSLS practices to broader safety strategies.

Many important dimensions of PSLS effectiveness, including organizational learning, communication, leadership engagement, feedback quality, and safety culture, are

multidimensional constructs that cannot be measured directly through a single indicator. Consequently, future PSLS evaluation frameworks should incorporate both structural indicators (e.g., presence of reporting infrastructure, governance mechanisms, training availability) and perception-based indicators (e.g., staff confidence, communication quality, and psychological safety).

STRENGTHS AND LIMITATIONS

This thesis contributes to the evolving field of PSLS measurement by providing: an evidence-informed conceptual framework describing the domains influencing PSLS effectiveness; a preliminary standardized instrument for organizational self-assessment of PSLS practices; and an empirical examination of methodological considerations related to scoring, interpretation, and identification of system gaps. Together, it advances current understanding of how PSLSs can be systematically evaluated and highlight the conceptual and methodological challenges involved in measuring complex organizational learning systems within healthcare.

The initial systematic review included a wide range of healthcare settings, clinical departments, and geographic contexts, contributing to a broader understanding of PSLS barriers and facilitators across diverse healthcare environments.

By focusing exclusively on qualitative studies, the review provided rich, in-depth insights that informed the structured development of a novel, evidence-based self-assessment survey. This tool was carefully validated through expert feedback and psychometric testing, which confirmed its face validity, internal consistency, and relevance to the diverse healthcare environments.

The subsequent application of the survey in a real-world setting, well-established hospitals in Ontario, enabled the strengths and gaps in current PSLS practices to be identified. The study's response rate, inclusion of experienced Q&S professionals, and adherence to best-practice reporting standards (e.g., CHERRIES) further reinforce the validity and reliability of the findings. Collectively, the thesis demonstrates methodological rigor, foundational generalizability, and practical relevance, offering valuable tools and insights that can inform policy, guide organizational improvement, and support future research aimed at reducing preventable patient harm through learning-based systems.

A limitation specific to the first study is that the researcher–participant relationships are ill-defined in many of the included studies, which could have introduced bias into the collection and interpretation of the data. Additionally, some studies exhibited selection bias due to non-random sampling, potentially affecting the generalizability of the results. Variability in methodological quality across the included studies also raises concerns about the consistency and reliability of the synthesized findings. Furthermore, a few studies did not clearly define or report data saturation, which might have impacted the depth and completeness of the analysis.

The second study was limited by the survey undergoing only preliminary testing to assess its validity, comprehensibility, and reliability. While these initial evaluations are valuable, further validation is needed to confirm its effectiveness across diverse healthcare settings. Additionally, the study highlights the need for a larger and more diverse sample in future research to ensure the survey's applicability to different hospital environments. Furthermore, the survey was not tested for time sensitivity (e.g., test–retest reliability), which signals an opportunity for future research to evaluate it further. Addressing these

limitations in future studies will be essential to strengthening the survey's reliability and ensuring its effectiveness in evaluating safety learning systems across various healthcare contexts.

A limitation of the third study is the lack of data on the differences in management style between departments, which was not assessed and might have influenced survey responses and personal experiences. Also, although the survey questionnaire was designed for Q&S experts and other healthcare professionals, the third study sampled Q&S experts alone. This was carried out to obtain a more precise evaluation of the system with fewer chances of errors. This approach, nevertheless, might have decreased the generalizability of the findings and could have introduced selection bias that impacts the validity and broader applicability of the results. However we tried to minimize the bias through following the CHERRIES in conducting the online survey.

The methodological differences between the second and third studies were limited to the analytical approach. In the second study, "partially agree" responses were grouped with positive responses because the primary goal was to evaluate the tool's performance and reliability. By contrast, the third study aimed to identify system barriers, and therefore, a more cautious approach was adopted by classifying "partially agree" responses with suboptimal ones. Although this decision might appear to bias the results toward a more negative interpretation, it was made deliberately to ensure a safety-focused and precautionary assessment. Moreover, the findings from the secondary and tertiary analyses helped mitigate this concern by demonstrating consistency across the different analytical approaches.

The thesis maintains a high degree of alignment with the proposed objectives. In

Chapter 2 we followed the same methodological structure, used identical inclusion/exclusion criteria, and applied the same quality assessment and data extraction tools as originally conceived. Any minor differences reflect the detail of methodological choices rather than a deviation from the original study design. In Chapter 3, the objective was refined to ensure a more structured and generalizable approach to assessing PSLSs. Initially, we aimed to conduct a case study at The Ottawa Hospital; however, upon further consideration, developing a standardized survey instrument was deemed more effective at capturing an organization's overall approach to learning from self-reported safety events. This change allowed for broader applicability beyond a single institution and provides a systematic, scalable method for evaluating safety learning processes across various healthcare settings. In Chapter 4, the objective of the third study was refined to enhance clarity, feasibility, and alignment with our overarching goals. Initially, the study aimed to prioritize factors for PSLS improvement based on input from Q&S experts at the Ontario Ministry of Health. However, upon further consideration, it was decided that targeting hospital-based Q&S leaders would yield more actionable insights. Apart from the revised objective and target participant group, this third study remained consistent with the original proposal in terms of data collection through a survey questionnaire, data analysis, and the final prioritization of barriers and facilitators of the PSLS in Ontario hospitals.

CONCLUSIONS

The three studies together provide a comprehensive understanding of the factors shaping patient safety learning systems in healthcare. Collectively, they underscore the need for stronger training, leadership support, user-friendly and confidential reporting tools, and

effective feedback mechanisms to improve the PSLS. The research contributed by identifying key barriers and facilitators (study 1), developing and validating a standardized self-assessment tool (study 2), applying it to evaluate Ontario hospitals (study 3) and examining important methodological considerations related to scoring and interpretation. Collectively, the findings highlight the complexity of measuring PSLSs and demonstrate that organizational learning, feedback processes, governance structures, and analytical approaches all influence how PSLS performance is interpreted. This thesis contributes to current knowledge by providing an evidence-informed framework for evaluating PSLSs and by identifying conceptual and methodological challenges that should be considered in future PSLS measurement and validation research.

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APPENDIX A

Reprint of Mahmoud HA, *et al.* Barriers and facilitators to improving patient safety learning systems: a systematic review of qualitative studies and meta-synthesis. *BMJ Open Qual* 2023;12:e002134.

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BMJ Open Quality

Barriers and facilitators to improving patient safety learning systems: a systematic review of qualitative studies and meta-synthesis

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ABSTRACT

Background The implementation and continuous improvement of patient safety learning systems (PSLS) is a principal strategy for mitigating preventable harm to patients. Although substantial efforts have sought to improve these systems, there is a need to more comprehensively understand critical success factors. This study aims to summarise the barriers and facilitators perceived by hospital staff and physicians to influence the reporting, analysis, learning and feedback within PSLS in hospitals.

Methods We performed a systematic review and meta-synthesis by searching MEDLINE (Ovid), EMBASE (Ovid), CINAHL, Scopus and Web of Science. We included English-language manuscripts of qualitative studies evaluating effectiveness of the PSLS and excluded studies evaluating specific individual adverse events, such as systems for tracking only medication side effects, for example. We followed the Joanna Briggs Institute methodology for qualitative systematic reviews.

Results We extracted data from 22 studies, after screening 2475 for inclusion/exclusion criteria. The included studies focused on reporting aspects of the PSLS, however, there were important barriers and facilitators across the analysis, learning and feedback phases. We identified the following barriers for effective use of PSLS: inadequate organisational support with shortage of resources, lack of training, weak safety culture, lack of accountability, defective policies, blame and a punitive environment, complex system, lack of experience and lack of feedback. We identified the following enabling factors: continuous training, a balance between accountability and responsibility, leaders as role models, anonymous reporting, user-friendly systems, well-structured analysis teams, tangible improvement.

Conclusion Multiple barriers and facilitators to uptake of PSLS exist. These factors should be considered by decision makers seeking to enhance the impact of PSLS.

Ethics and dissemination No formal ethical approval or consent were required as no primary data were collected.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Patient safety learning systems (PSLSs) are viewed as an important tool for improving the quality and outcomes of hospital-based care.

WHAT THIS STUDY ADDS

⇒ This review identifies barriers and facilitators for different stages of system implementation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our findings can inform decision makers in establishing or improving their PSLS. Further research can build on these results.

BACKGROUND

Patient safety learning systems (PSLSs) support healthcare staff in documenting patient safety events and concerns, facilitate immediate corrective actions including communication, and promote the learning and improvement required to prevent future similar occurrences.[1] Use of PSLS involves four related and sequential efforts[2]: (1) structured reporting, (2) collation of data, (3) analysis and (4) learning from the reported incident.[3] In their 1999 report, the Institute of Medicine strongly recommended the use of incident reporting as a means to improve patient safety.

The success of PSLS in improving patient safety is debatable,[4] as errors and adverse events continue to occur in all healthcare settings. It is also important to note that using percentage of reported incidents as a measure of improvement after implementing PSLS might be unreliable as the true number of incidents (the denominator) is unknown because of under-reporting.[4] Although there are no published reports demonstrating a reduction in adverse events, many studies have evaluated the adoption of PSLS.[5] These studies identified factors associated with improving the use of PSLS, but tended to focus on the reporting of events rather than the factors improving the downstream actions

Figure 1 Shows the different steps in the patient safety management toolkit developed by the CPSI (5). CPSI, Canadian Patient Safety Institute.

of analysis and learning. As these later steps are the actions that will lead to improved safety, it is important that they are addressed in efforts to improve PSLS.[1] To address this potential gap, we conducted a systematic review to identify the perceived barriers and facilitators for effective PSLS adoption in hospital settings. We assessed factors related to all phases of PSLS, not just the reporting of events. A fulsome description of all aspects of PSLS will help design future studies, support our understanding of ways to improve the effectiveness of PSLS, and enable hospitals and health systems to assess their own efforts. To guide our qualitative evaluation, we meta-characterised factors based on the Patient Safety Toolkit developed by the Canadian Patient Safety Institute (CPSI) (figure 1).[6]

METHODS

To synthesise the large array of qualitative findings in the literature, we first identified an overarching conceptual framework for safety reporting and response; then we mapped the factors related to the barriers and facilitators to this framework. This inductive approach resulted in the development of emerging themes. A protocol was registered a priori (CRD42021220504).[7]

Search strategy

An experienced medical librarian (LS) was consulted to develop a search strategy. The strategy was piloted in MEDLINE (Ovid), and then translated to include EMBASE (Ovid), CINAHL, Scopus and Web of Science. We manually searched Google Scholar, Grey Literature Reports, the CPSI and the WHO for unpublished studies. The multifield search query we used in our study is shown in online supplemental appendix 1.

We used the PICO approach (suited to qualitative systematic reviews and meta-synthesis) for selecting our primary studies.[8] The participants in these studies were healthcare professionals, quality and safety experts. According to the criteria discussed below, we included qualitative studies that investigated the problem of the continuous occurrence of patient safety incidents and the factors perceived to be responsible for ineffective PSLS.

Inclusion criteria

Studies published in English and discussing the perceived barriers and/or facilitators to the use of PSLS in hospitals were included. No restrictions on the type of incidents, demographic or geographical areas, sampling, or type of participant were applied.

Exclusion criteria

We excluded studies that evaluated the effectiveness of PSLS, those focused on a single incident and those examining the effect of a specific factor on PSLS. Studies investigating the criteria for reporting incidents and the trends in doing so were also excluded.

Study screening and selection

Two reviewers (HAM and MAA) independently screened the titles, abstracts and full text (in that sequence) of citations using Covidence software.[9] Any disagreement between the two reviewers was resolved through discussion with a third reviewer (AAM).

Data extraction

Data were extracted into an Excel spreadsheet for analysis, including the following data points: study characteristics (authors, year of publication, journal); methodology (design, research purpose and/or questions, method of analysis); participant characteristics; country in which the study took place; setting; population descriptors; sample size; barriers, facilitators and conclusions reported. We used the qualitative assessment and review instrument for qualitative data extraction tool from the Joanna Briggs Institute (see online supplemental appendix 2).[10] Data were extracted by one reviewer (HAM), and the second (MAA) verified the extracted data. Disagreements were resolved through discussion with a third reviewer (AAM).

Assessment of methodological quality

The purpose of assessing methodological quality for qualitative research is to describe the overall robustness and validity of the findings. It is not to be used to weight results or support the exclusion of studies as it is possible to find important themes from research with relatively weak designs. We; therefore, assessed quality using the Critical Appraisal Skills Programme (CASP) Qualitative Checklist (see online supplemental appendix 3: CASP Qualitative Checklist) by two independent reviewers (HAM and MAA), and any disagreement was resolved through discussion with a third researcher (AAM). However, this process did not lead to any studies being excluded from the analysis.

Guiding framework

The Patient Safety Toolkit[6] is derived from the best available evidence and expert advice, and can be tailored for any healthcare setting. As such, we thought it might help us identify barriers to the success of PSLS, and used it as a

framework for summarising our findings. This framework is comprehensive in that as well as including the four steps of PSLS, it describes other aspects expected to influence the effectiveness of such systems, for example, those 'before the incident', which include the organisational culture that encourages reporting and the support from the leadership. The incident management domain within the tool was used to develop our themes and subthemes.

Data synthesis

Two reviewers (HAM and MAA) reviewed all articles to retrieve data describing the participants, study characteristics, and perceived barriers and facilitators. Directed analysis was done, including identification and classification of extracted factors (barriers and/or facilitators), and assigning factors to themes and subthemes according to the CPSI Patient Safety Toolkit. These data were entered into separate spreadsheets. The results from the two reviewers were compared and differences were resolved by consensus with a third reviewer (AAM). We then counted the number of factors identified within each subtheme to inform our narrative synthesis. After removing duplicates, these factors were analysed, merged and new definitions were developed. In the present report, the resulting synthesised factors are narrated and tabulated as a set of main findings.[11]

RESULTS

Study inclusion

A total of 3507 studies were identified from searched databases on 1 February 2021, leaving 2475 studies for title and abstract screening after removal of 1032 duplicates (figure 2). Of these, 2352 studies were excluded according to the following criteria: the language was not English, review articles or having different study designs or outcomes. After assessment of the full texts, a further 101 articles were excluded: different study design (70 articles), different outcome (13 articles), full text was not found (7), different intervention (4) or setting (3), specific incident type (2), different indication (1) and conference report (1). After this exclusion process, we included 22 full-text articles.

Study characteristics

All studies included were published in 2010–2021, except for three.[12–14] Five were conducted in England,[13 15–18] two in Australia,[12 14] Canada,[19 20] the USA,[21 22] Brazil,[23 24] and Iran,[25 26] and one in the Netherlands,[27] UAE,[28] Sweden,[29] Turkey,[30] Qatar,[31] and South Korea.[32] One included study was multinational.[33]

No data were provided regarding the sex, age or work experience of any of the participants. Participants in the 22 included studies were 781 healthcare professionals

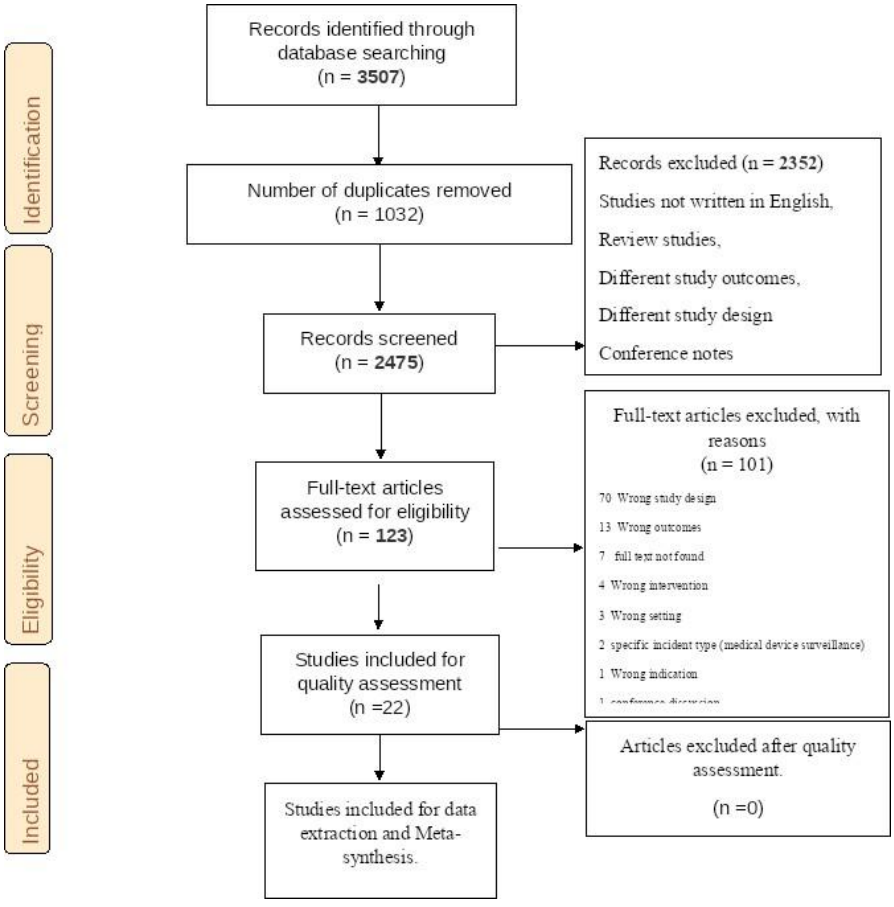

Figure 2 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2009 flow diagram.

including 359 nurses from different medical, intensive care and surgical departments, 190 physicians, 49 pharmacists, 42 quality and safety managers, and 5 allied health professionals. The profession of the remaining 136 participants were not mentioned in three of the studies.[17 23 24] Studies were conducted in intensive care units,[12] teaching hospitals,[15 20 23 27 30] university hospitals,[25] tertiary hospitals,[22 31 32] large general public or community hospitals[13 14 17–19 24 29 31] and children's hospitals[21]; 1 of the studies involved participants from 111 hospitals.[26]

In relation to sampling, eight studies used a purposive sampling technique[14 15 18 21 28–30 33]; two studies used purposive sampling and snowball sampling[20 31]; four studies used invitation letters[22 24 25 27]; the researchers of one study sought out their acquaintances by posting advertisements and using snowball sampling techniques[32]; one study used posters and nurse leader appeal in selecting their participants[12]; one study involved all nurses until saturation occurred[23]; four studies did not clearly describe their sampling methods.[16 17 19 26]

Assessment of methodological quality

All of the included studies clearly described how they were conducted, but eight articles failed to clarify the researchers' relationships to the participants (table 1).[12 13 19 20 22 23 29 31] In relation to sampling, 11 of the 22 studies carried a risk of selection bias (the researchers selected their participants) and/or a risk of non-representative sampling.[12 16 18 19 21–23 25 26 31 32] One study included only less-experienced residents.[22] Two studies did not report how data saturation was defined or achieved.[16 22] There was no weight to specific questions nor a scoring system for the CASP Qualitative Checklist. As qualitative studies, we included all primary studies regardless of the quality of their methodology, as even methodologically sound studies can be poorly interpreted thereby offering insufficient insight in a particular topic; conversely, studies of lower quality may provide new insights. This heterogeneity contributed to the interpretation of the overall findings.[34]

Summary of study findings

We extracted 375 reported factors from the 22 studies, all of which were either unequivocal or credible based on the participants' verbatim transcripts and researcher experience.

Six themes and 16 subthemes were developed based on the Patient Safety Toolkit and are outlined below and in table 2. Factors under the theme 'immediate response' were the most cited as perceived barriers to improving PSLS, cited 170 times out of 375 reported factors (45.3%). Its subthemes 'reporting the incident', 'secure items for confidentiality' and 'care for reporter' were cited 98, 41 and 31 times, respectively. The theme 'factors before the incident' was cited 134 times (35.7%) and included subthemes 'training' (46 times), 'organisational and leadership support' (39 times), 'cultivate just and safe culture' (28 times), and 'availability of resources' (21 times). Other factors were reported less frequently, however, this does not necessarily reflect lesser importance, as all of the included studies were more focused on reporting procedures of the PSLS and less on the subsequent steps.

Theme 1: before the incident (n=134)

Subtheme 1.1: training

Training was examined by 16 studies,[13–15 19–28 30 32 33] which identified a 'lack of training'—for both reporters and managers—as a major barrier (46 of 134 responses, 34.3%). Facilitators included planning for and implementation of continuous training, which should be effectively communicated to staff and managers.

Subtheme 1.2: organisational and leadership support

Factors related to organisational and leadership support were mentioned 39 times (29.1%) and included: lack of accountability that would make staff feel more responsible; ineffective reporting systems[19 20 24 25 33]; lack of definitions, policies or standards[14 18 19 21 26 32]; poor communication[19 26]; negative responses to reporting by leaders[13 18 22 26 27 30–32]; lack of authority[25] and role models.[32] Related facilitators included: incentives and initiatives to report more[31]; professional accountability and supportive atmospheres[19 20 25 28 29 33]; writing and dissemination of a guiding manual; increased confidentiality and security of the reporting process[14]; motivate staff to report through the display of posters[27]; eliminating blame by seniors or doctors.[29 30]

Subtheme 1.3: cultivate a just and safe culture

This subtheme was cited 28 times (20.9%). Barriers included a blaming and punitive culture[14 18 21–23 25 32]; an attitude of the administration for personalising errors[27 30]; a lack of awareness about safety culture, which subsequently fostered a lack of responsibility and undervaluing the reporting system[14 30]; a defective culture unwilling to accept responsibility for errors[25]; a culture of low expectations, for example, 'Well they're in a hospital and things happen'.[22] Facilitators included balancing the need for responsibility and accountability[15]; building trust in a non-punitive system attained by supporting the reporters, promoting peer reporting, anonymous reporting to an independent body[20 29 31]; belief that this promotes patient protection[19]; stimulating role of superiors.[27]

Subtheme 1.4: availability of resources

Reported 21 times (15.7%), this subtheme comprised the following barriers: manual reporting systems or defective electronic systems can be time-consuming[18]; shortage of time and equipment for reporting.[14–16 18 19 21 22 25 26 29 32] Facilitators included carrying a pocket-size plasticised card that outlines the reporting process[27]; electronic systems together with human and financial resources[18 28 29]; the option of faster reporting processes (eg, telephone reporting).[14]

Table 1 A summary of the overall methodological quality of the included studies

First author and year	Clear aim of research?	Appropriate qualitative methodology?	Appropriate design?	Appropriate recruitment strategy to address the aim?	Appropriate method of data collection?	Researcher-participants relationship considered?	Ethical issues considered?	Rigorous data analysis?	Clear findings?	Valuable results?
Alqubaisi 2016[28]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anderson 2013[15]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Burns 2018[16]	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Carlfjord 2018[29]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Elder 2008[12]	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Hartnell 2012[19]	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No
Hashemi 2012[25]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Hewitt 2017[20]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Howell 2017[33]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Kingston 2011[21]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Kingston 2004[14]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Lee 2018[32]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Martowirono 2012[27]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
McArdle 2003[13]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Nicolini 2011[17]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mirbaha 2015[26]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Siman 2017[23]	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Soydemir 2017[30]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Stewart 2020[31]	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Szymusiak 2020[22]	Yes	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes
Varallo 2018[24]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Williams 2013[18]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes

Table 2 Identified themes and subthemes based on the CPSI safety tool kit and their proportions

Theme	Subtheme	Subtheme domains	Frequency	% of total	% within theme
Before the incident			134	35.7	
	Training		46		34.3
	Organisational and leadership support		39		29.1
	Just and safe culture		28		20.9
	Availability of resources		21		15.7
Immediate response			170	45.3	
	Care for reporter		31		18.2
	Confidentiality		41		24.1
	Reporting the incident		98		57.6
		User friendly	37		37.8*
		External and internal influencers	32		32.7*
		Incident characteristics	29		29.6*
Prepare for analysis			12	3.2	
	Preliminary investigation		5		41.7
	Appropriate analysis methods		0		
	Identify team		6		50.0
	Interview plan		1		8.3
Analysis process			12	3.2	
	Investigate what happened		5		41.7
	Understand why and how happened		1		8.3
	Develop and manage recommendations		6		50.0
Follow through			16	4.3	
	Implement		11		68.8
	Follow and assess		5		31.3
Close the loop			31	8.3	
	Share learn internally and externally		31		100
Total			375		

*The percentage of reported factors to total number under the subtheme 'reporting the incident'.
CPSI, Canadian Patient Safety Institute.

Theme 2: immediate response to the incident (n=170)

Subtheme 2.1: reporting the incident

Factors in this subtheme were reported 98 times (57.6%) and were classified further into three categories: 'user friendly' (reported 37 times, 37.8%), 'external and internal reporter influencers' (32 times, 32.7%) and 'incident related factors' (29 times, 29.6%).

Under the 'user friendly' category, participants reported the following barriers: complex systems and forms asking for unnecessary data[13 14 16 18 19 22 24 27–30 33]; poor quality of the incident report[15]; reporting is time-consuming[12 16 19 25 27 29 32]; limited access to forms[29]; the extra work burden on the reporter[19 27 32]; duplication of work being registered in patient files and in the PSLS or rereporting by other staff.[18 22 24] Facilitators included profession-specific forms[14 18]; forms that balance the amount of information requested with time.[18 19 27 29]

A second category is 'internal and external influencers to report', which included the following barriers: juniors are afraid to report seniors' errors; seniors preventing juniors from reporting; the norm that doctors never report but nurses should[12 18 20 28]; avoiding reports that might cause internal disputes[12 18 19 22 25 28 32]; negative attitudes to reporting (eg, it is 'a waste of time')[27 29 32]; reporting yields a feeling of failure[12]; the perception that reporting brings no personal benefit[12 19 25]; non-mandatory reporting[19 20 25]; a lack of perceived ability to report or that staff simply do not think of reporting[27] or consider errors a normal part of daily events.[30] Facilitators included a belief in learning from errors,[20] that this benefits patients[19 25] and showing commitment to adhering to policies.[19]

A third category, 'incident related factors', includes 'seriousness of incidents regarding impact, consequences, severity and frequency', that is, the more

serious incidents are more likely to be reported, whereas near misses are perceived to have less chance of being reported[12 18–25 27 29 30 32 33]; no clear cause for the error.[24] The facilitators included: focusing on reporting serious prioritised incidents, which allows better analysis and management[18 29]; errors with serious consequences and high frequency of occurrence influence reporting.[25 32]

Subtheme 2.2: care for and support for reporter

This subtheme was mentioned 31 times (18.2%) in the primary studies, 25 of which described barriers, including: 'reporters feel worse, guilt, shame, uncertainty, disloyal to colleagues and emotionally charged'; a lack of a supporting manager[12 13 18 21 22 24 27 30 32]; the feeling that reporting the error might cause loss of honour, respect, reputation and dignity along with perceived incompetence[19–21 25]; inappropriate responses by managers.[21 25] Six facilitators included protecting reporters against legal and non-legal actions.[14 19]

Subtheme 2.3: confidentiality

This subtheme was reported 41 times (24.1%) and some barriers were directly related to 'breach of confidentiality that might cause loss of reputation, career, relationships, friendships and respect'[12 13 15 16 19 20 28 30]; 'fear of blame or punishment or legal action'[12 13 16 19 20 22 25–27 29 30]; 'lack of anonymity and lack of trust in system confidentiality'[18–20 22 25 32]; 'fear of economic losses'.[25] Confidentiality and anonymous reporting to independent bodies have been repeatedly reported as positive system influencer.[18 21 27 31]

Theme 3: prepare for analysis

Subtheme 3.1: preliminary investigation

Factors related to preliminary investigations were mentioned five times and were all barriers such as lack of time and resources[15] and poor communication.[18] Furthermore, anonymity was cited as making information about the incident more difficult to obtain.[17 32]

Subtheme 3.2: identify team

Factors related to 'identify team' were cited six times, and included the following barriers: lack of front-line engagement[15]; complex organisations, in which it is difficult to assemble the appropriate team[15 17]; lack of cooperation between units related to the incident.[29] Building fully representative teams was reported as an aspect that might improve PSLS.[31]

Subtheme 3.3: plan for interview

In thinking about planning for incident-related interviews, participants only reported fearing loss of reputation as a barrier for participation.[17]

Theme 4: analysis process

Subtheme 4.1: investigate what happened

One barrier and four facilitators were related to investigation: mass reporting might interfere with accurate analysis and capacity for learning[33]; 'multidisciplinary meetings ensure equal and fair participation'[17]; applying tools and analytical approaches, avoiding analytical myopia,[15 17] and to have open communication.[31]

Subtheme 4.2: understand why and how it happened

This subtheme was represented only by one facilitator of PSLS: use of proper analysis tools.[18]

Subtheme 4.3: develop and manage recommendations

Factors in this subtheme were reported six times, including poor-quality recommendations such as 'too much details or too simple',[15] contradictions with other change agendas and initiatives.[17] 'Avoid giving undue attention to the report'[17] was reported as a facilitator.

Theme 5: follow through

Subtheme 5.1: implement

Reported 11 times, this subtheme includes a lack of effective measures that make tangible changes[22 24 27 29] and also time-consuming recommendations,[29] difficult to implement recommendations,[32] existence of plans that contradict recommendations.[26] Visible change was reported as a facilitator.[18]

Subtheme 5.2: follow and assess

Factors in this subtheme were reported five times, four of which were facilitators. Two of these were the use of risk-assessment tools to prioritise actions for follow-up[14] and formal (eg, targets, audits and score cards) and informal (keeping on meeting agenda, management oversight, risk officer spot-checks) performance management for evaluating changes.[15] Only one barrier was reported under this subtheme: data processing does not reflect the real number of reports due to under-reporting.[23]

Theme 6: close the loop

This theme was reported 31 times (8.3%) and includes only one subtheme 'share learning internally and externally'. The barriers are lack or defective feedback resulting in loss of trust in the system.[12–14 16 22 24 26–28 32] Facilitators include: feedback mechanisms that motivate reporting[15 18 19 29]; improving error-related communication from senior management to healthcare professionals[19]; to 'definitely collect less data of better quality of learning and feedback'; to 'share learning horizontally (with peers), and also for vertical accountability'[33]; transparency in sharing data[21]; the type and timing of feedback depend on the severity of the incident or the degree of risk to the organisation; individual and group feedback about action taken will increase trust in the system.[14]

DISCUSSION

In this systematic review, we identified all barriers and facilitators reported in the literature for PSLS. In those studies, recommendations were reported by participants encountering such barriers. The results also revealed the participants' perceptions of how these barriers might prevent improvement of the system. By including

all the aforementioned factors and recommendations, managers and other decision makers have a wide range of options for taking innovative actions to improve their safety systems.

We included 22 primary studies. We sorted the reported factors (barriers and facilitators) into themes based on a framework derived from the CPSI Patient Safety Toolkit. Facilitators and barriers related to 'before the incident' included the preparedness of a hospital to implement PSLS through planning, training, assignment of resources, a well-established safety culture that focuses on systems not people and ensures top-level commitment and support, and well-developed policies and procedures. Related to 'the immediate response', some studies recommended that hospitals support reporters emotionally and against legal action. Factors related to 'analysis process' and 'follow through' included having a well-trained multidisciplinary team to ensure high-quality investigations of safety incidents. Analysis should start with the selection of the most appropriate analytical approaches, followed by investigating the incident and development and implementation of smart recommendations that make tangible system changes. Factors related to 'closing the loop' included providing timely feedback to reporters and sharing results of the analysis internally with other departments as well as externally with other hospitals to facilitate learning on a wider scale.

Our results are consistent with other systematic review studies; however, we identified a gap in the research—the predominant focus is the reporting stage, leaving the subsequent stages of the learning system neglected. Vrbnjak *et al*[35], stated that 'a non-blaming, non-punitive and non-fearful learning culture' is needed to encourage incident reporting. They grouped most of the system barriers into three main areas: the efficiency of the reporting system, management behaviour and staff education.[35] In 2015, Health Quality Ontario identified the barriers and facilitators of PSLS, all of which are consistent with our results, including a non-accusatory environment, improving safety culture, training, enhanced transparency and effective feedback, role models (such as managers), protecting reporters, anonymous reporting, and clear operational policies. Barriers identified for other steps of PSLS have been derived from the WHO guidelines and not primary studies.[36] Similar findings by other studies include a blame-free culture, clear guidelines on how and what to report, user-friendly systems, organisational support for data analysis to generate meaningful learning outcomes and multiple mechanisms to provide feedback through routes to reporters and the wider community.[6 36 37]

Gaps in the research

It is important to note that identified barriers to the reporting stage are also pertinent to the three themes not addressed in 19 of our included studies[12–14 16 18–25 27 28 30–33 38]: 'prepare for analysis', 'analysis process' and 'follow-up'. These include a lack of time, resources and training for analysis, and a lack of direct communication between responsible departments. Under these circumstances, developing analysis teams is difficult, especially in complex organisations. Also, staff are unwilling to participate in these teams because they are afraid of losing reputation. The corresponding facilitator to these barriers is to bridge the gap in communication through holding regular meetings and structuring well representative teams with front-line engagement and top-level commitment. A newly reported barrier was related to the anonymity of the system, making it difficult to clarify incidents for which data is missing. Modifying an electronic system to not accept incomplete reports was suggested to overcome this barrier.[39] It is also important to mention the problem of under-reporting and its effect on the accuracy of data processing with subsequent failure of follow-up. This can be improved through audits, use of performance scorecards and spot checks.

Participants did not reveal any barriers or facilitators under the 'select appropriate analysis method' subtheme. This can be attributed to being outside the scope of the included studies.

Strengths and limitations

Our study is unique as it included a variety of safety incidents including medication-related and device-related incidents. As it is more comprehensive than prior published studies, its results are more applicable to the common setting of a general hospital with a need to track all patient safety events. Our review included 22 primary studies with 781 participants, making it the largest published review on this topic, increasing the likelihood we have not omitted important published information. In addition, the participants represent different departments in hospitals, further increasing the general applicability of our findings. Furthermore, the included studies were done in geographically and economically diverse countries, representing both the developed and the developing world. We included only qualitative studies that gave more chance for participants to express their concerns about the system, which was reflected in the number of perceived system barriers and facilitators. We ensured valid results by including studies of high-quality methodology. Although 9 of the 22 studies involved relationships between the researchers and the participants with a risk of selection bias, no potential bias in their studies was reported.[25]

One limitation of our study related to the selection methods of the included studies. More than half of the included studies selected participants non-representative of the healthcare worker population, that is, either only doctors[13 16 27] or only nurses,[12 21 25] or residents. This potentially limits the generality of each study's conclusions. However, taking the totality of findings across all studies and the consistency of the findings, we are confident our results are valid. Another limitation was an inability to perform subgroup analyses based on healthcare worker characteristics (eg, age, sex, occupation and years of experience of the participants) as studies did not

consistently provide that information. Given our findings, we do not feel this limits our conclusions.

Finally, this study is based on what hospital staff perceive as factors affecting PSLS as opposed to actual quantifiable effects. This is a limitation of the existing knowledgebase that needs to be addressed in future studies.

CONCLUSION

Our review found that most studies on the effectiveness of PSLS relate to aspects 'before the incident' and the 'immediate response'. Themes related to investigations, follow through, and 'closing the loop' have received less attention, and it is likely that health systems have spent less time considering them. As it is these stages that lead to improvements in safety, it is not surprising that PSLS have not achieved desired success. We recommend that researchers, safety leaders and health system policy makers focus more of their attention on these aspects of PSLS.

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APPENDIX B

Reprint of Mahmoud HA, *et al.* Development of a survey to support assessment of safety learning systems. *BMJ Open Qual* 2024;13:e002738.

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Development of a survey to support assessment of safety learning systems

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ABSTRACT

Background Patient safety learning systems play a critical role in supporting safety culture in healthcare organisations. A lack of explicit standards leads to inconsistent implementation across organisations, causing uncertainty about their roles and impact. Organisations can address inconsistent implementation by using a self-assessment tool based on agreed-on best practices. Therefore, we aimed to create a survey instrument to assess an organisation's approach to learning from safety events.

Methods The foundation for this work was a recent systematic review that defined features associated with the performance of a safety learning system. We organised features into themes and rephrased them into questions (items). Face validity was checked, which included independent pre-testing to ensure comprehensibility and parsimony. It also included clinical sensibility testing in which a representative sample of leaders in quality at a large teaching hospital (The Ottawa Hospital) answered two questions to judge each item for clarity and necessity. If more than 20% of respondents judged a question unclear or unnecessary, we modified or removed that question accordingly. Finally, we checked the internal consistency of the questionnaire using Cronbach's alpha.

Results We initially developed a 47-item questionnaire based on a prior systematic review. Pre-testing resulted in the modification of 15 of the questions, 2 were removed and 2 questions were added to ensure comprehensiveness and relevance. Face validity was assessed through yes/no responses, with over 80% of respondents confirming the clarity and 85% the necessity of each question, leading to the retention of all 47 questions. Data collected from the five-point responses (strongly disagree to strongly agree) for each question were used to assess the questionnaire's internal consistency. The Cronbach's alpha was 0.94, indicating a high internal consistency.

Conclusion This self-assessment questionnaire is evidence-based and on preliminary testing is deemed valid, comprehensible and reliable. Future work should assess the range of survey responses in a large sample of respondents from different hospitals.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Development and implementation of the safety learning system varies from one hospital to another. There is a notable gap in the availability of validated and reliable tools for hospitals to self-assess the implementation of their safety learning system (SLS) at various stages. This highlights the urgent need to create a high-quality, standardised survey tool specifically designed for SLS evaluation.

WHAT THIS STUDY ADDS

⇒ We developed an evidence-based self-assessment questionnaire that on preliminary testing is deemed valid and reliable.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ With this tool, hospitals and health systems can pinpoint areas in their SLS needing enhancement, while researchers can assess the effectiveness of SLS programmes across the board.

BACKGROUND

Many healthcare systems and accrediting bodies require institutions to implement a safety learning system (SLS)[1 2] to track patient safety incidents, the learnings arising from them and the completion of actions to mitigate or prevent similar events in the future.[3] An SLS typically includes a digital platform and associated policies and procedures to support reporting, investigating, learning and improving following an unsafe act and/or patient harm. The premise underlying SLSs is that errors and harmful events might re-occur if predisposing factors are not addressed.[4] They also contribute to a culture of safety by creating the expectation that events are followed and acted on in a fair and transparent manner.[5 6]

Although most hospitals and accrediting bodies have adopted and promoted SLSs, their value is a subject of debate.[7] Indeed, multiple failures in their implementation and use could be detrimental; for example, failure to report events, investigate and learn from them and, most importantly, failure to act to prevent them.[8–10] We recently performed a systematic review to identify the features associated with the effective use of SLSs.[11] These features were classified according to the stages of the SLS derived from the Patient Safety and Incident Management Toolkit.[12] Most of the included literature focuses on the reporting and feedback of incidents; event

analysis and mechanisms to support learning were less prominent.[11] That literature might reflect actual practice in which organisations spend more time collecting data rather than developing action plans for improving.[13] Further, we documented the variability in the SLS factors evaluated, which likely reflects an underlying inconsistency in how organisations implemented their SLS.[11] Thus, it seems plausible that the effectiveness of SLSs might be a result of a combination of local factors,[10] in addition to generic factors. These generic factors include cultural factors (eg, lack of safety culture), educational factors (eg, lack of training on the SLS and statistical analysis), governing and regulatory bodies (eg, legislation that supports reporting and protects reporters).[11 14] To deepen our understanding of the impact of an SLS, a unified approach is crucial for evaluating the complete range of required activities post-safety event. Currently, there is a notable gap in the availability of validated and reliable tools for hospitals to self-assess the effectiveness of SLS at various stages.[15] This highlights the urgent need to create a high-quality, evidence-based, standardised survey tool specifically designed for SLS evaluation.

This paper outlines the creation of such a tool and was intended for diverse applications, whether by individual hospitals, entire health systems or researchers. With this tool, hospitals and health systems can pinpoint areas in their SLS needing enhancement, while researchers can assess the effectiveness of SLS programmes across the board.

METHODS

Overview

Our work consisted of three steps (figure 1). First, based on our previous systematic review, we developed questions pertaining to the specific barriers and facilitators of SLS effectiveness. Next, patient safety and methodological experts (AJF, DM, SM, KT) reviewed the questions for their comprehensibility and perceived importance. Third, we tested the questions on a representative sample of staff members responsible for aspects of patient safety at a single teaching hospital in Ottawa, Ontario, Canada (The Ottawa Hospital).

Patient and public involvement

Patient and public involvement was out of the scope of this study.

Step 1: establishing candidate questions and their response variables

We developed the questionnaire using findings from our systematic review, which identified 68 factors associated with SLSs.[11] We organised the questions into the same domains and subdomains used in the review, which were derived from the Canadian Patient Safety Institute's Patient Safety and Incident Management Toolkit.[12]

We used an iterative approach to develop the questionnaire, carefully refining questions to eliminate redundancy. To that end, we collected different questions that evaluate the same area or process in the SLS together, then formulated single comprehensive statements to address them. This process reduced the initial 68 statements down to 47 questions for evaluation. We chose a five-point response scale (strongly disagree, disagree, partially agree, agree and strongly agree) to allow accurate SLS assessment and to help participants better understand the questions' intent.

Step 2: input from methodology experts (pre-testing)

To ensure the clarity and relevance of the questions together with their response variables, we invited three health services researchers who participated in the systematic review to assess them independently. Using an online tool, each reviewer provided feedback on the relevance

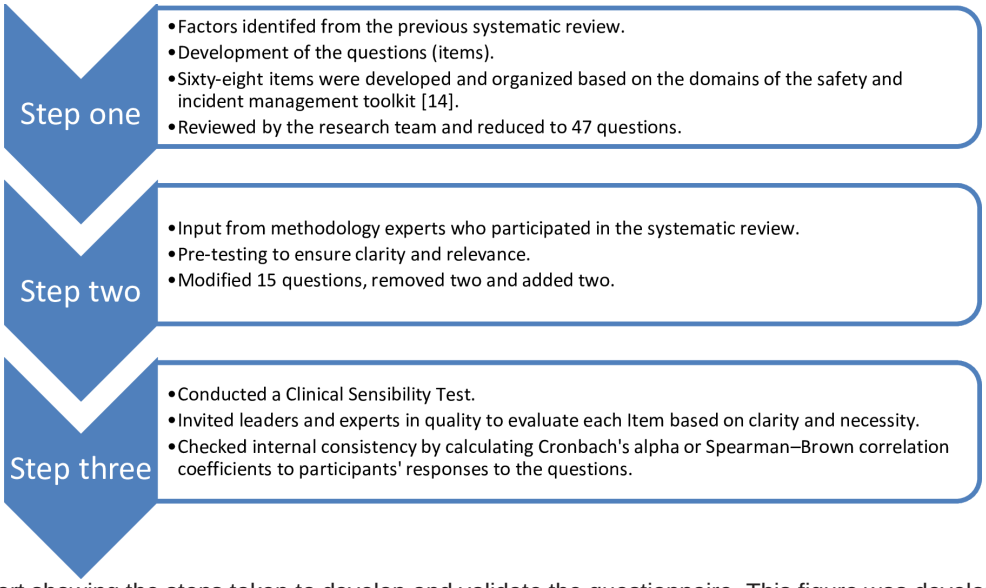

Figure 1 Flow chart showing the steps taken to develop and validate the questionnaire. This figure was developed by the corresponding author.

and clarity of every question. To simplify their input, they indicated whether the question should be included in the final SLS survey tool using the following responses: 'no', 'uncertain', 'yes, with modification' or 'yes, as is'. The reviewers were asked to ground their responses such that 'no' meant no relevance or poor clarity, and 'yes' meant high relevance and clarity. If two reviewers or more rated the relevance of a statement 'no', the statement was removed from the draft. If the reviewer rated 'yes, with modification' they were asked to suggest new wording for consideration by the research team. If two or more rated 'uncertain', they were contacted for clarification and the sentence was edited. The research team met to discuss the feedback and make changes accordingly. We also asked the researchers to determine the target group—either quality and safety (Q&S) managers and leaders or frontline workers—for each question to ensure precise and accurate results.

Step 3: questionnaire testing in a representative sample of respondents (clinical sensibility and internal consistency)

This step assessed the necessity, clarity and the internal consistency of the questionnaire by seeking input from Q&S managers and leaders at The Ottawa Hospital. We identified all the Q&S experts employed at the hospital as nurses, physicians and so forth, and with a role in managing patient safety events and invited them to participate in the study (N=56). All participants were expected to be aware of the Q&S management activities in their hospital and were required to answer the entire questionnaire. We sent all participants a letter detailing our study objectives and emphasised that their participation was voluntary, anonymous and would not impact their employment. Three follow-up emails were sent 2 weeks apart to the participants as reminders to answer the questionnaire. Participants were not compensated for answering the questionnaire. The survey (LimeSurvey) was distributed using the hospital's internal network, which facilitated tracking of completion rates and analysis.

We asked the experts to answer each survey question about the hospital by selecting one response. These data were used to measure the internal consistency of the questionnaire rather than evaluate the hospital's SLS. They were also asked to answer the two clinical sensibility check questions ('Do you find the question easy to understand (clear)?' and 'Do you think this question is important (necessary)?') by choosing either 'yes' or 'no' for each question. We developed these two questions (based on prior work by Karen *et al*[16]) to assess the question's perceived utility and comprehensibility. We determined that questions should be modified or removed if more than 20% of respondents selected 'no' for 'clear' or 'necessary', respectively. We determined this threshold based on experts' and researchers' feedback to strike a balance between addressing potential issues and avoiding unnecessary changes that could impact the validity of the survey results.

Statistical analysis

We report the frequencies and descriptive statistics for all questions in the survey. We assessed the internal consistency for the whole questionnaire and at the domain level using the Cronbach's alpha coefficient. This is a test that measures the internal consistency, or reliability, of a set of survey items. We used this statistic to help determine whether a collection of items consistently measures the same underlying concept.[17] It quantifies the level of agreement on a standardised 0–1 scale. It is also important to note that Cronbach's alpha underestimates the reliability of domains having two questions; for those we used the Spearman-Brown correlation coefficient.[18] For both tests, we considered values of 0.7 or greater to be reliable.[18] All statistical analysis was conducted using Microsoft Excel V.16.

RESULTS

Step 1

From the 68 factors identified in a previous systematic review,[11] we developed a questionnaire consisting of 47 statements. These questions were organised within the domains and subdomains of the Patient Safety and Incident Management Tool Kit (figure 2).[12]

We also thought it important to know the years of experience and place of work as this might affect our interpretation of their answers and subsequently the development of the recommendations. Accordingly, we added 'Section A: Demographics' to the questionnaire (table 1).

Step 2

Based on the feedback from the three researchers all the questionnaire items were relevant. Clarity assessment resulted in questionnaire modifications as follows: 15 questions were edited, four of which were rated 'uncertain' by two of the researchers and 11 were rated 'yes (with modification)' by 1 or more; 2 questions were removed; 2 questions were added. The reviewers also reported that all 47 questions were applicable to be answered by the Q&S managers and leaders, whereas front-line workers could only answer 30 of these questions (table 1). At the end of this step, there were 47 statements in the questionnaire in addition to four demographic questions that all participants were required to answer.

Step 3

Of the 56 employees who have a role in managing patient safety events at The Ottawa Hospital, we received complete responses from 20 (36%), whereas 19 (34%) provided incomplete responses and 17 (30%) did not participate in the study. We considered respondents as only 'complete responders'. Respondents were doctors (n=11; 55%), nurses (n=3; 15%), engineers (n=2; 10%), pharmacists (n=1; 5%), physiotherapists (n=1; 5%) and quality coordinators (n=2; 10%). Their years of experience in quality

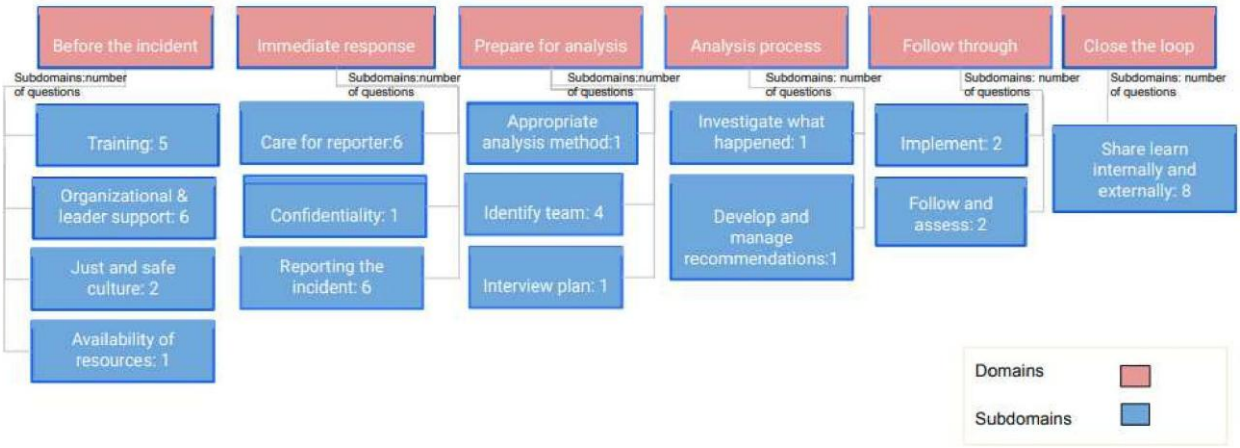

Figure 2 The domains, subdomains and the number of questions under each subdomain. This figure was developed by the corresponding author.

and safety varied between 1 and 25 years, with an average of 4.35 years (SD=4.72).

Regarding clarity and necessity, no question exceeded the threshold of 20% negative responses, thus all were adjudged clear and necessary (table 1). Two questions received low scores (<90%) for clarity: 'I must report the same incident using different approaches. (eg, Patient files, nursing reporting system, safety department)' was rated 'unclear' by only three participants, whereas the second question 'The management has a defined communication approach to share learning externally'. was rated 'unclear' by four participants. The two questions that received the lowest scores for necessity were 'Management ensures analysis teams are composed of representative expertise'. and 'The management has a defined communication approach to share learning internally'. Both were reported 'unnecessary' by three participants.

To get a more accurate measure of the internal consistency and reliability of the questionnaire, and to mitigate the effect of low participation, we used Cronbach's alpha statistics.[19] This mainly depends on measuring the correlation between the responses of each participant. We measured the correlation between all the participants' responses (strongly disagree–strongly agree) to all the questions, and measured it separately for the responses within each domain.

Based on the participants' responses to the 47 statements in the questionnaire, Cronbach's alpha was calculated to be 0.94. The Cronbach's alpha coefficients for each domain were as follows: domain A 'before the incident', 0.77; domain B 'immediate response', 0.77; domain C 'prepare for analysis', 0.61; domain E 'follow through', 0.92; domain F 'close the loop', 0.88. For domain D 'analysis process', which has only two questions, we found it more reliable to calculate the Spearman-Brown reliability coefficient, which was 0.89. This indicates excellent agreement.

Table 1 also shows the percentages of the participants who agreed (total 'partially agree', 'agree' and 'strongly agree') on each question based on the status of their SLS in the hospital. We found that the questions 'All staff have access to an electronic system for reporting safety events' and 'The management has a defined communication approach to share learning externally'. received the two lowest agreement scores (40% and 50%, respectively).

The percentages of combined 'disagree' and 'strongly disagree' scores were also calculated at the domain level. Domains C ('prepare for analysis') and F ('close the loop') received the highest disagreement scores (30.8% and 29.4%, respectively), compared with domain A ('before the incident', 20.8%), domains B ('immediate response', 21.2%), D ('analysis process', 17.5%) and E ('follow through', 12.5%).

In conclusion, step 3 confirmed the high reliability and validity of the 47 questions and did not result in the removal or modification of any.

DISCUSSION

We systematically developed a survey to assess institutional SLSs. The tool builds on a previous systematic review of SLS outcome factors, and was refined with input from experts in patient safety and quality, ensuring comprehension, face validity and internal consistency. The study had three steps. Initially, we developed the survey's questions and their corresponding response options, culminating in a draft of 47 questions. During the second step, experienced researchers who were also involved in the systematic review conducted a pre-test. This led to the elimination of two questions, the revision of 15 and the introduction of two new ones. Additionally, to reduce bias, it was determined that 17 questions focused on SLS management should be exclusively answered by Q&S experts and leaders, while the rest could be addressed by both Q&S professionals and other staff members involved in the study. The final step involved clinical sensibility testing—evaluating the clarity and necessity of the questions—by Q&S experts at The Ottawa Hospital. Despite receiving the lowest scores in these areas, four questions (numbers 15, 30, 44 and 45) were retained by the research team

Table 1 The SLS self-assessment questionnaire and participants' assessment of questions' clarity and importance, and the percentage of their rating for the SLS in The Ottawa Hospital (N=20)

Section A: Demographics	1. **Institution** 2. **Position title (quality and safety role)** 3. **What is your professional designation?** 4. **Years of experience**

Section B: Domains	**Questions/responses***	**Comprehension= clear yes, n (%)**	**Importance= necessary yes, n (%)**	**Number and percentage of respondents rating they partially agree or agree, or strongly agree (%), N=20**
Before the incident	I received training on our patient SLS at least once during my employment.	19 (95)	20 (100)	N/A
	It should be my responsibility to undergo re-training on the SLS periodically.	18 (90)	19 (95)	18 (90)
	My training on reporting and/or analysing incidents was effective in preparing to fulfil my responsibilities.	18 (90)	20 (100)	16 (80)
	Training material describes how to classify safety events in terms of their severity and recurrence risk.	19 (95)	20 (100)	16 (80)
	The training plan for SLS is well-developed, monitored and tailored to each member of staff according to their role in the system.	19 (95)	19 (95)	12 (60)
	I have access to all policies and procedures related to the SLS.	19 (95)	19 (95)	15 (75)
	The policies and procedures related to the SLS are easy to understand.	20 (100)	20 (100)	15 (75)
	I am recognised positively for reporting safety events by my supervisor or leader.	20 (100)	19 (95)	19 (95)
	Hospital leadership provides rewards and incentives to encourage safety event reporting.	20 (100)	19 (95)	11 (55)
	The reporting system prevents individuals from being unfairly blamed for making errors.	20 (100)	19 (95)	15 (75)
	†11. Managers regularly review and update system-related policies and procedures.	19 (95)	20 (100)	19 (95)
	I believe reporting incidents is my responsibility as it will lead to preventing future events.	19 (95)	19 (95)	20 (100)
	The SLS is integrated in everyday work to ensure high compliance.	19 (95)	19 (95)	14 (70)
	†14. Management allocates sufficient resources for reporting, analysis and investigating incidents.	20 (100)	20 (100)	17 (85)

Continued

Table 1 Continued

Section A: Demographics	1. **Institution** 2. **Position title (quality and safety role)** 3. **What is your professional designation?** 4. **Years of experience**			
Section B: Domains	**Questions/responses***	**Comprehension= clear yes, n (%)**	**Importance= necessary yes, n (%)**	**Number and percentage of respondents rating they partially agree or agree, or strongly agree (%), N=20**
Immediate response	I must report the same incident using different approaches (eg, patient files, nursing reporting system, safety department).	17 (85)	18 (90)	17 (85)
	Reporting incidents have never caused troubles with my colleagues and is viewed favourably within my unit's culture.	20 (100)	20 (100)	15 (75)
	†17. Managers and leaders have the authority to support reporters.	19 (95)	18 (90)	18 (90)
	Policies and protocols support the non-punitive reporting environment.	19 (95)	19 (95)	20 (100)
	There are policies and protocols to protect reporters against legal and non-legal actions.	19 (95)	19 (95)	14 (70)
	The hospital requires reporting to an independent body to avoid blaming and enhance fair analysis.	18 (90)	18 (90)	14 (70)
	I have no concern about confidentiality when I complete the incident report forms.	20 (100)	20 (100)	19 (95)
	All staff have access to an electronic system for reporting safety events.	19 (95)	19 (95)	8 (40)
	I have alternative reporting options to enhance efficiency, such as telephone reporting, manual and electronic reporting.	19 (95)	18 (90)	19 (95)
	Incident review forms are self-explanatory and time efficient to complete.	20 (100)	20 (100)	18 (90)
	I understand that Incident reporting is the responsibility of the person who witnessed the event and should not be delegated.	19 (95)	18 (90)	12 (60)
	Incident reporting is mandatory.	20 (100)	19 (95)	11 (55)
	†27. The hospital has a list of prioritised incidents to be reported.	19 (95)	19 (95)	20 (100)

Continued

Table 1 Continued

Section A: Demographics	1. **Institution** 2. **Position title (quality and safety role)** 3. **What is your professional designation?** 4. **Years of experience**			
Section B: Domains	**Questions/responses***	**Comprehension= clear yes, n (%)**	**Importance= necessary yes, n (%)**	**Number and percentage of respondents rating they partially agree or agree, or strongly agree (%), N=20**
Prepare for analysis	†28. The investigation team uses appropriate analysis tools to describe the findings of the review.	18 (90)	19 (95)	15 (75)
	†29. Management ensures engagement of the front-line workers in the investigation team.	18 (90)	18 (90)	14 (70)
	†30. Management ensures analysis teams are composed of representative expertise.	18 (90)	17 (85)	17 (85)
	†31. There are well trained investigation experts participating in each team.	18 (90)	19 (95)	13 (65)
	†32. The incident investigating team ensures equal and fair multidisciplinary participation.	19 (95)	18 (90)	11 (55)
	Staff and management are capable in performing incident investigation.	20 (100)	19 (95)	13 (65)
Analysis process	†34. Interviewers investigating the incidents consider and confirm the confidentiality of the interviewees.	19 (95)	19 (95)	17 (85)
	†35. Recommendations are professionally developed.	18 (90)	18 (90)	16 (80)
Follow through	†36. Implementation of recommendations is well monitored.	18 (90)	19 (95)	18 (90)
	I observe enhancements to safety based on previously reported incidents.	20 (100)	20 (100)	18 (90)
	†38. Management evaluates compliance with recommended safety enhancements using formal (eg, audits, and score cards) methods.	20 (100)	19 (95)	17 (85)
	†39. Management evaluates compliance with recommended safety enhancements using informal (eg, risk officer spot check) methods.	18 (90)	19 (95)	17 (85)

Continued

Table 1 Continued

Section A: Demographics	1. **Institution** 2. **Position title (quality and safety role)** 3. **What is your professional designation?** 4. **Years of experience**			
Section B: Domains	**Questions/responses***	**Comprehension= clear yes, n (%)**	**Importance= necessary yes, n (%)**	**Number and percentage of respondents rating they partially agree or agree, or strongly agree (%), N=20**
Close the loop	I can track the processing of my reported incidents.	20 (100)	19 (95)	17 (85)
	People receive feedback on their reported events.	20 (100)	20 (100)	12 (60)
	There are regular communications between senior management and front-line staff with respect to values, expectations and the results of learning from incident reporting.	19 (95)	19 (95)	15 (75)
	†43. There are regular communications between senior management and quality leaders with respect to values, expectations and the results of learning from incident reporting.	18 (90)	18 (90)	11 (55)
	†44. The management has a defined communication approach to share learning internally.	19 (95)	17 (85)	15 (75)
	†45. The management has a defined communication approach to share learning externally.	16 (80)	18 (90)	10 (50)
	There is transparency in data sharing about the findings of reviews.	19 (95)	20 (100)	14 (70)
	Serious and high-risk incidents have their own feedback route.	20 (100)	19 (95)	19 (95)

*Each question has a five-point scale as response variables (strongly disagree, disagree, partially agree, agree and strongly agree) evaluating the SLS. In step 3, each participant was asked to evaluate each question based on the clarity and necessity using either a yes or no response.
†Questions assigned only for quality and safety leaders and managers to answer.
SLS, safety learning system .

because their approval ratings exceeded the 80% benchmark set for question inclusion.

Four demographic questions were also added. The first three questions 'Institution', 'Position title' and 'What is your professional designation?' can help to direct improvement efforts to the right hospital department, while the fourth question 'Years of experience' can help to either include or exclude participants based on their experience, which might affect their answers. Finally, the questionnaire was tested for internal consistency using the participants' evaluation of their SLS; high reliability was indicated with a Cronbach's alpha score of 0.94.

Although this study did not intend to evaluate the hospital's SLS, we grouped the responses of the participants' opinions into either 'agree' or 'disagree' and only present the percentage agreement in table 1 for simpler reporting. It is also important to mention that improving the SLS is a continuous process; therefore, decision-makers can work on any of the system areas even those with high agreed percentages. We also wish to highlight that the domains 'prepare for analysis' and 'closing the loop' received the highest totals of 'disagree' or 'strongly disagree' scores.

This study's unique strength lies in the rigorous steps taken to develop the survey. To ensure the accuracy of the collected data, we followed the methods of Karen *et al*[16] for face validity checks, based our questions on evidence from a systematic review and piloted the survey at a large, reputable hospital. This pilot allowed us to assess the applicability, clarity and necessity of all items. Finally, we incorporated feedback from both SLS experts and experienced Q&S professionals working within the SLS at The Ottawa Hospital.

Our newly developed questionnaire has many points in common with a 44-item self-assessment tool developed by the WHO in 2020.[20] That tool was developed based on feedback from international experts in SLS. Both questionnaires use similar rating scales and cover many of the same major topics, including safety culture, leadership support, training, analysis and investigation, blame-free culture, availability of resources, feedback and the internal and external sharing of learning. On the other hand, our questionnaire was rigorously developed to enhance accuracy and clarity. We carefully formulated the questions to ensure understanding across diverse participant backgrounds. The questions were organised into domains to focus improvement efforts. We divided participants into two groups for obtaining tailored, precise results. To ensure practicality and relevance, we incorporated feedback from Q&S leaders working directly within a large accredited hospital's SLS system. Finally, demographic data will inform recommendations, allowing us to target improvements for specific departments or employee groups.

Another study developed and validated an online questionnaire survey to test recently graduated doctors' knowledge and experience of patient safety and incident reporting, and assess-related attitudes and behaviours.[21] It was developed based on previously published questionnaires for medical students and nurses. It included 21 questions that partly overlap with our questionnaire including the principles of patient safety in their hospitals, their views on local reporting, training, the reporting stage, blame-free environment, involvement in incident discussions and 1 question on feedback. Our questionnaire has more items to assess feedback in addition to a detailed evaluation of the management role and the analysis process.[21] Our questionnaire was tested for validity and reliability to ensure highly precise data collection. Being based on a systematic review, our collected data and subsequent recommendations are more generalisable and applicable.

The strengths of this study include the testing of the face validity of the questionnaire. A group of experienced health services researchers who are experts in patient safety reviewed and gave feedback on each item to ensure it is fit for the purpose. The questionnaire was evaluated again in the clinical sensibility test by experts in the field. Finally, internal consistency was measured and was found to be high. Therefore, we are highly confident that no irrelevant questions were included and that all critical topics were covered. In addition, our questionnaire was based on a systematic review study that included 22 primary research studies conducted worldwide. It collected the views of a range of healthcare professionals on the barriers and facilitators of SLSs. This would be reflected on the generalisability of our results. Being standardised, it might help to compare SLS performances among different hospitals.

All the safety experts, leaders and managers at The Ottawa Hospital were invited to participate in the internal consistency assessment; however, the response rate was low at 36%. Domain C had the lowest Cronbach's alpha score (0.61), which can be explained by the low number of questions (six) known to affect the accuracy of the test; however, the result is still close to the lower reliability limit. Everyone rating the hospital's SLS were experts in Q&S and could be concerned with the reputation of their hospital, so the possibility of bias in their responses exists. However, generalisability of the questionnaire is not expected to be affected as questions were based on the result of a systematic review that included studies from all over the world. Furthermore, testing the questionnaire for clarity, necessity and reliability depended mainly on participants' general knowledge on Q&S. However, despite this theoretical consideration, further testing in a large sample of participants from multiple settings is required

CONCLUSION

This SLS self-assessment questionnaire is an evidence-based tool that on preliminary testing is deemed valid and reliable. The questionnaire created and evaluated in this study provides a reliable means for healthcare

providers to self-assess their SLS. Using this questionnaire within a larger sample of respondents from different institutions will be required to further assess the survey psychometric properties as well as determine possible differences in SLS practices.

Contributors Corresponding Author HAM was responsible for the whole research at its different stages (protocol development, planning, survey development, data collection and analysis, writing of the manuscript, editing and publication. AJF is the research supervisor responsible for planning, supervision and revision of the final manuscript. Contributing authors, they all participated in development of the protocol, revision and approval of the analysis, writing the manuscript and revision of the different edits of the manuscript they also participated in the pretesting step in survey development.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The Research Ethics Board at The Ottawa Hospital (OHSN-REB Number: 20210441-01H (2658)) approved the protocol.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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