Title	An international perspective on definitions and terminology used to describe serious reportable patient safety incidents: A systematic review
Authors	Hegarty, Josephine;Flaherty, Sarah Jane;Saab, Mohamad M.;Goodwin, John;Walshe, Nuala;Wills, Teresa;McCarthy, Vera J. C.;Murphy, Siobhan;Cutliffe, Alana;Meehan, Elaine;Landers, Ciara;Lehane, Elaine;Lane, Aoife;Landers, Margaret;Kilty, Caroline;Madden, Deirdre;Tumelty, Mary;Naughton, Corina
Publication date	2020-04
Original Citation	Hegarty, J., Flaherty, S. J., Saab, M. M., Goodwin, J., Walshe, N., Wills, T., McCarthy, V. J. C., Murphy, S., Cutliffe, A., Meehan, E., Landers, C., Lehane, E., Lane, A., Landers, M., Kilty, C., Madden, D., Tumelty, M. and Naughton, C. (2020) 'An international perspective on definitions and terminology used to describe serious reportable patient safety incidents: A systematic review', Journal of Patient Safety, 17(8), pp. p e1247-e1254. doi: 10.1097/PTS.0000000000000700
Type of publication	Article (peer-reviewed)
Link to publisher's version	10.1097/PTS.0000000000000700
Rights	© 2020, The Authors. Published by Wolters Kluwer Health, Inc. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. - https://creativecommons.org/licenses/by-nc-nd/4.0/
Download date	2025-07-30 13:47:56
Item downloaded from	https://hdl.handle.net/10468/13154

University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

OPEN

An International Perspective on Definitions and Terminology Used to Describe Serious Reportable Patient Safety Incidents: A Systematic Review

Josephine Hegarty, PhD, Sarah Jane Flaherty, PhD,* Mohamad M. Saab, PhD,* John Goodwin, MA,* Nuala Walshe, MSc, MTLHE,* Teresa Wills, PhD,* Vera J.C. McCarthy, PhD,* Siobhan Murphy, MSc,* Alana Cutliffe, BSc,* Elaine Meehan, PhD,* Ciara Landers, MSc,* Elaine Lehane, PhD,* Aoife Lane, PhD,* Margaret Landers, PhD,* Caroline Kilty, PhD,* Deirdre Madden, PhD,† Mary Tumelty, PhD,† and Corina Naughton, PhD**

Objectives: Patients are unintentionally, yet frequently, harmed in situations that are deemed preventable. Incident reporting systems help prevent harm, yet there is considerable variability in how patient safety incidents are reported. This may lead to inconsistent or unnecessary patterns of incident reporting and failures to identify serious patient safety incidents. This systematic review aims to describe international approaches in relation to defining serious reportable patient safety incidents.

Methods: Multiple electronic and gray literature databases were searched for articles published between 2009 and 2019. Empirical studies, reviews, national reports, and policies were included. A narrative synthesis was conducted because of study heterogeneity.

Results: A total of 50 articles were included. There was wide variation in the terminology used to represent serious reportable patient safety incidents. Several countries defined a specific subset of incidents, which are considered sufficiently serious, yet preventable if appropriate safety measures are taken. Terms such as "never events," "serious reportable events," or "always review and report" were used. The following dimensions were identified to define a serious reportable patient safety incident: (1) incidents being largely preventable; (2) having the potential for significant learning; (3) causing serious harm or have the potential to cause serious harm; (4) being identifiable, measurable, and feasible for inclusion in an incident reporting system; and (5) running the risk of recurrence.

Conclusions: Variations in terminology and reporting systems between countries might contribute to missed opportunities for learning. International standardized definitions and blame-free reporting systems would enable comparison and international learning to enhance patient safety.

Key Words: patient safety, adverse event, serious incident, reporting, systematic review

(*J Patient Saf* 2021;17: e1247–e1254)

From the *Catherine McAuley School of Nursing and Midwifery, and †School of Law, University College Cork, Cork, Ireland.

Correspondence: Mohamad M. Saab, PhD, Catherine McAuley School of Nursing and Midwifery, University College Cork, College Road, Cork, Ireland, T12 AK54 (e-mail: msaab@ucc.ie).

The authors disclose no conflict of interest.

This work was commissioned and funded by the National Patient Safety Office, Department of Health, Republic of Ireland.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (http://www.journalpatientsafety.com).

Patient harm is one of the major causes of global disease burden and represents the leading cause of injury and potentially avoidable harm in healthcare systems internationally.[1] Patient safety is a global priority given the increasing evidence that patients are unintentionally, but frequently, harmed in situations often deemed to have been preventable.[2,3] One of the fundamental means of preventing avoidable harm is by learning from failures of the healthcare system via incident reporting systems and implementing appropriate changes.[4,5]

There is, however, variability in the approaches taken in relation to incident reporting. This may cause confusion as to what is considered a reportable patient safety incident.[6] This lack of clarity may lead to inconsistent or unnecessary patterns of incident reporting, which fails to allow identification of the most serious patient safety incidents to enable relevant learning and systems improvement.[5] The World Health Organization (WHO) outlined a number of priority areas to improve patient safety and support learning healthcare systems, and a shared understanding may be critical to their achievement.[1] Consequently, there is a need for standardized and consistent approaches to defining serious incidents and associated reporting protocols.

Although previous attempts at standardization have been made, there is a continual need to review and refine relevant terminology as reporting approaches evolve to enable translation of learning across healthcare systems.[6] Therefore, it is important to understand the approaches that are used internationally to identify common elements, which may contribute to a more consistent means of incident reporting and a greater shared learning.[3] The aim of this review is to describe international approaches in relation to the reporting of serious patient safety incidents with a particular focus on exploring definitions and terminology used to represent serious patient safety incidents.

METHODS

This systematic review was guided by the principles of conducting systematic reviews,[7] and the latest Cochrane Handbook for Systematic Reviews,[8] and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist.[9]

Eligibility Criteria

Eligibility criteria were predetermined using the SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, and Research type) framework.[10] The full inclusion and exclusion criteria and associated search terms are presented in Table 1. National reporting systems focusing on patients or any members of the public interacting with the healthcare system, regardless of speciality,

TABLE 1. Database Search Terms and Eligibility Criteria

SPIDER Framework	General Term	Detailed Search Terms	Inclusion Criteria	Exclusion Criteria
Sample	Patient/public	Patient OR client OR user OR family OR public	Patients/members of the public interacting with the healthcare system, regardless of speciality	Patients/members of the public outside of the healthcare system
Phenomenon of ***I***nterest	Serious safety incident reporting	Report OR national OR system OR database OR (mandatory adj2/N2/W2 disclosure) OR (open adj2/N2/W2 disclosure) OR "duty of candor" AND (critical OR sentinel OR serious) adj2/N2/W2 (incident OR event OR harm OR error) OR "medical error" OR "clinical error" OR "never event" OR "adverse event" OR "serious patient safety incident" OR "patient safety learning system" OR "critical incident reporting system"	1. Takes a national or state or regional level approach 2. Describes the processes underpinning the collection, collation and reporting of data pertaining to serious patient safety incidents i.e. safety incident learning system(s) or critical incident reporting system(s) 3. Describes the collection, collation and reporting of incidents (medication error, etc.) or reporting within one speciality or condition or error type, provided the reporting is at a national level	1. Set in a context outside of a national public healthcare system 2. Deals with "no harm" or "near miss" incident reporting 3. Identifies trends and patterns of serious incidents reported in a patient safety learning system 4. Low human development index countries
Design	Not specified	Not specified	Details of a national guideline or national policy or national reporting systems	Reporting within a professional group or discipline-specific focus
Evaluation and ***R***esearch type	Not specified	Not specified	1. Study of any design 2. Systematic/discursive review 3. National report/policy	1. Editorial 2. Thesis/dissertation 3. Conference abstract

Adj (adjacent), N (near), and W (within) were proximity indicators used to search for 2 or more words that occur within a specified number of words (or fewer) of each other within the databases.

were eligible for inclusion. Empirical studies, including systematic and discursive reviews, and national reports and policies were included. Editorials, theses, and conference abstracts were excluded.

Information Sources and Search

The following electronic databases were searched: CINAHL, MEDLINE, PsycINFO, PsycARTICLES, Psychology and Behavioral Sciences Collection, SocINDEX, UK/Ireland Reference Centre, ERIC, Cochrane Library, Campbell Collaboration, OTseeker, PeDRO, Social Care Online, Philosophers index, Scopus, Global Ethics Observatory, Global Digital Library On Ethics, Sage, Hein Online, JSTOR, Lexis, Oxford Journals Online, Practical Law (Thomson Reuters), and Westlaw Ireland/Westlaw UK/Westlaw International. The search was limited to studies published between January 2009 and January 2019 in English. Search terms were predetermined based on the review eligibility criteria. These are detailed in Table 1.

A robust gray literature search was undertaken for gray literature databases, customized Google search engines, and targeted Web sites, with a focus on England, Wales, Scotland, Northern Ireland, Republic of Ireland, the Netherlands, Sweden, Denmark, the United States (U.S.), Canada, Australia, and New Zealand. These countries were chosen as they have similar healthcare systems and related infrastructure and score high on the human development index. The Web sites included in the gray literature search are outlined in online supplementary file 1 (Supplemental Digital Content 1, http://links.lww.com/JPS/A304). A comprehensive search of each Web site was undertaken, and their potential functionality was leveraged to maximize retrieval. Where possible, results were organized based on relevance, and the first 100 hits were reviewed for each search. Reference lists were screened to locate additional articles. The search for each country was conducted independently in pairs (J.G. and V.J.C.M.; J.H. and S.J.F.; M.M.S. and S.M.; N.W. and T.W.).

Study Selection

All potentially eligible articles were exported to a reference management software (Endnote X7, Thomson Reuters, New York, NY) where duplicates were removed. Articles were then transferred to an online software for screening and data extraction (Covidence, Veritas Health Innovation Ltd, Melbourne, Australia). Articles were initially screened on title and abstract independently in pairs to determine whether a full-text review was merited (A.C., E.M., J. H., S.J.F.). Full texts were then independently evaluated in pairs (A.C. and S.J.F.). Screening conflicts were resolved by consensus or by a third reviewer (J.H.).

Data Extraction and Synthesis

Data extracted from empirical articles included: author(s), year, country, design, aim, and findings. Data extraction was conducted by one researcher (A.C.) and cross-checked by other researchers to ensure accuracy (J.G., M.M.S., N.W., S.M., T.W., V.J.C.M.). Data extracted from the gray literature included the following: author(s), year, country, design, incident definitions, reportable incidents, and procedures for the collation and monitoring of these incidents. Data extraction from the gray literature and subsequent cross-checking were undertaken in pairs (J.G. and V.J.C.M.; J.H. and S.J.F.; M.M.S. and S.M.; N.W. and T.W.).

Given the heterogeneity of the included articles in terms of methodologies and geographical spread, a narrative data synthesis was conducted.

Level of Evidence

Studies were graded according to the Scottish Intercollegiate Guidelines Network (SIGN) level of evidence criteria.[11] The SIGN tool assesses the potential risk of bias associated with different study designs and assigns a numerical level of scientific evidence (1++ to 4). High-quality meta-analyses or systematic reviews with very little risk of bias are assigned a value of 1++, whereas expert opinions are assigned a value of 4.

RESULTS

Study Selection

The study selection process is presented in Figure 1. A total of 4458 records were identified through electronic database searching. After deletion of duplicates, 3661 records were screened on title and abstract and 3596 irrelevant records were excluded. After reviewing the full text of eligible articles (n = 65), including reference lists, 32 articles met the inclusion criteria. An additional 18 articles were identified in the gray literature search, yielding a total of 50 articles that were included in this review.

Study Characteristics

Most records related to European countries (n = 30), with the United Kingdom (UK) being the main contributor (n = 16). The remaining records were from North America (n = 13), Australia (n = 2), New Zealand (n = 2), and Iran (n = 1). Two publications did not have a specific country focus. Most of the included records were international, European, and national guidance documents (n = 18), followed by narrative, scoping, and systematic reviews (n = 13). Study characteristics and findings from individual studies are presented in online supplementary file 2 (Supplemental Digital Content 2, http://links.lww.com/JPS/A305).

Level of Evidence

The level of evidence was relatively low across the reviewed articles. Of the articles sourced via electronic databases, 2 articles were categorized as 2++ (high-quality systematic reviews) and 7 were categorized as 2− (cohort, or similar, studies with high risk of bias). Most articles (n = 23) were categorized as level 3 or 4 (nonanalytical studies or expert opinion). Most records sourced from the gray literature were government documents outlining national policy and/or relevant legislation.

Reporting Serious Patient Safety Incidents

There was considerable variability between countries in the terminology used to represent and define serious reportable patient safety incidents. Table 2 presents the definitions used in relevant national documents. Further complexity is introduced as different organizations within a country may use different terminology, or particular terms may be used interchangeably, such as "never events," "sentinel events," "serious reportable events," or "always review and report." Such inconsistency has been acknowledged by the WHO.[1]

An international expert panel sought to provide clarity in this area and developed conceptual definitions relating to patient safety incidents and incident reporting.[27] Serious (adverse) incidents or events were the terms primarily used, although sentinel event was also used, as illustrated in definitions from Australia,[12] and the Netherlands.[18]

Several countries have defined a specific subset of incidents, which were considered sufficiently serious but viewed as wholly preventable if appropriate safety measures are implemented. The terms "never events," "serious reportable events," or "always review and report" were used in this context, with examples evident in Canada,[14] England and Wales,[17] and New Zealand.[20] The reporting of serious incidents was mandated in legislation and/or national policy in several countries including the Republic of

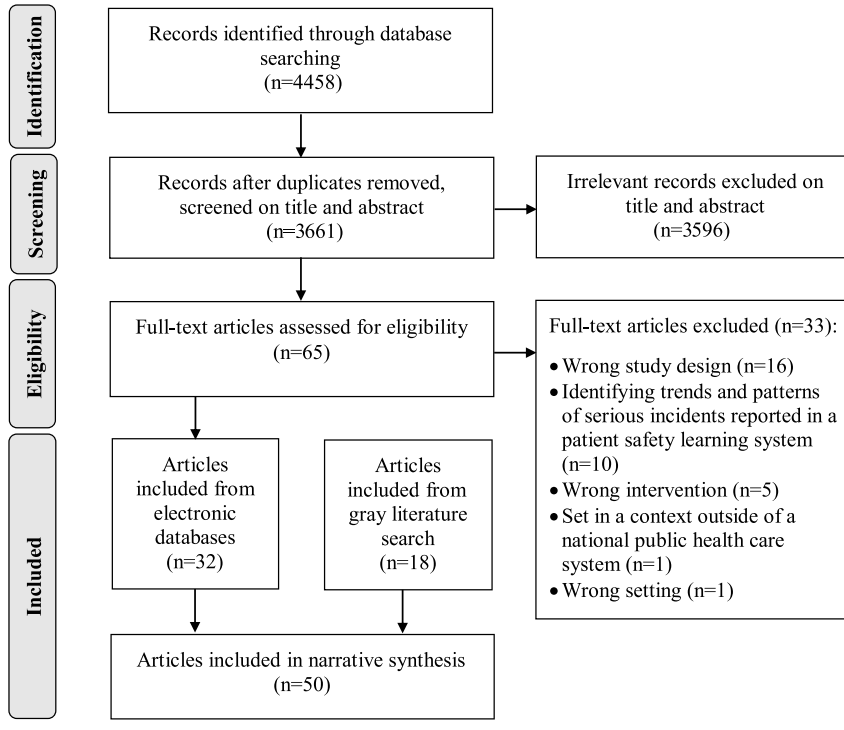

FIGURE 1. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

TABLE 2. International Definitions of Serious Patient Safety Incidents

Country	Definition
Australia	**Sentinel Event:** Serious incident that is wholly preventable and has caused serious harm to, or death of, a patient.[12]
Canada	**Patient Safety Incident:** Event or circumstances which could have resulted or did result in unnecessary harm to a patient.[13] **Never Events:** Patient safety incidents that result in serious patient harm or death, and that can be prevented by using organizational checks and balances.[14]
Denmark	**Adverse Event**: Event resulting from treatment by or stay in a hospital and not from the illness of the patient, if such event is at the same time either harmful or could have been harmful had it not been avoided beforehand, or if the event did not occur for other reasons.[15]
England and Wales	**Serious Incident:** Event in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organizations are so significant, that they warrant using additional resources to mount a comprehensive response.[16] **Never Event**: Serious incident that is wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.[17]
Netherlands	**Sentinel Event:** Unintended and unexpected event related to the quality of care and having caused death or serious harm to the patient.[18]
New Zealand	**Adverse Event:** Event with negative or unfavorable reactions or results that are unintended, unexpected or unplanned.[19] **Always Report and Review Event**: Adverse event that can result in serious harm or death but are preventable with strong clinical and organizational systems.[20]
Northern Ireland	**Serious Adverse Incident**: Any event or circumstances that led to harm, loss or damage to people, property, environment or reputation.[21] **Never Event**: Serious incident that is wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.[17]
Republic of Ireland	**Serious Reportable Event**: Incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers.[22]
Scotland	**Adverse Event**: Event that could have caused (a near miss), or did result in, harm to people or groups of people.[23]
Sweden	**Serious Adverse Event**: Event where severe injury occurred, and care-related injury is permanent and has resulted in the patient having a significant increase in their need for care or their death.[24]
U.S.	**Serious Event:** Event that can result in death, loss of a body part, disability, loss of bodily function, or require major intervention for correction, e.g., higher level of care, surgery.[25] **Serious Reportable Events**: To qualify for the list of Serious Reportable Events in Healthcare, an event must be unambiguous, largely, if not entirely, preventable, serious, and be any of the following: adverse; indicative of a problem in a healthcare setting's safety systems; important for public credibility or public accountability. In addition, items included on the list are events that are: of concern to both the public and healthcare professionals and providers; clearly identifiable and measurable; and thus feasible to include in a reporting system; and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility.[25] **Sentinel Event:** Patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following: death, permanent harm, or severe temporary harm and intervention required to sustain life.[26]

Ireland, the UK, Denmark, the Netherlands, Sweden, Canada, Australia, and New Zealand. When incorporated into legislation, it was typically the reporting process that was specified rather than an incident list. Associated incident lists were ordinarily published in a relevant policy, which was reviewed and revised regularly. A mixed-method case review found that actual reporting remains suboptimal, even in the presence of such statutory obligations.[28]

The WHO's International Classification for Patient Safety was identified as a key reference document in relation to defining and coding of patient safety incidents, particularly in Europe.[1] This classification was often amended to individual healthcare contexts.[4,29,30] In the U.S., there was greater emphasis on the definitions and coding formats developed by the Agency for Healthcare Research and Quality (AHRQ)[31] and the National Quality Forum (NQF).[25,32,33] The AHRQ is developing and validating the Quality and Safety Review System to collect comparable patient safety data over time for acute care hospitals using standardized definitions and algorithms.[31] More than half of the U.S. states and the District of Columbia have enacted reporting systems using at least some portion of NQF's list to help stakeholders identify and learn from serious reportable events.[25] Tsang et al[34] acknowledged the potential differences between these classification systems and related definitions and called for a greater examination to allow translation across healthcare systems and support a greater consistency in the reporting of patient safety incidents.

Dimensions of Reportable Serious Patient Safety Incidents

In examining the definitions and systems used to report serious patient safety incidents, several dimensions were identified as fundamental in defining a serious reportable patient safety incident. These dimensions are described in Table 3 and include: the

following: incidents being largely preventable; having the potential for significant learning; having caused serious harm or the potential to cause serious harm; being identifiable, measurable, and feasible for inclusion in an incident reporting system; and running the risk of recurrence. These dimensions align somewhat with the 5 dimensions of safety measurement and monitoring proposed by the Health Foundation Inspiring Movement,[35] which are as follows: past harm, reliability, sensitivity to operations, anticipation and preparedness, and integration and learning.

Preventable

Incidents were viewed as "wholly preventable" or "preventable" when guidance or safety recommendations were available at a national level that offered strong systemic protective barriers. The implementation of such guidance or recommendations would prevent incident occurrence, whereas failure to do so is recognized as a serious flaw in a learning healthcare system. The U.S. serious reportable events list is a compilation of serious, largely preventable, and harmful clinical events, designed to help in the assessment, measurement, and reporting on the provision of safe care.[25] It is considered important to separate incidents that relate to patient safety from those relating to the quality of healthcare delivery.[36] Although both are interdependent, the emphasis in safety has to do with preventing errors, learning from errors, and building a safety culture, whereas quality relates to the efficient, effective, and purposeful care delivery, which increases the likelihood of anticipated health outcomes and are consistent with current professional evidence-based practice.

Potential for Significant Learning

Although variation is apparent, there seems to be a core emphasis on creating learning healthcare systems where learning is appropriately shared across and within organizations. This dimension relates to incidents where the potential for learning is so great or the consequences to patients, families and carers, staff, or organization are so significant that they warrant additional resources to implement a comprehensive response.

One of the key differences between reporting systems seems to be the focus on learning from all events versus learning from all events but with a particular focus on a specific list of serious reportable events.[29] Although there is learning from all patient safety incidents, reporting systems need to prioritize very serious incidents that require a more comprehensive investigation and critical system change.[37] The mandatory reporting of specific incidents was viewed as beneficial in relation to identifying rare events, recognizing the safety needs of an organization, and sharing appropriate safety solutions.[38] These benefits were considered especially relevant for certain incidents, such as medication errors, device failures, and hospital-acquired infections, where national solutions were considered necessary.[38] Macrae[5] argued that too much information is collected whereas little use is made of this information. He highlighted that a reporting system should allow identification and prioritization of those aspects of a healthcare system that require additional examination and subsequently enable improvement and learning to address such risks.[5]

Greater feedback on incident analysis directly to staff and service users was identified as a fundamental element of a learning healthcare system.[39–41] The separation of disciplinary action and legal repercussions was emphasized alongside confidentiality and anonymity for the individual reporting with a shift from a culture of blame to one of learning and support.[39,42] The sharing of learning from incident analysis must move beyond internal organization dissemination and should contribute to learning across an entire healthcare system.[38] There is a further opportunity to develop transnational networks where learning can be shared between countries to inform policy development and improve patient safety.[4,29,43]

Unexpected or Avoidable Death or Serious Injury

Unexpected or avoidable death, or unexpected or avoidable injury resulting in serious harm to patients or any members of the public who are interacting with the healthcare system, are core components of all definitions of serious reportable incidents, regardless of speciality. The potential for an incident to result in patient death or serious harm is incorporated into the definitions of North America, Denmark, New Zealand, and the UK. In England, Northern Ireland, and Wales, though "never events" have the potential to cause serious patient harm or death, this outcome is not required for the incident to be categorized as a "never event." This emphasis has been introduced to proactively identify problems within the system rather than react solely on the outcome of the incident.[17]

Identifiable, Measurable, and Feasible to Include in Reporting System

Another common component is that serious reportable incidents should be identifiable, measurable, and feasible for inclusion in a reporting system. An incident must be clearly defined with clear discrimination between incidents in a reporting system, and its occurrence must be easily recognized in practice. Improved

TABLE 3. Dimensions of Incidents Termed as Serious Reportable Events

Dimension	Description
Preventable	Event is largely preventable because guidance or safety recommendations that provide protection are available nationally.
Potential for significant learning	Event where there is considerable potential for learning or consequences are sufficiently significant to warrant additional resources to mount a comprehensive response. Occurrence of event is indicative of a problem in a healthcare provider's safety system.
Cause unexpected or avoidable death or injury or potential to cause serious harm	Event caused unexpected or avoidable death, or injury resulting in serious harm or potential for serious harm to patients or any members of the public who are interacting with the healthcare system, regardless of speciality.
Identifiable and measurable	Event is clearly identifiable, measurable and feasible to include in a reporting system. Duplication in reporting elsewhere is avoided to minimize confusion in the system.
Run the risk of reoccurrence	There is evidence that the event has occurred in the past and that the risk of recurrence remains a concern for the system.

clarity in relation to the definition of a serious incident and how it differs from the patient's clinical condition or ongoing disease progression is required to foster an improved learning environment.[42,44] International approaches to the reporting of serious patient safety incidents varied in relation to the number and type of incidents that are considered reportable. Australia[12] and New Zealand[20] listed 10 and 6 incidents, respectively, that require reporting to the relevant national agency, whereas there were 34 reportable incidents listed for the Republic of Ireland.[22] In most countries, reportable incidents typically related to surgical or other health procedures (e.g., wrong site surgery), patient protection (e.g., child discharged to wrong individual), and care management (e.g., administration of incompatible blood products).

Run the Risk of Reoccurrence

The fifth and last dimension is that incidents should have occurred in the past, and the risk of recurrence should remain. In the broader field of risk management, safety was primarily concerned with prevention of recurrence of specific incidents.[45] For example, in England, Northern Ireland, and Wales, "never events" were identified through their previous occurrence and a continued risk of recurrence.[17] In the Republic of Ireland, the primary purpose of incident reporting systems "is to ensure that individual incidents are appropriately reviewed… and ensure that any underlying safety issues are addressed.[46]" This was identified as key to preventing the recurrence of serious patient safety incidents.

DISCUSSION

This systematic review illustrates that there continues to be variation internationally in relation to the reporting of serious patient safety incidents and what incidents are considered reportable within a healthcare system. Despite such variation, however, commonalities were also apparent. There is a clear emphasis on creating a learning healthcare system, although how this is achieved and the degree to which it is achieved within an organization differ. Certain dimensions of patient safety incidents were common across definitions and may constitute core components of a risk management system. Drawing on these common dimensions, serious patient safety incidents may be defined as those incidents which are (1) largely preventable; (2) have the potential for significant learning; (3) cause serious harm or have the potential to cause harm; (4) are identifiable, measurable, and feasible for inclusion in an incident reporting system; and (5) run the risk of recurrence. This captures the key elements of what is considered a serious reportable incident and may provide a useful foundation of a shared definition to support improved consistency in both research and practice. Of note, the dimensions of incidents termed as serious reportable events identified in the present review are comparable with the Health Foundation's 5 dimensions of safety monitoring and measurement,[35] namely: (1) past harm, encompassing both psychological and physical measures; (2) reliability, encompassing measures of behavior and systems; (3) sensitivity to operations, covering the information and capacity to monitor safety; (4) anticipation and preparedness, including the ability to anticipate and prepare for problems; and (5) integration and learning, which is operationalized as the ability to respond to and to improve safety information.

The apparent inconsistency persists despite the attempts of the WHO to provide clarity to key concepts in patient safety reporting.[6,27] This is recognized in particular areas, such as primary care,[47] and home care services,[36] where ongoing work is focusing on creating greater consensus in the terminology used with the aim of supporting improved coherency in incident reporting. Notably, most published serious reportable events lists are hospital centric in their outlook, which is a concern given that mechanisms are needed to closely track patient safety across health services from primary, secondary, tertiary, to quaternary care. A greater uniformity may facilitate the translation of learning at an international level and across healthcare contexts and ultimately contribute to improvements in patient safety.[3,6,34] It is, however, important to acknowledge the influence of the health care context in which reporting occurs. As highlighted by Yarmohammadian et al,[39] the "social, political and cultural infrastructure affect the purpose of a reporting system and the purpose itself determines type, confidentiality, reported events scope and contributory factors of a reporting system."(p143) This emphasizes the need for flexibility and pragmatism in relation to incident reporting and related definitions, which must be considered in different contexts.[5] It is evident that a balance must be achieved between the standardization of terminology and reporting protocols and their practical implementation in a healthcare system. Enshrining serious reportable events lists in primary legislation has some benefits; however, such legislation can be very restrictive and unwieldy to update and amend; thus, it is preferable to have the broad reporting requirements and process in primary legislation with serious reportable events lists within secondary legislation or guidance or policy documents, thereby enabling regular update. It is unclear how the lists of serious reportable events are derived internationally and how such lists are supported by evidence as definitions of serious harm vary across jurisdictions.

This review illustrates that there is continued inconsistency, in research and practice, in relation to the reporting of serious patient safety incidents, both in terms of the approach implemented and the terminology used. Although there is potential learning from all incidents, it is crucial that the most serious and preventable incidents are identified and addressed in a timely manner. This necessitates a focus on a specific set of incidents of relevance to the particular healthcare context.

Identifying and addressing barriers to learning from incident reporting are vital to the reporting of serious patient safety incidents.[48] Barriers identified in the international literature include the following: lack of training in the use of incident reporting systems, lack of user-friendliness of preexisting systems, uncertainties around reportable incidents, organizational culture of blame, bureaucracy, fear of negative repercussions, lack of feedback, perceived lack of learning, and absence of change in practice as a result of incident reporting.[49–51] These barriers can be addressed using various strategies. A worked example is a case-based 60-minute discussion and analysis of patient safety incidents delivered to 1169 National Health Service stakeholders in the UK.[52] This discussion led to significant improvements in knowledge, skills, and behaviors relating to patient safety and resulted in 32 national quality improvement projects aimed at developing novel clinical protocols and implementing user-informed and user-friendly learning.[52]

By drawing on international evidence, this review has identified the core dimensions of what is considered to constitute a serious reportable incident. Given the agreed importance of translating serious incidents across healthcare systems into learning formats and sharing learning between networks, developing an understanding of these core components is essential to allow for the pragmatic implementation of effective reporting and learning systems. There is an absence of discussion regarding the issue of enforcement for nonreporting or failure to disclose serious reportable events, perhaps in recognition of the primary need to create an open and just culture and the potential for such enforcement impacting negatively on this. Fifteen years after the Institute of Medicine's report, To Err is Human, Mitchell et al[53] interviewed 11 international patient safety experts about challenges that were not met by incident reporting since the release of the report.

As a result, the following challenges were identified: (1) inadequate report processing; (2) lack of adequate medical engagement; (3) insufficient feedback loop to the reporter; (4) inadequate funding and institutional support; and (5) failure to capture evolving health information technology. Similar challenges were iterated by Macrae[5] who argued that a solution to many of the patient safety incident reporting challenges is to perceive incidence reporting as an opportunity for learning, rather than as a mechanism to collect and analyze data. Similarly, this review highlighted the importance of fostering a blame-free reporting culture where the emphasis is placed on learning from incident occurrence rather than legal or disciplinary action. Therefore, legislation and related policies must be designed appropriately to support such a cultural shift. Classen et al[54] evaluated adverse event incidences in 3 U.S. hospital using 3 methods (Institute for Healthcare Improvement's [IHI] Global Trigger Tool, AHRQ Patient Safety Indicators, and Hospital Voluntary Reporting System). It was found that the AHRQ indicators and Voluntary Reporting System missed 90% of adverse events, whereas he IHI Global Trigger Tool found at least 10 times more serious adverse events than the other 2 methods.[54] This tool depends on retrospective reviews of patient records to identify adverse events.[55] Therefore, the IHI's Global Trigger Tool relies heavily on the vigilance of those reporting adverse events,[56] which further stresses the need to foster a blame-free reporting culture and putting policies in place in support of such a culture.

This systematic review was rigorously conducted and incorporated a comprehensive coverage of both peer-reviewed and gray literature. It provides a clear outline of the core dimensions of serious reportable incidents, which can support future research and practice. There is, however, a lack of empirical evidence on the organizational or clinical impact of national reporting systems in relation to patient safety outcomes or cultural change,[57] highlighting an important gap in the evidence base. Moreover, a clear limitation of this review is that the level of scientific evidence is relatively low, with most publications categorized as level 3 or 4, according to the SIGN level of evidence criteria, reflecting a large proportion of nonanalytical studies and expert opinions. Another limitation is the inclusion of studies published within the past 10 years. Although this helps identify the most recent evidence relating to the definitions used to describe serious reportable patient safety incidents, it may lead to the omission of seminal articles and reports published in this area.

CONCLUSIONS

The reporting of serious patient safety incidents is an evolving area, which highlights the continuous learning that exists in relation to patient safety. Despite efforts at an international level to bring uniformity to this area, disparity still exists as to what constitutes a serious reportable incident and effective reporting system. This review reiterates the importance of focusing on creating a learning healthcare system to support patient safety. This can be achieved, for example, by ensuring the confidentiality and anonymity of the individual reporting and establishing a blame-free culture. This review also emphasizes the value of focusing on a clearly defined set of serious and preventable incidents to extract appropriate learning that can be translated into systemwide improvements. A key recommendation from this review is to address the lack of relevant empirical research which limits the conclusions that may be drawn.[58] There is a need to critically examine the impact of different reporting approaches on organizational culture and patient safety outcomes to address this gap.

ACKNOWLEDGMENTS

The authors thank Susan Reilly, Jenny Hogan, Elizabeth Adams, David Keating, Sarah Condell, Marita Kinsella, and Dr Joan McCarthy for their support with this work.

REFERENCES

1. World Health Organisation. Patient safety. Global action on patient safety. Report by the Director-General. 2018. Available at: https://apps.who.int/gb/ebwha/pdf_files/EB144/B144_29-en.pdf. Accessed January 15, 2020.
2. Makeham M, Dovey S, Runciman W, et al. Methods and measures used in primary care patient safety research. 2008. Available at: http://www.who.int/patientsafety/research/methods_measures/makeham_dovey_full.pdf. Accessed January 15, 2020.
3. Panesar SS, deSilva D, Carson-Stevens A, et al. How safe is primary care? A systematic review. *BMJ Qual Saf*. 2016;25:544–553.
4. European Commission. Key findings and recommendations on reporting and learning systems for patient safety incidents across Europe. 2014. Available at: http://buonepratiche.agenas.it/documents/More/8.pdf. Accessed January 15, 2020.
5. Macrae C. The problem with incident reporting. *BMJ Qual Saf*. 2016; 25:71–75.
6. Runciman W, Hibbert P, Thomson R, et al. Towards an international classification for patient safety: key concepts and terms. *International J Qual Health Care*. 2009;21:18–26.
7. Centre for Systematic Reviews and Dissemination. Systematic reviews. CRD's guidance for undertaking reviews in healthcare. 2009. Available at: https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf. Accessed January 15, 2020.
8. Higgins JPT, Thomas J, Chandler J, et al. (editors). Cochrane handbook for systematic reviews of interventions version 6.0. 2019. Available at: http://handbook.cochrane.org. Accessed January 15, 2020.
9. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med*. 2009;6:e1000097.
10. Cooke A, Smith D, Booth A. Beyond PICO: the SPIDER tool for qualitative evidence synthesis. *Qual Health Res*. 2012;22:1435–1443.
11. Scottish Intercollegiate Guidelines Network. SIGN 50: a guideline developer's handbook. 2015. Available at: https://www.sign.ac.uk/assets/sign50_2015.pdf. Accessed January 15, 2020.
12. Australian Commission on Safety and Quality in Health Care. Australian sentinel events list. 2018. Available at: http://www.safetyandquality.gov.au/our-work/indicators/australian-sentinel-events-list/. Accessed January 15, 2020.
13. Canadian Patient Safety Institute. Canadian incident analysis framework. 2012. Available at: http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF. Accessed January 15, 2020.
14. Canadian Patient Safety Institute. Never events for hospital care in Canada: safer care for patients. 2015. Available at: http://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care%20in%20Canada.pdf. Accessed January 15, 2020.
15. Rasmussen LL. Act on patient safety in the Danish health care system. 2003. Available at: http://www.arkiv.patientsikkerhed.dk/media/566771/act_on_patient_safety.pdf. Accessed January 15, 2020.
16. NHS England. Serious incident framework: supporting learning to prevent recurrence. 2015. Available at: http://www.improvement.nhs.uk/resources/serious-incident-framework/. Accessed January 15, 2020.
17. NHS Improvement. Never events policy and framework. 2018. Available at: http://www.improvement.nhs.uk/documents/2265/Revised_Never_Events_policy_and_framework_FINAL.pdf. Accessed January 15, 2020.
18. Leistikow I, Mulder S, Vesseur J, et al. Learning from incidents in healthcare: the journey, not the arrival, matters. *BMJ Qualit Saf*. 2017; 26:252–256.

19. Health Quality & Safety Commission New Zealand. National adverse events reporting policy. 2007. Available at: http://www.hqsc.govt.nz/assets/Reportable-Events/Publications/National_Adverse_Events_Policy_2017/National_Adverse_Events_Policy_2017_WEB_FINAL.pdf. Accessed January 15, 2020.
20. Health Quality & Safety Commission New Zealand. Always report and review list 2018–2019. 2018. Available at: http://www.hqsc.govt.nz/assets/Reportable-Events/Publications/National_Adverse_Events_Policy_2017/Always-report-and-review-list-2018-19-Final.pdf. Accessed January 15, 2020.
21. Health and Social Care Board Northern Ireland. Procedure for the reporting and follow up of serious adverse incidents. 2016. Available at: http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf. Accessed January 15, 2020.
22. Health Service Executive. Serious reportable events (SREs) HSE implementation guidance document. 2015. Available at: http://www.hse.ie/eng/services/publications/performancereports/srejan15.pdf. Accessed January 15, 2020.
23. Healthcare Improvement Scotland. Learning from adverse events through reporting and review: a national framework for Scotland. 2018. Available at: http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx. Accessed January 15, 2020.
24. The Swedish Parliament. Swedish patient safety act. 2010. Available at: http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patientsakerhetslag-2010659_sfs-2010-659. Accessed January 15, 2020.
25. National Quality Forum. Serious reportable events in healthcare – 2011 update: a consensus report. 2011. Available at: https://www.doh.wa.gov/Portals/1/Documents/2900/NQF2011Update.pdf. Accessed January 15, 2020.
26. The Joint Commission. Sentinel event policy. 1996. https://www.jointcommission.org/en/resources/patient-safety-topics/sentinel-event/sentinel-event-policy-and-procedures/ Accessed January 13, 2020.
27. Larizgoitia I, Bouesseau M-C, Kelley E. WHO efforts to promote reporting of adverse events and global learning. *J Public Health Res*. 2013;2:e29.
28. Wahid NNA, Moppett SH, Moppett IK. Quality of quality accounts: transparency of public reporting of never events in England. A semi-quantitative and qualitative review. *J R Soc Med*. 2016;109:190–199.
29. Doupi P. National reporting systems for patient safety incidents: a review of the situation in Europe. Available at: https://thl.fi/documents/10531/104907/Report%202009%2013.pdf. Accessed January 15, 2020.
30. Carson-Stevens A, Hibbert P, Williams H, et al. Characterising the nature of primary care patient safety incident reports in the England and Wales national reporting and learning system: a mixed-methods agenda-setting study for general practice. *Health Serv Deliv Res*. 2016;4. Available at: https://www.ncbi.nlm.nih.gov/books/NBK385186/pdf/Bookshelf_NBK385186.pdf. Accessed March 21, 2020.
31. Agency for Healthcare Research and Quality. Common formats. 2016. Available at: https://pso.ahrq.gov/common. Accessed January 15, 2020.
32. A national survey of medical error reporting laws. *Yale J Health Policy Law Ethics*. 2009. Winter;9:201–286.
33. Elkin PL, Johnson HC, Callahan MR, et al. Improving patient safety reporting with the common formats: common data representation for patient safety organizations. *J Biomed Inform*. 2016;64:116–121.
34. Tsang C, Palmer W, Bottle A, et al. A review of patient safety measures based on routinely collected hospital data. *Am J Med Qual*. 2012;27:154–169.
35. Health Foundation Inspiring Movement. The measurement and monitoring of safety. 2013. Available at: https://www.health.org.uk/sites/default/files/TheMeasurementAndMonitoringOfSafety_fullversion.pdf. Accessed January 15, 2020.
36. Doran DM, Baker GR, Szabo C, et al. Identification of serious and reportable events in home care: a Delphi survey to develop consensus. *International J Qual Health Care*. 2014;26:136–143.
37. Cooper J, Williams H, Hibbert P, et al. Classification of patient-safety incidents in primary care. *Bull World Health Organ*. 2018;96:498–505.
38. Howell AM, Burns EM, Hull L, et al. International recommendations for national patient safety incident reporting systems: an expert Delphi consensus-building process. *BMJ Qual Saf*. 2017;26:150–163.
39. Yarmohammadian MH, Rezaei F, Ferdosi M, et al. Healthcare incident reporting system in several countries: concepts, infrastructure and features. *Int J Health Syst Disaster Manag*. 2013;1:143–149.
40. Reed S, Arnal D, Frank O, et al. National critical incident reporting systems relevant to anaesthesia: a European survey. *Br J Anaesth*. 2014;112:546–555.
41. Pettker CM. Systematic approaches to adverse events in obstetrics, part I: event identification and classification. *Semin Perinatol*. 2017;41:151–155.
42. Health Quality Ontario. Patient safety learning systems: a systematic review and qualitative synthesis. *Ont Health Technol Assess Ser*. 2017;17:1–23.
43. Hohenstein C, Hempel D, Schultheis K, et al. Critical incident reporting in emergency medicine: results of the prehospital reports. *Emerg Med J*. 2014;3:415–418.
44. Donnelly P. Improving reporting of critical incidents through education and involvement. *BMJ Qual Improv Rep*. 2015;4:u206996. w3776.
45. Zwart DLM, de Bont AA. Introducing incident reporting in primary care: a translation from safety science into medical practice. *Health Risk Soc*. 2013;15:265–278.
46. Health Service Executive. Incident management framework. 2018. Available at: https://www.hse.ie/eng/about/qavd/incident-management/hse-2018-incident-management-framework-guidance-stories.pdf. Accessed January 15, 2020.
47. de Wet C, O'Donnell C, Bowie P. Developing a preliminary 'never event' list for general practice using consensus-building methods. *Br J Gen Pract*. 2014;64:e159–e167.
48. Sujan M. An organisation without a memory: a qualitative study of hospital staff perceptions on reporting and organisational learning for patient safety. *Reliab Eng Syst Safe*. 2015;144:45–52.
49. Braithwaite J, Westbrook MT, Travaglia JF, et al. Cultural and associated enablers of, and barriers to, adverse incident reporting. *Qual Saf Health Care*. 2010;19:229–233.
50. Pasquini A, Pozzi S, Save L, et al. Requisites for successful incident reporting in resilient organisations. In: Hollnagel E, Paries J, Woods DD, et al, eds. *Resilience Engineering in Practice: A Guidebook*. Farnham: Ashgate; 2011:237–254.
51. Sujan MA, Pozzi S, Valbonesi C. Reporting and learning: from extraordinary to ordinary. In: Braithwaite J, Wears R, Hollnagel E, eds. *Resilient Health Care III: Reconciling Work-as-Imagined With Work-as-Done*. Farnham: Ashgate; 2016:103–110.
52. Ahmed M, Arora S, Tiew S, et al. Building a safer foundation: the lessons learnt patient safety training programme. *BMJ Qual Saf*. 2014;23:78–86.
53. Mitchell I, Schuster A, Smith KM, et al. Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after 'To Err is Human'. *BMJ Qual Saf*. 2015;25:71–75.
54. Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)*. 2011;30:581–589.
55. Institute for Healthcare Improvement. IHI global trigger tool for measuring adverse events. 2020. Available at: http://www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx. Accessed January 15, 2020.
56. James JT. A new, evidence-based estimate of patient harms associated with hospital care. *Patient Saf*. 2013;9:122–128.
57. Stavropoulou C, Doherty C, Tosey P. How effective are incident-reporting systems for improving patient safety? A systematic literature review. *Milbank Q*. 2015;93:826–866.
58. Hegarty J, Flaherty SJ, Saab MM, et al. The collection, collation and reporting of data pertaining to serious patient safety incidents: an international perspective. Unpublished Report for the Department of Health, Dublin, Ireland; 2019.