Supplementary file 2. Data extraction table with findings from individual studies (n=48)

Reference and Country	Aim	Design	Key Findings
Act on Patient Safety in the Danish Health Care System (2003) Denmark	Relates to national legislation rather than research or guidance.	National guidance document.	Act on Patient Safety in the Danish Health Care System. The objective of the Act is to improve patient safety within the Danish health care system. An adverse event is an 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.
Agency for Healthcare Research and Quality (2019) USA	AHRQ created the Common Formats (common definitions and reporting Formats) to help uniformly report patient safety events and to improve health care providers' efforts to minimize and potentially eliminate harm.	National guidance document developed with authorization of national legislation.	Incidents: patient safety events that reached the patient, whether or not there was harm involved. Near misses (or close calls): patient safety events that did not reach the patient. Unsafe conditions: circumstances that increase the probability of a patient safety event occurring. In 2019, the Common Formats allow for event reporting within three settings of care: hospitals, nursing homes, and community pharmacies.
Akers *et al.* (2018) Australia	Describe the Serious Transfusion Incident Reporting programme (STIR) for haemovigilance in relation to RhD immunoglobulin (Ig) administration.	Discussion.	STIR was developed in 2015. It is a voluntary, central reporting system for serious adverse events, managed by the Blood Matters programme (a collaboration between the Victorian Department of Health and Human Services and the Australian Red Cross Blood Service). STIR receives reports from public and private health services in Victoria, Tasmania, the Australian Capital Territory and the Northern Territory. STIR's aim is to report the number and types of adverse events associated with transfusion for the purpose of developing recommendations for practice improvement. Each health service should have robust haemovigilance systems in place, which require support of the hospital executive, and depending on the hospital size, may include hospital transfusion committees with input from obstetric, haematology and pathology departments. The addition of RhD Ig incidents to STIR allows the systematic collection of data related to the use of this product and identifies potential opportunities for practice improvement and staff knowledge. However, in order to accurately identify the incidence of RhD Ig errors and assess response to recommendations made by STIR, mandatory reporting to STIR would be required.
Andersen *et al.* (2010) Denmark	Identify, analyse and categorise critical incidents related to cardiac arrests reported to the	Cross-sectional analysis.	The Danish Patient Safety Database is a mandatory reporting system and receives critical incident reports submitted by hospital personnel.

	Danish Patient Safety Database.		The Danish Act on Patient Safety, which was the first national, confidential and non-punitive adverse incident reporting system, was introduced in 2004 with the purpose of supporting learning from experience. It requires healthcare personnel to report any adverse event they may observe. Personnel reporting events are protected by law against disciplinary or any legal sanctions based on information contained in their reports. Reports are submitted and analysed at a local level and are subsequently collected in anonymous form by the Board of Health.
Australian Commission on Safety and Quality in Health Care (2018) Australia	Outline the review process of the Australian sentinel event list; and define, in detail, the included sentinel events.	National guidance document.	Sentinel events are a subset of adverse patient safety events that are wholly preventable and result in serious harm to, or death of, a patient. According to the Productivity Commission, sentinel events: • Occur relatively infrequently and are independent of a patient's condition • Have the potential to seriously undermine public confidence in the healthcare system. It was intended that public reporting against the sentinel events list would provide an opportunity to share learning about these events at the national level to prevent, or reduce the risk of, recurrence of the sentinel events. Serious harm is defined as that which "requires life-saving surgical or medical intervention, shortened life expectancy, permanent or long-term physical harm, or permanent or long-term loss of function".
Canadian Patient Safety Institute (2012) Canada	Support individual and organizational learning, as well as quality improvement, in response to a patient safety incident(s).	National guidance document.	Patient Safety Incident: An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. Harmful Incident: A patient safety incident that resulted in harm to the patient. Replaces "adverse event", "sentinel event" and "critical incident".
Canadian Patient Safety Institute (2015) Canada	Outline the approach taken to achieve consensus on the top priorities for Canadian never events in hospitals; detail the 15 never events for hospital care in Canada, and strategies that are effective in identifying and reducing these events.	National guidance document.	Never events: Patient safety incidents that result in serious patient harm or death, and that can be prevented by using organisational checks and balances. Never events do not imply blame; "never" is a call-to-action, not a demand or an attempt to shame mistakes. Serious harm is defined as "a significant permanent change in the ability of patients to function as they did before the event."
Care Quality Commission (Registration) Regulations (2009) England	Relates to national legislation rather than research or guidance.	National guidance document.	Care Quality Commission (Registration) Regulations (2009) states that the incidents referred to in paragraph (1) are (a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in— (i) an impairment of the sensory, motor or intellectual functions of the service user, which is not likely to be temporary, (ii) changes to the structure of a service user's body, (iii) the service user experiencing prolonged pain or prolonged psychological harm, or (iv) the shortening of the life expectancy of the service user;

			(b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent— (i) the death of the service user, or (ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a)… (e) any abuse or allegation of abuse in relation to a service user; (f) any incident which is reported to, or investigated by, the police; (g) any event which prevents, or appears to the service provider to be likely to threaten to prevent, the service provider's ability to continue to carry on the regulated activity safely. [(h) any placement of a service-user under the age of eighteen in a psychiatric unit whose services are intended for persons over that age where that placement has lasted for longer than a continuous period of 48 hours].
Carson-Stevens *et al.* (2016) UK	Characterise the nature and range of incidents reported from general practice in England and Wales (2005–13) in order to identify the most frequent and most harmful patient safety incidents, and relevant contributory issues, to inform recommendations for improving the safety of primary care provision in key strategic areas.	Cross-sectional mixed-methods evaluation of general practice patient safety. Incident reports that included exploratory thematic analysis: n = 571 locations n = 42,729 reports.	WHO's International Classification for Patient Safety was used as the foundation for development of the classification system for coding of incidents, which incorporated incident description, contributory factors, and type and level of harm. Regular team meetings ensured an iterative process such that codes were continually reviewed and updated, as necessary. Health-care professionals have a duty to report incidents, which are then anonymised and uploaded to the NRLS (National Reporting and Learning System). Incident reports contain structured information about location, patient demographics and reporter perception of severity of harm. Staff also provide unstructured free-text descriptions of the incident, potential contributory factors and planned actions to prevent recurrence. One-third of reports contained descriptions of contributory factors which was considered a major missed opportunity for learning. Over half of the reports were from just 30 organisations which implies that some organisations do not report general practice safety incidents to the NRLS, or do not have mechanisms for receiving reports from general practice in its organisation. Need to change and manage the culture of blame within health services for more open reporting of patient safety incidents and move towards focusing on the system rather than the individual. Patients and carers need to feel empowered to report or should be involved in reporting system design. At organisational level responsible persons should analyse incident reports to identify themes and implement system changes in local practices. there are several portals for reporting that do not communicate with each other. A national portal for all reports recommended. Analysis of incident reports at a national level needs a combined enterprise between clinical, research and patient safety experts to regularly review the output of analyses, to corroborate with existing insights from research studies and improvement initiatives, and to develop potential action-orientated solutions with strong face validity among the profession. An appropriate and efficient IT structure is crucial for accurate reporting and sharing of learning across and within organisations.

Cooper *et al.* (2018) International	Investigate how other classification frameworks used in the field aligned with WHO's International Classification and then, by building on WHO's International Classification, develop a new, more comprehensive system for the classification of harm severity in patient-safety incidents occurring in primary care.	Review.	Harm is defined as "impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death." Mild harm: Incident in which: (i) patient was harmed, with mild and short-term impact, on physical, mental or social functioning, that was expected to resolve in a few hours; (ii) patient was harmed but required no or minimal intervention/treatment, e.g. anti-emetic, oral antibiotic or repeat of a minor procedure such as vaccination or insertion of contraceptive implant; and/or (iii) patient or their loved ones experienced transient emotional distress but no long-term consequences and incident report contains words, e.g. angry, anxious, confused, distressed, frightened, frustrated, humiliated or upset, that might describe a feeling that occurs at the time of the incident but soon passes. Moderate harm: Incident in which: (i) patient was harmed, causing a medium term impact on physical, mental or social functioning that was expected to resolve in days; (ii) patient required medical intervention in the form of treatment, e.g. antibiotics or intravenous fluids; (iii) patient required short-term hospitalization for assessment and/or minor treatment in either ED or a hospital ward; and/or (iv) patient or their loved ones experienced psychological difficulty of a more longstanding nature but not requiring formal treatment, e.g. as indicated by evidence in the report of more longstanding anxiety, insomnia, or low mood. Severe harm: Incident in which: (i) patient was harmed, causing a major long-term or permanent impact on physical, mental or social function or shortening of life-expectancy; (ii) patient was harmed and required major medical or surgical intervention that, most often, was delivered in a hospital setting, e.g. cardioversion, any major surgery; (iii) patient was harmed and required prolonged hospitalization or admission to CCU, HDU and/or ICU; and/or (iv) patient or their loved ones experienced enduring psychological difficulty that required specialist treatment, e.g. as indicated in the report by evidence of chronic anxiety or depression or psychosis
De Wet *et al.* (2014) UK	Develop a preliminary list of never events for general practice.	345 general practice team members proposed possible never events. Consensus-building methods – consensus-building workshop (n=15 informed staff), modified Delphi exercise (n=17 experts) and a content validation exercise	721 never events were revised down to 10 never events Medication errors were prominent in the never-events list reflecting the effect drug related errors have on patient safety.

Donnelly (2015) UK	Establish the barriers to reporting critical incidents within a community paediatric setting and to implement plan-do-study-act (PDSA) cycles to create a climate for change.	Longitudinal incident analysis.	Incident reports were reviewed from a database of incident reports submitted via an online reporting system used within the Belfast Health & Social Care Trust. There were 28 barriers selected within the 12 forms divided into five categories: time pressures (n=9), unsure of what constitutes a critical incident (n=7), apathy about reporting (n=5), unfamiliar with the reporting system (n=4) and scared of getting someone in trouble (n=3). Eight respondents reported never receiving feedback from incident reports. Ensuring staff members were trained on the use of the reporting system facilitated educating staff on how to complete the incident report in a timely manner - thereby addressing time pressures, as well as ensuring staff members were now familiar with the reporting system itself.
Doran *et al.* (2014) Canada	Assess which client events should be considered reportable and preventable in-home care (HC) settings in the opinion of HC safety experts.	A 29-item electronic survey that included potential healthcare safety issues was used in a two-round Delphi study. Twenty-four pan-Canadian healthcare safety experts participated in electronic survey.	The WHO's framework guided the conceptualization of the patient safety variables in this study. The Centre for Medicare and Medicaid Services (CMS) instituted the use of the Outcomes and Assessment Information Set (OASIS) in 1999 for all homecare agencies. CMS currently identifies 13 potential adverse event indicators for clients receiving homecare. Utilisation of a guiding framework or matrix for separating healthcare events that constitute quality issues from events that pose threats to client safety would be beneficial. Literature suggests that there are many adverse events worthy of reporting but preventable adverse events are those that can be attributed to health care and cause unnecessary harm. This notion of attribution can be problematic because of the following: variety of service providers/agencies engaged in delivering care in the home; interaction between client characteristics, contributing factors and health care; and client/family involvement in processes of care.
Doupi (2009) Findland	Investigate the experiences of other European countries with national level patient safety reporting and monitoring systems, analyse the data and provide information that would be meaningful in supporting the decision-making process on the national level.	Review.	All of the data elements are also central in the development of the WHO's International Classification for Patient Safety. Three different types of national patient safety incident reporting systems: systems for sentinel events only (often obligatory by law); systems focusing on specific clinical domains (reporting often voluntary); and healthcare system-wide, comprehensive reporting systems (which include both adverse events and 'near misses'). Data elements that are common to all existing national level reporting systems are: organisation information, details on the specific incident (type and description), contributing factors and patient- related information. Following lessons were learned: • Build on existing system and improve quality • Make system quicker and easier to use • Streamline routes of reporting • Provide more targeted feedback • Identification of events that are low frequency on the organisation level, but through aggregation can allow the early recognition of previously unknown hazards • Possibility to identify common contributing factors, through the analysis of many events at different locations • Central analysis allows the dissemination of individual organisations' experiences and best practices. • Better understanding of types of injuries and their respective causes can guide preventive efforts.
Editorial Board (2009) USA	Catalogue and describe the medical error reporting regimes established in the	Multiple reviews	Many of these state efforts have utilised a list of serious reportable events created by the National Quality Forum (NQF), a non-profit organization that promotes system-wide quality improvement in health care.

	twenty-seven jurisdictions with reporting systems.		There is some evidence that pay-for-performance programs combined with reporting programs may make headway towards improving the quality of care.
Elkin *et al.* (2016) USA	Describe the development of patient safety reporting and learning through the Patient Safety Organizations (PSO) and the Common Formats and gives readers an overview of how the system is expected to function and the breadth of development of the Common Formats to date.	Review	As part of the PSO law, a set of patient safety common definitions and reporting formats was developed, which is now known as the AHRQ common formats. The common formats have been created and maintained by AHRQ with public review with the help of the National Quality Forum (NQF) Common Formats Expert Panel. Vendors of reporting systems are actively encouraged to integrate common formats into their systems. Providers can voluntarily collect and submit patient safety event and quality information to their Patient Safety Organizations (PSOs) with the assurance of confidentiality and protections from discovery in a court of law. In turn, the PSOs work with their client providers to help create a culture of safety and assist with analysis of quality and/or event data which may include root cause analysis, under the protections of the law. Congress passed and the president signed the 2005 Patient Safety and Quality Improvement Act (PSQIA), providing legal protections around reporting and analysis of patient safety events when reported to designated Patient Safety Organizations.
European Commission (2014) Europe	Describe reporting and learning systems for patient safety incidents across Europe.	All countries were asked to update information about their reporting systems in the EUNetPaS database.	WHO's International Classification for Patient Safety has been used by a number of Member States but they vary in relation to what ICPS elements they use. Most Member States have one nationwide reporting system or a nationwide reporting system associated with several regional or local systems. A few Member States have local independent reporting systems operating at individual hospitals. Member states had various definitions for reportable events. 'Reportability' is normally defined based on the severity of the incident, the type of incident, or a combination of both of these, near misses. Sanction free reporting and rules around confidentiality should be part of a mandatory system. Reports from patients and families can be very informative and provide valid learning on patient safety improvement. Measures should be taken to encourage and facilitate these. Healthcare professionals who report should be protected from disciplinary, legal or formal procedures. It should be a confidential report with the data anonymised. Blame-free, non-punitive reporting should be reinforced by senior managers. The healthcare provider should be given feedback on the investigation and measures taken. Publication of anonymised reports should be used to develop and support initiatives to improve patient safety. Legislation is required for the protection of information collected (event of court or police).
Flug *et al.* (2018) USA	Describe a. the errors that may occur in an imaging department that are and usually preventable with a review of the causative factors and b. strategies to eliminate and reduce the adverse effects of these avoidable errors.	Discussion.	The National Quality Forum identified 27 never events, or "serious reportable events" in 2002, and the list was expanded to 29 serious reportable events in 2011. These events are grouped into seven categories: surgical or procedural events, product or device events, patient protection events, care management events, environmental events, radiologic events, and criminal events. The Leapfrog Group recommends that these events should be disclosed to the patients, that an apology should be given and that costs associated with the event should be waived. The Joint Commission for the Environment of Care Standards require that accredited hospitals establish procedures for identification and management of safety and security risks, including workplace violence, to safeguard patients, visitors and staff. According to the Joint Commission's Sentinel Event Alert, the most common contributing factors with regard to falls pertain to: a. inadequate patient assessment; b. communication failures; c. lack of adherence to protocols and safety

			practices; d. inadequate staff orientation, supervision, staffing levels, or skill mix; e. deficiencies in the physical environment; and f. a lack of leadership.
Guillod *et al.* (2013) Switzerland	Discuss in which ways the law can contribute to reducing the number of preventable adverse events.	Review.	In most jurisdictions, the traditional legal answer to the issue of patient safety has been brought by the tort system, i.e. the regime of professional liability, the legal rules on professional liability are supposed to fulfil two different functions: on the one hand, they must fairly compensate the victim of negligent care; on the other hand, they must play a preventive role by giving health care providers (both individuals and hospitals) incentives to improve care in order to prevent damage. Several countries have also enacted so-called apology laws, i.e. laws providing that an apology given after an adverse event cannot be used in ulterior legal proceedings (Australia for instance has enacted such a law). States should also envision enacting laws that either mandate or encourage hospitals to set up a Critical Incident Reporting System (CIRS).
Health and Social Care Board Northern Ireland (2016) Northern Ireland	Provide a consistent approach to: what constitutes a serious adverse incident; clarifying the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning; fulfilling statutory and regulatory requirements; and provide tools and resources that support good practice.	National guidance document.	A Serious Adverse Incident is defined as any event or circumstances that led to harm, loss or damage to people, property, environment or reputation and met the criteria outlined in the listing (next column). Never Events are SAIs that are wholly preventable, as guidance or safety recommendations that provide strong systemic protective barriers are already available at a national level and should have been implemented by all health care providers.
Health Foundation Inspiring Movement (2013) UK	Produce a framework for safety measurement and monitoring.	Multiple reviews	The authors cite five dimensions of safety monitoring and measurement: • *Past harm:* this encompasses both psychological and physical measures • *Reliability:* this encompasses measures of behaviour and systems • *Sensitivity to operations:* the information and capacity to monitor safety on an hourly or daily basis • *Anticipation and preparedness:* the ability to anticipate, and be prepared for, problems • *Integration and learning:* the ability to respond to, and improve from, safety information. Several organisations use prospective or targeted incident reporting to address a known safety issue. In some primary care practices there are set weeks when every adverse event is recorded. From this, staff may be asked to report specific issues such as missing test results on a targeted basis for the following month. In the English NHS divisional, departmental and trust risk registers are commonly used across healthcare settings and are mandated by external regulators like the NHS Litigation Authority. Typically, a quarterly risk capture process is carried out, led by the trust's risk manager (or equivalent).

Healthcare Improvement Scotland (2018) Scotland	Provide an overarching approach developed from best practice to support care providers effectively manage adverse events.	National guidance document.	An adverse event is defined as an event that could have caused (a near miss), or did result in, harm to people or groups of people. There is no specific definition for serious adverse event but appear to be those that fall into Category 1 events, which are defined as events that may have contributed to or resulted in permanent harm. Category 1 incidents, those viewed as most serious, include events such as unexpected death, intervention required to sustain life, severe financial loss (£>1m), and ongoing national adverse publicity.
Health Quality & Safety Commission New Zealand (2017) New Zealand	Contribute to improved quality, safety and experience of health and disability services through systems that: are consumer and whānau-centred; provide for early identification and review of adverse events affecting consumers of health and disability services; ensure lessons are learnt so the risk of repeating preventable adverse events is minimised; demonstrate public accountability and transparency; and are safe. Support a national approach to reporting, review and learning from adverse events and near misses.	National guidance document.	Adverse event: event with negative or unfavourable reactions or results that are unintended, unexpected or unplanned (also referred to as 'incident' or 'reportable event'). Near miss: event which, under different circumstances, could have caused harm to a consumer but did not, and which is indistinguishable from an adverse event in all but outcome. Adverse events rated as SAC 1 (Severe) or SAC 2 (Major) must be reported. There is no defined list of those events rated as SAC 1 or 2. SAC 1 events relate to death or permanent severe loss of function, while SAC 2 events relate to permanent major or temporary severe loss of function.
Health Quality & Safety Commission New Zealand (2018) New Zealand	Detail the patient safety incidents that must always be reported and reviewed regardless of actual harm to the patient.	National guidance document.	Subset of adverse events that "*can result in serious harm or death but are preventable with strong clinical and organisational systems*". This list is used in conjunction with the National Adverse Events Reporting Policy. Always Report and Review events should be reported and managed in the same way as SAC 1 and 2 rated events, irrespective of whether or not there was harm to the consumer.
Health Quality Ontario (2017) Canada	Determine what factors stop health care professionals from reporting problems and from making changes that will make patients safer in the future. The authors also looked at what factors make reporting and changes easier for health care professionals.	Systematic Review.	People were more willing to report and learn from systems that increased patient safety if others did not try to lay blame for the problems, if reporting and learning were encouraged, if they were told clearly what and how to report, if the organization supported data analysis to come up with useful lessons, and if feedback was offered in several ways, such as local meetings, email messages, and bulletins). Hospital management should define the purpose of the system before implementation to make staff aware of a new system, should define what must be reported, and should communicate these definitions explicitly stating the goals, mechanics, limitations, and protections of the system . The organization should prepare a "starter kit" for potential users and, if overlapping systems already exist in the hospital, decide how they will interact with the new system. The hospital should address existing legal barriers to

			reporting and provide reporters with protection from disciplinary action.
Health Service Executive (HSE) (2015) Republic of Ireland	Define serious reportable events and provide guidance on the required reporting procedure.	National guidance document.	Serious Reportable Events (SRE) are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers.
Health Service Executive (HSE) (2017) Republic of Ireland	Outline the key terms used in the national guidance documentation.	Guidance document for national consultation process.	Serious injury is defined as "injury which creates a substantial risk of death of which causes serious disfigurement or substantial loss or impairment of the mobility of the body as a whole or of the function of any particular bodily member or organ."
Hohenstein *et al.* (2014) Germany	Describe critical incident reporting systems in emergency medicine in German-speaking countries.	Observational study.	An expert committee defined an incident as any event that influenced or could have impacted patient safety and outcome. Incidents were classified as: • staff related (knowledge and experience, communication skills, social competence, working technique). • equipment related (lack of equipment, broken equipment, wrong equipment used). • organisation and tactics (organisation of EMS as well as interface with emergency department). • other. • no incident but unfavourable condition, which cannot be influenced (e.g. weather). Knowledge about incidents that happen in one country or district and could have a tremendous impact on patient safety should be readily available for the rest of the emergency medical society. It is important, therefore, that transnational networks are developed predominantly happen when a patient is in a life-threatening situation. It might not only be due to reporting bias that most incidents in our database describe situations with severely ill or injured patients.
Howell *et al.* (2017) UK	Establish international, expert consensus on the purpose of Patient Safety Incident Reporting Systems (PSRS) regarding monitoring and learning from incidents and developing recommendations for their future role	A scoping review of the literature followed by semi-structured interviews	'Incident' refers to patient safety incident that is an event during patient care that has the potential to or does cause injury or harm to the patient. Incidents include 'errors' and 'harm'. Errors are defined as actions or omissions that may or may not lead to patient harm, including near misses or no harm events. Harm refers to physical injury or complication requiring further treatment, prolonged hospital stay, morbidity or mortality as a result of the process of care delivery. The WHO published draft guidelines for reporting systems in 2005 and provided recommendations for the establishment of reporting systems. These included the need to clearly set out the objectives of the system as well as guidance on issues such as how to keep reports confidential and deal with serious hazards rapidly. Consensus recommendation was for hospitals to take responsibility for creating safety solutions locally that could be shared nationally. The benefit of a national system was clear with respect to medication error, device failures, hospital-acquired infections and never events as these problems often require solutions at a national level. Experts recommended training for senior healthcare professionals in incident investigation. All experts recommended that hospitals should have an executive board member responsible for patient safety. It was suggested that hospitals should make giving feedback their own responsibility rather than relying on a national process and that feedback should be specific.
Joint Commission (updates published on website for different areas with different dates, https://www.jointcommission.org/en/resources/patient-safety-	Sentinel Event Policy and Procedures	Policy	The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help health care organizations that experience serious adverse events improve safety and learn from those sentinel events, the policy is updated regularly and published on website for different areas. "A sentinel event is a Patient Safety Event that reaches a patient and results in any of the following: death; permanent harm; severe temporary harm and intervention required to sustain life. An event can also be considered sentinel event even if the outcome was not death, permanent harm, severe temporary harm and intervention required to sustain life". "Such events are called "sentinel" because they signal the need for immediate investigation and response".

topics/sentinel-event/sentinel-event-policy-and-procedures/) USA			
Larizgoitia *et al.* (2013) Switzerland	Describe WHO efforts to promote reporting of adverse events and global learning.	Review	The pursuit of a common language for patient safety has driven much scholar effort and debate. Over 3 years, WHO assembled an international panel, the *Drafting Group*, comprised of experts in patient safety, classification theory, health informatics, consumer/patient advocacy, law and medicine, with the task of defining, harmonizing and grouping core patient safety concepts as an initial step to set up a common terminology. The Drafting Group understood that the most crucial task was to agree and clarify a core set of conceptual definitions, while in a second instance, assign terms or labels to these concepts. As a consequence, they defined 48 key concepts and labelled them with agreed preferred terms. The Conceptual Framework is comprised of 10 high-level classes that together depict the universe of the concepts that are related to the occurrence and consequences of an incident. Gravitating around the *Incident type*, the framework recognises the contributing factors, patient characteristics, and the set of outcomes the incident caused to both the patient and the organisation. The framework ends with a cycle provided by the different actions that might be done to detect the incident, mitigate its impact, and prevent it from happening again. Reporting and learning systems have to be considered as part of person-centred care, aiming to empower patients and enable them to take part in decision-making processes. Currently, there is not a set of universal standards for data collection and storage, nor an agreed set of terminologies for incidents and their related factors and consequences. Most reports are provided by healthcare workers or patients, each having a partial understanding of an event and their circumstances, thus often lacking essential data to facilitate a complete analysis of the incident. To be consistent with ethical principles, reporting and learning systems require specific measures to be taken: a clear legal framework has to be developed to establish modalities of confidentiality, define liabilities and responsibilities; educational programs and capacity strengthening activities are needed for different stakeholders to help them better understand the use of reporting tools.
Leistikow *et al.* (2017) Netherlands	Illustrate how the theories in the evolving scientific literature on incident reporting apply to the Dutch situation.	Review.	A sentinel event (Dutch: calamiteit) is defined in the 1996 Healthcare Organisations Quality Act as an unintended and unexpected event, related to the quality of care and having caused death or serious harm to the patient. All healthcare organisations are mandated to report sentinel events to the Healthcare Inspectorate within 3 days after discovery.
Levy *et al.* (2010) USA	Analyse the Patient Safety and Quality Improvement Act (PSQIA) and its implications for patient safety.	Discussion.	The Joint Commission promotes patient safety by requiring member organizations to report serious adverse patient health events and performing root cause analysis on those events. The PSQIA aims to encourage providers to openly discuss their patient safety experiences through a series of legal protections. The PSQIA also allows for the creation of entities called Patient Safety Organisations (PSOs) that are primarily responsible for aggregating and analysing provider error data. The PSQIA creates the same legislative protections for all participating providers. Accordingly, it allows for a more uniform standard of data protection that can encourage the sharing of information among various jurisdictions.
Li *et al.* (2014) USA	Describe two phenotyping adverse event and medical error detection algorithms (i.e., IV infiltrations, narcotic medication over	Methods development.	One method currently used for AE detection is a trigger tool methodology. Triggers are data or combinations of data that may signal an underlying event of interest. Risk MonitorPro is used to collect voluntary incident reporting. Reports can be submitted either anonymously or with identification, and by any hospital employee. Access to the program is provided on all hospital computers through either an intranet link or directly through an HER use interface.

	sedation and dosing errors) and describe manual annotation of airway management and medication/fluid AEs from NICU electronic health records.		
Macrae *et al.* (2016) UK	Discuss problems with incident reporting.	Discussion.	Analysing incidents alone does not produce learning. Equally, 'lessons learnt' from patient safety incidents are often held up as taking the form of an 'organisational safety alert', an updated policy, or a new set of recommendations. Managers must account for the improvements made as a result of incident investigations. Rather than assigning responsibility for causing failures, incident reporting should assign responsibility for improving systems.
National Quality Forum (2011) USA	Outline the approach taken to inform the development of the serious reportable event list; and outline in the detail these events and reporting guidelines.	National guidance document.	Serious reportable event defined as "an 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)". "To qualify for the list of Serious Reportable Events in Healthcare—2011 Update an event must be unambiguous, largely, if not entirely, preventable, serious, and any of the following: adverse; indicative of a problem in a healthcare setting's safety systems; important for public credibility or public accountability. Additionally, 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". Injury is defined as "physical or mental damage that substantially limits one or more of the major life activities of an individual in the short term, which may become a disability if extended long term. Injury includes a substantial change in the patient's long-term risk status such that care or monitoring, based on accepted national standards, is required that was not required before the event". Of note, states and other entities may use alternate definitions for the term "disability."
NHS England (2015) England	Explain the responsibilities and actions for dealing with Serious Incidents and the tools available, and outline the process and procedures to ensure that Serious Incidents are identified correctly, investigated thoroughly and, most importantly, learned from to prevent the likelihood of similar incidents happening again.	National guidance document.	Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.
NHS Improvement (2018) England	Provide healthcare workers, clinicians, managers, boards and accountable officers with clarity on their	National guidance document.	Never Events are defined as serious incidents that are 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. Serious harm is defined as "severe harm (incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care), chronic pain (continuous, long-term pain of more than 12 weeks or after the time

	responsibilities and on the principles of Never Events.		that healing would have been thought to have occurred in pain after trauma or surgery), or psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days)."
Ohrn *et al.* (2011) Sweden	Compare the extent and pattern of reporting of serious adverse events in a mandatory national reporting system to the reporting of adverse events based on patient claims.	Observational cohort.	Sweden's mandatory national reporting system requires health care organizations to report cases of serious adverse events – sentinel events – to the National Board of Health and Welfare. Patients in Sweden may file a claim for economic compensation from the national insurance system, the country Councils' Mutual Insurance Company, if they believe they have sustained an injury. The system is non-punitive, confidential and independent from sanctioning authorities. Health care organisations should consider using a portfolio of tools, including incident reporting, medical record review, and analysis of patient claims, to gain a comprehensive picture of adverse events.
Pettker (2017) USA	Review the various systems that are used to identify adverse events, in particular sentinel events, state reportable events, and the significant local adverse "trigger" events in obstetrics.	Discussion.	Formal policies and procedures were issued by The Joint Commission (TJC) in 1996 in relation to the management of sentinel events. These policies and procedures are requirements for accreditation. TJC introduced a classification system for safety events in 2003, published in 2005 but it was not widely implemented. In 2007, Healthcare Performance Improvement produced 6 classifications: procedural, environmental, patient protection, care management, product or device and criminal. TJC give very specific criteria around the reporting of a sentinel event. This includes: a formalised team response, stabilising the patient, disclosure and support; informing hospital leaders; immediate investigation into the event; complete a detailed systematic analysis; cause and any contributing factors identified; identify corrective actions; set timelines for implementing corrective actions; and system improvement The National Quality Forum (NQF) in 2011 published "Serious Reportable Events", which has developed TJC list further including events such as wrong-site surgery, unintended retained foreign bodies, and medication errors. No standard for the reporting of events across the country. Lack of feedback for nurses and doctors in relation to reporting is viewed as a barrier.
Reed *et al.* (2014) UK	Compare the different incident reporting systems operating in' six European countries with a view to gathering intelligence that might help others establish new systems.	Cross-sectional survey. Sample - Representatives of national Incident Reporting Systems (IRS). N=6 European countries (Denmark, Finland, Germany, Spain, Switzerland, UK).	WHO definition of a 'reportable incident' used in Spain ('an event or circumstance that could have resulted in or did result in unnecessary harm to a patient'). Denmark: Patient safety unit with between five and ten managers regionally, central authority (the Danish National Agency for Patients' Rights and Complaints) has 4 full-time employees nationally disseminating learning. Reporting open to all including member of the public since 2011. Finland: IRS HaiPro, is a national online system financed by each hospital district. Reporting (anonymous) and analysis of incidents are done locally. This is being reviewed in order to share learning. German Society for Anaesthesiology and Intensive Care (DGAI) and the Association of German Anaesthetists (BDA) sanctioned the nationwide implementation of a web-based specialty-specific reporting and learning system, called the Patient Safety Optimisation System (PaSOS). PaSOS was developed in 2006 by the Patient Safety Centre in Tubingen. A parallel system was also in use CIRSmedical.de. In 2009 the BDA and DGAI integrated the 2 recording systems into one national IRS (CIRSmedical.de).

			Spain: SENSAR anaesthetic confidential and anonymous database funded by government grants in addition to industry support. No IP address taken which is important because Spanish law does not protect the reporter. However, this nullifies further analysis of the incident (can't be traced back) allowing only for local analysis. Switzerland: Critical Incident Reporting and Reacting NETwork (CIRRNET) since 2006. Local level risk managers determine which incident reports to upload to the online, encrypted, anonymous national database. UK: National healthcare-wide IRS [the National Reporting and Learning System (NRLS)] since 2006 gathering patient safety incidents from public hospitals in Wales and England. Reporting of deaths and severe harm are mandatory. The system is funded by the National Health Service.
Stavropoulou *et al*. (2015) UK	Review the effectiveness of Incident-reporting systems (IRSs) as a method of improving patient safety through organizational learning	Systematic Review.	No strong evidence that IRSs performed better than other methods. IRSs could be more effective if the criteria for what counts as an incident were explicit, they were owned and led by clinical teams rather than centralized hospital departments, and they were embedded within organizations as part of wider safety programs.
Subheder *et al.* (2010) UK	Provide an overview of the incident reporting process and summarise local and national data of patient safety incidents reported in a neonatal population.	Review.	Critical incident-reporting systems (anonymous) operate locally and nationally. These systems capture raw data about incident nature, location, individuals involved, impact on patient, and contributing factors. Most hospital-based systems have adopted a voluntary non -punitive approach. Staff are encouraged to report incidents using paper forms (or more recently, online using a web-based guided by an incident 'trigger list'—a list of key events prompting staff to complete an incident form, triggering further investigation. Each incident, whether a harmful event or a near-miss, is initially reviewed by a risk coordinator or nursing shift leader in order to grade the seriousness of risk associated with it. The next step is to formulate and implement an action plan designed to make specific changes to the way care is delivered. This action plan is then formally reviewed quarterly to ensure that the necessary changes have been made. A full-time risk coordinator with a background in neonatal clinical practice has the responsibility for overseeing the incident-reporting system. Serious untoward incidents (SUIs) are handled differently in that they are reported directly to Strategic Health Authorities through the Strategic Executive Information System for SUI reporting, while undertaking an urgent detailed review and root cause analysis. Individual and group feedback is an important component in educating staff about what should be reported, how incidents are investigated and how action plans are developed and executed. Staff need to be reassured that the process is focused primarily on learning from errors and not designed to assign blame.

Swedish Patient Safety Act (2010) Sweden	Relates to national legislation rather than research or guidance.	National guidance document.	(Translated from Swedish using Google Translate). Serious adverse event refers to a health injury that is permanent and does not ring, or has led to the patient having a significantly increased need for care or death. Severe injury is defined as "care-related injury which is permanent and has resulted in the patient having a significant increase in their need for care or their death."
Tsang *et al.* (2012) UK	Review patient safety measures based on routinely collected hospital data.	Systematic review.	The most widely used and recognised set of screens based on routinely collected hospital data were created by the Agency for Healthcare Research and Quality (AHRQ) in the United States. AHRQ patient safety indicators (PSIs) initially were released in 2003. More than two thirds of the reviewed studies described the use of the AHRQ PSIs. As development of AHRQ PSIs and other indicators has been concentrated in the United States, differences between the US health system and those of other countries makes adaptation of these measures in Europe and elsewhere of paramount importance. Exploration of international variation in the rates of AHRQ PSIs will be supported by translation exercises using the tenth revision of the ICD (ICD-10) coding algorithms in countries that include Australia, Germany, and the UK.
van der Starre *et al.* (2012) Netherlands	Describe the number and nature of adverse events occurring in Dutch general paediatric practice, to describe factors contributing to the occurrence of these adverse events, and to report on the experience of paediatricians with reporting adverse events.	Prospective Cohort.	The general data collected were patient details (name, date of birth, sex, hospital ID, and dates of admission and discharge). The localisation is recorded, i.e., the body site or organ involved, and the nature of the event, i.e., what actually happened. Potentially contributing factors are registered, and the consequence of the adverse event. The Dutch Ministry of Health decreed that by January 1, 2008, all Dutch hospitals were to have a working patient safety management system. The Dutch Health Care Inspectorate subsequently established adverse event registration as a quality indicator for Dutch health care. The Paediatric Association of the Netherlands in collaboration with the Dutch Order of Medical Specialists developed an easy-to-use reporting system for adverse events. The paediatric registration system is modelled after the surgical adverse event registration system and is intended to be used by all paediatricians in the Netherlands. Real-time registration is proposed as more reliable in detecting actual harm than voluntary incident reporting.
Wahid *et al.* (2016) UK	Describe the quality of reporting and investigation into surgical Never Events in public reports.	Mixed-method case review.	One statutory requirement in the NHS is the annual publication of a 'Quality Account' by every NHS Trust. These Quality Accounts include a statement from the organisation detailing the quality of the services they provide. Every English hospital is required to report all Never Events to central reporting bodies. Transparent reporting of Never Events by English NHS Trusts in their Quality Accounts is generally poor, but there are examples of excellence.
World Health Organization (2011) International	Outline definitions of key concepts from the WHO Patient Safety Curriculum Guide	Guidance document.	Disability is defined as "any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm."
Yarmohammadian *et al.* (2013) Iran	Describe the incident reporting systems of United States, Australia, England, Ireland and Denmark.	Review.	Critical Incident Reporting Systems (CIRs) are any structured report of untoward and preventable outcomes of events that could lead to patient injury or harm. Patient Safety Reporting Systems (PSRS) are systems used to identify safety hazards, prioritize where to focus resources, develop interventions to mitigate these hazards, and evaluate whether the interventions reduced harm. In the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, six criteria in selected countries were reviewed. These included types of reporting systems (objectives, governmental or private or non-governmental,

			mandatory or voluntary), event types, reporters, techniques of reporting and analysis, dissemination and feedback of results. Lack of systematic analysis of the reports and feedback directly to the clinicians are seen as major barriers to clinical engagement. In open-reporting culture countries, reporters are not at risk of litigation, their identities will remain confidential, and thus incident-reporting systems are more efficient and successful.
Zwart & de Bont (2013) Netherlands	Examine how incident reporting procedures become part of the way primary health care professionals deal with safety problems.	Ethnography.	In risk management, safety is seen in terms of the prevention of recurrence of specific well-defined incidents. In medical practice, safety involves recognising uncertainties and strengthening implicit initiatives that underpin patient safety The two logics could conflict. Members of the incident reporting committee, who are care providers, made recommendations that conflicted with the implicit routines that make health care safer day-by-day. In addition, the 'systems approach' to incidents presented by an incident report system conflicted with the initial needs of providers to cope with an adverse event.