Patient safety reporting systems:

A literature review of international practice

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1. Introduction

> The most important knowledge in the field of patient safety is how to prevent harm to patients during treatment and care. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system.
>
> Sir Liam Donaldson (Chair, World Alliance for Patient Safety)[1]

Patient safety reporting in New Zealand is guided by the **National Reportable Events Policy**. Under this policy, all health and disability service providers who have obligations under the Health and Disability Services (Safety) Act 2001, and those providers who voluntarily comply with the policy, must report patient safety incidents to the Health Quality & Safety Commission ('the Commission') where significant harm or death may have occurred.[2] The Commission publishes an annual report on adverse events that have occurred within the health and disability sector.[3]

To inform a scheduled review of the National Reportable Events Policy, the Commission has conducted a brief scan of overseas literature on patient safety reporting systems (PSRS). Findings from the literature scan, along with feedback from stakeholder interviews in May and June 2016, will help identify key issues to explore during the policy review. Findings will also inform a wider review of the adverse event learning programme's strategic direction.

This report summarises the findings of the literature scan.

2. Approach

The overall objective of the literature scan was to **describe best and emerging practices for PSRS**, including approaches in overseas jurisdictions. This report provides the context for findings on best-practice and overseas approaches by giving a brief history of PSRS (Section 3), summarising key challenges facing PSRS (Section 4) and key features of successful PSRS (Section 5), and giving an overview of the role of national PSRS (Section 6). Detailed outlines of best-practice approaches for local and national PSRS follow, including brief commentary on approaches in overseas jurisdictions (Sections 7 and 8). In the final sections, the report briefly re-visits some of the key questions about PSRS (Section 9), highlights emerging thinking on patient safety and its management (Section 10) and draws together the key messages from the literature (Section 11). It is expected that findings on best practice for local PSRS, and emerging thinking on the role of PSRS, will interest those involved with patient safety reporting in district health boards and other health care organisations.

Scope: The literature search included published and unpublished ('grey') English language literature written since 2013.

Method: Finding relevant published literature involved searching four large databases: Ovid MEDLINE (R), Embase, Scopus and the Cochrane Library. For unpublished literature, the process was to use specialised Google searching and grey literature search engines (for example, greylit.org), as well as to review the websites of relevant non-governmental, government and think tank organisations. Search terms such as 'incident reporting', 'reporting and learning system', 'safety reporting system', 'organisational learning', 'near

miss' and 'adverse event' were used separately and in combination. Where articles gained through these methods made other relevant citations, those citations were also sourced.

Limitations: Findings are based on a limited scan of overseas literature rather than a systematic review. It is expected that additional key themes will emerge from stakeholder interviews and the wider policy review process.

Terms used: Patient safety terms used vary widely in the literature, in different jurisdictions and even between different New Zealand agencies. Drawing on the *World Health Organization Draft Guidelines for Adverse Event Reporting and Learning Systems*,[1] this report uses the following definitions.

- **Patient safety incident** is any deviation from usual medical care that causes harm to a patient or presents a risk of harm. This term includes adverse events and near misses.

- **Adverse event** is an incident relating to medical management that causes harm to a patient. Medical management covers all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Other sources sometimes use the terms 'sentinel event' or 'critical incident' to refer to an adverse event, but for this review we will use adverse event.

- **Near miss** is an incident that has the potential to cause an adverse event but fails to do so because of chance or because someone stops it from happening. It is assumed that the underlying systems failures for near misses are the same as for actual adverse events.

- **Never event** is a patient safety incident that results in serious patient harm or death and that could have been prevented by using organisational checks and balances.

- **Patient safety reporting system (PSRS)** is the processes and technology involved in standardising, formatting, communicating, giving feedback on, analysing, learning about and responding to reported incidents as well as in making known any lessons learned from such incidents. Other sources sometimes use 'incident reporting system' or 'reportable events system' to refer to PSRS.

The Commission will consider terms used in its review of the National Reportable Events Policy 2012 and adverse events learning programme.

3. History of PSRS

Health care systems originally adapted PSRS from the systems of aviation and other industries where safety is critical. They introduced PSRS into health care because they wished to achieve the level of resilience and response to error that high-risk industries have achieved. In 1999 the United States Institute of Medicine's landmark report, *To Err Is Human,* recommended sweeping changes to the health care system to improve patients' safety.[4] Drawing on the work of aviation and other high-risk industries, the report specifically recommended adopting nationwide mandatory reporting systems that provide for 'the collection of standardised information by governments about adverse events that result in death or serious harm'. In 2000 the United Kingdom's Department of Health published its own landmark report, *An Organisation with a Memory*, which also recommended creating a national system for reporting and analysing adverse health care events.[5]

PSRS are now one of the most widespread strategies for improving safety in health care. Recommended by international and national bodies as a key method to learn more about risks to patient safety and how to improve it, PSRS are part of health care systems around the world. They operate at various levels – national, regional, within health care organisations and within specialty areas or departments – and in both public and private organisations. Some focus on a specific type of incident or event. Although PSRS adopt various formats, most have the same core operating model.

- Frontline workers submit reports about situations in which a patient was harmed or had the potential to be harmed.
- Reported incidents are investigated.
- Key issues that need to be resolved and improved are identified and acted on.

4. Challenges facing PSRS

Although many countries have been quick to adopt them, PSRS around the world face many challenges, such as the following.

- **Lack of evidence** that patient safety reporting actually improves patient safety: In the 15-plus years since *To Err Is Human* was published, health care practitioners have submitted millions of patient safety incident reports around the world; in the United Kingdom alone, the National Reporting and Learning System (NRLS) receives more than 1.5 million reports each year.[6] As yet, however, there is little evidence that incident reporting helps to deliver safer health care.[7,8] There is also no strong evidence that PSRS perform any better than other methods of reporting.[9] In fact, research shows PSRS detect only a small percentage of relevant patient safety incidents.[10]

- Pressure on PSRS to provide **both a learning platform and a reporting and surveillance system**: PSRS are increasingly being drawn into performance management as incident data is used to hold organisations to account for safety performance.[11,12] A system that tries to perform both reporting and learning roles can create confusion and undermine its effectiveness. For example, in the United Kingdom the NRLS cannot work as a meaningful reporting or accountability system because reporting is voluntary with guaranteed anonymity at the national level. Yet it also cannot fulfil its learning role because it receives such an overwhelming volume of reports, it cannot give meaningful feedback to reporters.[13]

- **Barriers to reporting**: Research has identified a range of barriers to incident reporting including time pressures, resource constraints, uncertainty about what to report, apathy about reporting and its value, unfamiliarity with the reporting system, and fear of getting in trouble or getting someone else in trouble.[13] A recent study found that health care practitioners most often chose to 'fix and forget' safety problems, rather than 'fix and report' them, when they faced problems they themselves could resolve.[14] Under-reporting makes incident reporting less useful, not least because the reports that are submitted provide a biased snapshot of issues within a health care organisation.[15]

- **Inadequate report processing**: PSRS tend to generate a large volume of highly diverse reports that health care organisations often do not have the resources to process.[11,15,16] Experts consider that the reasons for high volumes of reports are that PSRS:

- focus on reporting at the expense of investigation, learning and sharing – 'we collect too much and do too little'[12]
- focus on increasing reporting rates, where high levels of reporting are equated with a stronger safety culture[11,12]
- have ambiguous and broad criteria for reportable incidents, leading to large numbers of reports on common events (for example, falls), many of which provide little or no new information for systems improvement[12,15,16]
- do not have effective triaging mechanisms to prioritise the reports that should be investigated further.[15]

- **Insufficient action from reporting**: One of the major weaknesses of incident reporting, which is likely to contribute to under-reporting, is that health care professionals tend not to gain feedback or see action taken after they report an adverse event.[15] PSRS often do not produce in-depth analyses or strong interventions to reduce risks to patient safety, with the result that meaningful change is rare and most interventions involve education and training. Many investigations are superficial because resources and expertise in incident investigation are limited.[16]

- **Few doctors are involved**: Doctors tend not to report events, limiting the type of events reported, which in turn limits learning opportunities for the organisation. Some reasons why doctors are less engaged in PSRS are that they mistrust patient safety reporting because they are afraid of how reports will be used, are uncertain about what to report, and do not get feedback or see action resulting from reporting. Other reasons are that PSRS tend not to produce learning relevant to local practices and there is little peer-reviewed literature that supports incident reporting.[11,15]

- **Inadequate funding and institutional support**: Some patient safety experts believe many PSRS have been under-resourced, at national, state and local levels, contributing to the problems with processing and acting on incident reports.[11] PSRS can be under-resourced both through inadequate financial support and through a shortage of adequately trained and skilled analysts to deal with the volume and diversity of reports. A related challenge that experts identify is that PSRS lack effective governance and clear roles and responsibilities.

- **Failure to capture developments in health information technology**: Experts agree that, in the future, adverse event reporting has to take full advantage of electronic health records and related technologies.[11]

Patient safety experts and health care organisations alike are working to **address the challenges faced by PSRS and improve their effectiveness**. They are exploring questions such as: What is the role of national versus local systems? What should be reported? How can we increase meaningful reporting? How can we give patients a stronger voice in reporting and learning? How do we enable reporting and learning from all care settings, across the patient journey? How do we close the feedback loop? The following sections consider expert views on these and other questions.

5. Characteristics of successful PSRS

A successful reporting and learning system to enhance patient safety is one in which reporting is safe for the individuals who report, reporting leads to a constructive response, expertise and adequate financial resources are available to allow for meaningful analysis of reports, and the reporting system is capable of disseminating information on hazards and recommendations for changes.[1]

In 2005 the *World Health Organization Draft Guidelines for Adverse Event Reporting and Learning Systems* set out basic design and implementation principles and success characteristics for PSRS. Although published more than a decade ago, many of the principles and approaches remain relevant today. Key elements are outlined below.[1]

- **Purpose:** The fundamental role of PSRS is to enhance patient safety by learning from failures of the health care system. Reporting – by health care practitioners within an organisation and by the health care organisation to a broader audience through a system-wide, regional or national reporting system – is a tool to help health care organisations and systems learn from incidents and improve patient safety.

- **Function:** The most important function of PSRS is to use the results of data analysis and investigation to make and communicate recommendations for systems change. Reporting in itself does not improve patient safety. It is the action taken in response to reporting that leads to change.

- **Objectives:** The objectives of PSRS tend to consider reporting and accountability as well as learning. Both types of objectives can support learning and improvement. However, the weighting applied to each one will influence system design features such as whether reporting is mandatory or voluntary and whether reports are held in confidence or made public. For example, a reporting system that focuses on learning and system design usually involves voluntary reporting and spans a broad scope of reportable incidents. A reporting system that focuses on accountability usually has mandatory reporting of selected types of serious incidents.

- **Characteristics:** Table 1 lists characteristics that various patient safety experts have identified (and that the World Health Organization has reproduced in its guidelines) as essential to the success of PSRS.

Table 1: Characteristics of successful patient safety reporting systems[17]

Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
Confidential	The identities of the patient, reporter and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organisation.
Expert analysis	Experts who understand the clinical circumstances and are trained to recognise underlying system causes evaluate the reports.
Timely	Reports are analysed promptly and recommendations are rapidly communicated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of communicating recommendations widely. Participating organisations commit to implementing recommendations whenever possible.

6. Role and characteristics of national PSRS

A national public safety reporting system is a mechanism for **collating, classifying, analysing and acting on patient safety problems at a national level**.[18] International bodies recommend states and countries establish national or regional reporting systems so that they can gather together, at a regional or national level, reports and analyses of incidents made at a local level.[4,5,19] Some specific benefits of analysing large collections of patient safety incidents are that this approach makes it possible to:[20]

- identify and understand risks to patient safety that rarely occur and so are unlikely to be characterised at a hospital or local level
- gain early warnings of the inevitable yet unforeseen new risks associated with changes in health care practices and the introduction of new technologies
- identify common contributing factors or repeated patterns of error by drawing together information on incidents from many different institutions.

National PSRS allow findings from local systems to be applied widely and have a national, system-wide impact. For an overall patient safety reporting system to work, national and local level systems need to complement each other. Systems at the local level must do the initial reporting on the incident, handle and analyse it, and deal with immediate implications. However, a national system can complement this work by establishing a framework to encourage and support local reporting, by sharing lessons learned across systems and by enabling wider surveillance of problems.[21]

Patient safety experts agree that the primary roles of national PSRS are to identify safety issues, detect uncommon conditions and share learning (see Table 2).[11] National PSRS cannot, and should not, monitor the incidence of harm in health care organisations or compare organisations (see Box 1). They can, however, provide indicators of the safety

culture of an organisation. These recommendations are consistent with those in other literature.[16,22,23]

Table 2: What PSRS can achieve and what they should not do[11]

Roles national PSRS can fulfil	Roles national PSRS cannot fulfil
Identify safety issues	Identify unsafe health professionals
Detect rare events	Identify unsafe hospitals
Share safety solutions between organisations	Measure how safe one health care organisation is compared with another
Provide indicators of the safety culture of an organisation	Measure the incidence of harm in a health system
Monitor never events (through mandatory reporting)	

Box 1: Why PSRS cannot measure safety[16]

Because events are under-reported, PSRS cannot provide an accurate measure of safety. In addition, different methods of detecting events identify different types of events so that it is difficult to draw firm conclusions about patient safety.

- Some types of events are reported more than others (bias).
- Among reported events, some types of events have a lower threshold for reporting than others. (For example, some report near misses; others report only those incidents that result in patient harm.)
- Some types of events are reported often (eg, falls) while others are under-reported (eg, medication incidents).
- Some groups of health professionals report adverse events regularly (eg, nurses) while others report incidents infrequently (eg, physicians).

To get a valid measure of the rate of adverse events, it is necessary to:

1. use a consistent surveillance system that detects both the event and the population at risk (as outlined above, adverse event monitoring does not gather this information consistently)
2. clearly define the event (few adverse events in health care are well defined)
3. clearly define the population at risk (the populations in health care are usually not defined).

The Australian Patient Safety Foundation has identified desirable attributes of national PSRS based on lessons learned from the Australian Incident Management System.[18] In particular, PSRS should have:

- an independent body for patient safety surveillance that coordinates the system
- agreed frameworks for: patient safety, reporting systems and a surveillance system
- agreed standards for reporting
- a single, clinically useful classification system for events that go wrong
- a national repository for data from all available sources about these events

- data collected across the whole spectrum of health care
- mechanisms for setting priorities at local, national and international levels
- a just system, accommodating the needs and rights of: patients and their relatives, friends and carers, health professionals, health facilities and society at large
- separate processes for accountability and 'systems learnings'
- explicit criteria for deciding whether the process should be open for accountability or provide protection and qualified privilege
- a blame-free culture for reporting
- the right to anonymity for reporters
- qualified legal privilege for quality and safety improvement ('systems learnings') information
- ownership of 'systems learnings' information by those who provide it
- systems for rapid feedback and evidence of action
- mechanisms for involving and informing all stakeholders
- mechanisms for sharing successful strategies internationally.

Authors with experience in managing large-scale PSRS in Australia, the United Kingdom and North America have identified the requirements for a population-level function to recognise and respond to patient safety risks using clinical expertise. As Table 3 shows, this framework sets requirements for the system, personnel and a multi-staged risk surveillance, review and response process. Like the Australian Patient Safety Foundation, the authors highlight the need for mechanisms to prioritise which local reports get reviewed at a national level and which trigger a national response. They also emphasise the importance of having a multidisciplinary team to manage the risk surveillance, review and response process.[20]

Table 3: Requirements for a population-level function to recognise and respond to patient safety risks using clinical expertise[20]

System requirements	1. A means for reporting incidents that is available to all health care workers and is adequately resourced, non-punitive, independent and confidential.
	2. Software to collect incidents and other information from multiple sources and institutions. This may directly collect information in one database (eg, Danish Patient Safety Database) or upload it from independent systems into a central repository (eg, NRLS).
	3. A system for producing and managing reports for each stage of the risk surveillance, review and response process (see below).
	4. A system to communicate corrective strategies to health care organisations.

Personnel requirements	A multidisciplinary team of clinicians, subject experts and human factors experts should advise and manage the risk surveillance, review and response process.
	• Clinicians' understanding of typical workflows and the operations of health care organisations helps them to interpret incidents.
	• Subject experts help in understanding the patterns of contributing and contextual factors.
	• Human factors personnel can advise on common error mechanisms and how to develop corrective strategies that are strong and sustainable.
Risk surveillance, review and response process	1. Undertake surveillance – categorical or free-text algorithms can extract those incidents more likely to require a national response. Prioritise those incidents associated with serious harm.
	2. Identify a 'trigger' incident – to identify new or under-recognised patient safety risks requiring a national response, criteria are risks: that are 'novel', not well known, involve new technologies or processes or are part of a pattern or trend of similar but previously unrecognised incidents; **and** for which there is evidence of actual or potential significant patient harm; **and** for which preventive and corrective actions are feasible, are not already widespread and may be implemented in a cost-effective manner.
	3. Collect like incidents.
	4. Characterise the relevant incident type – using a framework such as the International Classification for Patient Safety.
	5. Identify preventive and corrective strategies.
	6. Develop materials for a response (eg, an alert).
	7. Pilot test and refine.
	8. Share information about alerts and corrective strategies.
	9. Evaluate.

7. Best-practice approaches for local PSRS

Table 4 summarises best-practice approaches for local PSRS. Key sources include the 2005 World Health Organization guidelines, a 2016 Delphi consensus study with patient safety experts on the role of PSRS and a 2014 report by the Reporting and Learning Subgroup of the European Commission Patient Safety and Quality of Care working group.[1,11,22] For further information on what to report, ways to increase reporting and closing the feedback loop, see Section 9.

Table 4: Best-practice approaches for local PSRS

	Recommended approach
Reporting environment	• Just or no-blame cultural environment [1,22] – top management of health care systems and organisations should spread the message of a 'blame-free and non-punitive' objective. [23] • Strong leadership and accountability [22,23] – health care organisations should have an executive board member responsible for patient safety and should be accountable for investigating their own reports.[11] • Health care organisations should share an understanding of what a patient safety incident is and the purpose of incident reporting.[22,23]
Reportable incidents	• The system should define incidents broadly, allowing reporting of a wide range of safety information and events.[1,11,22] - Reporting systems may be open-ended and aim to capture incidents along the entire spectrum of care delivery, or they may focus on particular events or pre-defined serious incidents. - A simple list is easier to understand and helps personnel to focus on certain issues; however, if the criteria for what incidents to report are too limited, useful lessons may be missed. - With a broad definition, personnel may report any concerns, including near misses, providing a rich resource for learning and systems improvement; however, many events that offer no new learning also get reported. • Report near misses and never events.[11] • Health care organisations should not determine their own reporting priorities; a central system should set these.[11]
Requirement to report	• Make reporting voluntary, except in certain circumstances – see below.[1,19] • A voluntary system should gather information on near misses and medication incidents.[11] • A mandatory system should gather information on never events or serious events such as wrong site surgery, device failures and hospital-acquired infections.[11] • Regulations on sanctions-free reporting and clear rules of confidentiality should accompany mandatory systems.[22]
People who report	Reporters should include: • all health care organisation staff[22,23] • patients, relatives and other informal caregivers.[1,19]
Mode of reporting	Reporting should: • be confidential[1,19,22,23] • allow for the opportunity to report anonymously.[1,19,22]
Incident classification	• Use a common classification system that makes it easier to compare data across care providers.[1,11,22, 23]

Report form	• Standardised reporting forms, including free-text and structured response fields, are recommended because:[1,22,23]
	  - highly structured reporting helps with data analysis
	  - free-text or narrative reporting can capture context and story, allowing the conditions that contributed to the error to be explored and understood.
	• The minimum data set should cover:
	  - basic profile of patient (age, gender, ethnicity – anonymised), time, date and location of incident (care setting, specialty), identity of provider organisation (Some authors suggest that, to increase reporting, reporters should be required to provide only this information; a patient safety specialist can provide the rest[16])
	  - incident type and patient outcome (using classification scheme), description of what happened, action taken, root cause of event and preventative measures taken.
	• Reporters should have quick and ready access to report forms.[16,22,23]
	  Use simple systems so that staff can use them with little or no training.[16]
	• Use electronic/web-based reporting to promote data accuracy, make it easier to transmit information and simplify analysis.[22]
	• Use different reporting forms for health care professionals and for patients and relatives.[22]

Incident analysis	• Analyse incidents at the level of the health care organisation.[11] • Generate solutions locally and communicate them nationally.[11] • Experts who have insight into the subject and are trained to recognise underlying system causes should analyse the incident.[1,22] • Staff should be encouraged to propose solutions for incidents at the time of reporting.[11] • Analysis of all incident types is desirable; however, near misses are of a lower priority for investigation; prioritise never events and incidents leading to death and severe harm for investigation.[11] • Common findings of an incident analysis describe the problem, draw conclusions and set out an action plan.[22]
Feedback	• The receiving health care organisation should give timely, individual feedback to the person reporting; it should acknowledge to the reporter that it has received their report and keep them informed of next steps and actions taken.[11,22,23]
Learning	• Managers should share reports with staff.[16] • Share lessons at local, regional, national and international levels.[16]
Other data sources	• PSRS do not provide a complete picture of risks, hazards and system vulnerabilities; find support for patient safety reporting data from other sources of information on patient safety incidents (eg, complaints, administrative data, laboratory data, pharmacy data, staff surveys, patient surveys).[22]

8. Best-practice approaches for national PSRS

As Section 6 has explained, a national public safety reporting system is a system for collating, classifying, analysing and acting on local incidents at a national level. The World Health Organization guidelines suggest looking at national PSRS as an extension of local systems.[1] To this end, national reporting systems have many of the same characteristics and requirements as local systems (for example, non-punitive, independent, preferring voluntary reporting, using clinical expertise in analysis). Table 5 highlights recommended approaches for national PSRS that are distinct from those recommended for local systems. For more information on prioritising reporting and analysis at a national level, see Section 9.

Table 5: Best-practice approaches for national PSRS

	Recommended approach
Reportable incidents	• Prioritise which incidents to report to the national PSRS.[11,16] • Report and analyse both locally and nationally incidents with the potential to be solved nationally, such as never events, device failures, hospital-acquired infections and medication incidents.[11]
Report form	• To support learning, collect detailed data/reports for each individual incident (following the recommendations for the minimum data set for local PSRS) rather than summary tables for each health care organisation.[22]

Report review	• Have a process that anonymises all incoming reports and removes all personally identifiable information.[22]
	• Have a process to ensure the quality of data in incoming reports, including correct classification.[22]
	• Prioritise incoming reports for review using algorithms to extract incidents more likely to need a national response – prioritise incidents associated with serious harm.[20,22]
	• Review process should: [22]
	  - at a minimum, identify hazards in the health care system and prioritise them for further evaluation
	  - be **expert** – evaluated by experts who understand the clinical circumstances under which incidents occur and who are trained to recognise underlying systems causes
	  - be **credible** – involving both independence and content experts
	  - be **timely** – reviewing reports without delay and sharing recommendations promptly; when serious hazards are identified, give notification of it rapidly
	  - result in preventive recommendations.

Data transfer from local to national PSRS	• Provide for automatic, online dataflow between local and national systems using a Cloud platform or by integrating local systems with the national system.[22] • Avoid batched transfer of data to keep up speed of data processing and to minimise delays between local reporting and central review.[22] • Ensure data security (availability, integrity, access restriction) when transporting, storing, sharing and archiving data.[22] • Store basic data from all different sources of reports – or allow for it to be viewed as a unified structure – in a way that allows for integrated analysis [22]
Care settings	• Cover all care settings (hospitals, laboratory settings, imaging services, rehabilitation institutions, outpatient clinics, primary care, pharmacies, substance abuse treatment centres, ambulance services, home care agencies, providers of health care in social services).[22] • Involve both public and private organisations.[22]
Other data sources	• PSRS do not provide a complete picture of risks, hazards and system vulnerabilities. Use other sources of information to support incident report data, for example, incidents detected from administrative data, complaints, health and safety incidents, inquests, claims, clinical audits, routine data, observations and informal conversations with patients, families and staff. Introduce mechanisms at national level to collect this information and share the lessons learned.[1,22] • Link automatically with pharmacovigilance and other similar systems to avoid duplication of reporting.[22]
Sharing lessons learned	• Methods of learning from reports include: alerts about new hazards, sharing lessons learned from incident investigation; analysing multiple reports to find trends and hazards; analysing multiple reports to gain insights into underlying system failures and develop best-practice recommendations.[1] • Share preventive measures through existing channels where possible.[22] • Include changes in relevant, existing policies instead of merely issuing new standalone safety alerts.[22] • Consider providing central support for implementing change and, where appropriate, resource that support.[22]

Patient safety reporting in overseas jurisdictions: Appendix A provides an overview of some of the key features of PSRS in England and Wales (NRLS, the National Reporting and Learning System), Scotland (no national PSRS but a National Framework to guide local National Health Service (NHS) boards in managing adverse events), Denmark (DPSD, Danish Patient Safety Database) and British Columbia, Canada (BC PSLS, British Columbia Patient Safety and Learning System). Below is a summary of key information about these PSRS.

- **Reportable incidents**: The NRLS, Scottish National Framework and BC PSLS include near misses. The DPSD focuses on specified adverse events only. The NRLS includes never events.

- **Requirement to report**: Most reporting is voluntary, apart from mandatory reporting of specified serious incidents.

- **People who report**: The NRLS, DPSD and BC PSLS all enable patient reporting. The reporting form they give to patients is different from the one for health care organisations and practitioners. The Scottish system does not have patient reporting.

- **Mode of reporting**: The NRLS, DPSD and BC PSLS all ensure confidential reporting and enable (if not actively encourage) anonymous reporting. Only a small proportion of Scottish NHS boards enable anonymous reporting.

- **Incident classification**: Classification approaches tend to be based on the World Health Organization International Classification for Patient Safety, or at least align with it. Different jurisdictions use slightly different categories of severity.

- **Report form**: All reporting from local to national PSRS is electronic. Reporting to the NRLS, DPSD and BC PSLS is direct to a centralised database. Scotland has no mechanism for national reporting.

- **Incident analysis**: The systems analyse incidents at the local level. In addition, the NRLS and DPSD review more serious incidents at a national level.

- **Care settings**: The DPSD and PSLS receive reports from across the care spectrum, including private health care providers. The NRLS includes reporting from a wide range of NHS-funded organisations but not private providers. The Scottish national approach has so far focused on acute settings but is moving to include other care settings as well.

- **Information sharing**: The different systems use a wide range of mechanisms for sharing information and knowledge. Of particular note, the BC PSLS in Canada uses a publicly accessible online blog and the Scottish National Framework uses a Community of Practice website.

- **Future developments**: Key developments underway in the United Kingdom include conducting a significant project to re-develop the national patient safety management system and establishing the Healthcare Safety Investigation Branch to support incident analysis. Denmark is renovating its Knowledge Platform. Both Canada and Scotland are aiming to establish national PSRS.

9. Key questions for PSRS

This section specifically addresses the questions raised in Section 4, drawing together the best-practice approaches outlined in Tables 4 and 5 above with additional commentary and expert opinion.

What should be reported?

Use broad definitions of reportable incidents at the local level, to allow reporting of a wide range of safety information and incidents and generate a rich resource for learning and systems improvement.[22] Include near misses and never events – see below.[11]

Set priorities to determine which incidents get reported to national PSRS from local systems. National bodies can limit the volume of national reports by specifying incidents of national interest, rather than receiving all reports. They may then be able to focus on current safety priorities and be selective about which incidents they use national resources to investigate. Events such as patient falls may not need to be collected at a national level as they are well understood and their prevention well evidenced.[12] Some suggested approaches to prioritise reporting are to:

* focus on a finite set of events likely to be of greatest benefit to learning and systems improvement, which may be based on level of harm, frequency, preventability or regional/national priority[16]
* report incidents with the potential to be solved nationally such as never events, device failures, hospital-acquired infections and medication incidents.[11]

Near misses*:* Indistinguishable from adverse events in all but outcomes, near misses are opportunities for quality improvement. *The Measurement and Monitoring of Safety* states that 'the focus is moving from counting harms after the event towards looking at hazards that might give rise to error, or safety failure before harm has occurred'.[24] Experts strongly agree that incidents reported to local PSRS should include near misses.[11,22] There is less consensus about whether or which near misses should be reported at a national level.

Evidence indicates that near misses are under-reported and poorly understood in health care settings. One study found that health care practitioners tend to 'fix and forget' (rather than 'fix and report') when they encounter near misses. It also identified a view among health care practitioners that reporting near misses would create overburdening paperwork.[14] One suggestion for addressing under-reporting is to make it mandatory to report higher-risk near misses – those that could have resulted in death or disability.[25]

Never events*:* Reporting never events can raise the profile of patient safety and strengthen the focus on reducing and eliminating those events that can be prevented outright through strong clinical and organisational systems. An organisational culture that minimises or eliminates never events is also likely to reduce other preventable harms.[26] Experts consulted in the Delphi consensus study on the role of national PSRS agreed that reporting of never events should be mandatory, at both local and national levels.[11] Several jurisdictions, including Canada[26] and the United Kingdom,[27] have developed lists of never events.

The United Kingdom requires never events to be reported to the NRLS.[27] The NHS policy on never events states that this type of event has the potential to highlight weaknesses in

how an organisation manages fundamental safety processes. Reporting never events therefore provides the NHS with an essential lever for improving patient safety. The United Kingdom defines never events as a type of serious incident that meet the following criteria:

- they are wholly preventable
- they have the potential to cause serious patient harm or death
- there is evidence that the category of never event has occurred in the past
- occurrence of the never event is easily recognised and clearly defined.

How can we increase meaningful reporting?

Authors of recent studies have made some clear recommendations for how to improve meaningful reporting to PSRS (outlined below). For further important insights relevant to this question, see Section 10 on emerging thinking for patient safety and safety measurement, and the question below on 'closing the feedback loop'.

Make reporting easier: Health care providers should have quick and ready access to PSRS (electronic, web-based). Systems should be so simple that staff can use them with little or no training. Systems should ask for a minimal amount of information. Instead of asking the reporting health care practitioner to categorise the event, rate the event and identify causes, the report form might just need to ask for a free-text description and some identifying information; a patient safety expert familiar with incident reporting can further investigate events that have merit.[16]

Give feedback and take action. A lack of feedback and visible action as a consequence of reporting is one of the major weaknesses of incident reporting. Give timely feedback to the person who reports an event – this is a way of checking understanding of the report and communicates that somebody is listening and cares about the event. Managers should share reports with staff. In this way, they educate the staff about risks in their environment, gain their ideas on how to further reduce risk and inform them that action occurs in response to such staff reports. Share lessons at local, regional, national and international levels. Leaders should devote institutional resources to not just collecting data but also analysing events and mediating risk. When staff observe that the institution is willing to change based on their feedback, the safety culture really starts to change.[16]

Improve physicians' engagement: Support physicians to feel truly safe when reporting. Establish strong medical leadership of PSRS that values medical reporting and results-based reporting of adverse events. Demonstrate that reporting has led to tangible action locally. Link electronic health records to electronically submitted incident reports so that reporters can track the progress of their incident report. Clarify roles and responsibilities for incident analysis and ownership of related actions.[15]

How can we give patients a stronger voice in reporting and learning?

There is broad agreement that patients, relatives and, to a lesser extent, the public should be able to report to PSRS. Many jurisdictions, including those this review covers (Appendix A), allow patients to report.[28]

Patients and relatives are a potentially rich resource for learning and improving patient safety. Patients can provide timely and important information about the safety of care that complements information recorded in staff reporting systems.[29]

- Patients can report safety incidents that would otherwise go undetected.[30]
- Patients may be in a better position than their caregivers to identify failures in handovers and gaps between providers across the continuum of care.[1]
- A patient may experience an injury that is not obvious until after they are discharged from a hospital and therefore no one other than the patient or relative could report it.[1]
- Patients are highly motivated to report errors or problems in their care.[31] They are often experts in their disease and health condition and eager to participate in developing interventions to prevent clinical incidents.[32]

Few researchers have studied patient reporting of incidents. More research is needed on patient self-reporting systems, and on how well-used, usable and useful they are.[32] Areas of specific interest include: How can PSRS make patient and family reporting easier? What are the specific requirements of the system? What mechanisms are needed to capture the qualitative information patients provide? Do either systems or culture need to change? What extra resources are needed?[22]

Interventions to encourage and enable patients to become involved need to be developed and evaluated. Studies have indicated one barrier to patients using PSRS is that they often prefer to report incidents to a researcher rather than to a national or local reporting system.[30,33] In Denmark, when patient safety reporting is introduced, uptake is slow at first but increases over time as awareness of the opportunity grows.[22] This slow start may be in part because PSRS usually see patient reporting as an extension to health care providers' reporting, and add it to the reporting system in the later stages of development. The design therefore may not be optimal to encourage and enable patients and families to report. One solution may be for patients to design, manage and administer surveys, creating a tool that patients are more confident about using to report incidents.[31]

Where patients can report incidents as part of a wider PSRS, they should be made aware of this possibility in the same way as they are made aware that they can complain or receive compensation. They should also be made aware that incident reporting is separate from formal complaint and litigation procedures. Reporting should use a similar structure and classification as reporting for health care providers, making it easier to conduct a structured analysis of the data. However, the design of the report form should also keep in mind the needs of people who are not trained health professionals.[22]

How do we enable reporting and learning from all care settings, across the patient journey?

There is strong agreement that PSRS should cover all care settings and should enable reporting for both public and private health care organisations. Of the jurisdictions reviewed for this report, three (NRLS, DPSD and BC PSLS) have reporting from across the care spectrum. However, only the DPSD and BC PSLS include private health care providers.

Many PSRS are set up around acute care, which involves a range of different people. It can be difficult to apply this system to other care settings, such as primary care or specialised outpatient care, where providers are fragmented (for example, a single doctor with a single

nurse) and not part of a bigger organisation. Further, care settings may differ in their reporting methods. One recommendation is to develop PSRS based on generic best-practice and to add the specifics of care settings in later phases of development.[22] In the United Kingdom, where the NRLS accepts reports from primary care settings, only 1 percent of reports come from primary care. This lack of reporting reduces patient safety across care settings as secondary care staff have little information about incidents patients have experienced in their earlier interactions with the health service, which in turn limits understanding of where and to what extent patients experience incidents across the sector.[35] The United Kingdom is looking at how to enhance and support reporting from non-acute care settings, particularly primary care.

Some patient safety experts believe that, because primary care has specific complexities, and because physicians are important reporters of incidents in primary care (unlike in hospital settings), primary care needs a sector-specific PSRS. An expert group with extensive experience of working with European reporting systems has developed recommendations on the content and structure of such a system.[34]

Evidence shows PSRS can work in primary care settings. One study of a web-based primary care reporting system found that near misses occur frequently in office practice, mainly involve administrative and communication problems and occasionally present a significant risk of patient harm.[34]

How do we close the feedback loop?

Lack of feedback is a key barrier to incident reporting. 'Closing the safety feedback loop' means using information from reported incidents to improve the safety of frontline clinical work systems.

If feedback is to contribute meaningfully to the overall improvement project, it cannot just involve passively giving out the information. It is better understood as an active process of communication that sustains a continuous cycle of learning, reporting and learning. Feedback also plays a role in establishing accountability, as staff are more likely to report when they are certain that someone will review and act on their report.[35] Box 2 identifies essential elements of effective feedback.

The **Safety Action and Information Feedback from Incident Reporting (SAIFIR)** model sets out requirements for feedback in a patient safety incident reporting and learning system.[36] The model has been developed from a scoping review of research and expert advice from world leaders in safety in high-risk industries.

The SAIFIR model includes five distinct modes of action and information feedback and 15 system requirements for safety feedback processes at the organisational level (see Appendices B and C). An overall *Framework for Safety Action and*

Box 2: Effective feedback in incident reporting systems[35]

1. Includes visible sponsorship from local leadership.
2. Preserves anonymity without compromising learning.
3. Rewards reporters and reinforces reporting.
4. Supports prioritisation of resources for improvement.
5. Involves and engages frontline staff in the safety improvement process.
6. Is specific and relevant to its audience.
7. Occurs at multiple points in the alerting and response process.
8. Facilitates dialogue between relevant stakeholders.

Information Feedback from Incident Reporting draws together the feedback modes and system requirements (see Appendix D).

Key messages from the review are that:

- effective safety feedback is not just about publicising incident rates but rather involves timely, visible and repeatable corrective action and quality improvement processes
- it is important to use multiple ways of feeding back actions and safety information to promote safety awareness, improve clinical processes and maintain reporting
- risk management systems in health care organisations would benefit from a comprehensive, common framework that has multiple modes of feedback (such as the SAIFIR Framework).

A United Kingdom study of incident reporting in National Health Service trusts found that no trusts used all of the best-practice requirements outlined in the SAIFIR model or used all the five modes of feedback.[37] The authors recommended:

- building feedback into the regular reporting of patient safety issues at all levels, crucially to the board and externally, and evaluating that feedback
- providing feedback to reporters that covers all types in the SAIFIR model, using available information technology, paper and face-to-face methods of communication
- making the content and format of feedback part of working systems, not a bolt-on, and having users evaluate it regularly
- providing feedback involving both information and action in all SAIFIR feedback modes, with much greater emphasis on modifying working practices, monitoring impact, and publicising the success of individuals and the organisation in improving patient safety.

10. Emerging thinking on patient safety and management

This section briefly describes emerging perspectives on patient safety and how to manage it. It does not comprehensively summarise these perspectives nor analyse their implications for patient safety reporting. Instead, these perspectives are included to highlight different ways of thinking about patient safety that will offer both opportunity and challenge for patient safety reporting in the future.

Continuous improvement of patient safety

The Health Foundation's recent report, *Continuous Improvement of Patient Safety*, makes the case for changing the way the National Health Service approaches patient safety. It argues that change is needed in: how safety is understood, because current approaches to measurement don't provide the full picture; how safety is improved, because existing approaches alone will not address the most intractable problems; and how risk is perceived, because comfort-seeking behaviours will not create a genuine culture of learning.[38]

The report paints a picture of what safer care might look like in the future:

> A safer care system is conceived from the perspective of the patient, following his or her journey through different care settings, irrespective of organisational boundaries. It is networked, so that successes and failures identified in one part of the system can be readily accessed, understood and built on in another. And it is judged not by the prevalence of adverse events, but by the ability to proactively identify hazards and risks before they harm patients.

Safety strategies for the real world

In recent books, *Safer Healthcare: Strategies for the real world* and *The Measurement and Monitoring of Safety*, Charles Vincent and his colleagues pick up many of the themes highlighted by The Health Foundation.

In *Safer Healthcare,* Vincent and Amalberti argue that current patient strategies need to be complemented by strategies aimed at managing risk in 'the real world'.[39] They suggest that most current safety initiatives are 'optimising strategies' – either attempts to improve the reliability of clinical processes or wider system improvement initiatives. In contrast, we have few safety strategies aimed at managing risk in the often complex and adverse daily working conditions of health care. Developing considered approaches to managing risk in such situations is a priority for the next phase of patient safety.

Vincent and Amalberti outline key five transitions that they believe are needed to move from the current vision of patient safety to the broader vision we need for the future (see Box 3).

Considering what these new directions mean for incident analysis, Vincent and Amalberti point to an urgent need to return to the original purpose of incident analysis, comprehensively investigate a much smaller number of events and consider the findings in the context of an overall safety and quality improvement programme. In their opinion, we can largely achieve this approach with the methods we already have. However, we also need to think about how we include events seen as harmful from a patient perspective (for example, poor communication) and how we reflect the importance of improving care over time.

To this end, Vincent and Amalberti propose a new approach to incident analysis (ALARME). This approach extends the current ALARM framework/London Protocol to consider contributing factors along the whole patient journey and pays attention to successes, failures, recovery and mitigation. It involves patients, family, and hospital and community practitioners (see Appendix E).

The authors also suggest that patients and families should select a proportion of incidents for analysis and be encouraged to contribute as much as they can to analyses. The patient perspective will help us to understand the longer-term safety problems and to develop new techniques and innovations.

Box 3: Transitions to a broader vision of patient safety[39]

1. **See safety through the patient's eyes:** Our current approach to patient safety assumes the quality of health care is generally high but occasional safety incidents and adverse events occur; this is a vision of safety from the perspective of health care professionals. In seeing safety through the patient's eyes, we would focus on overall coordination of care rather than isolated errors and incidents, and on the role of patients and families in monitoring and maintaining safety.

2. **Consider benefit and harm along the patient journey:** If we see safety through the patient's eyes, we must also see safety in the context of the patient journey. This means we need to examine episodes of care and consider both benefit and harm over an extended time.

3. **Achieve patient safety by managing risk over time:** Achieving patient safety involves minimising incidents but also managing risk over longer periods, which will require additional skills and methods. We accept in this vision that errors are inevitable but that, in a safe system, very few of those errors will have any consequences for the patient.

4. **Adapt a range of safety models:** Different health settings need to approach safety in very different ways. Because health care covers many different types of activity and clinical settings, we cannot use one primary model.

5. **Develop a wider range of safety strategies:** We should extend our safety strategies to include risk control, monitoring and adaptation, and mitigation.

Measuring and monitoring safety

A lack of reliable information on safety and quality of care may be holding back improvements in patient safety. Some authors believe that a move from unsystematic methods, such as voluntary reporting, towards systematic measures is needed.[40] In *The Measurement and Monitoring of Safety*, Vincent and colleagues propose a framework for measuring and monitoring safety that brings together several conceptual and technical aspects of safety.[24] The framework highlights the key dimensions that the authors believe any safety and monitoring approach should include to give a comprehensive and well-rounded picture of an organisation's safety. These dimensions respond to five critical questions about an organisation's safety.

1. Has patient care been safe in the past?
2. Are our clinical systems and processes reliable?
3. Is care safe today?
4. Will care be safe in the future?
5. Are we responding and improving?

The five dimensions themselves are as follows (see also Figure 1).

1. **Past harm** covers both psychological and physical measures. Incident reporting is one approach to measuring past harm. The authors note the need for more specific and nuanced measures of harm that can be tracked over time and can demonstrate whether health care is becoming safer.

2. **Reliability**, or 'failure-free operation over time', applies to measures of behaviour, processes and systems. For health care to be truly reliable, the authors suggest organisations need to look towards the ambitious goal of identifying and monitoring all processes that are critical to safety.

3. **Sensitivity to operations** is the information and capacity to monitor safety on an hourly or daily basis.

4. **Anticipation and preparedness** mean the ability to anticipate, and be prepared for, problems. As these concepts are relatively undeveloped in health care, both research and practice need to explore them further.

5. **Integration and learning** mean the ability to respond to, and improve from, safety information. Health care organisations take many different approaches to integrating and learning from the various sources of safety information. Whatever the approach, feedback, action and improvement are key elements in integration and learning. Health care organisations must balance collecting and integrating safety information with appraising how to use it to deliver meaningful feedback, action and improvement (see 'How do we close the feedback loop?' in Section 9).

Figure 1: A framework for safety measurement and monitoring[24]

Vincent and colleagues suggest 10 guiding principles for safety measurement and monitoring.

1. A single measure of safety is a fantasy.
2. Safety monitoring is critical and does not receive enough attention.
3. Approaches to safety should involve anticipation and be proactive.
4. Integration and learning: Invest in technology and expertise in data analysis.
5. Map safety measurement and monitoring across the organisation.
6. Blend externally required metrics with local development.
7. Be clear about purpose when developing safety measures.
8. Empower health care professionals and devolve responsibility for developing and monitoring safety metrics.
9. Regulators and the regulated must collaborate.
10. Beware of perverse incentives.

Transforming patient safety: a sector-wide, systems approach

Other authors echo the call to revisit patient safety concepts and approaches and renovate PSRS.

The World Innovation Summit for Health (WISH) Patient Safety Forum 2015 makes the case for a systems approach to patient safety.[41] The authors state that the goals of patient safety must be clearly stated, designed throughout the health care sector, and woven into health care system operations. This approach also needs to use tools (or enablers) to move health care from its current state into one that has eliminated preventable harm (including metrics), as well as to address system-level gaps (including risk assessment) (see Box 4).

Box 4: Enablers and system-level gaps for transforming patient safety[41]

Enablers

- Policy and regulation help rather than hinder safety improvements and keep up minimum patient safety standards.
- Patient safety is a core value of the culture.
- Leadership influences patient safety at all levels of health care.
- Education leads to informed decision-making and a resilient system.
- Transparency and open disclosure are professional expectations.
- Metrics are used to evaluate progress and success.
- Technology helps in providing health care without constraining it.
- Patient safety is sustainable.
- Patients and their families are engaged partners in achieving patient safety.
- Patient safety research considers the different disciplines of health care.

System-level gaps

1. **Holistic sector-wide approach:** Patient safety interventions must: evolve to work for the safety of the whole health system; be designed using a systems approach; be implemented using proven methods for large-scale organisational change; be tailored to local cultures and resources; and align the perspectives of strategy, operation and implementation.
2. **System integrators:** Health care must fully embrace a disciplined approach to patient safety that other industries have used. Each element of patient safety, such as legal, regulatory and technical systems, needs system integrators. In turn, these integrators must work together to create an overall integrated system of safety.
3. **Risk assessment and performance reporting:** PSRS require comprehensive and methodical analyses coupled with industry-wide learning and improvement, similar to programmes implemented in the aviation and transportation industries.
4. **Patient safety regulation:** Patient safety requires a regulatory body at the national or regional level that has legal powers to strongly enforce the system, along with standards of performance, robust data collection, and methodical analysis.
5. **Cross-disciplinary science for safety:** Research laboratories for health care that combine basic and applied research and development involving diverse fields of expertise must be created. Open business models for communicating their findings widely must also be supported.

Patient safety management models and systems

A 2011 Finnish report notes that safety concepts and how they are understood shape the success of efforts to manage and improve safety in health care, as in any other sector where safety is critical. Yet theoretical foundations are often unstated or unclear in patient safety research and development. The authors clarify basic concepts related to patient safety management as a first step towards developing a general model for patient safety management.[42]

- **Patient safety** (the desired result of safety management) is an organisation's ability to function safely. Safety comes from the way social and technological factors interact in an organisation. An organisation improves safety by creating good conditions for work, rather than just by constraining performance.
- **Safety model** represents patient safety as a phenomenon affected by the system and describes what makes a system safe or unsafe. A systemic approach considers both successes and failures to be inevitable in organisational behaviour. It emphasises non-

linear interactions, in which many parties and actions can contribute to an event at many different parts of a sequence.

- **Safety management model** should be in line with both the definition of patient safety and the safety model. It identifies the elements necessary to manage and improve patient safety. An organisation should consider safety together with the overall management of the organisation.

- **Safety management system** consists of the systematic organisational processes needed to steer the organisation to ensure and develop safety. An organisation must make it part of its management approach. It aims at both assessing and eliminating risks and ensuring the organisation has appropriate conditions for safety throughout its lifetime. It takes into account the specific characteristics of the organisation.

Renovating the NRLS and ideas for other national reporting systems

The *NRLS Research and Development* programme report describes the current state of patient safety incident reporting in the National Health Service. Building on NRLS research, it also suggests how systems like the NRLS can take advantage of developments in technology and understanding of human behaviour.[35]

The authors suggest improving the NRLS and related local reporting systems in the following ways.

- Differentiate national from local systems. At a national level, creating a working incident **reporting** system is an end in itself but in local systems it can also be a means to support a relevant **learning** system.

- Provide data about frequent incidents to local improvement bodies, which should continue to collect data on, assess and respond to common patient safety incidents ('casting the net wide and shallow').

- Specify a limited number of incidents for which reports will be collected nationally and collect structured and free-text data about them through a web portal.

- Nationally track patient safety incidents in priority areas like primary care, mental health and community care.

- Improve the reporting functions with features such as user-friendly interfaces, effective incident classification systems and new technologies for better platforms, feedback and analytics.

In future, incident reporting systems should use digital resources such as smartphone technology, so that staff can report in near real-time using a device they are accustomed to. From there, the organisation could then store this information in a Cloud-based system. It will also be important to build new systems based on behavioural insights from user-centred design with the aim of limiting the burden on staff and reducing human error. Designing a reporting system that invites staff to use it will be paramount (for example, making reporting interfaces visually pleasing, and providing an approachable amount of text and question fields). By taking advantage of these technological developments, the NRLS will be better placed to modernise and engage people more strongly in the reporting process. Box 5 briefly describes CareReport, a prototype, app-based incident reporting system that the authors of this report developed.

Box 5: CareReport[35]

- Provides a platform for collecting and storing staff reports about patient safety incidents, including a feedback loop between reporters and risk managers.

- Works online but has also been designed to operate as an app for smartphones or tablets capable of offline reporting.

- Requires a significantly reduced number of fields for reporters to complete.

- Has an interface based on behavioural insights to limit scope for human error and confusion (for example, the data is presented as a scroll-down menu rather than in free-text boxes). It includes a free-text box to allow reporters to give further details of the event.

- Uses natural language processing to automatically classify events described in free-text boxes based on a defined taxonomy.

- Provides a dashboard feature that automatically feeds is fed into an analysis system, which in turn can produce easy-to-understand graphs and charts.

- Directs learning from local safety initiatives to a national shared learning platform.

This brief overview of emerging thinking on patient safety and its management reminds us of the critical importance of a systems approach to patient safety and the need to see patient safety reporting in the context of a wider patient safety management system. It provides us with new ways of thinking about, understanding and measuring patient safety that better reflect the realities of today's health care systems and the role of patients. Finally, in view of all the work involved in renovating the United Kingdom's patient safety management system, it highlights and reinforces the critical issues for national-level PSRS.

11. Summary and key messages

This scan of overseas literature has explored a wide range of topics relating to patient safety reporting. It began by describing the introduction of PSRS to health care systems around the world and the challenges that have emerged since then: there is a shortage of evidence that PSRS are effective; PSRS objectives are unclear; PSRS are receiving large volumes of reports but these seem to be producing little action; and people face barriers to reporting. By setting out the characteristics of successful PSRS, outlining the role of national PSRS as distinct from local PSRS and detailing best-practice approaches to national and local PSRS, this report has highlighted some possible solutions to the challenges for PSRS and has answered some questions about PSRS. From the discussion of new ways of thinking about patient safety, coupled with information about approaches in other jurisdictions and planned directions, it further indicates how patient safety measurement might develop in the future.

The following clear directions have emerged from this review.

- Be clear about the distinct yet complementary roles of national versus local PSRS and design systems that take account of these different roles.
- Be clear about what role of a particular patient safety reporting system is. In particular, identify whether its primary focus is on learning or on reporting and accountability.
- Prioritise reports submitted at national level and, at both national and local levels, prioritise degree/level of investigation.
- Improve feedback. This is a critical dimension of a learning system and essential for motivating reporting.
- Take full advantage of new digital technologies, electronic health records and understanding of human behaviour to make reporting easier and more engaging and to improve the quality and effectiveness of data transfer and information sharing.
- Re-orient PSRS to put patients and their experience of health and the health care system at the centre.

This report has presented findings of a limited scan of overseas literature. It has not been possible to address all relevant aspects of the wider topic and some of the topics it has addressed broadly would benefit from more in-depth investigation.

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Appendix A: Patient safety reporting systems in overseas jurisdictions

	United Kingdom (England and Wales)[44]	Scotland[43,44]	Denmark[44]	British Columbia, Canada[44]	EU Member States[22]
Name of system	National Reporting and Learning System (NRLS) Patient Safety Domain of NHS England oversees the NRLS; The Imperial College Healthcare NHS Trust* administers it	No national PSRS NHS regional boards use standalone patient safety management system National Framework provides national approach to support providers to effectively manage adverse events; NHS boards are expected to adopt this Framework	Danish Patient Safety Database (DPSD) DPSD administered by National Agency for Patients' Rights and Complaints (independent government institution; also maintains complaints and compensation cases systems – the three are not linked)	No national PSRS for adverse events BC Patient Safety and Learning System (PSLS) (provincial)	
Reportable incidents	Any unintended or unexpected incident that could have led to harm (near miss) or did lead to harm for one or more patients receiving NHS-funded health care Includes never events Actual (not potential) level of harm must be reported Serious incidents	No common definitions National Framework: - All events that could have resulted in harm (near misses) or did result in harm to people or groups of people (patients, service users, staff) - Includes clinical and non-clinical events	Specified adverse events Includes near misses	All patient safety incidents including adverse events, near misses, safety hazards, patient complaints and claims	Definitions vary across Member States –for example: - severity of incident (Norway) - incident type (Hungary) - combination of incident severity and type (Denmark and Italy) - near misses only (Germany)

	United Kingdom (England and Wales)[44]	Scotland[43,44]	Denmark[44]	British Columbia, Canada[44]	EU Member States[22]
	(includes never events) must be reported on Strategic Executive Information System and to the Care Quality Commission via the NRLS				- broadly defined (NRLS)
Requirement to report	Voluntary Mandatory for serious incidents NHS organisations 'obliged' to report patient safety incidents to NRLS	Voluntary Specific adverse events required to be reported to national or UK-level systems National Framework - Mandatory for specified events for NHS boards	Mandatory for specified adverse events for health professionals (provided for in legislation)	Voluntary Mandatory for serious events	Mix of mandatory and voluntary systems
People who report	Health professionals Health organisations Patients and relatives Public	Health professionals	Health professionals Patients and relatives	Health professionals Patients and relatives	Varies: health professionals, health organisations, patients, relatives, public
Mode of reporting	Anonymous and confidential (NHS trust identifier maintained)	Anonymous reporting available in some NHS boards	Anonymous reporting available but discouraged; identifying oneself seen as expression of confidence in 'just culture' and the reporting system	Anonymous reporting available but discouraged; identifying oneself seen as expression of confidence in 'just culture' and the reporting system	Different approaches to keeping incidents confidential and anonymous

	United Kingdom (England and Wales)[44]	Scotland[43,44]	Denmark[44]	British Columbia, Canada[44]	EU Member States[22]
Incident classification	Own classification system, closely aligned with World Health Organization's International Classification for Patient Safety Incident types classified into categories (eg, patient accident, treatment, procedure) and by degree of harm (no harm, mild, low, severe, death)	No common classification National Framework: - Incidents categorised on impact of harm: (1) permanent harm; (2) temporary harm; (3) no harm	Danish classification system, similar to International Classification for Patient Safety Categories of severity: no harm, mild harm, moderate harm, serious harm, death	Modified version of International Classification for Patient Safety	Several Member States draw on International Classification for Patient Safety
Report form	e-forms for health professionals, the patients and public	National Framework: - Electronic - Minimum information set	Electronic	Patient's view	Data sets exchanged between local and central level PSRS vary across Member States but data set outlined in Table 4 is usually the minimum
Incident analysis	Local analysis All serious incidents investigated through Patient Safety Domain, including incidents that offer potential for national learning or represent new or	Local analysis by NHS boards National Framework: - All adverse events subject to review - Guidance provided on level of review and review process	Local analysis National Agency for Patients' Rights and Complaints: - Analyses more serious incidents at national level - Conducts specific		Most Member States use an epidemiological analysis model, including root cause analysis

	United Kingdom (England and Wales)[44]	Scotland[43,44]	Denmark[44]	British Columbia, Canada[44]	EU Member States[22]
	emerging risks	(including standardised approach to writing adverse event review reports[1]) Human factors approach emphasised	analyses based on alerts and special focus areas		
Data transfer from local to national PSRS	Online reporting direct to NRLS or through local NHS organisation (reports can be uploaded from local risk management systems to NRLS or submitted via NRLS e-form)	No national measurement around adverse events	Online; direct to the national database Reports are automatically forwarded to the county where the event occurred, where reports are recorded, analysed and de-identified, and to the National Board of Health, which keeps a register of adverse events	Online reporting to central database	Almost all Member States have online reporting, often in combination with paper reporting. Hungary has a reporting app that can be used on any internet-enabled device
Care settings	Available to NHS-funded health care organisations, including primary care and pharmacies	NHS boards only National Framework: - Intention to cover all care settings (initially focused on acute care)	Available across care spectrum, including private providers	Available across care spectrum, including private providers	Some Member States include care settings other than hospitals

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[1] www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/adverse_events_consultation1.aspx

	United Kingdom (England and Wales)[44]	Scotland[43,44]	Denmark[44]	British Columbia, Canada[44]	EU Member States[22]
Other data sources	Data sharing agreements NRLS data triangulated with other data sources	NHS boards share information with different national and UK agencies	Data sharing agreements	Participation agreements between PSLS and health authorities govern data flows	
Learning	Safety alerts (shared via National Patient Safety Alerting System) Organisational-level patient safety incident reports NRLS data published online Plans to report never events six-monthly	Safety alerts No national reporting Community of Practice aims to share tools and key learnings from adverse event reviews	Safety alerts Various information sharing channels used by DPSD Danish Patient Safety Agency required under legislation to share learnings from system nationally and with other agencies	Safety alerts Various reports published through BC PSLS publications My Reports supports quick analysis of incidents and issues Online blog available to the public	
Other	NHS England Patient Safety Concern process – framework to share and manage patient safety concerns, as identified by Patient Safety Domain, at regional level Quality Surveillance Groups coordinate patient safety intelligence National Patient Safety	National Framework promotes a just and positive safety culture Community of Practice website supports sharing of good practice	Focus on 'just culture', supported in legislation Danish health system supplements patient safety information from DPSD with other tools and methods (eg, audits using IHI Global Trigger tool, patient safety walkarounds)	Focus on 'just culture', supported in legislation PSLS comprises online modules and tools: Safety Events (primary module); Complaints; Claims; Safety Alerts; Risk Register; Recommendations	

	United Kingdom (England and Wales)[44]	Scotland[43,44]	Denmark[44]	British Columbia, Canada[44]	EU Member States[22]
	Alerting System (NPSAS) alerts NHS organisations to risks and provides guidance on potential patient safety incidents				
Developments	Patient Safety Incident Management System project – redeveloping patient safety management system, due 2016/17 Healthcare Safety Investigation Branch, operating since April 2016, offers support and guidance to NHS organisations on investigations, and carries out certain investigations itself Work underway to support non-acute sectors of health care to report more	Long-term aspiration to have a national system for sharing learning from adverse events National Information and Intelligence Framework for Health and Social Care – Scottish government's strategic framework for sharing patient safety data and intelligence for 2014 to 2020	Approach to information and knowledge sharing is under review; Knowledge Platform being developed	National System for Incident Reporting (which collects medication incident data) is expected to expand to provide Canada-wide adverse event reporting system Working on development of indicators for patient safety-related measures	

* The National Patient Safety Agency, which has recently been disestablished, previously managed the NRLS. NHS England's Patient Safety Domain has taken over its key functions.

Appendix B: Five general modes of feedback for incident reporting systems, with examples

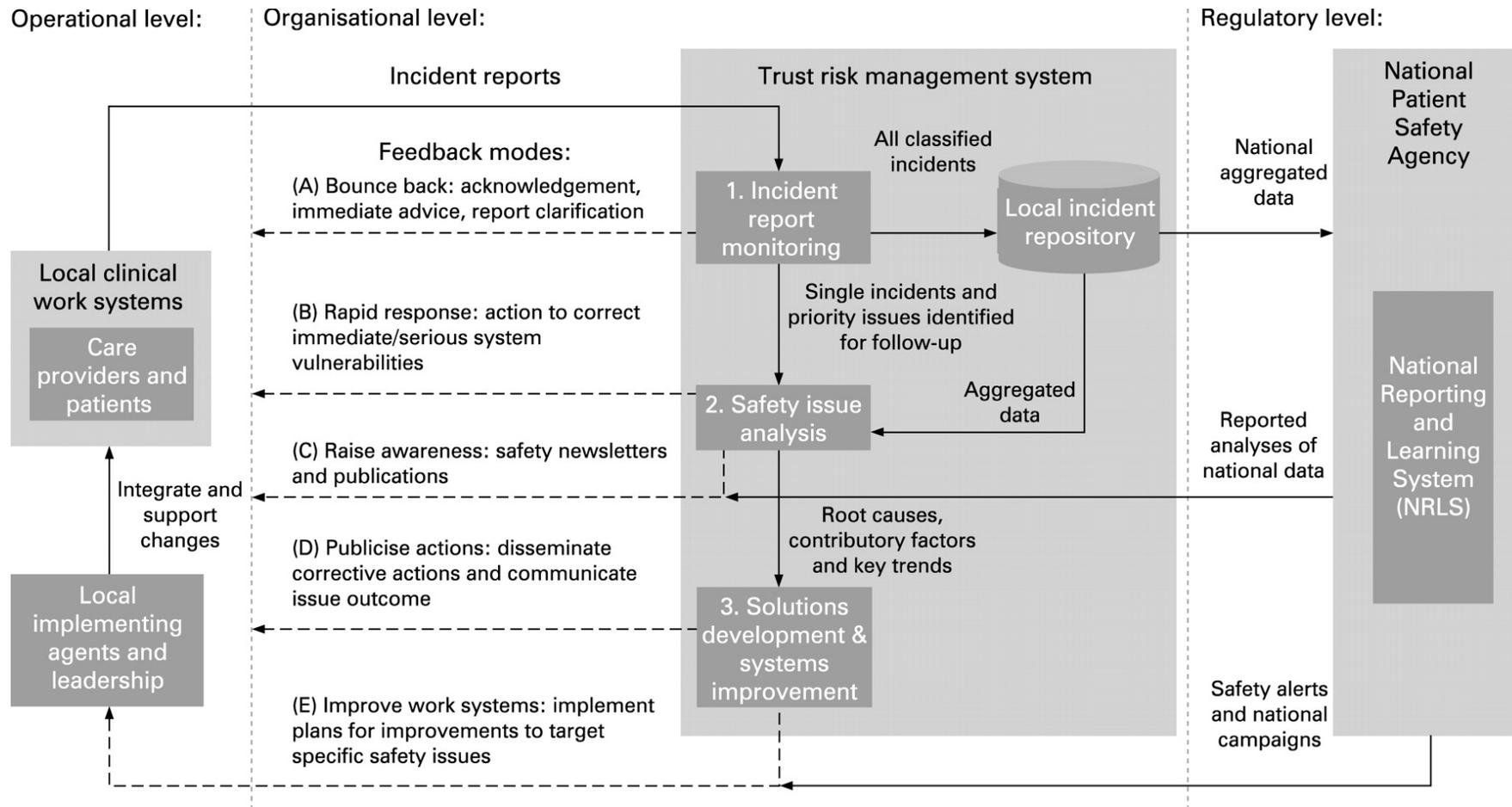| Mode	Type	Content and examples
A. Bounce back	Information to reporter	Acknowledge report filed (eg, automated response)
		Debrief reporter (eg, telephone debriefing)
		Provide advice from safety experts (feedback in issue type)
		Outline issue process (and decision to escalate)
B. Rapid response	Action within local work systems	Measures taken against immediate threats to safety or serious issues that have been marked for fast-tracking
		Temporary fixes/workarounds until in-depth investigation process can be completed (withdraw equipment; monitor procedure; alert staff)
C. Raise risk awareness	Information to all frontline personnel	Safety awareness publications (posted/online bulletins and alerts on specific issues; periodic newsletters with example cases and summary statistics)
		Highlight vulnerabilities and promote correct procedures
D. Inform staff of actions taken	Information to reporter and wider reporting community	Report back to reporter on issue progress and actions resulting from their report
		Widely publicise corrective actions taken to resolve safety issue to encourage reporting (eg, using visible leadership support)
E. Improve work systems safety	Action within local work systems	Specific actions and implementation plans for permanent improvements to work systems to address contributing factors evident in reported incidents
		Changes to tools, equipment, working environment, standard working procedures, training programmes etc
		Evaluate and monitor effectiveness of solutions and repeat

Source: NIHR Imperial Patient Safety Translational Research Centre. 2016. *NRLS Research and Development*. A report prepared for NHS England. URL: www.imperial.ac.uk/media/imperial-college/institute-of-global-health-innovation/IMPJ4219-NRLS-report_010316-INTS-WEB.pdf (accessed 18 June 2016).

Appendix C: Fifteen system requirements for effective safety feedback for incident reporting

1. Feedback at multiple levels of the organisation or system

2. Appropriateness of mode of delivery or channel for feedback

3. Relevance of content to local work place and systems

4. Integration of feedback within the design of safety information systems

5. Control of feedback and sensitivity to information requirements of different user groups

6. Empowering frontline staff to take responsibility for improving safety in local work systems

7. Capability for rapid feedback cycles and immediate comprehension of risks

8. Direct feedback to reporters and key issue stakeholders

9. Feedback processes are established, continuous, clearly defined and commonly understood

10. Integration of safety feedback within working routines of frontline staff

11. Improvements made within local work systems are visible

12. Frontline personnel consider the source and content of feedback to be credible

13. Feedback preserves confidentiality and fosters trust between reporters and policy developers

14. Visible senior-level support for systems improvement and safety initiatives

15. Double-loop learning to improve the effectiveness of the organisation's safety-feedback process

Appendix D: Framework for safety action and information feedback from incident reporting

Operational level: | Organisational level: | Regulatory level:

Incident reports — Trust risk management system — National Patient Safety Agency

Feedback modes:

(A) Bounce back: acknowledgement, immediate advice, report clarification

(B) Rapid response: action to correct immediate/serious system vulnerabilities

(C) Raise awareness: safety newsletters and publications

(D) Publicise actions: disseminate corrective actions and communicate issue outcome

(E) Improve work systems: implement plans for improvements to target specific safety issues

Local clinical work systems — Care providers and patients

Local implementing agents and leadership

Integrate and support changes

1. Incident report monitoring

2. Safety issue analysis

3. Solutions development & systems improvement

All classified incidents

Local incident repository

Single incidents and priority issues identified for follow-up

Aggregated data

Root causes, contributory factors and key trends

National aggregated data

Reported analyses of national data

Safety alerts and national campaigns

National Reporting and Learning System (NRLS)

Source: NIHR Imperial Patient Safety Translational Research Centre. 2016. *NRLS Research and Development.* A report prepared for NHS England. URL: www.imperial.ac.uk/media/imperial-college/institute-of-global-health-innovation/IMPJ4219-NRLS-report_010316-INTS-WEB.pdf (accessed 18 June 2016).

Appendix E: Analysis of safety along the patient journey
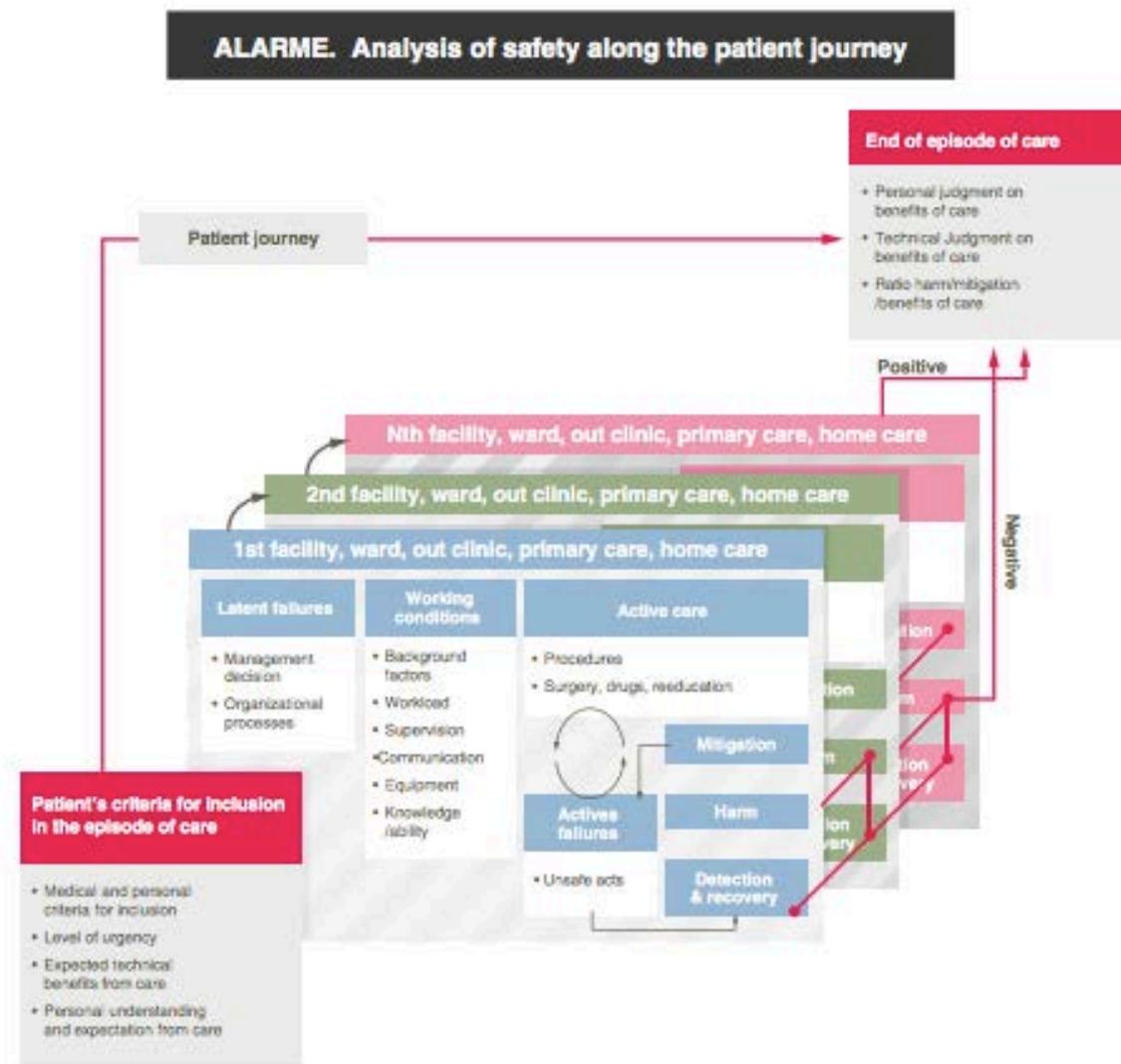
Source: Vincent C, Amalberti R. 2016. *Safer Healthcare: Strategies for the real world*. URL: http://link.springer.com/book/10.1007/978-3-319-25559-0 (accessed 16 June 2016).