International recommendations for national patient safety incident reporting systems: an expert Delphi consensus-building process

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ABSTRACT

Background Patient safety incident reporting systems (PSRS) have been established for over a decade, but uncertainty remains regarding the role that they can and ought to play in quantifying healthcare-related harm and improving care.

Objective To establish international, expert consensus on the purpose of PSRS regarding monitoring and learning from incidents and developing recommendations for their future role.

Methods After a scoping review of the literature, semi-structured interviews with experts in PSRS were conducted. Based on these findings, a survey-based questionnaire was developed and subsequently completed by a larger expert panel. Using a Delphi approach, consensus was reached regarding the ideal role of PSRSs. Recommendations for best practice were devised.

Results Forty recommendations emerged from the Delphi procedure on the role and use of PSRS. Experts agreed reporting system should not be used as an epidemiological tool to monitor the rate of harm over time or to appraise the relative safety of hospitals. They agreed reporting is a valuable mechanism for identifying organisational safety needs. 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. Consensus recommendation was for hospitals to take responsibility for creating safety solutions locally that could be shared nationally.

Conclusions We obtained reasonable consensus among experts on aims and specifications of PSRS. This information can be used to reflect on existing and future PSRS, and their role within the wider patient safety landscape. The role of PSRS as instruments for learning needs to be elaborated and developed further internationally.

INTRODUCTION

The integration of patient safety reporting systems (PSRS) in healthcare organisations stemmed from a desire to achieve the level of resilience and response to error that has been achieved in other industries, such as aviation.[1 2] In the USA, the Aviation Safety Reporting System is central to risk management and the benefits in this context are well described.[3] Seeing this, and other 'success stories' for reporting, in 2004 the Institute of Medicine, which was the US non-governmental advisory body (now the National Academy of Medicine), recommended the national adoption of PSRS.[4 5] Proposed as a key method to gain understanding of patient safety risks in hospitals, PSRS now exist in healthcare systems internationally—including the Advanced Incident Management System run by the Australian Patient Safety Foundation in South Australia and the Danish Patient Safety Database.[6 7] In the UK, the National Patient Safety Agency established the National Reporting and Learning System (NRLS) in 2003. This database has grown and currently receives >1 million reports per year in England.[8] Many governments are now making PSRS a mandatory requirement for hospitals.[9 10]

The premise of PSRS in healthcare, as in other industries, is that they allow the regular recording of patient safety

incidents captured by healthcare providers at the frontline of service delivery. Incident reports have the potential to provide insights into patient harm and allow the development of preventative strategies.[11] The aims of PSRS were initially broad: monitoring levels of harm, identifying rare events and rapidly disseminating knowledge about high-risk processes of care. The intent was for PSRS to be 'blame-free', used for learning, solution generation and designed to foster a cycle of improvement.

Reporting has had relatively rapid uptake internationally. This success may reflect considerable organisational drives to improve patient safety and contribute to a learning culture among healthcare professionals. There are many examples of instances where the effective use of PSRS has enhanced safety or provided greater understanding of system weakness or failure.[12–15] Encouraging staff to report and creating an environment where mistakes are treated as opportunities for learning and solution development are critical in enhancing patient safety. A key premise of reporting has been that detecting harm, especially when deemed preventable, can trigger safety initiatives and interventions, such that similar safety incidents do not reoccur in the future.[16]

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.[17] Despite such guidelines, concern remains that the objectives of PSRS are not clear.[18] Considerable investment and resources have been devoted to reporting—including major drives to increase the volume of reported incidents.[19] Focusing on increasing reporting rates in isolation is likely to create new challenges—a significant increase in the number of reports would more than likely result in a bottleneck in which a large proportion of reports simply 'get lost' in the system. Thus, if the aim of PSRS is to promote learning and to improve patient safety, achieving it is compromised by the heterogeneity and volume of incidents.[16] A recent interview study of safety experts by Mitchell *et al* suggested systems were overwhelmed by the unprecedented volume of incidents collected that were impossible to process.[20]

Critically for PSRS, over a decade since reporting began at large scale, it is unclear whether hospitals are indeed safer.[21–23] More incidents are reported each year—however, increased reporting rates likely reflect increased awareness of patient safety incidents rather than more occasions of unsafe care. Such awareness may be enhanced for those incidents that occur more regularly and are easy to define, including patient falls and drug errors. Often, these incidents do not actually result in patient harm. Documenting the causal or contributing factors to such patient safety incidents through a 'system-failures' approach provides more actionable data.[17 18] These include reports of diagnostic delay, faulty processes, communication problems and staffing shortages. Even though a vast number of reports are collected annually, if the detection of all adverse events is the overall aim of PSRS, then this aim has not been achieved. Despite increased awareness, large PSRS, such as the NRLS in England, still underestimate the incidence of adverse events, detecting only 5% of incidents leading to harm.[24]

With increasing demand from government bodies and the public to be more transparent about healthcare-related harm, it is important to consider whether PSRS can provide monitoring, enhance learning from errors and generate solutions—as they have achieved in other industries.

The objective of this study is to gain consensus from academic experts regarding the role of PSRS in monitoring and learning from hospital safety incidents.

METHODS

A multimethod, multiphase approach was adopted to establish expert-derived recommendations on patient safety incident reporting. The Delphi consensus methodology, as described by Jones and Hunter,[25] was employed and is described in detail below. Certain terms are used in this study that should be defined. '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.[26] 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.[27 28] 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.[29]

Stage 1: literature review and expert identification

A scoping review of the literature was conducted to understand the evidence base, develop research questions relevant to PSRS and identify academic experts in the field. The following keywords were used in combinations with the Boolean terms AND and OR: patient safety (AND) reporting systems (OR) voluntary reporting (OR) incident reporting were searched in PubMed in May 2013. In addition, the reference lists of the relevant articles were hand-searched to identify any additional articles/experts. The experts identified were then screened to meet the inclusion criteria.

Experts were identified through peer-reviewed publications using a previously specified method for consensus-driven recommendation development.[30] Experts were invited to participate in the interview stage of the Delphi if they met three inclusion criteria. The first requirement for inclusion was publication of

over six peer-reviewed articles in English on PSRS. The second requirement was expertise in the development, management or evaluation of a reporting system. The final prerequisite was a role at a national level for patient safety. Academic experts who had published ≥3 peer-reviewed articles on reporting systems were identified and invited to participate in the expert Delphi consensus panel (stages 3 and 4). The primary researcher (A-MH) reviewed all identified articles to outline the main areas of academic debate regarding the role of PSRS. These were addressed in the second stage of the Delphi process using semi-structured interviews.

Stage 2: semi-structured interviews with incident reporting system experts

Fifteen international experts were identified and invited to participate in this stage. Of these, 14 experts (93.3%) agreed to participate. An interview topic guide was developed by a team of clinicians (A-MH, EMB, EM) and psychologists/patient safety experts (LH, NS) (see online supplementary appendix 1). One pilot interview was conducted with a member of the research team and expert in PSRS (NS) to ensure relevance and clarity. Piloting resulted in expanding the theme regarding accountability for error in healthcare. All interviews were semi-structured in nature, were conducted by A-MH (3 in person, 10 by telephone and 1 conducted via email exchange) and were recorded and transcribed verbatim. The interview topic guide was structured around three key themes derived from the literature:

1. What can reporting systems achieve? What are the strengths and weaknesses of using PSRS to monitor and/or learn from healthcare errors?
2. How can national reporting systems, such as the NRLS, be improved to maximise their utility?
3. What incidents should be prioritised for reporting? Who should be accountable for analysis, investigation, feedback and solutions based on reported incidents?

Thematic analysis

All interviews were analysed thematically to identify emergent themes by the primary researcher. The thematic analysis incorporated a deductive and inductive approach; topics/themes explored in the semi-structured interviews were used as a template to guide the deductive thematic analysis;[31] additional themes that emerged were identified using an inductive approach.[32] A second reviewer with expertise in qualitative methodology (LH) analysed a subset (3/14) of the interviews to ensure consistency in theme extraction and reduce bias.

Stage 3: Delphi survey round 1

The themes that emerged from the expert interviews were used to inform the development of the Delphi survey. The survey was developed and piloted with patient safety experts (LH, NS, EM) to assess content and flow, as well as comprehension and clarity of questions. The survey was administered electronically via Qualtrics survey software (http://www.qualtrics.com). In total, the survey contained 58 statements, which experts were required to state their level of agreement, either using 5-point Likert scales for agreement or multiple-choice options. The survey was emailed to a wider panel of 30 experts (including the original 14 interviewees) based on their peer-reviewed publications. Two separate reminder emails were sent at two weekly intervals. Likert scores were analysed as follows: where the response was 'agree' or 'strongly agree' the response was classed as 'agree', whereas the responses 'neutral', 'disagree' or 'strongly disagree' were classed as 'disagree'. Consensus was set a priori at 70% agreement for a statement to be included as a recommendation, as per standard Delphi method criteria.[33] Experts were invited to provide free-text comments for each question in order to better understand the rationale behind their responses.

Stage 4: Delphi survey round 2

Responses to the questions received within round 1 of the Delphi were analysed and then individually fed back to each expert in round 2—alongside their own responses. For example, if an expert agreed with a statement, they would be reminded of this and shown a chart showing what percentage of the panel also agreed versus those who disagreed or were neutral. This allowed the experts to see their response as well as the responses of the rest of the panel without knowing the identity of the individuals represented. They were then asked the same question again and were able to keep their original answer or modify it. This approach allowed participating experts to review their prior responses and also to change them in light of what their peers had responded. The analysis of Likert scales was performed as described for round 1.

RESULTS

Literature review and semi-structured interview

The 14 experts who had published ≥6 peer-reviewed publications related to PSRS and took part in this study represent an international body of experts in reporting systems across five countries (table 1). Together, they had published 90 peer-reviewed papers on PSRS at the time of the study.[5–7 9 11 16 21 29 34–116] The median interview length was 41.0 min (IQR 12.8 min). Eight main themes for subsequent Delphi consensus were generated with 58 questions regarding specific issues in reporting.

In the interviews, the experts discussed a broad range of issues related to reporting. They identified the demands placed on reporting systems to provide both a learning platform and a surveillance system. They addressed the burden of numerous different types of incidents that could be reported and

Table 1 Semi-structured interview expert panel (listed alphabetically)

Expert	Institution	Role	Patient safety and reporting system expertise	Country
Professor James Bagian	Ann Arbor University of Michigan	Director of Center for Healthcare Engineering and Patient Safety	▶ Chief Patient Safety Officer and Founding Director of the National Center for Patient Safety for Department of Veterans Affairs 1999–2010 ▶ NASA Aerospace Advisory Panel 2006–2014 ▶ Over 10 years experience in developing reporting systems	USA
Professor G. Ross Baker	University of Toronto	Professor of Health Policy, Management and Evaluation	▶ Professor and Program Director, MSc. Quality Improvement and Patient Safety Institute of Health Policy, Management and Evaluation ▶ Steering Committee Member for Safer Healthcare Now (National Patient Safety Program) 2005–2010 ▶ Co-Chair Methods and Measures for Patient Safety WHO 2005–2009	Canada
Professor David Bates	Harvard Medical School	Professor of Medicine Professor of Health Policy and Management	▶ Chief Quality Officer Brigham and Women's Hospital 2011–2014 ▶ President of the International Society for Quality in Healthcare 2013–2014 ▶ Chairman of the American Medical Informatics Association 2008–2009	USA
Professor Liam Donaldson	Imperial College London	Chair in Health Policy	▶ WHO envoy for patient safety ▶ Chief Medical Officer for England 1998–2010 ▶ Chairman of the National Patient Safety Agency and Founder of the National Reporting and Learning System	UK
Professor Wilson Pace	University of Colorado	Professor of Family Medicine	▶ Director of DARTNet (research network that includes electronic health records, claims and patient outcomes) ▶ Committee for Institute of Medicine: studying medication errors ▶ Taxonomy development for adverse events	USA
Professor Peter Pronovost	Johns Hopkins School of Medicine	Professor of Anesthesiology and Critical Care Medicine, Surgery, Nursing	▶ Chairman of ICU Advisory Panel for Quality Measures of the Joint Commission ▶ Chairman of the ICU Physician Staffing Committee for the Leapfrog Group ▶ Member of the Quality Measures Work Group of the National Quality Forum ▶ Senior Vice President for Patient Safety and Quality and Director of the Armstrong Institute for Patient Safety and Quality Johns Hopkins	USA
Professor Bill Runciman	University of South Australia	Professor of Patient Safety and Healthcare Human Factors	▶ President of the Australian Patient Safety Foundation 1988–2014 ▶ Founder of the Advanced Incident Management System (national incident system) ▶ On the Australian Council for Safety and Quality in Health Care and the Australian Health Information Council	Australia
Professor Kaveh Shojania	University of Toronto	Director of the Center for Quality Improvement and Patient Safety	▶ Canada Research Chair in Patient Safety and Quality Improvement ▶ Associate Professor, Department of Medicine, University of Toronto ▶ Editor-in-chief, *British Medical Journal Quality & Safety*	Canada
Professor Andrew Smith	University of Lancaster	Professor of Clinical Anaesthesia	▶ Director of the Lancaster Patient Safety Research Unit ▶ Part of the joint National Patient Safety Agency/Royal College of Anaesthetists' 'Safe Anaesthesia Liaison Group' ▶ Involved in producing the Helsinki Declaration on Patient Safety in Anaesthesiology	UK
Professor Charles Vincent	University of Oxford	Health Foundation Professor, Department of Experimental Psychology	▶ Involved in implementation and advisor for the National Reporting and Learning System ▶ Director of the National Institute of Health Research Center for Patient Safety & Service Quality at Imperial College Healthcare Trust. ▶ Commissioner on the UK Commission for Health Improvement 1999–2003	UK

Continued

Table 1 Continued

Expert	Institution	Role	Patient safety and reporting system expertise	Country
Professor Robert Wachter	University of California	Professor and Associate Chairman of the Department of Medicine	▶ Lead for the AHRQ Patient Safety Network ▶ Chair of the American Board of Internal Medicine 2013–2014 ▶ Member of the Board, Lucian Leape Institute of the National Patient Safety Foundation.	USA
Professor Cordula Wagner	VU University Medical Center	Professor of Patient Safety	▶ Head of Quality and Organization of hospital- and long-term care at NIVEL Netherlands Institute for Health Services Research ▶ Responsible for the National Patient Safety Research Program in the Netherlands ▶ Head of the patient safety research centre 'Safety 4 Patients', a collaboration of EMGO+ and NIVEL	Netherlands
Dr. Saul Weingart	Tufts Medical Center	Chief Medical Officer and Senior Vice President of Medical Affairs	▶ Vice President for Quality Improvement and Patient Safety Dana-Farber Cancer Institute ▶ Chair of the Board of Governors at the National Patient Safety Foundation ▶ Editorial advisory boards of the Joint Commission Journal on Quality and Patient Safety	USA
Professor Albert Wu	Johns Hopkins Bloomberg School of Public Health	Professor of Health Policy and Management and Medicine	▶ Director, Center for Health Services and Outcomes Research ▶ Member of the Institute of Medicine committee on identifying and preventing medication errors ▶ Senior Adviser for Patient Safety to WHO 2007–2009	USA

discussed how inclusive systems should be. There was enthusiastic discussion about ways in which to improve reporting quality and the importance of embedding reporting into the culture of hospitals, stressing that reporting should be used for system improvement and not punishment of individuals. There were mixed views regarding the optimum ways to collect data and feed back to staff. Some experts had a hospital-focused perspective, whereas others were nationally centred with respect to where reports should be collated. All experts agreed the responsibility for improvement lay with the hospitals.

From these interviews, seven topic areas for the subsequent Delphi expert review were generated as follows:

1. roles that reporting systems can achieve
2. roles reporting systems cannot fulfil
3. methods to maximise learning and feedback from reporting systems
4. the role of national and local data collection and safety solutions
5. voluntary versus mandatory data collection
6. investigation of incidents and accountability
7. staff training in reporting and investigating incidents.

Delphi survey

A total of 60 experts were invited to complete the Delphi survey of whom 30 agreed to participate (50% response rate). Of these, 90% had >10 years expertise in incident reporting and 87% had been involved in the development of an incident reporting system. Interestingly, the median number of published papers on reporting was higher among those experts who agreed to take part than those who did not (median=4, IQR: 3, vs median=3, IQR 1; p=0.003). Significantly more experts from English-speaking countries agreed to participate than experts from non-English-speaking countries (100% vs 86.7%, p=0.038).

After the first round, experts reached consensus (>70% agreement) on 25 statements regarding the purpose and remit of national PSRS. All 58 statements including the consensus statements were included into the second round to check for consistency of response and to increase levels of consensus.

In total, 26/30 (87%) experts completed the second round of the survey. From the 58 questions, 40 reached formal consensus and formed the expert-derived recommendations of this part of the study (table 2). A further seven statements achieved >65% consensus, thus approaching the set 70% criterion; finally, 11 statements remained unresolved with no clear agreement at the end of the Delphi (table 2).

Role of reporting systems

Experts agreed that the incidents reported to PSRS should be used to identify the type of safety problems that exist and to detect rare events not identified by other methods (96.4% and 92.3%, respectively) (box2). PSRS should ideally be used to share safety solutions between hospitals. Shared learning was identified as a primary role of reporting (92.3% agreed). Experts recommended that for selected rare types of events such as 'never events' (defined within the National Health Service (NHS) in England as serious incidents that are wholly preventable), mandatory reporting could be used to detect the incidence (73.1% agreed).[117]

Table 2 Recommendations for national patient safety incident reporting systems

No.	Recommendation	% Consensus (n=26)
Role of reporting systems		
1.	Reporting systems should be used to identify the types of safety problems that exist	96.2
2.	Reporting systems should be used to detect rare events not picked up by other methods	92.3
3.	Reporting systems should be used to share learning between hospitals	92.3
4.	Reporting system data should be used as indicators of the safety culture of a hospital	80.8
5.	Mandatory system reporting systems should be used to measure the rate of specific types of reported harm (eg, wrong site surgery) in a hospital	73.1
Roles reporting systems cannot fulfil		
6.	Reporting systems are a not a valid and reliable measure of how safe a hospital is	80.8
7.	Reporting system data should not be used to measure the national incidence of harm (eg, within the national health service)	76.9
	Reporting systems should not be used to identify unsafe hospitals	*69.0*
	Voluntary system reporting systems should not be used to measure the rate of harm in a hospital	*65.4*
	Reporting systems should not be used to identify unsafe healthcare professionals (eg, doctors and nurses)	*65.4*
Methods to maximise learning from reporting systems		
8.	Near misses or no harm events should be reported	96.2
9.	Anonymous reporting data should be readily available to research groups for analysis	92.3
10.	Incident reports should be used in educational programmes for trainees to promote quality improvement	92.3
11.	Incident classification systems should be standardised to/allow comparisons	84.6
12.	Minimum data set should include hospital number, patient age, time/date and location of incident and specialty caring for patients	84.6
13.	Staff should be encouraged to propose solutions for events at the time of the report	84.6
14.	Reports should contain patient identifiers so they can be linked to other data sets	73.1
15.	There should be national priorities for reporting certain events	77.0
16.	The quality of incident reports submitted to a reporting system is more important for learning than the quantity of reports	77.0
17.	All reporters should have the option to keep their report anonymous so that they are not identified	73.1
	Minimum data set should include national identifying number (eg, NHS number or social security number)	*53.8*
	Fewer and better described incidents should be encouraged compared to more and less well described	*42.3*
	Minimum data set should include the consultant or attending involved in patient care or attending in charge of care	*42.3*
Where different types of incidents should be reported		
18.	Hospitals should submit their solutions to safety problems nationally for shared learning	88.0
19.	Device incidents should be reported both nationally and locally	88.0
20.	Never events should be reported both nationally and locally	88.0
21.	Hospital-acquired infections should be reported both nationally and locally	80.8
22.	Medication incidents should be reported both nationally and locally	76.9
23.	Staff shortages should be reported locally only	72.0
24.	Initiatives to prevent harm should be generated at a hospital level	72.0
25.	Incidents that lead to harm should be reported both nationally and locally	77.0
	Reports should objectively classify what harm was caused and not the potential for harm	*65.3*
	There should be specific criteria for what to report	*65.4*
	Reports of misconduct by other healthcare professionals should be reported locally only	*61.5*
	Events from morbidity and mortality meetings should be reported to a national system	*46.2*
	Complaints about other members of staff or staffing issues should NOT be reported to a national system	*46.2*
	Near misses should be reported locally only (other options: nationally or nationally and locally)	*42.3*
	Professional misconduct incidents should be reported locally only (other options: nationally or nationally and locally)	*42.3*
Voluntary and mandatory data capture		
26.	There should be mandatory reporting of never events or serious events such as wrong site surgery	92.0
27.	Near misses should be captured by a voluntary system	88.0
28.	Medication incidents should be captured by a voluntary system	80.8
29.	Device incidents should be captured by a mandatory system	80.8
30.	Hospital-acquired infections should be captured by a mandatory system	77.0
	Staff shortages or risk assessments should be captured by a voluntary system	*53.8*

Continued

Table 2 Continued

No.	Recommendation	% Consensus (n=26)
Investigation of incidents and accountability		
31.	Hospitals should have an executive board member responsible for patient safety	100
32.	Hospitals should be accountable for investigating their own reports	84.6
33.	Hospitals should not determine their own reporting priorities	84.6
34.	Reporting systems should give individual feedback to reporters	84.6
35.	Never events and incidents leading to death and severe harm should be prioritised for investigation	80.8
36.	Reporters who report deaths should receive specific feedback after analysis	80.8
37.	Reporters who report never events should receive specific feedback after analysis	76.9
38.	Analysis of all incident types is desirable; however, near miss incidents are less of a priority for investigation than never events and incident leading to death and severe harm	73.1
	Reporters who report device incidents should receive specific feedback after analysis	*69.2*
	Clinical teams external to the hospital should investigate reports of severe patient harm	*61.5*
	Who should provide feedback for harm or death incidents (multiple-choice options):	
	National patient safety experts	*34.6*
	External investigating clinician	*30.8*
	Consultant/attending involved in patient care	*26.9*
	Local risk manager	*7.7*
Staff training		
39.	Greater emphasis needs to be placed on training staff to identify and report safety incidents	80.8
40.	Senior nurses, doctors, managerial staff and other healthcare professionals should be trained to routinely investigate patient/safety incidents	73.1
	Junior nurses, administration staff and medical students should be trained routinely to investigate patient safety incidents	*65.3*

Italicised statements indicate areas not reaching consensus.

Roles reporting systems cannot fulfil

The expert panel considered what were the most valid and reliable methods for measuring the rate of harm or error within a hospital or health service (box 1). The majority (80.8%) of participants agreed that prospective observation of care processes was the most robust method of six methods considered. These methods included expert, retrospective case-note review, trigger tool-based case-note review, electronic database record monitoring such as Hospital Episode Statistics (HES) or/Agency for Healthcare Quality (AHRQ) Patient Safety Indicators (PSIs),[i] voluntary reporting and mandatory reporting. There was substantial agreement that data obtained from PSRS are not a reliable or valid measure of the safety of a hospital or the incidence of patient harm (80.8% and 76.9%, respectively). Similarly, the expert panel approached consensus that PSRS data should not be used to identify unsafe hospitals or to identify unsafe healthcare professionals (69·0% and 65·4%, respectively).

Methods to maximise learning from reporting systems

Ten recommendations were made by the expert panel to improve patient safety incident data capture and maximise the potential for learning from reported patient safety incidents (box 2). These recommendations included the importance of standardising and linking data sets (84.6% and 73.1% agreed, respectively), educating staff on national priorities for reporting and educating staff that the quality of reports rather than quantity was most useful for learning (77.0% agreed). The importance of ensuring the anonymity of the reporter was emphasised (73.1% agreed) and sharing data and using reports in educational programmes was recommended (92.3% favoured this statement). It was agreed that the greatest value of reporting was obtaining solutions to errors from frontline staff (84.6%).

The role of national and local data collection and safety solutions

There was consensus as to what types of events should be collected at a national level (box 3). Incidents with the potential to be solved nationally such as device failures (88.0% agreed), never events or serious untoward incidents (88.0% agreed), hospital-acquired infections (80.8% agreed) and medication incidents (76.0% agreed) were examples of incidents the panel recommended to be reported and analysed locally and nationally. In contrast, issues such as staffing problems were more relevant locally (72.0% agreed). Of greater importance was the concept that initiatives to prevent harm and safety solutions should be generated locally

[i]HES data are the routinely collected hospital UK electronic data records from which adverse events can be derived. AHRQ PSIs are US indicators taken from routinely collected hospital data.

Box 1 Themed expert views expressed during semi-structured interviews

Roles that reporting systems can achieve

"It flags issues that, you know, experts can think about and interpret".

"Incident reports are mainly for things which are surprises or unusual…not things you monitor routinely".

Roles reporting systems cannot fulfil

"Reporting systems are not a valid source for detection or delineation of incidence or prevalence of events, they just tell you they are occurring…it's the starting point".

Methods to maximize learning and feedback from reporting systems

"Definitely collect less data of better quality".

"Share learning horizontally, to create a structure for peer learning but also for vertical accountability".

"Feedback from incidents is best handled locally because if there are changes to be made then that's where they should happen and the further you are away both geographically and conceptually from where the incident occurred the less engaged you feel and the harder it is to feed back".

The role of national and local data collection and safety solutions

"The reporting system should be as close as possible to the care unit itself to optimize learning".

"Change the form so it said 'does this have national implications this incident, if so please state why and what you believe needs to be done at national level'".

"People at the coalface do not have the perspective by and large to know what has national impact".

Voluntary versus mandatory data collection

"I think focusing on certain events would be useful as there are a handful of events that a nation or a region could decide are particularly memorable to incident reporting and that there is no other way of getting that information".

"Distinguish between reporting that you want to use for learning and…for accountability…they need to be absolutely firewalled and separate".

Investigation of incidents and accountability and staff training

"A very top down system…creates a level of learned helplessness on the part of the frontline clinicians that I think is destructive".

"Have the colleges develop education programmes especially for the knowledge deficit or skill deficit in reporting and analysis".

"People are more likely to report things if they feel that something's going to happen as a result, that people within their tribe are the ones who are assessing the incidents".

and fed nationally rather than the reverse top-down approach (88.0%).

Voluntary versus mandatory data capture

The panel recommended that 'never events' or serious events such as wrong site surgery (92.0% agreed), device failures (80.8% agreed) and hospital-acquired infections (77.0% agreed) should be mandatory incidents for reporting. 53.8% of experts agreed that staff shortages and risk assessments should be captured by a voluntary system.

Investigation of incidents and accountability

All experts recommended (ie, 100%) that hospitals should have an executive board member responsible for patient safety and that hospitals should be accountable for investigating their own reports (84.6% agreed) (box 2). Experts agreed that hospitals should not determine their own reporting priorities (84.6% agreed). Consensus was reached that never events and incidents leading to death and severe harm should be prioritised for investigation (73.1% agreed). Individual feedback after investigation should be provided to reporters (84.6%). However, there was lack of consensus regarding who should provide feedback to reporters.

Staff training in reporting and investigating incidents

The expert panel agreed that the value of reporting systems would increase if staff were better trained to identify and report safety incidents (80.8%). It was recommended that senior nurses, doctors and other healthcare professionals be trained to investigate incidents (73.1% agreed).

DISCUSSION

This study reached some key conclusions regarding the role of PSRS in healthcare. Of primary importance

Box 2 What can reporting systems achieve and what should they not be used for?

Role for patient safety reporting systems
- Identifying safety issues
- Detecting rare events
- Sharing safety solutions
- Monitoring 'never events'

Avoid using reporting systems to
- Measure how safe one hospital is compared with another
- Identify unsafe healthcare professionals
- Identify unsafe hospitals
- Measure the incidence of harm in a health system

is the consensus that PSRS cannot, and should not, be used to monitor the incidence of harm in hospitals.[118 119] This has important implications for governing bodies wishing to identify 'unsafe' hospitals and using incident reporting data to do so. Previous research also found no evidence to suggest that higher reporting rates are associated with higher mortality ratios or data collected from other safety-related reporting systems.[120] Further, there was agreement in our expert panel that reporting rates reflect the safety culture of an institution, in keeping with other literature.[28] All experts in this study agreed that other data collection methods (such as prospective observation) are superior to incident reporting data to monitor the rate of incidents and the safety of practices. However, there was agreement that for rare and serious events such as wrong site surgery, where it is mandatory to report, reporting systems may be useful for monitoring frequency of incidents. Given that the denominators of incidents are unknown, it is difficult to speculate what the sensitivity of PSRS for detecting reported 'never events' might be.[59] Nevertheless, for rare incidents, prospective observational methods or even retrospective methods would require significant resources to record infrequent events and reporting is likely to be the most feasible option.[107]

Box 3 Maximising learning and improving accountability

Protect and educate staff
- Keep reporting anonymous
- Share data and results with staff and other academics
- Standardise and link data sets so the same data is captured in each hospital
- Educate and train staff to report
- Prioritise specific events for reporting and make staff aware

Local reporting national learning
- Device failures, never events and hospital-acquired infections are useful at a national level
- Staffing issues and no harm/low harm events useful at a local level
- Solutions should be generated locally and shared nationally

Hospital responsibility for solving safety problems
- Executive board member for patient safety
- Feedback to staff should be hospital priority
- Hospitals take responsibility for investigating own reports and generating preventative action

Other than the exceptions above, experts recommended that reporting systems should be used to describe the types of safety issues rather than the rate of incidents in organisations. An example of this would be incident reports concerning delayed diagnosis. It has been suggested that regardless of whether a hospital reports 1 delayed diagnosis per month or 10, such reports indicate that diagnostic delay is a safety problem requiring further investigation.[85] Reports act as a signal of underlying problems.[119] This view may explain why experts in this study agreed that the quality of reports was more important than their quantity.[121] Along with this theme was the consensus that certain events were more useful locally than nationally, such as staff shortages. Limiting the volume of national reports by specifying incidents of national interest while enabling local hospitals to continue collecting data, rather than feeding all reports nationally, may allow national bodies to focus on current safety priorities and be selective about national resource allocation.[119] This has advantage for reporters: reducing the burden of reporting events that provide limited learning can reduce resource wastage and frustration.[122] Events such as patient falls, which comprise the bulk of the NRLS data, for example, may not need to be collected at a national level—as they are well understood and their prevention well evidenced.

The panel recommended that learning from error should be the main aim of reporting systems. Enabling staff to propose solutions and training them to take responsibility for investigating and understanding system failures was deemed to be important. Exactly how staff should be trained and in what methods of incident analysis and investigation, such as root cause analysis (RCA), was not explored in the current study. Research conducted by Bowie *et al* found that NHS healthcare workers trained in RCA do not necessarily participate in incident investigations and that current training in RCA needs to be improved.[123] Whether it is feasible for all staff to be trained or whether this should be for selected staff is debatable, which may explain why experts only reached agreement that senior staff members should be trained in analysis. Training in event investigation was beyond the remit of this study and requires further attention. Consensus was reached that

staff should be trained on how and what to report; this has been shown to increase the number and also, importantly, the quality of reports.[6 53]

To improve shared learning between hospitals, consistent, minimum data sets were recommended. Anonymity of reporters was emphasised; a recommendation that concurs with that of the draft WHO guidelines and other studies. Anonymity is critical for protecting and enabling reporters to share experiences without fear of recrimination.[124 125] The issue of mandatory versus voluntary reporting was also explored as it has been a subject of much debate in the literature.[126 127] The lack of any valid method for governing how well hospitals comply with reporting means that although certain types of report are mandated, compliance cannot be easily assessed. The expert panel suggested reporting specific, important and clearly defined events such as wrong site surgery, hospital-acquired infections and device failures on a mandatory basis. Reinforcing that reporters must report certain events may increase general awareness of their importance and thus help embed reporting as a cultural norm. Experts considered whether hospitals should determine their own reporting priorities. There was widespread disagreement with this approach; experts recommended instead that reporting priorities of national interest for mandatory monitoring purposes should be determined, and healthcare professionals should be made aware of what these are.

Feedback is an essential element of a reporting system. The importance of feedback is widely recognised in the literature as an integral part of learning from error.[86 124 128] The expert panel reemphasised this view. 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. Considering the large volume of reported incidents, experts recommended that feedback to staff that reported incidents of death or severe harm should be prioritised, while recognising that feedback for all types of incidents are valuable for learning. Hospitals should focus on generating solutions to their own safety problems that can then be shared nationally. Creating a 'solution centre' or national repository of safety ideas would enable this process. Hospitals should take responsibility for feedback of solutions to errors to their own staff who report and be accountable for learning from reporting.

All experts recommended that hospitals should have an executive board member responsible for patient safety. This recommendation will enable hospitals to focus on and demonstrate that learning from harm is a top priority. Botje and colleagues showed that having quality as an item on the executive board agenda increased efforts to improve standards.[129] Although safety is everybody's responsibility, having an executive directly accountable for the issue allows safety to be placed firmly on the executive board's agenda.[129] Healthcare quality comprises three strands: clinical outcomes, patient experience and patient safety.[130] We suggest that appointing safety champions to actively engage staff and allocate resources for safety is vital to ensure safety is not overlooked.[20 131]

Topics that failed to reach consensus

There were some areas where opinion remained divided or no strong conclusions were reached (table 2)—which are important to consider. Experts rejected the idea of setting strict criteria for what to report, although they agreed that there should be mandatory reporting for specific never events and serious untoward events. This may be to preserve the freedom that reporters have to report unusual and new types of events. Although not reaching consensus, >65% of experts agreed that reporting systems should not be used to identify unsafe hospitals or healthcare professionals. The difficulty in ruling out reporting systems as a tool for monitoring dangerous practices is possibly due to the lack of other methods able to do so. However, consensus was reached that reporting systems were unsuitable instruments for measuring how safe a hospital is. On the same theme, there was indecision regarding where reports of healthcare professional misconduct should be reported. The experts did not agree to the inclusion of consultant/attending names or national identifying numbers in data collection. This may have been to ensure the protection of confidentiality and maintenance of anonymity. There was also no agreement that morbidity and mortality conference outcomes should be reported nationally. Although experts were keen for reports of severe patient harm to be reported nationally, the suggestion for clinical teams external to the hospital being employed to investigate severe harm reports was not approved.

LIMITATIONS

This study has recognised limitations. Delphi consensus groups can produce collective answers but this does not always mean the consensus is valid. Since there is uncertainty regarding the utility of reporting systems, a Delphi method was deemed appropriate to draw together a wealth of expertise to address the question. Consensus methods should not be a substitute for rigorous, prospective studies, but conducting such studies to answer the questions posed in this Delphi would not be feasible. The study was further limited by potential selection bias as only 50% of experts invited to participate in the second stage agreed to do so. We feel that this selection bias is somewhat mitigated as the experts that participated were all internationally renowned with >10 years experience with reporting systems and numerous peer-reviewed publications on the topic. The second round of the Delphi had an acceptable response rate of 86.7%, thereby reducing attrition bias. This study was

also limited as the experts interviewed only represented a small number of countries. This may be due to our inclusion criteria extending to articles in English only—indeed, there were more experts from English-speaking countries in the respondent group. Future work should seek to understand how a wider group of countries report patient safety incidents and their views on reporting. Finally, the Delphi was limited by not seeking the views of frontline healthcare workers. Such views were represented partly as many of the experts were practising clinicians—though engaging with stakeholders other than patient safety academics was outside the remit of this study. Future studies should certainly aim to capture the views of healthcare workers, patients and other stakeholders, regarding the future of reporting systems.

CONCLUSIONS

The study has produced international expert consensus-based recommendations regarding optimal application of reporting systems. To the best of our knowledge, this is the first time such an exercise has been carried out. These recommendations can now be used to enable systems to evolve and be further developed. More research is required to maximise learning from error, through reporting.

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REFERENCES

1 Kohn LT, Corrigan JM, Donaldson MS. *To err is human: building a safer health system*. Washington DC: Institute of Medicine National Academy Press, 2000.
2 Donaldson LJ. *An organisation with a memory*. London: Department of Health, 2000.
3 Hudson P. Applying the lessons of high risk industries to health care. *Qual Saf Health Care* 2003;12(Suppl 1):i7–12.
4 Medicine Io, ed. *Patient safety: Achieving a new standard for care*. Washington DC: National Academies Press, 2004.
5 Runciman WB, Williamson JA, Deakin A, *et al*. An integrated framework for safety, quality and risk management: an information and incident management system based on a universal patient safety classification. *Qual Saf Health Care* 2006;15(Suppl 1):i82–90.
6 Beckmann U, Bohringer C, Carless R, *et al*. Evaluation of two methods for quality improvement in intensive care: facilitated incident monitoring and retrospective medical chart review. *Crit Care Med* 2003;31:1006–11.
7 Benveniste KA, Hibbert PD, Runciman WB. Violence in health care: the contribution of The Australian Patient Safety Foundation to incident monitoring and analysis. *Med J Aust* 2005;183:348–51.
8 NRLS. NRLS Quarterly Data Workbook up to December 2014. Secondary NRLS Quarterly Data Workbook up to December 2014. 2014. http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/?entryid45=135253
9 Mellin-Olsen J, Staender S, Whitaker DK, *et al*. The Helsinki Declaration on Patient Safety in Anaesthesiology. *Eur J Anaesthesiol* 2010;27:592–7.
10 Herzig CT, Reagan J, Pogorzelska-Maziarz M, *et al*. State-mandated reporting of health care-associated infections in the United States: trends over time. *Am J Med Qual* 2015;30:417–24.
11 Runciman WB, Sellen A, Webb RK, *et al*. The Australian Incident Monitoring Study. Errors, incidents and accidents in anaesthetic practice. *Anaesth Intensive Care* 1993;21:506–19.
12 Clark BG, Brown RJ, Ploquin J, *et al*. Patient safety improvements in radiation treatment through 5 years of incident learning. *Pract Radiat Oncol* 2013;3:157–63.
13 Donaldson LJ, Panesar SS, Darzi A. Patient-safety-related hospital deaths in England: thematic analysis of incidents reported to a national database, 2010–2012. *PLoS Med* 2014;11:e1001667.
14 Burnett SJ, Deelchand V, Franklin BD, *et al*. Missing clinical information in NHS hospital outpatient clinics: prevalence, causes and effects on patient care. *BMC Health Serv Res* 2011;11:114.
15 Thompson DA, Lubomski L, Holzmueller C, *et al*. Integrating the intensive care unit safety reporting system with existing incident reporting systems. *Jt Comm J Qual Patient Saf* 2005;31:585–93.
16 Donaldson L. An organisation with a memory. *Clin Med (Lond)* 2002;2:452–7.
17 Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. *Bmj* 1998;316:1154–7.
18 Reason J. Understanding adverse events: human factors. *Qual Health Care* 1995;4:80–9.
19 NPSA, ed. *Seven steps to patient safety*. NHS, 2004.
20 Mitchell I, Schuster A, Smith K, *et al*. Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after 'To Err is Human'. *BMJ Qual Saf* 2016;25:92–9.
21 Shojania KG, Thomas EJ. Trends in adverse events over time: why are we not improving? *BMJ Qual Saf* 2013;22:273–7.
22 Shekelle PG, Pronovost PJ, Wachter RM, *et al*. Advancing the science of patient safety. *Ann Intern Med* 2011;154:693–6.
23 Vincent C, Aylin P, Franklin BD, *et al*. Is health care getting safer? *BMJ* 2008;337:a2426.
24 Sari AB, Sheldon TA, Cracknell A, *et al*. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ* 2007;334:79.
25 Jones J, Hunter D. Consensus methods for medical and health services research. *BMJ* 1995;311:376–80.
26 Runciman W, Hibbert P, Thomson R, *et al*. Towards an International Classification for Patient Safety: key concepts and terms. *Int J Qual Health Care* 2009;21:18–26.
27 Vincent C. *Patient Safety*. 2nd edn. Oxford, UK: BMJ Publishing Group Limited, Wiley-Blackwell, Elsevier Limited, 2010.
28 Thomas EJ, Petersen LA. Measuring errors and adverse events in health care. *J Gen Intern Med* 2003;18:61–7.
29 Fernald DH, Pace WD, Harris DM, *et al*. Event reporting to a primary care patient safety reporting system: a report from the ASIPS collaborative. *Ann Fam Med* 2004;2:327–32.

30 Hull L, Arora S, Symons NR, *et al*. Training faculty in nontechnical skill assessment: national guidelines on program requirements. *Ann Surg* 2013;258:370–5.
31 Crabtree B, Miller W. *A template approach to text analysis: developing and using codebooks*. Newbury Park, CA: Sage, 1999.
32 Boyatzis R. *Transforming qualitative information: thematic analysis and code development*. Thousand Oaks, CA: Sage, 1998.
33 Fink A, Kosecoff J, Chassin M, *et al*. Consensus methods: characteristics and guidelines for use. *Am J Public Health* 1984;74:979–83.
34 Arnot-Smith J, Smith AF. Patient safety incidents involving neuromuscular blockade: analysis of the UK National Reporting and Learning System data from 2006 to 2008. *Anaesthesia* 2010;65:1106–13.
35 Reed S, Arnal D, Frank O, *et al*. National critical incident reporting systems relevant to anaesthesia: a European survey. *Br J Anaesth* 2014;112:546–55.
36 MacLennan AI, Smith AF. An analysis of critical incidents relevant to pediatric anesthesia reported to the UK National Reporting and Learning System, 2006–2008. *Paediatr Anaesth* 2011;21:841–7.
37 Smith AF, Wild C, Law J. The Barrow-in-Furness legionnaires' outbreak: qualitative study of the hospital response and the role of the major incident plan. *Emerg Med J* 2005;22:251–5.
38 Smith AF, Mahajan RP. National critical incident reporting: improving patient safety. *Br J Anaesth* 2009;103:623–5.
39 Rooksby J, Gerry RM, Smith AF. Incident reporting schemes and the need for a good story. *Int J Med Inform* 2007;76 (Suppl 1):S205–11.
40 Micieli JA, Micieli A, Smith AF. Identifying systemic safety signals following intravitreal bevacizumab: systematic review of the literature and the Canadian Adverse Drug Reaction Database. *Can J Ophthalmol* 2010;45:231–8.
41 Parnes B, Fernald D, Quintela J, *et al*. Stopping the error cascade: a report on ameliorators from the ASIPS collaborative. *Qual Saf Health Care* 2007;16:12–16.
42 Singh R, Pace W, Singh A, *et al*. A visual computer interface concept for making error reporting useful at the point of care. In: Henriksen K, Battles JB, Keyes MA, *et al*., eds. *Advances in Patient Safety: New Directions and Alternative Approaches (Vol*. 1: Assessment). Rockville (MD), 2008: http://www.ncbi.nlm.nih.gov/books/NBK43644/
43 Singh R, Pace W, Singh S, *et al*. A concept for a visual computer interface to make error taxonomies useful at the point of primary care. *Inform Prim Care* 2007;15:221–9.
44 Zafar A, Hickner J, Pace W, *et al*. An adverse drug event and medication error reporting system for ambulatory care (MEADERS). *AMIA…Annual Symposium proceedings / AMIA Symposium. AMIA Symposium*; 2008:839–43.
45 Hickner J, Zafar A, Kuo GM, *et al*. Field test results of a new ambulatory care Medication Error and Adverse Drug Event Reporting System--MEADERS. *Ann Fam Med* 2010;8:517–25.
46 Pace WD, Fernald DH, Harris DM, *et al*. Developing a Taxonomy for Coding Ambulatory Medical Errors: A Report from the ASIPS Collaborative. In: Henriksen K, Battles JB, Marks ES, *et al*, eds. *Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology)*. Rockville, MD, 2005: http://www.ncbi.nlm.nih.gov/books/NBK20493/
47 Pace WD, Staton EW, Higgins GS, *et al*. Database design to ensure anonymous study of medical errors: a report from the ASIPS Collaborative. *J Am Med Inform Assoc* 2003;10:531–40.
48 Magrabi F, Ong MS, Runciman W, *et al*. An analysis of computer-related patient safety incidents to inform the development of a classification. *J Am Med Inform Assoc* 2010;17:663–70.
49 Beckmann U, Baldwin I, Hart GK, *et al*. The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. An analysis of the first year of reporting. *Anaesth Intensive Care* 1996;24:320–9.
50 Beckmann U, West LF, Groombridge GJ, *et al*. The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. The development and evaluation of an incident reporting system in intensive care. *Anaesth Intensive Care* 1996;24:314–19.
51 Thomas MJ, Schultz TJ, Hannaford N, *et al*. Mapping the limits of safety reporting systems in health care–what lessons can we actually learn? *Med J Aust* 2011;194:635–9.
52 Jones DN, Benveniste KA, Schultz TJ, *et al*. Establishing national medical imaging incident reporting systems: issues and challenges. *J Am Coll Radiol* 2010;7:582–92.
53 Evans SM, Smith BJ, Esterman A, *et al*. Evaluation of an intervention aimed at improving voluntary incident reporting in hospitals. *Qual Saf Health Care* 2007;16:169–75.
54 Runciman WB. Lessons from The Australian Patient Safety Foundation: setting up a national patient safety surveillance system--is this the right model? *Qual Saf Health Care* 2002;11:246–51.
55 Kluger MT, Tham EJ, Coleman NA, *et al*. Inadequate pre-operative evaluation and preparation: a review of 197 reports from The Australian incident monitoring study. *Anaesthesia* 2000;55:1173–8.
56 Runciman WB, Webb RK, Klepper ID, *et al*. The Australian Incident Monitoring Study. Crisis management—validation of an algorithm by analysis of 2000 incident reports. *Anaesth Intensive Care* 1993;21:579–92.
57 Webb RK, Currie M, Morgan CA, *et al*. The Australian Incident Monitoring Study: an analysis of 2000 incident reports. *Anaesth Intensive Care* 1993;21:520–8.
58 Kachalia A, Shojania KG, Hofer TP, *et al*. Does full disclosure of medical errors affect malpractice liability? The jury is still out. *Jt Comm J Qual Saf* 2003;29:503–11.
59 Shojania KG. The frustrating case of incident-reporting systems. *Qual Saf Health Care* 2008;17:400–2.
60 Wachter RM, Shojania KG. The faces of errors: a case-based approach to educating providers, policymakers, and the public about patient safety. *Jt Comm J Qual Saf* 2004;30:665–70.
61 Wachter RM, Shojania KG, Minichiello T, *et al*. AHRQ WebM&M-Online Medical Error Reporting and Analysis. In: Henriksen K, Battles JB, Marks ES, *et al*, eds. *Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools, and Products)*. Rockville, MD, 2005: http://www.ncbi.nlm.nih.gov/books/NBK20609/
62 Shojania KG, Wald H, Gross R. Understanding medical error and improving patient safety in the inpatient setting. *Med Clin North Am* 2002;86:847–67.
63 Astion ML, Shojania KG, Hamill TR, *et al*. Classifying laboratory incident reports to identify problems that jeopardize patient safety. *Am J Clin Pathol* 2003;120:18–26.
64 Yardley IE, Donaldson LJ. Patient safety matters: reducing the risks of nasogastric tubes. *Clin Med (Lond)* 2010;10:228–30.
65 Pham JC, Gianci S, Battles J, *et al*. Establishing a global learning community for incident-reporting systems. *Qual Saf Health Care* 2010;19:446–51.

66 Donaldson L. Toward safer care: reporting systems, checklists and process standardization. *Journal* 2011;77:b123.
67 Rocos B, Donaldson LJ. Alcohol skin preparation causes surgical fires. *Ann R Coll Surg Engl* 2012;94:87–9.
68 Blain PA, Donaldson LJ. The reporting of in-patient suicides: identifying the problem. *Public health* 1995;109:293–301.
69 Bagian JP, King BJ, Mills PD, *et al*. Improving RCA performance: the Cornerstone Award and the power of positive reinforcement. *BMJ Qual Saf* 2011;20:974–82.
70 Heget JR, Bagian JP, Lee CZ, *et al*. John M. Eisenberg Patient Safety Awards. System innovation: Veterans Health Administration National Center for Patient Safety. *Jt Comm J Qual Improv* 2002;28:660–5.
71 Bagian JP, Lee C, Gosbee J, *et al*. Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you Don't know about. *Jt Comm J Qual Improv* 2001;27:522–32.
72 Bagian JP, Gosbee J, Lee CZ, *et al*. The Veterans Affairs root cause analysis system in action. *Jt Comm J Qual Improv* 2002;28:531–45.
73 Weeks WB, Bagian JP. Developing a culture of safety in the Veterans Health Administration. *Eff Clin Pract* 2000;3:270–6.
74 Bagian JP. Patient safety: lessons learned. *Pediatr Radiol* 2006;36:287–90.
75 Mills PD, Neily J, Kinney LM, *et al*. Effective interventions and implementation strategies to reduce adverse drug events in the Veterans Affairs (VA) system. *Qual Saf Health Care* 2008;17:37–46.
76 Jansma JD, Wagner C, ten Kate RW, *et al*. Effects on incident reporting after educating residents in patient safety: a controlled study. *BMC Health Serv Res* 2011;11:335.
77 Christiaans-Dingelhoff I, Smits M, Zwaan L, *et al*. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *BMC Health Serv Res* 2011;11:49.
78 Martowirono K, Jansma JD, van Luijk SJ, *et al*. Possible solutions for barriers in incident reporting by residents. *J Eval Clin Pract* 2012;18:76–81.
79 Jansma JD, Zwart DL, Leistikow IP, *et al*. Do specialty registrars change their attitudes, intentions and behaviour towards reporting incidents following a patient safety course? *BMC Health Serv Res* 2010;10:100.
80 Lubberding S, Zwaan L, Timmermans DR, *et al*. The nature and causes of unintended events reported at 10 internal medicine departments. *J Patient Saf* 2011;7:224–31.
81 Smits M, Groenewegen PP, Timmermans DR, *et al*. The nature and causes of unintended events reported at ten emergency departments. *BMC Emerg Med* 2009;9:16.
82 Vidyarthi AR, Auerbach AD, Wachter RM, *et al*. The impact of duty hours on resident self reports of errors. *J Gen Intern Med* 2007;22:205–9.
83 Wachter RM. The end of the beginning: patient safety five years after 'to err is human'. *Health affairs* 2004;Suppl Web Exclusives: W4-534–45.
84 Pronovost PJ, Miller M, Wachter RM. The GAAP in quality measurement and reporting. *JAMA: the journal of the American Medical Association* 2007;298:1800–2.
85 Sevdalis N, Jacklin R, Arora S, *et al*. Diagnostic error in a national incident reporting system in the UK. *J Eval Clin Pract* 2010;16:1276–81.
86 Wallace LM, Spurgeon P, Benn J, *et al*. Improving patient safety incident reporting systems by focusing upon feedback—lessons from English and Welsh trusts. *Health Serv Manage Res* 2009;22:129–35.
87 Benn J, Koutantji M, Wallace L, *et al*. Feedback from incident reporting: information and action to improve patient safety. *Qual Saf Health Care* 2009;18:11–21.
88 Olsen S, Neale G, Schwab K, *et al*. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review May all have a place. *Qual Saf Health Care* 2007;16:40–4.
89 Tighe CM, Woloshynowych M, Brown R, *et al*. Incident reporting in one UK accident and emergency department. *Accid Emerg Nurs* 2006;14:27–37.
90 Vincent C, Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. *J Eval Clin Pract* 1999;5:13–21.
91 Stanhope N, Crowley-Murphy M, Vincent C, *et al*. An evaluation of adverse incident reporting. *J Eval Clin Pract* 1999;5:5–12.
92 Doran DM, Hirdes JP, Blais R, *et al*. Adverse events among Ontario home care clients associated with emergency room visit or hospitalization: a retrospective cohort study. *BMC Health Serv Res* 2013;13:227.
93 Walji R, Boon H, Barnes J, *et al*. Reporting natural health product related adverse drug reactions: is it the pharmacist's responsibility? *Int J Pharm Pract* 2011;19:383–91.
94 Walji R, Boon H, Barnes J, *et al*. Adverse event reporting for herbal medicines: a result of market forces. *Healthc Policy* 2009;4:77–90.
95 Doran DM, Hirdes J, Poss J, *et al*. Identification of safety outcomes for Canadian home care clients: evidence from the resident assessment instrument—home care reporting system concerning emergency room visits. *Healthc Q* 2009;12(Spec No Patient):40–8.
96 Espin S, Regehr G, Levinson W, *et al*. Factors influencing perioperative nurses' error reporting preferences. *AORN J* 2007;85:527–43.
97 Needham DM, Thompson DA, Holzmueller CG, *et al*. A system factors analysis of airway events from the Intensive Care Unit Safety Reporting System (ICUSRS). *Crit Care Med* 2004;32:2227–33.
98 Holzmueller CG, Pronovost PJ, Dickman F, *et al*. Creating the web-based intensive care unit safety reporting system. *J Am Med Inform Assoc* 2005;12:130–9.
99 Weingart SN, Price J, Duncombe D, *et al*. Enhancing safety reporting in adult ambulatory oncology with a clinician champion: a practice innovation. *J Nurs Care Qual* 2009;24:203–10.
100 Weingart SN, Ship AN, Aronson MD. Confidential clinician-reported surveillance of adverse events among medical inpatients. *J Gen Intern Med* 2000;15:470–7.
101 Levtzion-Korach O, Frankel A, Alcalai H, *et al*. Integrating incident data from five reporting systems to assess patient safety: making sense of the elephant. *Jt Comm J Qual Patient Saf* 2010;36:402–10.
102 Wu JH, Shen WS, Lin LM, *et al*. Testing the technology acceptance model for evaluating healthcare professionals' intention to use an adverse event reporting system. *Int J Qual Health Care* 2008;20:123–9.
103 Linder JA, Haas JS, Iyer A, *et al*. Secondary use of electronic health record data: spontaneous triggered adverse drug

event reporting. *Pharmacoepidemiol Drug Saf* 2010;19:1211–15.
104 Levtzion-Korach O, Alcalai H, Orav EJ, *et al*. Evaluation of the contributions of an electronic web-based reporting system: enabling action. *J Patient Saf* 2009;5:9–15.
105 Kim J, Bates DW. Results of a survey on medical error reporting systems in Korean hospitals. *Int J Med Inform* 2006;75:148–55.
106 Cullen DJ, Bates DW, Small SD, *et al*. The incident reporting system does not detect adverse drug events: a problem for quality improvement. *Jt Comm J Qual Improv* 1995;21:541–8.
107 O'Neil AC, Petersen LA, Cook EF, *et al*. Physician reporting compared with medical-record review to identify adverse medical events. *Ann Intern Med* 1993;119:370–6.
108 Wu AW, Pronovost P, Morlock L. ICU incident reporting systems. *J Crit Care* 2002;17:86–94.
109 Wahr JA, Shore AD, Harris LH, *et al*. Comparison of intensive care unit medication errors reported to the United States' MedMarx and the United Kingdom's National Reporting and Learning System: a cross-sectional study. *Am J Med Qual* 2014;29:61–9.
110 Noble DJ, Panesar SS, Pronovost PJ. A public health approach to patient safety reporting systems is urgently needed. *J Patient Saf* 2011;7:109–12.
111 Millman EA, Pronovost PJ, Makary MA, *et al*. Patient-assisted incident reporting: including the patient in patient safety. *J Patient Saf* 2011;7:106–8.
112 Martinez EA, Shore A, Colantuoni E, *et al*. Cardiac surgery errors: results from the UK National Reporting and Learning System. *Int J Qual Health Care* 2011;23:151–8.
113 Howard J, Levy F, Mareiniss DP, *et al*. New legal protections for reporting patient errors under the Patient Safety and Quality Improvement Act: a review of the medical literature and analysis. *J Patient Saf* 2010;6:147–52.
114 Bell S, Benneyan J, Best A, *et al*. Mandatory public reporting: build it and who will come? *Stud Health Technol Inform* 2011;164:346–52.
115 Ogrinc G, Mooney SE, Estrada C, *et al*. The SQUIRE (Standards for QUality Improvement Reporting Excellence) guidelines for quality improvement reporting: explanation and elaboration. *Qual Saf Health Care* 2008;17(Suppl 1): i13–32.
116 Pham JC, Colantuoni E, Dominici F, *et al*. The harm susceptibility model: a method to prioritise risks identified in patient safety reporting systems. *Qual Saf Health Care* 2010;19:440–5.
117 NHS England Patient Safety Never Events. Secondary NHS England Patient Safety Never Events. https://http://www.england.nhs.uk/patientsafety/never-events/
118 Vincent C. Incident reporting and patient safety. *BMJ* 2007;334:51.
119 Macrae C. The problem with incident reporting. *BMJ Qual Saf* 2015; doi:10.1136/bmjqs-2015-004732
120 Hutchinson A, Young TA, Cooper KL, *et al*. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from The National Reporting and Learning System. *Qual Saf Health Care* 2009;18:5–10.
121 Vincent CA. Analysis of clinical incidents: a window on the system not a search for root causes. *Qual Saf Health Care* 2004;13:242–3.
122 Raja PV, Davis MC, Bales A, *et al*. NPITxt, a 21st-Century Reporting System: Engaging Residents in a Lean-Inspired Process. *Am J Med Qual* 2015;30:255–62.
123 Bowie P, Skinner J, de Wet C. Training health care professionals in root cause analysis: a cross-sectional study of post-training experiences, benefits and attitudes. *BMC Health Serv Res* 2013;13:50.
124 Holmström AR, Airaksinen M, Weiss M, *et al*. National and local medication error reporting systems: a survey of practices in 16 countries. *J Patient Saf* 2012;8:165–76.
125 WHO. WHO Draft Guidelines for Adverse Event Reporting and Learning Systems and Learning Systems. Wold Health Organisation, 2005.
126 Pearson A, Chronias A, Murray M. Voluntary and mandatory surveillance for methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-susceptible S. aureus (MSSA) bacteraemia in England. *J Antimicrob Chemother* 2009;64 (Suppl 1):i11–17.
127 Flink E, Chevalier CL, Ruperto A, *et al*. Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems. In: Henriksen K, Battles JB, Marks ES, *et al*, eds. *Advances in patient safety: from research to implementation (Volume 3: Implementation Issues)*. Rockville, MD, 2005: http://www.ncbi.nlm.nih.gov/books/NBK20547/
128 Evans SM, Berry JG, Smith BJ, *et al*. Attitudes and barriers to incident reporting: a collaborative hospital study. *Qual Saf Health Care* 2006;15:39–43.
129 Botje D, Klazinga NS, Suñol R, *et al*. Is having quality as an item on the executive board agenda associated with the implementation of quality management systems in European hospitals: a quantitative analysis. *Int J Qual Health Care* 2014;26(Suppl 1):92–9.
130 Horton R. The Darzi vision: quality, engagement, and professionalism. *Lancet* 2008;372:3–4.
131 Goeschel CA, Wachter RM, Pronovost PJ. Responsibility for quality improvement and patient safety: hospital board and medical staff leadership challenges. *Chest* 2010;138:171–8.