The Netherlands has a two-tiered process. The Health Care Inspectorate, the agency accountable for taking actions against substandard performance, mandates hospitals to report adverse events that have led to death or permanent impairment. Other adverse events are reported voluntarily. There is interest in moving towards a more uniform blame-free reporting system to aggregate events nationally.

A number of states in the United States have reporting systems that require hospitals or other providers to report certain types of serious, usually preventable events (see Section 6).

Most accountability systems not only hold health-care organizations accountable by requiring that serious mishaps be reported, they provide disincentives to unsafe care through citations, penalties or sanctions. The effectiveness of these systems depends on the ability of the agency to induce health-care organizations to report serious events and to conduct thorough investigations.

Accountability systems can (and should) be learning systems if investigations are carried out and if the lessons learned are disseminated to all other providers by the agency. For example, the Danish Health Care System recently passed an Act on Patient Safety that requires health-care providers to report adverse events so information can be shared and aggregated for quality improvement.

Confidentiality and public access to data

Experience has shown that learning systems are most successful when reports are confidential and reporters do not feel at risk in sharing information about errors. Indeed, some feel it is only with such safe reporting systems that subtle system issues and the multitude of contributing factors will be uncovered. From a pragmatic standpoint, many believe that protecting the confidentiality of health-care organizations significantly enhances participation in reporting (1, 2).

However, some citizen advocacy groups have called for public disclosure of information uncovered during investigations of serious adverse events, asserting the public's right to know about these events. Surveys in the United States show that 62–73% of Americans believe that health-care providers should be required to make this information publicly available (3, 4). Nonetheless, all but three states in the United States have statutes that provide legal protection of confidentiality (5).

Internal reporting

Reports to an agency or other national body from a hospital or other health-care organization usually originate from a report within the institution. While such reports may merely reflect statutory requirements, an institution that values patient safety will have an internal reporting system that captures much more than that.

The objectives of an internal reporting system for learning are first, to identify errors and hazards, and then through investigation to uncover the underlying sys-

tems failures, with the goal of redesigning systems to reduce the likelihood of patient injury. The key conceptual point here, and the heart of a non-punitive approach to error reporting, is the recognition that adverse events and errors are symptoms of defective systems, not defects themselves. Reporting, whether retrospective (adverse events and errors) or prospective ("hazards", or "errors waiting to happen") provides the entry point into investigation and analysis of systems' defects, which, if skillfully done, can lead to substantial system improvements. Reporting is one way to get this type of information, but not the only way (see Section 4).

Ideally, internal reporting systems should go hand in hand with external reporting systems, by identifying and analysing events that warrant forwarding to external reporting agencies. Conversely, external reporting systems are most effective when they are an extension of internal systems.

Process

What is reported

Types of reports

Reporting systems may be open-ended and attempt to capture adverse events and close-calls along the entire spectrum of care delivery, or may focus on particular types of events, such as medication errors or pre-defined serious injuries. In general, focused reporting systems are more valuable for deepening the understanding of a particular domain of care than for discovering new areas of vulnerability. While these guidelines focus on reporting systems related to adverse events and medical errors, other types of health-related reporting systems focus on medical devices, epidemiological outcomes such as emergence of antimicrobial resistance, post-marketing medication surveillance, and specific areas such as blood transfusions.

Formats and processes vary from prescribed forms and defined data elements to free-text reporting. The system may allow for reports to be submitted via mail, telephone, electronically, or on the World Wide Web.

Types of events

Adverse events. An adverse events is an injury related to medical management, in contrast to a complication of disease (6).Other terms that are sometimes used are "mishaps", "unanticipated events" or "incidents", and "accidents". Most authorities caution against use of the term accident since it implies that the event was unpreventable.

Adverse events are not always caused by an error. For example, one form of adverse drug event, "adverse drug reaction" is, according to the WHO definition, a complication that occurs when the medication is used as directed and in the usual

dosage (7). Adverse drug reactions are, therefore, adverse drug events that are not caused by errors.

Many adverse events are caused by errors, either of commission or omission, and do, in fact, reflect deficiencies in the systems of care (8). Some reporting systems require that only preventable adverse events be reported, while others solicit reports whether or not a medical error occurred. One advantage of focusing reporting on adverse events rather than on errors is that it is usually obvious when a mishap has occurred; actual events focus attention.

Error. Error has been defined as "the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)" (9). Although reporting of errors, whether or not there is an injury, is sometimes done within institutions, if reporting of all errors is requested, the number may be overwhelming. Therefore, some sort of threshold is usually established – such as "serious" errors, or those with the potential for causing harm (also called "near misses" or "close calls"). Establishing such a threshold for a reporting system can be difficult. Hence, most "error reporting systems" are actually "adverse events caused by errors" systems.

"Near miss" or "close call". " A near miss" or "close call" is a serious error or mishap that has the potential to cause an adverse event, but fails to do so by chance or because it was intercepted. It is assumed (though not proven) that the underlying systems failures for near misses are the same as for actual adverse events. Therefore, understanding their causes should lead to systems design changes that will improve safety.

A key advantage of a near miss reporting system is that because there has been no harm the reporter is not at risk of blame or litigation. On the contrary, he or she may be deserving of praise for having intercepted an error and prevented an injury. This positive aspect of reporting of near misses, has led some to recommend near miss systems for internal reporting systems within health-care organizations or other health-care facilities where a blaming culture persists. However, any hospital that is serious about learning will also invite reports of near misses.

Hazards and unsafe conditions. Reporting of hazards, or "accidents waiting to happen" is another way to achieve prevention without the need to learn from an injury. If health care were as safe as some other industries, reports of hazards – potential causes of adverse events (as opposed to near misses, which are actual errors) – would outnumber those of actual events. Of all major systems, the Institute for Safe Medication Practices system for medication-related events has been most successful at capturing hazards (e.g. "look alike" packaging and "sound alike" names.) and calling for their remedy before a predictable error occurs.

Within a health-care organization, hazard reports raise alerts about unsafe conditions. Providers can imagine accidents waiting to happen based on their observations of weakness in the system and their experience as users. With appropriate analysis, these reports can provide valuable information for changes to systems design.

Who reports

Reporting systems must specify who files reports. In accountability systems, such as state health department systems and the JCAHO in the United States, reporting is done by the organization. Many also solicit and receive reports from caregivers (doctors and nurses). Some jurisdictions require caregivers to file reports. Some reporting systems allow patients, families and consumer advocates to report events. The latter are typically merely a notice that an event has occurred. In general, learning systems solicit reports from caregivers or organizations. Focused systems targeting specific areas such as medication errors or intensive care errors solicit reports from specialists such as pharmacists or intensive care specialists, while broad-based systems look to organizations and caregivers, but usually accept reports from anyone.

A potential source of reports that has not been significantly used is patients and families who have experienced medical error. Patients often report a high desire to see remedial action taken to prevent future harm to others. Reporting can initiate that process. Patients may report otherwise unidentified issues that help health-care organizations understand where the holes in their safety nets are, identify root causes, and mitigate harm. A patient may experience an injury that does not manifest until after discharge from a hospital and therefore is not otherwise captured. Patients may be better positioned than their care providers to identify failures in hand-overs and gaps between providers across the continuum of care.

How do they report

Method: e-mail, fax, Internet, mail, phone calls

Methods for submitting reports vary according to local infrastructure and technology. They can range from mailing written reports to a central address, to web-based systems that centralize and aggregate multiple reports into a highly structured database. Mail, fax, and phone calls are most widely used, since these mechanisms are widely available. A streamlined process can be set up to receive reports by e-mail or over the Internet; for users who have access to these technologies, this can be very quick and easy (although it may be costly to establish the technical infrastructure). Systems that use e-mail or the Internet must be able to provide technical support for users.

Structured forms or narrative text

Reports may be highly structured, requiring specific types of information, or provide for a narrative description of events for analysis. The extent to which datasets can be developed for analysis depends in part on the degree of standardization inherent in the data reported. Events based on commonly accepted data elements, such as the classification of medication errors into wrong medication, wrong dose, wrong frequency and so on, can be readily configured into a standardized reporting format.

A higher level of structured reporting asks reporters to select options from defined fields as part of the reporting process. This can greatly facilitate input into datasets developed for analysis. The Australian Patient Safety Foundation's Advanced Incident Management System (AIMS), offers a highly sophisticated customizable data entry form that guides users through a cascade of natural questions and response choices that are structured and consistent.

However, much of what promotes learning in patient safety lacks crisply defined data elements, so most authorities believe it is important for reports to include narrative to convey meaning. Narrative reports provide the opportunity to capture the rich context and storyline that allow the conditions that contributed to the error to be explored and understood. Indeed, some believe that only narrative reports are capable of providing information that provides meaningful insight into the nature of the underlying systems defects that caused the incident (Richard Cook, personal communication).

The vast majority of reporting forms have at least some room for a narrative description, and some, such as the United States Food and Drug Administration (FDA) MedWatch programme include open narrative for other relevant medical information such as laboratory data or patient condition.

Because of the nature of analysis that is required, systems that elicit open-ended, narrative texts require additional resources for data analysis and interpretation. In contrast, reports to systems with a standardized format, fixed fields, and predefined choices are swiftly entered and readily classified, making possible aggregated analysis at lower cost.

Another consideration is the effect of reporting on the reporter. Providing reporters with the chance to tell their stories implicitly values their observations. When the reporter can trust in a considered and non-punitive response, the process raises the individual's awareness of patient safety and sense of responsibility for reporting.

Classification

Reporting of events is of little value unless the data are analysed. Regardless of the objective of the system – whether to identify new and previously unsuspected hazards, discover trends, prioritize areas for remedial efforts, uncover common contributing factors, or develop strategies to decrease adverse events and patient harm – neither the act of reporting nor the collection of data will accomplish that objective unless the data are analysed and recommendations are made for change. Classification of the event is the first step in the analysis.

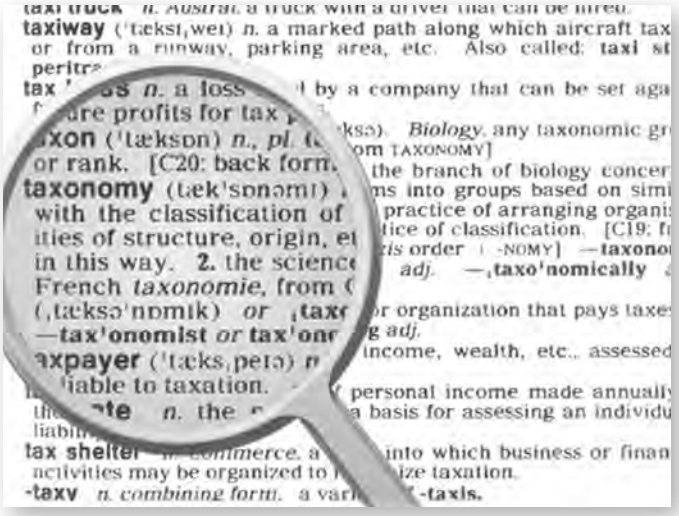
Why classify?

Recall the case presented in Section 1 of the inadvertent connection of oxygen tubing to an intravenous line the result being an air embolism. After the incident is reported, classification by the reporting system turns a specific event into an example that could happen anywhere; this particular incident becomes an example of "tubing mix-up". When aggregated with similar incidents, depending on the availability of contextual information, a variety of solutions can emerge, ranging from changes in nursing practice standards to a requirement for medical device manufacturers to develop incompatible connectors for all medical tubing. Classification starts the process of developing solutions that can be generalized.

Classification systems (taxonomies)

A number of quite different systems have been used for classifying patient safety incidents. These systems are also called "taxonomies". Because of differences between taxonomies, data can often not be shared among systems. Further, none have been validated, in the sense of studies that demonstrate that the classification and analysis method used leads to significant improvements in patient safety. As a result, the WHO World Alliance for Patient Safety has included in its Forward Programme 2005 an action area focusing on the development of an internationally agreed taxonomy of events.

Some of the factors that have been used to classify events include: error type (wrong dose, wrong diagnosis, etc.), patient outcome (level of harm, from none to death), setting, personnel involved, product or equipment failures, proximal (obvious) causes (misidentification of a patient), underlying causes (lack of knowledge, information, skills, etc.), contributing factors (organizational factors, environmental factors, etc.), stage in process of care (ordering, implementation, responding to laboratory results), and mechanism of error (knowledge-based, rule-based, skill-based). These taxonomies tend to fall into three major categories: classification by event, by risk, or by causation.



A taxonomy of adverse events classifies by event type, such as how many medication errors are attributable to "wrong dose" or "wrong patient". Event classification schemes work best when describing a specialized medical domain, such as medication errors, dialysis events or transfusion mismatches.

Several systems use taxonomies to assess risk, in order to prioritize events for action or to determine if further investigation is warranted. The United States Pharmacopoeia (USP) uses a nine-tier approach to rank medication risk. The Veterans Health Administration (VHA) uses a scoring system to prioritize both the potential severity, and the likelihood of occurrence of events, based on specific

scales and definitions; these are organized into a "safety assessment code" matrix (10). See Figure below.

The Australian Patient Safety Foundation uses explicit criteria for assessing the degree of risk expressed as a risk matrix that plots the severity of the outcome against the likelihood of its recurrence (11). The United States Agency for Healthcare Research and Quality (AHRQ) has indicated that a risk assessment scale should be included in its Patient Safety Network reporting system currently being developed in collaboration with the Institute of Medicine's Committee on Data Standards for Patient Safety

Figure: Safety Assessment Code (SAC) Matrix

		SEVERITY			
		Catastrophic	Major	Moderate	Minor
PROBABILITY	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

Source: Veterans Health Administration National Center for Patient Safety, United States of America

The earliest classification system that focused on causation was the Eindhoven Classification Model, developed at Eindhoven University of Technology in the Netherlands. It is used in high-risk industries such as chemical manufacturing. It has recently been adapted for use in the VHA root cause analysis to identify factors based on the principles of human, organizational, and technical factors.

Another causation-oriented system is the Australian Incident Monitoring System developed by the Australian Patient Safety Foundation. This classification system comprises more than a million permutations of terms to describe an incident or adverse event. The system allows the end user to deconstruct an incident into a very detailed data set that defines the relationships between the component factors of the classification system.

A related system is classification by contributing factors, used at the Clinical Risk Unit at University College in London, England to identify patient, provider, team, task, work environment, organizational and other factors, through comprehensive systems analysis (12).

Design of a classification system

At least three key factors should be considered in the design of a classification system:

- The purpose of the reporting system. What is the expected product? How will the classification scheme facilitate analysis that will produce the desired outcome?
- The types of data that are available. Are reporters expected to have carried out an investigation and analysis of the event? If not, it is

unlikely that they will be able to provide useful information concerning underlying systems causes, and events will not be able to be classified at that level.

- Resources. The more detailed and elaborate the classification system is, the more expertise will be required, and the costlier the system will be to maintain.

A report commissioned by WHO and prepared by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) notes that the following attributes are desirable in an ideal classification scheme (13):

- It should address a broad and diverse range of patient safety issues and concerns across multiple health-care settings.
- It should identify high-priority patient safety data elements that are important to health-care systems.
- It should classify information related to what, where and how medical management goes wrong, the reasons why medical incidents occur, and what preventive and corrective strategies can be developed to keep them from occurring or to ameliorate their effects in health care.
- It must provide a meaningful and comprehensive linkage between the contributory factors and the errors and systems failures that lead to adverse events.
- It should facilitate the monitoring, reporting, and investigation of adverse events and near misses at the public health level – allowing aggregated data to be combined and tracked.

Because the resources required for taxonomy and analytical development tools are substantial, development of classification schemes is probably better left to national or international agencies rather than individual health-care systems.

The role of classification

Classification can be the cornerstone of what the system does. If the main goal is to produce data on the frequency of different types of events, as in the USP MedMARx^{SM} system, then performing the classification, determining frequencies, and feeding back that information may be all that is needed to meet the objective of the reporting system.

More commonly, classification is the beginning of more complex analysis, the first step. A direct link exists between the type and complexity of the classification scheme, and the level of analysis that is possible. That is, the analytic plan should determine the classification scheme, not the reverse.

Analysis

Hazard identification

At a minimum, a reporting system should permit identification of new and unsuspected hazards, such as previously unrecognized complications associated with use of a medication or a new device. A simple way this can be done is by direct human review of incoming reports. For example, if even a few people report that free flow protection on a particular pump model can fail, that may be sufficient for the receivers of the reports to recognize the problem, alert the providers and communicate directly with the pump manufacturer.

This type of analysis requires that knowledgeable experts review reports, but the reports do not need to be based on extensive investigation by the reporting organization. A good example of a hazard identification model is the Institute for Safe Medication Practice (ISMP) Medical Error Reporting Program, where a small group of pharmacists reviews all reports, identifies new hazards, and prioritizes them for action. Recommendations are then disseminated to the participants (most hospitals) every two weeks via a newsletter, Medication Safety Alert.

Both JCAHO, through its sentinel events alert warning and ISMP have legitimately taken credit for the success in removing concentrated potassium chloride from nursing units in the United States (14). ISMP alerts have also led to drug name and label changes, as well as the removal or restriction of the use of many drugs (15). MedMARx[SM] analysis revealed reports of three drugs with a high frequency of medication errors: insulin, heparin, and warfarin (16).

Summaries and descriptions

At the next level, a simple classification scheme can provide summaries and descriptions that permit determination of frequencies or ranking by order of frequency. An example of this would be a reporting system that records medication errors classified by dose, route, patient, etc. Calculating frequencies permits prioritization that can be used by focused systems to allocate further resources.

Trend and cluster analysis

Trend analysis, obtained by calculating and observing rates of events over time, can identify significant changes that suggest new problems (or, if improving, that safety measures are working). Trends can also be detected using statistical control methodologies. These assist a particular organization in discerning whether its own trends, when compared with benchmarks, are attributable to what is known as "special cause" variation, rather than stemming from normal process fluctuations.

A cluster of events that suddenly arises suggests a need for inquiry. It is important to note that trends or clusters identified by reporting systems are those of reported events, not those of the events themselves. For example, the JCAHO recently released a sentinel event alert concerning wrong site surgery when the rate of reports it received increased substantially over a two-year period. However, it acknowledged that only a small fraction of events are reported, so the data may not be representative. The United States Pharmacopeia (USP) MedMARxSM system analyses events to identify trends. Such trends may influence standard-setting practices. Large-scale reporting systems such as the National Reporting and Learning System, of the National Health Service in England, also provide pattern analysis and recognition of trends or clusters (17).

Correlations

While trends over time or control charts are ways of using the factor of time, other analytical methods are available for additional cofactors. To take the example of 'medication error – wrong patient', other factors captured may include, for example, the health-care setting (whether clinic or hospital), the patient diagnosis, or the age of the patient. These can be subjected to an analysis of correlations to evaluate the strength of the relationship between two variables, such as whether dosing errors occur more frequently among chemotherapy patients than among patients undergoing other treatments, or whether wrong patient medication errors are more highly correlated with elderly patients than with younger (and perhaps more alert) patients.

Risk analysis

With adequate data, a reporting system can develop valuable information about risk. With a large number of reports, estimations of the probability of recurrence of a specific type of adverse event or error can be calculated. Analysis of reported outcomes can also produce an estimate of the average severity of harm caused by the incident. The Safety Assessment Code of the United States Veterans Health Administration uses these two factors, probability of recurrence and severity, to calculate a score for prioritizing incidents for safety initiatives.

Causal analysis

When many factors are classified and coded along with the event, a more complex set of correlations and relationships among the factors can be considered and tested in the database. If causal factors such as workloads, communication, teamwork, equipment, environment, staffing and the like are included, then correlations among many cause and effect relationships can yield important insights into a health-care system's vulnerabilities.

Another analytical tool that can be applied to datasets with a rich set of cofactors is regression analysis, which assesses the predictive value of multiple factors upon

the outcome. For example, regression analysis can be used to investigate whether patient diagnosis is a predictive factor for dosing error. The major use for this analytical approach is to go beyond identifying relationships to hypothesis testing.

The sentinel event alerts issued by JCAHO include risk reduction strategies based on causal analyses submitted with reports, such as finding that medication errors attributable to illegible handwriting or poor communication are more common when abbreviations are used. Eliminating abbreviations has thus become one of the JCAHO patient safety goals for hospital accreditation.

Systems analysis

The ultimate aim of reporting is to lead to systems improvements by understanding the systems failures that caused the error or injury. At the organizational level, this requires investigation and interviews with involved parties to elicit the contributing factors and underlying design failures. A national reporting system must receive this level of information in order to identify common and recurring systems failures. For example, if analysts repeatedly find similar underlying systems defects in reports of a specific type of error, then remedial actions should focus on correction of that failure.

The Australian Patient Safety Foundation identified problems with valve-controlled flow and pressure occurring with anaesthetic machines. Query of the database provided a deconstruction of the malfunction types and suggested, among other things, that frequent maintenance and audible alarms on pressure relief valves could prevent these mishaps (18).

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4. ALTERNATIVE SOURCES OF INFORMATION FOR PATIENT SAFETY

Key messages

- **Reporting systems are clearly of value for learning from others' experience.**
- **Reporting systems do not provide a complete picture of risks, hazards and system vulnerabilities.**
- **There are other valuable sources of information that can be used within a health service and nationally to complement reporting.**
- **These options may present less expensive options than establishing national reporting systems.**

National or system-wide reporting systems are clearly of great value for learning from others' experience. Many adverse events occur rarely, and thus to observers in the institution may seem to be isolated (outlier) cases. Commonality and common causation only emerge with analysis of aggregated data. Similarly, demonstrating occurrence of serious events in respectable peer institutions helps counteract a typical response of "that could never happen here", which providers may genuinely feel when asked about a serious adverse event, such as amputation of the wrong leg.

However, there are other valuable sources of patient safety information that can be used at both the internal health-care organizational level and nationally. Many are much less expensive, and therefore constitute important options for states and health-care organizations that are unable to finance a large reporting system. They are worthy of consideration even for those with highly developed reporting systems. We look at internal options first.

Internal alternative sources of safety information

An effective internal reporting system is an essential component of a hospital patient safety programme. However, even a simple reporting system can be a significant expense. For many institutions, providing the financial resources and expertise required to establish a reporting system may be a burden, and may not be the wisest use of scarce funds. Another problem is compliance. Studies have repeatedly shown that many events are not captured by typical reporting systems. Personnel often fail

to make reports for a host of reasons: because they forget, are too busy, or think it is unimportant, or because the reporting does not lead to significant change. Too often, failure to report reflects a punitive environment in which it can be harmful to the reporter or colleagues to report.

Fortunately, reporting is not the only way to obtain information about hazards and systems defects. Hospital personnel – nurses, pharmacists, doctors, risk managers, and others – are a rich source of information that even well run reporting systems do not fully exploit. Medical records, laboratory reports, and other routinely collected data can also be used to find evidence of safety problems. Several methods that have been found useful for utilizing these resources are described in this section. In addition, several alternative methods for collecting data on quality and safety of care are described that do require more extensive resources but offer the promise of more complete and less intrusive data collection. These alternatives are presented in order of increasing resource intensity.

Safety WalkRounds

A "Safety WalkRound" is a process whereby a group of senior leaders visit areas of a health-care organization and ask front-line staff about specific events, contributing factors, near misses, potential problems, and possible solutions. The leaders then prioritize the events and the patient safety team develops solutions with the clinicians. The results are fed back to the staff (1).

The information gleaned in this process often has the solution embedded in the event description. Thus, this process can often result in prompt changes that improve care and safety. It also can lead to culture change, as the concerns of front-line staff are addressed and as front-line staff are engaged in continuous observation of hazards and solutions for discussion with senior leadership. Leadership walkrounds are a low-cost way to identify hazards of concern to front-line staff and make needed changes. They require no additional staff, equipment, or infrastructure.

Focus groups

Focus groups are facilitated discussions with staff or with patients and families to elicit insights, concerns, and perceptions in an open, learning environment. Most nurses, for example, are aware of hazards in their daily work, accidents "waiting to happen", and are willing to discuss them if given the opportunity. A few hours with front-line people can generate a safety improvement agenda that will keep a hospital busy for months.

Focus groups offer an opportunity for a very rich learning environment as members within the group discuss and develop ideas. While this method of information gathering cannot provide trends or benchmarks like a reporting system, it can identify both hazards and potential solutions that otherwise remain hidden.

Medical record review

Medical record review has historically been the major method for oversight of quality. While labour intensive, record review often provides the reviewer with the story and context in which to understand events. In addition, medical record review allows for evaluation of processes as well as outcomes, and can yield information about whether important processes occurred, such as communication, documentation, use of a checklist, or administration of an evidence-based therapy.

Record reviews may be explicit, in which the reviewer searches for specific types of data that define events (such as "failure to rescue") or implicit, in which a clinical expert makes a judgment as to whether an adverse event and/or error has occurred (such as failure to follow up a positive laboratory test). Record reviews have been the cornerstone of the major population-based studies that defined the extent of medical injury (2-6). They are also widely used to monitor progress in preventing adverse events when new safe practices are implemented.

The major limitations of record review are its cost, and variability of content. Aside from laboratory reports and orders, much of the content is determined by the subjective judgments of those who write notes. While serious adverse events are almost always mentioned, errors and underlying conditions almost never are. "Near misses" are rarely noted. Thus, records can be valuable for case finding, but provide only limited contextual information.

Focused review

Medical record reviews that focus on a specific type of event can identify critical points of care that represent widespread vulnerabilities. Focused reviews of adverse drug events, for example, might show that ordering medications for patients with renal impairment, managing anticoagulation, and tracking allergies are areas that warrant widespread, systematic improvements. A focused record review might reveal not only the incidence of wrong-site surgery, but also whether a site checklist was executed and a time-out took place during each operation. Other focused analyses might include identifying high complexity processes.

Failure modes and effects analysis

Adverse events can be viewed as the outcomes of vulnerable systems. In addition to acquiring information about the outcomes, or events, it is very helpful to learn about the vulnerabilities in the system and about possible solutions to buffer and strengthen the systems of care.

Failure modes and effects analysis (FMEA) is a widely used tool for proactively identifying process vulnerabilities. It begins by systematically identifying each step in the process and then searches out "failure modes", that is, noticing what could go wrong. The next step is to evaluate how the failure mode could occur, and what are the "effects" of this failure. If a failure mode could result in catastrophic effects, the

process must be corrected or buffered. The FMEA is a proactive tool, used to evaluate a new process, or an existing process for proposed design changes.

Screening

Screening is the use of routine data to identify a possible adverse event. It can be performed retrospectively, or in "real" time, either by analysis of traditional paper records or automatically by computer programs if patient clinical and laboratory data are available in electronic form. "Occurrence" screening identifies when a predefined event occurs, such as a return to the operating room within an admission or a readmission for the same problem.

Screening criteria are sometimes referred to as "triggers". When a screening criterion is met, further investigation, usually in person by an expert, is needed to determine whether an event has, in fact, occurred.

For example, laboratory data can be screened for out of range International Normalized Ratio (INR) results in patients taking warfarin. Records of patients with a positive screen – defined as values above or below a defined range – are then reviewed to determine if an episode of haemorrhage or thrombosis has occurred.

The Institute for Healthcare Improvement (IHI) has pioneered in the use of a "trigger tool" to retrospectively discover adverse drug events (ADE) (7). Records are searched for the presence of any of a list of highly sensitive indicators (such as prescribing a narcotic antidote or out of range INR). If the trigger is found, further investigations are carried out to determine if the ADE did in fact occur. This tool can be used both to assess the rate of selected ADEs and to measure progress when new safe practices are implemented.

Observation

The observation method for discovering errors consists first of a knowledgeable expert (such as a nurse or pharmacist) observing a process and writing down precisely the steps that are taken by the provider. This log is then compared with the written orders to identify deviations. Observational studies of nurse administration of medications in a large number of hospitals have shown high error rates (average 11% of doses) (8). The nurses were not aware of the errors which would, thus, not be captured in a reporting system.

The observation method is very labour-intensive, and therefore costly. However, it yields very rich data that facilitate understanding, not only about what events occur, but also about the processes and dynamics that affect the outcome. It is a tool that can be used intermittently, as resources permit, both to identify and understand systems breakdowns and to monitor improvement after changes are implemented.

Observing the hand-over during a transition between caregivers, for example, will yield not only whether there is an error, but also meaningful clues as to the barriers

and solutions. Observation can also identify areas where process designs such as standardization, simplification, and forcing functions may be useful to avoid harm.

External alternative sources of safety information

At the national or systems level, alternatives to reporting have not been widely employed. Medical record reviews have been occasionally used in random audits to identify adverse events and estimate frequency. Specific one-off studies, such as the Confidential Enquiries in the United Kingdom have served this function for several decades (9,10). This type of sampling can identify system weaknesses that require attention with much fewer resources than required by a reporting system. Several other methods of gathering safety data are available, as described below.

Malpractice claims analysis

Where frequent, as in the United States, malpractice claims can provide a rich source of data concerning a small number of serious events. When a serious incident occurs, risk managers typically start a patient file (called a claim, even if no litigation ever ensues) and promptly conduct an investigation, interviewing all personnel involved to understand and correctly document exactly what happened. This type of analysis, while much less sophisticated than a root cause or systems analysis carried out by experts, produces far more information than the usual hospital reporting systems.

Analysis of claims, for example, has identified the factors that increase the probability of a foreign body being retained following surgery and demonstrated the need for fail-safe follow-up systems to ensure that positive mammograms lead to biopsy (11).

The limitation of malpractice claims is their non-representativeness. However, they do provide data on events that are significant – serious injuries – as well as data that are typically much more comprehensive than provided to most reporting systems.

Surveillance

Surveillance systems collect specific case data, checking for predefined factors and outcomes on all patients in a defined category (such as those with infection). These systems can identify the prevalence of risk and risk factors for key events, as well as provide benchmarks for organizations and assist in monitoring progress.

One of the best examples of a surveillance system is the National Nosocomial Infections Surveillance System, a voluntary, confidential cooperative effort between the United States Centers for Disease Control and Prevention (CDC) and participating hospitals to identify hospital-acquired infections and create a national database that is used to understand the epidemiology of nosocomial infections and antibiotic

resistance trends, and to provide robust benchmarks for organizations to track their own performance (12,13).

Another form of surveillance focuses on review of hospital discharge diagnostic codes. A list has been developed in the United States by the Agency for Healthcare Research and Quality (AHRQ) of specific discharge codes, called Patient Safety Indicators (PSI), that are highly correlated with "problems that patients experience as a result of exposure to the healthcare system and that are likely amenable to prevention"(14). Examples include retention of foreign bodies, complications of anaesthesia, obstetric trauma, decubitus ulcers, and postoperative hip fracture. Hospitals can use the PSI to identify potential systems failures and to monitor improvement in safety. As the indicators are refined, it seems likely that they will be used in a national monitoring programme.

Routine data collection

A variant of surveillance on a much larger scale is exemplified by the United States Veterans Health Administration National Surgical Quality Improvement Program (NSQIP) (15). Trained surgical clinical nurse reviewers collect data on 129 clinical and outcome variables (including 30-day postoperative outcomes) for all major operations performed at each Veterans Health hospital. These data are electronically transmitted to a coordinating centre that uses predictive models to generate risk-adjusted predicted probability of death or complications for each patient.

Observed and expected ratios of complication rates and mortality are then calculated for each hospital and service for all major surgical procedures and for each of the subspecialties and fed back to each hospital, together with de-identified benchmark data from all institutions for comparison. A central committee annually reviews the data, commends low outliers, and issues warnings to high outliers. Recurrent high outlier status leads to review by regional authorities and, when indicated, site visits to assist hospitals in identifying and remedying deficiencies. Since inception of NSQIP, data for more than 1 million cases have been entered into the national database.

Over a ten-year period, 1991-2000, after implementation of NSQIP, surgical mortality decreased by 27% and complications by 45% (16). Programme leaders attribute most of these reductions to changes made by the hospitals in response to data feedback. The total cost of the program is US$ 4 million annually, approximately US$ 12 per case. The savings from reduced mortality and complications are several multiples of this expense; thus there is a net saving with this method.

The success of NSQIP in reducing adverse events and mortality can be attributed to five factors: (i) data collection is automatic part of the daily routine for all patients, not just those with complications; (ii) designated trained individuals are responsible for data collection; (iii) results are risk-adjusted; (iv) results are fed back to hospitals as site-specific data with peer hospital comparisons; (v) outcomes are monitored

by a central oversight authority with the power to conduct site visits and require changes. After initial resistance, these systems have been well-accepted by physicians and hospitals.

Routine data collection bodes well for ultimately replacing reporting as the primary source of safety information in the future. For highly developed health-care systems that have fully electronic medical records, automated data collection and analysis can provide continuous monitoring of quality and safety at a fraction of the cost of a reporting system. Similarly, automatic feed of data to a central authority (as in the Veterans Health system) can occur rapidly and inexpensively. In such a system "reporting" would be much less important, and full attention could be given to analysis and focused investigation of key events uncovered by the data analysis.

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5. NATIONAL REPORTING SYSTEMS

Key messages

- **Existing national reporting systems exhibit great variation in sponsorship, support, participation, and function.**
- **All of these reporting systems aim to improve patient safety.**
- **Reporting to most national systems is voluntary.**
- **A major issue for all reporting systems, public or private, mandatory or voluntary, is confidentiality.**

Existing national reporting systems exhibit great variation in sponsorship, support, participation, and function. Some, such as the National Reporting and Learning System (NRLS) in England and Wales, and those of Denmark, the Czech Republic, and Sweden were developed by governmental agencies to provide information to improve patient safety. Others, such as the Australian Incident Monitoring System (AIMS) sponsored by the Australia Patient Safety Foundation and the JCAHO Sentinel Events Reporting System, have been developed within the private or non-government sector.

All of these reporting systems aim to improve patient safety. However, their ability to do that varies considerably according to the sophistication of the analyses and the vigour with which efforts are pursued to turn insights into changes in practice. Patient safety is a relatively new concern for most governments. Not surprisingly, many still do not have a large cadre devoted to advancing safety or resources to carry out the plans they do make. A number of Member States have no current governmental initiatives in safety and no reporting system.

Reporting to most national systems is voluntary. However, systems in the Czech Republic and Slovenia require hospitals to report, and reporting of some especially serious events is required in the Netherlands, Japan, and other systems as well (see below for details).

Voluntary systems invite a professional ethic of participation in continuous learning and prevention, encouraged by acknowledgement and the reward of visible change. Experience from industries outside of health care, particularly aviation, as well as from some long-standing health-care reporting systems, for example, the Institute for Safe Medication Practice, shows that reporting systems are more likely to be successful if those reporting do not need to worry about adverse consequences to themselves or others.

A major issue for all reporting systems, public or private, mandatory or voluntary, is confidentiality. There is broad agreement across many systems that patients' and caregivers' names should not be disclosed, and these are protected by almost all systems. However there is much less agreement on whether the public should have access to hospital-level information.

Governmental health-care systems have a fiduciary responsibility to the public to ensure reasonable levels of safe care in health-care organizations, and reporting systems are one mechanism for discharging that responsibility.

Although accountability does not require release of all information, some form of public disclosure of adverse incidents seems indicated. Some systems make the events themselves available to the public; others disclose results of investigations or summary reports. Another option is to provide public notice of the occurrence of a serious event and of the actions taken in response by the institution and the government. Some agencies issue annual reports that summarize events and actions taken.

Types of patient safety reporting systems

The following information has been provided by representatives of reporting systems from across the world as a result of a survey undertaken for these guidelines.

Czech Republic

Type of reporting system: The Czech Republic has a mandatory reporting system. Voluntary reporting has also been in place for two years in 50 hospitals, and a national pilot project has been launched for voluntary reporting.

What is reported: Reportable events include nosocomial infections, adverse drug reactions, transfusion reactions, and medical equipment failures.

Who reports: Health care professionals.

How they report: Reports yield simple statistics of adverse events.

Analysis: Information is aggregated at different levels, including by hospital, medical specialization, region, and the republic. Analysis of sentinel event reporting in the field of acute hospital care launched in 2004; a similar project has been launched in long term care.

Response, dissemination and application of results: Reports are not accessible to the public.

Denmark

Type of reporting system: The Act on Patient Safety in the Danish Health Care System came into force January 1, 2004. The objective of the Act is to improve patient safety within the Danish health care system. The law obligates health care professionals to report specified adverse events to a national database. To support learning, this national mandatory system is sharply separated from the system of sanctions.

What is reported: Reportable adverse events are "events resulting from treatment by or stay in a hospital and not from the illness of a patient, if such event is at the same time either harmful, or could have been harmful had it not been avoided beforehand, or if the event did not occur for other reasons. Adverse events shall comprise events and errors known and unknown" Surgical events and medication errors, including close calls, must be reported.

Who reports: Healthcare professionals who become aware of an adverse event in connection with a patient's treatment or hospital stay are required to report the event.

How they report: Health care professionals report to the national database. Reports are automatically forwarded to the county where the event occurred and county councils record, analyse, and de-identify the reports. Lastly, reports are forwarded to the National Board of Health, which maintains a national register of adverse events.

Analysis: Although there are no national requirements for analysis, there is general use of the Safety Assessment Code (SAC) score. Adverse events with less serious SAC scores are acted upon locally, whereas serious adverse events (SAC score of three) prompt a root cause analysis.

Response, dissemination and application of results: Hospital owners are obligated by the Act on Patient Safety to act on reports, while the National Board of Health is charged with dissemination of lessons learnt. The National Board of Health issues alerts in the form of regular newsletters, in addition to an annual report.

Further information: www.patientsikkerhed.dk

England and Wales

Type of reporting system: The National Reporting and Learning System (NRLS) has been developed by the National Patient Safety Agency (NPSA) to promote an open reporting culture and a process for learning from adverse events. The purpose of the NRLS is to elicit reports of patient safety incidents, identify themes and patterns in the types of incidents being reported including major systems failures, and to develop and promote implementation of solutions.

The NRLS was launched in February 2004. As of July 2005, 548 NHS organizations have successfully connected to NRLS (90% of the total number).

What is reported: Patient safety incidents to be reported are defined as "any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare". Reports are anonymous, although a NHS Trust identifier is maintained; if staff or patient names are provided, they are removed before data are entered in the database.

Who reports: Any health care staff member can report a patient safety incident to the NRLS. The NPSA receives reports from NHS Trusts who in turn encourage reporting of patient safety incidents from each organization. The Trusts can be Acute, Primary Care, Mental Health or Ambulance Service oriented. Participation by health care services is voluntary.

How they report: Health care organizations with electronic risk management systems can use a technical link to submit reports directly from this local system into the NRLS. The NPSA has worked with local risk management software vendors to establish compatibility and interfaces. The objective is to have reports that are already collected for local use forwarded seamlessly to the national repository, therefore avoiding any duplication of data entry. Data are submitted to the NRLS at a rate of around 10,000 reports a week. The NSPA has worked with every Trust to 'map' its dataset to that of the NRLS (1).

The NPSA has also developed an electronic reporting form, the 'eForm', for use by organizations without compatible commercial risk management system software or for reports submitted independently of an organization's risk management system. The NRLS provides a detailed report form that guides the user through multiple question categories with coded options defining categories of where, when how, and what occurred. Brief sections for narratives are embedded throughout the form.

Patients and carers can telephone reports to the relevant Trusts' NHS Patient Advice and Liaison Service. Staff can also send in reports directly and plans exist to enable patients and from 2006 carers to report via an eForm.

Analysis: After data cleansing (the removal of identifying information), the NPSA database supports the identification of trends based on the specific data elements defined in the reporting formats. Standardized data are extracted that include the 'when and where', level of patient harm, patient characteristics, and contributing factors.

Adverse events are categorized into classes such as a medication event; these are further broken down into descriptors such as wrong quantity, wrong route, etc. The report form allows for narrative throughout, but the data provided in the structured, standardized format, can be automatically entered in the database and correlated to identify trends and relationships among the events and causes.

Reports are aggregated and analysed with expert clinical input to help understand the frequency of types of patient safety incidents, patterns and trends and underlying contributory factors. Investigation of reports submitted locally remains the responsibility of the local organizations. The NPSA does not investigate individual incidents or become involved in discipline or performance management.

Response, dissemination and application of results: Lessons learnt from NRLS are disseminated through the publication of NPSA Patient Safety Observatory reports and through feedback to reporting organizations on incident trends and solutions. Lessons learned from the NRLS feeds into the NPSA work on safety solutions.

Incident reports are not accessible to the public, but NHS Trusts may (and do) make information available at their discretion. The NPSA also provides root cause analysis training.

Further information: www.npsa.nhs.uk

The Netherlands

Type of reporting system: Non-punitive, voluntary reporting systems for adverse events are in place within most hospitals and other health care organizations. A mandatory system also exists for reporting serious adverse events (with permanent injury or death as result) which is monitored by the Health Care Inspectorate. There is considerable under-reporting.

What is reported: There is a legal requirement that serious adverse events are reported to the Health Care Inspectorate; adverse events resulting in persistent patient injury or death are reported, as well as suicides and acts of sexual harassment. Medical equipment failures are reported by manufacturers in accordance with legal European obligations.

Who reports: Voluntary reporting is conducted by anonymous sources, hospital or health care organizations, other health care organizations, patients, health care professionals and members of the public. Mandatory reporting is conducted by hospital or healthcare organizations, other health care organizations or by licensing or disciplinary actions.

How they report: Reports can be submitted by mail, fax, or phone.

Analysis: Data classification among the hospital systems is not standardized, meaning no national aggregation of data. The national mandatory system collates data.

As part of a regulatory response all hospitals are required to investigate serious events and redesign systems.

Response, dissemination and application of results: Following receipt of reports by the agency, most reports are investigated; receive analysis of incident causation and feedback to the reporter. The classification and collation of data is not solid and, therefore, may be unreliable. The Health Care Inspectorate received 2716 reports in 2003; average annual number of reports 3000. Committees for the investigation of adverse events in individual health care institutions are required to make an annual report. The Health Care Inspectorate produces an annual report of summary data which is made publicly available.

Further information: www.minvws.nl

Ireland

Type of reporting system: The Republic of Ireland established enterprise liability under a Clinical Indemnity Scheme (CIS) in 2002 to promote safe patient care, to reduce the number of claims and to manage claims in a timely fashion. A secure web based Clinical Incident Reporting System is being rolled out nationally.

What is reported: Reportable adverse incidents include "events arising as consequence of provision of, or failure to provide clinical care that results in injury, disease, disability, death or prolonged hospital stay for the patient" and "near misses".

Who reports: All enterprises covered by the CIS are required to report on a mandatory basis, all adverse clinical events and "near misses".

How they report: Paper reports are submitted to local risk management personnel. These data are then transmitted electronically to the Clinical Indemnity Scheme central database via a secure web based system (STARSweb).

Analysis: STARSweb enables aggregated statistical analysis and supports detection of trends both at the enterprise and national level.

Response, dissemination and application of results: Lessons learnt will be disseminated through quarterly newsletters, topic-based seminars, and via a regularly updated website.

Further information: www.dohc.ie

Slovenia

Type of reporting system: A voluntary national reporting system for sentinel events was established in 2002, similar to that developed by the Joint Commission on Accreditation of Healthcare Organizations in the United States.

What is reported: Sentinel events reported include: unexpected death; major permanent loss of function; suicide of a patient while in the hospital; discharge of a newborn infant to a wrong family; hemolytic transfusion reaction following administration of blood or blood products because of the incompatibility of major blood groups; surgery on a wrong patient or body part; and neglect which has a possible characteristic of a criminal offence.

Who reports: Hospitals

How they report: Reported information is analyzed at the Ministry of Health, who also provide an initial feedback to the health care organization where the error occurred.

Response, dissemination and application of results: Reports are accessible to the public as anonymous summaries disseminated via the internet.

Sweden

Type of reporting system: The Swedish healthcare law of 1997 requires every medical institution to have a quality system; most medical institutions have implemented different forms of quality systems, which are regulated by Statutes issued by the National Board of Health and Welfare (NBHW). The reporting and learning system is part of a regulatory response that requires hospitals to investigate serious events and redesign systems.

What is reported: Events resulting in unanticipated serious injury or disease or risk thereof are reported; this covers adverse events, near misses, equipment failures, suicide and other hazardous events.

Who reports: Reports are received from hospital and health care organizations and health care professionals.

Hospitals, heath care organization, licensing and disciplinary bodies are required to report adverse events to their nearest superior offices. Patients, health care professionals and members of the public voluntarily report events.

How they report: Reporting is done in paper format via mail or fax. The National Board of Health and Welfare receives reports; approximately 1100 mandatory and 2400 voluntary reports are received annually. The board investigates most reports and provides an analysis of incident causation; in all cases feedback is provided to the reporter.

Analysis: Regional supervisory units of the NBHW receive reports and carry out inspections. In a limited number of cases reports are sent to the Medical responsibility board (HSAN), where certified health care personnel may be subject to disciplinary actions.

Response, dissemination and application of results: The Board issues recommendations to influence statutes in order to promote patient safety.

All reports to the NBHW are accessible to the public, but all personal data about any patients involved are confidential.

United States of America

Type of reporting system: The United States does not have a national governmental reporting system, but 21 of the 50 state governments operate mandatory reporting systems. Many of these have been in place for decades. All 21 mandate reporting of unexpected deaths, and several mandate reporting of wrong-site surgery. Beyond this, definitions of reportable events vary widely. Reports of serious events may trigger on-site investigations by state health departments. Less serious reports usually do not elicit a visible response. States cite insufficient staff as a barrier to follow-up, education, consultation, and oversight. Some degree of public disclosure occurs in all states, but the degrees of protection and methods of public release of information vary considerably.

Private and non-government initiated systems

Australia - the Australian Incident Monitoring System (AIMS)

Type of reporting system: The Australian Incident Monitoring System (AIMS) was founded in 1993, as an extension of the Anesthesia AIMS, formed in 1987. The objectives of AIMS is to promote learning of new hazards, trends, risk factors and contributing factors.

What is reported: AIMS is designed to receive a wide range of events, including pre-defined "Sentinel" events, all adverse events, near misses, equipment failures, new hazards, and specific events such as suicide and abduction. AIMS can accept and classify incident information from any source including incident reports, sentinel events, root cause analysis, coroner's findings, consumer reports, and morbidity and mortality reviews.

Deliberately unsafe, abusive or criminal acts are not reported to AIMS but to mandatory reporting agencies.

Who reports: Reports are accepted from all sources, including hospitals, outpatient facilities, emergency departments, aged care (long term care), community care, professionals, patients and families, and anonymous sources.

The system is voluntary and confidential. By law, AIMS databases have been designated a formal quality assurance activity. This status confers protection from legal disclosure; revealing or disseminating individually-identifying information that becomes known solely as a result of safety and quality activities is a criminal offense.

Databases reside in a fully secure location with strictly limited access.

How they report: A single system (incorporating different forms) is used for all incidents. Reports are submitted by paper, electronically, or by phone.

Analysis: The classification system in AIMS is perhaps the most highly developed of any known reporting system, comprising more than a million permutations of terms to describe an incident or adverse event. The purpose of the classification process is to translate information about an incident into a common language and create an electronic record that can be compared with other records and can be analysed as part of a larger set of data. The latest classification is based on the Professor Runciman's Generic Reference Model (GRM). The GRM is based on the Reason model of complex system failure (2).

The GRM has the components contributing factors (environmental, organizational, human, subject of incident, agents), details of the incident (type, component, person involved, timing of the incident, timing of detection, method of detection, preventability), factors minimizing or aggravating outcomes or consequences, and outcomes for the patient and organization.

The GRM is implemented via Healthcare Incident Types (HITs). HITs are a series of cascading, hierarchically based questions and answers designed to "de-construct" the information in a way that facilitates subsequent analysis and learning.

AIMS allows the reporter to deconstruct an incident into a very detailed data set that can be used for analysis, aggregation, and trending. Owing to the rich "natural categories" in the classification scheme, interrelationships among event types, risk factors, and contributing causes can be probed.

A specific data module allows the user to develop a risk matrix to determine the severity of risk. Statistical correlations among the many elements in each category are explored to identify meaningful relationships and provide analysis that can generate insights into the overall systems of care.

AIMS has a hierarchically-based, completely customizable organization tree. All wards, departments, divisions, hospitals, health services, states or territories and nations can be represented. The organization tree has the potential for 13 levels.

Incidents can be analysed at the organization level and below at which the analyst has security rights (security constraints prevent analysts querying incidents above the organization node where they security privileges).The organization tree structure allows the whole spectrum of analysis from local management of problems to aggregated analysis at a national level. The AIMS system is well equipped to provide reports and queries on any term in the database, which makes it possible for institutions or departments to compare data.

Response, dissemination and application of results: The Australian Patient Safety Foundation provides newsletters, publications, and advice at a system level. The Health Departments who use AIMS also distribute information in the form of newsletters and publications.

Putting the information, trends, and recommendations into action is the responsibility of reporting facilities. Health care facilities and organizations are able to access AIMS findings from problem-specific task forces to lead patient safety initiatives.

Further information: www.apsf.net.au

Japan

Type of reporting system: In Japan, hospitals are mandated by the Ministry of Health, Labour and Welfare to have internal reporting systems. The Japan Council for Quality Health Care collects voluntary incident reports and implemented a national reporting system in 2004. Reporting to the new system is mandatory for teaching hospitals, voluntary for others

Reporting systems exist on three levels; hospital or health facility; voluntary system in several different forms such as accreditation body for hospitals and a research group, and at national level which is mandatory.

What is reported: Patient injuries, sometimes referred to as adverse events are reported along with near-misses and equipment failures.