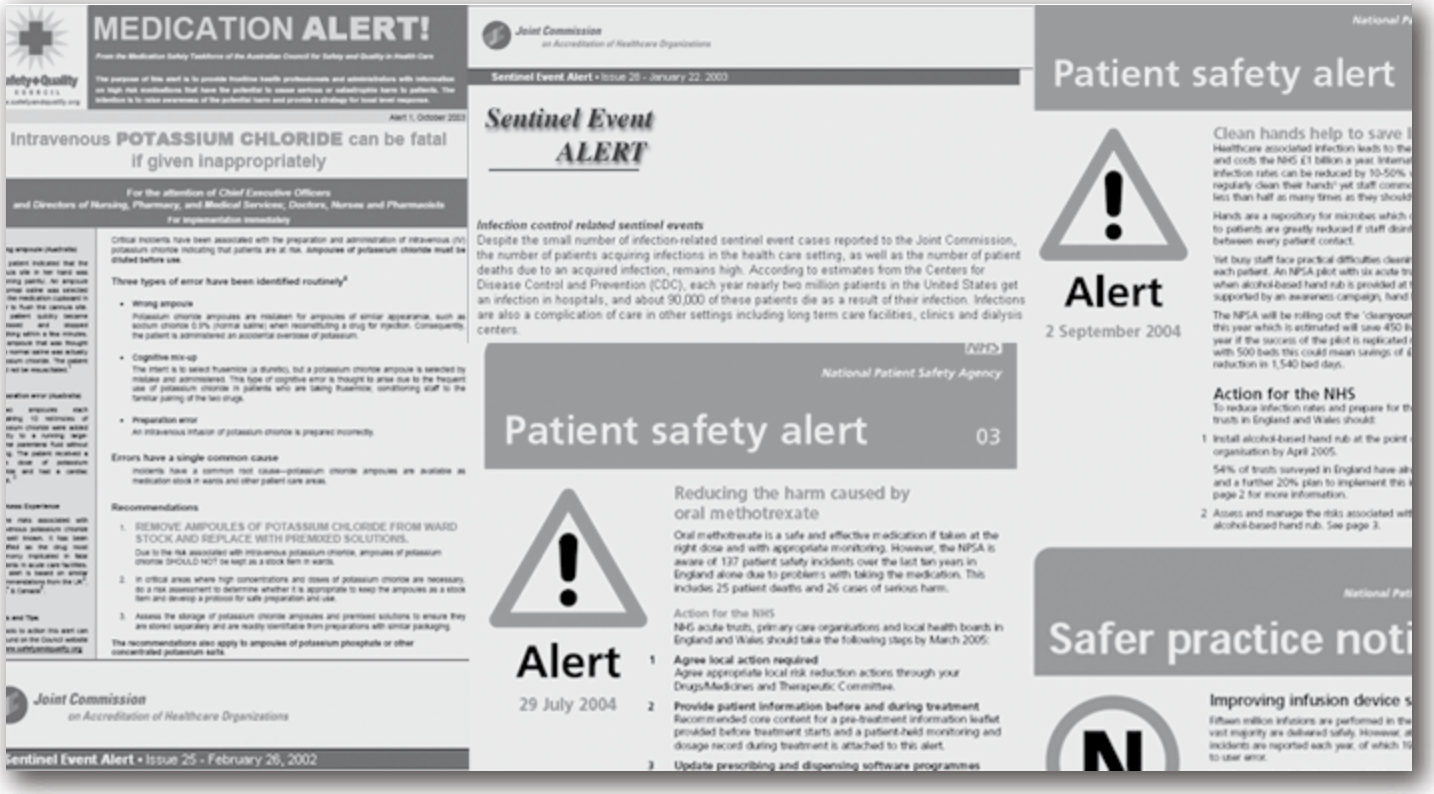
investigating a serious event can be disseminated. Third, analysis of many reports by the receiving agency or others can reveal unrecognized trends and hazards requiring attention. Finally, analysis of multiple reports can lead to insights into underlying systems failures and generate recommendations for "best practices" for all to follow.

### Alerts

Even a small number of reports can provide sufficient data to enable expert analysts to recognize a significant new hazard and generate an alert. An excellent example of this function is the series of warnings issued every two weeks by the Institute for Safe Medication Practices entitled "Medication Alert". This system was one of the first to call attention to the high risk of death following accidental injection of concentrated potassium chloride and recommend that this substance be removed from patient care units.




### Investigation of serious events

In a health-care organization committed to safety, a serious (especially disabling or life-threatening) event will trigger an investigation to search for underlying causes and contributing factors. Ideally, every institution will respond to a serious event with an investigation. Alternatively, an external authority (such as the health ministry) can conduct an independent investigation. If the investigation is done well, systems analysis of a serious adverse event can yield significant insights into the vari-

ous contributing factors that lead to a mishap, and often suggest potential remedies. This information can then be disseminated to other organizations. Solutions to some common hazards, such as wrong site surgery, have been developed in response to lessons learned from investigations of serious incidents.

### Analysis of large datasets

Detailed analysis of thousands of reports also makes it possible to identify hazards (1). In the Australian Incident Monitoring System (AIMS) classification system, information about an incident is entered into the database using the generic classification scheme of clinically relevant categories. Natural questions guide analysts through details of context and contributing causes to probe interrelationships among event types, risk factors, and contributing causes. Statistical correlations identify meaningful relationships and provide analyses that can generate insights into the overall systems of care.

In the United States, USP's MedMARx[SM] system receives thousands of reports of medication errors and adverse drug events confidentially from participating health-care organizations. These data are classified and fed back to health-care organizations with benchmarking from the entire database and with their own prior experience, to identify targets for improvement as well as providing monitoring of progress.

### Systems analysis and development of recommendations

The most important function that a large reporting system can perform is to use the results of investigations and data analyses to formulate and disseminate recommendations for systems changes. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has performed this function using a relatively small number of thoroughly investigated incidents reported to its sentinel events monitoring programme. Similarly, in the United States, some of the state reporting systems have developed safety recommendations from their data.

An example of a system aimed at translating learning into safety improvements is the relatively new National Reporting and Learning System (NRLS) developed by the National Patient Safety Agency (NPSA) in England and Wales. Reports are aggregated and analysed with expert clinical input to understand the frequency of types of incidents, patterns, trends, and underlying contributory factors. The NPSA has a "solutions" programme, involving all stakeholders. Recent initiatives include reducing errors associated with infusion devices, changes in doses of methotrexate, and a hand hygiene campaign.

## Accountability

Some reporting systems, such as those of state health departments in the United States have been developed primarily to hold health-care organizations accountable for ensuring safe practice. Accountability systems are based on the notion that the government has a fiduciary responsibility to ensure that health-care organizations take necessary precautions to ensure that care is safe (2). A serious and presumably preventable injury, such as amputation of the wrong leg, suggests that the hospital's error prevention mechanisms are defective (3). Knowing that there is oversight by a government agency helps maintain the public's trust.

Accountability reporting systems hold health-care organizations responsible by requiring that serious mishaps be reported and by providing disincentives (citations, penalties, sanctions) to continue unsafe practices (4). Reporting in these systems can also lead to learning, if lessons are widely shared (2). However, if the government agency does not have sufficient resources to investigate or to analyse reports and disseminate results, the opportunity for learning is lost. In addition, the risk of sanctions may make health-care organizations reluctant to report events that can be concealed.

Since most reports elicit no response, and lessons from investigations are seldom shared, health-care organizations often perceive reporting in these systems as all risk and no gain (5). The result is that typical accountability systems receive relatively few reports. This is unlikely to change unless more resources are provided for analysis and reporting, and the consequences of reporting are made less punitive.

## References


1. Runciman WB. Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system - is this the right model? *Quality and Safety in Health Care*, 2002, 11:246-251.
2. Kohn L, Corrigan JM, Donaldson MS. *To err is human: Building a safer health system*. Washington, DC, National Academy Press, 1999.
3. *Serious reportable events in patient safety: A National Quality Forum Consensus Report*. Washington, DC, National Quality Forum, 2002.
4. Flowers L, Riley T. *State-based mandatory reporting of medical errors. An analysis of the legal and policy issues*. Portland, ME, National Academy for State Health Policy, 2001.
5. Rosenthal J, Booth M, Flowers L, Riley T. *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives*. Portland ME, National Academy for State Health Policy, 2001.

# 3. COMPONENTS OF A REPORTING SYSTEM

## Key messages

- **Current reporting systems span a spectrum of objectives incorporating both learning and accountability considerations.**
- **The primary objectives of a reporting system will determine the design, for example, whether reporting is voluntary and confidential.**
- **Reporting systems need to be clear on who reports, the scope of what is reported and how reports are made.**
- **Reporting of incidents is of little value unless the data collected are analysed and recommendations are disseminated.**
- **Experts who understand statistical methods, the practice concerns, clinical significance, systems issues, and potential preventive measures are essential to analyse reported incidents.**
- **Classification and simple analytic schemes start the process of categorizing the data and developing solutions that can be generalized.**

## Types of systems

Current reporting systems span a spectrum of specific aims. At one end of the spectrum are reporting systems that focus on learning and contributing to system redesign. At the other end are systems developed by external regulatory or legal agencies primarily to ensure public accountability. These latter systems typically seek to identify health-care organizations where the level of care is unacceptable, for corrective action or discipline.

In practice, reporting systems may seek to address multiple objectives. Striking a balance within a single system between the aims of public accountability and learning for improvement is possible, but most reporting systems focus on one or the other. Although these aims are not necessarily incompatible, the primary objectives of the system will determine several design features, including whether the reports

are mandatory or voluntary, and whether they are held in complete confidence, or reported to the public or to regulatory agencies.

### Learning systems

Reporting to learning systems is usually voluntary, and typically spans a wider scope of reportable events than the defined set of events typically required by a mandatory system. Rather than assure a minimum standard of care, learning systems are designed to foster continuous improvements in care delivery by identifying themes, reducing variation, facilitating the sharing of best practices, and stimulating system-wide improvements. Following careful expert analysis of underlying causes, recommendations are made for system redesign to improve performance and reduce errors and injuries.

In Australia, for example, over 200 health-care organizations or health services voluntarily send incident reports to the Australian Incident Monitoring System (AIMS) sponsored by the Australia Patient Safety Foundation (APSF). AIMS uses the Healthcare Incident Types (HIT) classification system, which elicits very detailed information from the reporter regarding generic incident types, contributing factors, outcomes, actions, and consequences.

The Japan Council for Quality Health Care collects voluntarily reported adverse events from health-care organizations in Japan, particularly sentinel cases with root cause analysis. A research team led by Tokai University asks health-care organizations to voluntarily pool their events, which are then aggregated and results disseminated. In 2003, the Ministry of Health, Labour and Welfare patient safety committee recommended a national reporting system.

The National Reporting and Learning System (NRLS) in England and Wales is another example of a learning system. NRLS receives reports of patient safety incidents from local health-care organizations.

For more details about the above systems, see Section 5.

### Accountability systems

Reporting in accountability systems is usually mandatory and restricted to a list of defined serious events (also called "sentinel" events) such as unexpected death, transfusion reaction, and surgery on the wrong body part. Accountability systems typically prompt improvements by requiring an investigation and systems analysis ("root cause analysis") of the event. Few regulatory agencies have the resources to perform external investigations of more than a small fraction of reported events, however, which limits their capacity to learn. In Slovenia, a brief description of a sentinel event must be sent to the Ministry of Health within 48 hours, and 45 days later a satisfactory analysis with corrective actions must be submitted or else a follow-up consultation with the Ministry occurs. The Czech Republic has reporting requirements that follow from their accreditation standards.