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Reporting of adverse events

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WHEN the Institute of Medicine (IOM) issued *To Err Is Human*,¹ the recommendation to expand reporting of serious adverse events and medical errors, particularly mandatory reporting, received the most attention and sparked controversy.² The American Medical Association and the American Hospital Association raised strong objections, claiming that mandatory reporting would increase liability and drive reporting underground.³ Clearly, the report struck a nerve.

Although the response of the American Medical Association reflected some confusion about the IOM's advice - the call for mandatory reporting was directed at hospitals, not physicians - the discussion brought to the surface the unresolved conflict between the public's desire for accountability and doctors' and hospitals' fear of damage to their reputations and of malpractice liability. But the IOM also called for expanded voluntary reporting, raising the hopes of those who seek to improve patient safety through greater sharing of information about errors and adverse events.

According to the IOM, more than 1 million preventable adverse events occur each year in the United States, of which 44,000 to 98,000 are fatal.¹ Although the accuracy of these numbers has been challenged,⁴⁻⁶ there is general agreement that the problem is serious. Because a greater understanding of the types of injuries and their causes is essential for the development of more effective methods of prevention, it seems evident that improved reporting of accidents and serious errors that do not cause harm ("close calls") must be an essential part of any strategy to reduce injuries. Yet physicians have been reluctant partners in reporting.⁷

In this article, I examine the role of reporting in efforts to improve safety, assess the evidence that current reporting systems improve safety, review the characteristics of successful systems, and explore options for developing new reporting systems.

THE ROLE OF REPORTING

Reporting systems collect information on adverse events, errors, or both. Adverse events have been defined as injuries related to medical management (in contrast to complications of disease).⁸ Preventable adverse events are those that result from errors or equipment failures.⁹ 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)."¹

The primary purpose of reporting is to learn from experience. Many other methods are also used to identify threats to safety, but a good internal reporting system ensures that all responsible parties are aware of major hazards. Reporting is also important for monitoring progress in the prevention of errors. Thus, the reporting of close calls, as well as adverse events, is valuable. External reporting allows lessons to be shared so that others can avoid the same mishaps. State-run mandatory reporting systems have an additional purpose: to hold hospitals accountable for safe practices.^{1,10}

Ideally, when an adverse event occurs in a hospital, it is reported to the administration, an investigation is carried out to uncover the causes, and changes are made to prevent a recurrence.^{11,12} The results of the investigation are then reported to an external body, which aggregates and analyzes data from multiple sources and disseminates information broadly.

External reporting can lead to improved safety in several ways. First, alerts about new hazards (e.g., complications of a new drug) can be generated from even a few reports. Second, information about the experience of individual hospitals in using new methods to prevent errors can be disseminated. Third, central analysis of many reports can reveal trends and hazards that require attention. Fourth, central analysis can lead to recommended "best practices" for all to follow.¹⁰ These objectives can be achieved with either voluntary or mandatory systems.

Current reporting practices fall short of these objectives at every stage. In hospitals, staff members often fail to report incidents primarily because of time pressure, fear of punishment, and lack of a perceived benefit.¹³ Among physicians, shame and fear of liability, loss of reputation, and peer disapproval are particularly strong disincentives.⁷ On the other hand, striking increases in internal

Only 20 states have mandatory reporting systems (Rosenthal J: personal communication). The types of events that must be reported vary widely, from specific events, such as brain or spinal cord damage in Florida, to general events, such as those that "seriously compromise quality assurance or patient safety" in Pennsylvania. The only reportable event common to all state programs is unanticipated death.

Health departments sometimes investigate a serious accident in a hospital or require the hospital to do so, but most reports elicit no response. Few states have the experts to analyze more than a small fraction of reports. Thus, most hospitals receive no feedback after investigations, and no state tracks trends.

Some findings are usually made public, but detailed information is generally insulated from legal discovery.²⁶ Aggregate facility-specific data are published by Colorado and New York and are available by request in other states. Four states (Colorado, Kansas, Massachusetts, and Florida) issue regular reports of their activities, and four (Colorado, Kansas, Massachusetts, and New York) issue periodic alerts or newsletters.²⁶ In addition to the reporting system run by the Massachusetts Department of Public Health, which is accessible to the public, Massachusetts has a confidential mandatory reporting system administered by the Board of Registration in Medicine, which holds hospitals accountable for making changes and issues advisories but publishes no reports.

Some have called for public disclosure of all information uncovered during investigations, arguing that the public has a right to know about these events.¹ There is broad public support for disclosure: 62 to 73 percent of Americans believe that health care providers should be required to make this information publicly available.²¹ Others claim that public disclosure is necessary to drive improvements.²⁶ Few states agree with either argument; all but three (Massachusetts, South Carolina, and Washington) have regulations specifying that the reporting of adverse events is confidential.¹⁰

Although those who administer the programs have no doubt that mandatory reporting and investigations of serious events have sometimes led hospitals to introduce changes in order to prevent recurrence of the event, the evidence is anecdotal.^{26,28} No controlled studies have been performed. Low reporting rates suggest that the effect of these systems is small. The effect of newsletters or advisories is not known. It is also not known whether state oversight makes hospitals more careful or prompts them to take corrective actions that they would not otherwise take.

States typically measure the success of their mandatory reporting systems according to the number of reports received. By this measure, the systems fare poorly: only six state systems receive more than 100 reports annually.²⁶ Even in New York, where 15,127 reports were received in 1999, the hospital reporting rates ranged from 0 to more than 11 reports per 1000 discharges.²⁸

REASONS FOR THE INADEQUACY OF CURRENT REPORTING SYSTEMS

On the basis of either evidence of changes made to improve patient safety or the number of reports received, both voluntary and mandatory reporting systems fall short of their objectives. Analysis of the highly touted Aviation Safety Reporting System suggests the reasons. Charles Billings, the architect of this system, attributes its success to three factors: reporting is safe (pilots are immune from disciplinary action if they report promptly), simple (a one-page report is made), and worthwhile (experts analyze the confidential reports and disseminate recommendations to pilots and the Federal Aviation Administration).²⁹ The Aviation Safety Reporting System receives more than 30,000 reports annually and has contributed substantially to aviation safety over the years.³⁰

The most successful voluntary programs for reporting medical errors - the Medication Error Reporting Program, MedMARx, and the National Nosocomial Infection Survey - share these characteristics. Reporting to these programs is safe and is not viewed as onerous, and the programs provide timely feedback of useful information from expert analysis.

Conversely, reports made to most mandatory state programs or the JCAHO are seldom simple, safe, or worthwhile. Reporting is cumbersome and time-consuming, and it carries the risk of loss of license or accreditation. Since most state reports elicit no response and the lessons learned from investigations are seldom shared, hospitals often view reporting as all risk and no gain.²⁶ Hospitals also fear public disclosure of reports, with damage to their reputations, loss of business, and litigation.^{3,26,31,32} The media usually learn about embarrassing accidents from other sources, but the fear of disclosure by reporting systems remains.

The fear of litigation may also be overblown. No link between reporting and litigation has ever been demonstrated. In addition, hospitals have an ethical obligation to inform patients fully of the causes of their injuries, and such disclosure was recently made a requirement by the JCAHO.³³ If patients know, then so could their lawyers. In fact, several reports indicate that full disclosure reduces the risk of litigation.^{34,35}

IMPROVING REPORTING SYSTEMS

Table 2 lists the characteristics that have been identified by various authors as essential for a successful reporting program.^{22,30,36,37} Any changes that move programs in these directions will most likely result in improvement. Although historically confidentiality has not been breached, concern about disclosure inhibits reporting for many voluntary programs, particularly the JCAHO.³⁸ To address this issue and to encourage the development of voluntary reporting systems, bills have been introduced recently in the U.S. House and Senate to provide protection for those who voluntarily share information about medical accidents and errors.^{39,40}

Characteristic	Description
Reporting	Requires all (or the vast majority) of providers or personnel that others do as a part of reporting.
Confidential	The names of the patients, reports, and facilities are never revealed to a third party.
Independent	The program is independent of any authority with power to control the practice of the profession.
Report audit	Requires an independent review of the clinical circumstances and the response to the reported incident.
Timely	Requires an initial prompt and complete review and timely identification of those who need to take appropriate action through the system.
Source-protected	Requires that the source of the information is protected, either from the individual profession or from the public.
Responsive	The agency that receives reports is capable of disseminating corrective action and participating in the development of reporting systems.

TABLE 2.

Making mandatory state reporting programs safer and more productive is a much greater challenge. Reporting adverse events to state programs can never be totally safe; to ensure accountability, they must be able to impose sanctions. However, if sanctions are limited to serious violations and if the program provides hospitals with useful information, the program may be perceived by hospitals as both just and justifiable. The experience with the Massachusetts Board of Registration in Medicine's confidential program bears this out. Hospitals are required to demonstrate to the board's satisfaction that they have taken appropriate steps to remedy the defects that led to the reported event. In this system reports and responses are not made public.

The sticky issue is public disclosure. Accountability does not require the release of all information, but the public wants evidence of oversight. One compromise would be to withhold the details of an investigation of a serious event but to provide public notice of its occurrence and of the actions taken to address it. Alternatively, the agency could issue annual reports summarizing events and actions taken (as some states now do²⁶). Neither alternative will satisfy either hospitals or advocates of full disclosure. However, these approaches represent a reasonable middle ground and would provide needed public evidence of accountability.

Lack of resources limits the ability of state systems to provide better oversight and more useful feedback to hospitals.^{26,41} Sixty percent of states have no programs at all.⁴² Of the 20 state reporting systems, only 3 (those in Florida, Massachusetts, and New York) employ five or more full-time-equivalent staff members; annual funding ranges from \$200,000 to \$1,500,000.^{26,41} Except for recent additional funding in New York, there is little evidence that support will be increased in the foreseeable future.²⁸ The outcry by the American Medical Association and the American Hospital Association, among others, seems to have neutralized the pressure to provide a federal subsidy for these programs, as recommended by the IOM.

States could make reporting more efficient for themselves and for hospitals if they restricted mandatory reporting to "unambiguous, usually preventable, serious" events, as carefully defined by the National Quality Forum²⁵ (Table 3). This approach would also facilitate the dissemination of data among states.'

A NATIONAL VOLUNTARY REPORTING SYSTEM?

Some believe that a national voluntary system for the reporting of all medical errors and adverse events has great potential for improving safety.^{1,43} A national system would have several advantages. The large number of reports would help prioritize hazards so that resources could be efficiently targeted. Identification of low-frequency events would permit earlier identification of unsuspected hazards. Analysis of many events at different sites could lead to the identification of common contributing factors. Successful experiences could be widely shared. A national error-reporting system in Australia has yielded useful information.⁴⁴

Despite these attractions, it is doubtful that a national system is feasible in the United States. Not only would it be difficult to satisfy the criteria in Table 2, but the costs and technical challenges would also be substantial. The numbers are daunting. Studies estimate that 1 million serious error-related adverse events occur annually.^{1,9} If close calls were also reported, the total number of reportable events could be 5 million⁴⁵

Even if only 10 percent of errors were reported, that number - 500,000 - is 15 times the number processed by the Aviation Safety Reporting System. Such a system would be expensive (the Aviation Safety Reporting System costs \$70 per case)⁴³ and would require a huge cadre of expert analysts. Recruiting and training them would be difficult and expensive. It seems unlikely that federal support for such a system could be obtained.

A more realistic alternative would be an expansion of systemwide programs, such as the Veterans Affairs program¹⁷ and specialty-based, focused reporting programs, such as those for neonatal and adult intensive care units.¹⁸⁻²⁰ These programs have the advantages of the commitment of those who ran them, the allegiance of reporters who trust fellow experts, and the ability to be tailored to practice needs.³⁶ Similar programs could be developed by other specialties.

CONCLUSIONS

Interest in developing new voluntary reporting systems is high. If reporting is safe and provides reporters with useful information from expert analysis, it can measurably improve safety. Most of the benefits can be obtained with specialty-based or systemwide reporting programs, which are much more feasible than a national system. Although some of these programs are being developed in spite of concern about the risk of disclosure, federal legislation to protect shared information from disclosure would enhance reporting in all systems and accelerate expansion.

Table 3. List of Serious Reportable Events*

Medical events
Major performed on the wrong body part
Major performed on the wrong patient
Major medical procedure performed
Retention of foreign object in a patient after surgery or another procedure
Death or permanent loss of A&P that is a direct result of or immediately after surgery
Event involving products or devices
Death or serious disability associated with the use of contaminated drugs, devices, or supplies provided for the health care facility
Death or serious disability associated with the use or function of a device that is other than the intended use or function
Death or serious disability associated with the manufacture or delivery of a drug while the patient is receiving care in a health care facility
Event involving patient personnel
Infant discharged to the wrong parent
Death or serious disability associated with a patient's disappearance that occurs after final check-out, or a physical security breach of critical facilities, while patient is receiving care in a health care facility
Event involving care
Death or serious disability associated with a medication error (e.g., an error involving the wrong drug, wrong dose, wrong patient, wrong time, wrong test, wrong preparation, or wrong route of administration)
Death or serious disability associated with a transfusion reaction due to the administration of blood components, blood or blood products
Death or serious disability associated with failure to identify or identify a low-risk newborn receiving care in a health care facility
Death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is receiving care in a health care facility
Death or serious disability associated with failure to identify and treat hyperkalemia in a patient
Death or serious disability associated with failure to identify and treat hypocalcemia in a patient
Death or serious disability associated with failure to identify and treat hypomagnesemia in a patient
Death or serious disability associated with failure to identify and treat hypophosphatemia in a patient
Death or serious disability associated with failure to identify and treat hypocalcemia in a patient
Death or serious disability associated with failure to identify and treat hypomagnesemia in a patient
Death or serious disability associated with failure to identify and treat hypophosphatemia in a patient
Environmental events
Death or serious disability associated with an oxygen bleed while patient is receiving care in a health care facility
Any incident in which a fire designated fire trigger or other gas or fire detector in a patient's room or in the vicinity of a patient's room is compromised by smoke or fire
Death or serious disability associated with a toxic incident while patient is receiving care in a health care facility
Death associated with a fall while patient is receiving care in a health care facility
Death or serious disability associated with the use of restraint or holds while patient is receiving care in a health care facility
Systemic events
Any instance of an infant or newborn provided by someone impersonating a physician, nurse, pharmacist, or other health care provider
Abduction of a patient or staff member
Death or serious disability of a patient or staff member resulting from a physical assault (i.e., battery) on or on the grounds of a health care facility
Death or serious disability of a patient or staff member resulting from a physical assault (i.e., battery) on or on the grounds of a health care facility

*Modified from the National Quality Forum.
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TABLE 3.

The future of mandatory reporting is less clear. Despite calls for increased accountability on the part of hospitals and the availability of the National Quality Forum's standardized list of serious reportable events, mandatory systems appear to lack a major constituency in most states and therefore fail to receive adequate financial support. Unless that changes, mandatory reporting systems are likely to remain relatively ineffective.

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