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Advancing Patient Safety Through State Reporting Systems

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Perspective

Seven years ago, the Institute of Medicine (IOM) called on states to create mandatory reporting systems as part of a strategy to identify and learn about medical errors and ultimately to improve patient safety.(1) Since then, many states have responded by creating or improving reporting systems to collect information about hospital-based adverse events. These systems can provide states with an opportunity to strengthen their facility oversight functions, safeguard the public, and partner with providers to improve health care quality.

As of April 2007, more than half of states (27) had passed legislation or created regulations related to hospital reporting of adverse events (26 are mandatory systems, one is voluntary).(2)

The goals of state reporting systems may be twofold. First, many of these requirements are intended to hold health care facilities accountable for weaknesses in their systems. Secondly, they may strive to improve patient safety through analysis and dissemination of best practices and lessons learned, which could prevent recurrences.

In this article, I will review the evolution of state error reporting systems, current trends, common criticisms, and state responses.

State Reporting Systems Continue to Improve

Despite their potential, there has been significant discussion and controversy about the purpose and usefulness of these systems. Reasons vary, from the perception that they are punitive, to fear of malpractice litigation associated with reporting, to lack of confidence in the usefulness or availability of the data gathered.

To be sure, states face challenges in patient safety data collection, analysis, and feedback. Reporting systems that were created prior to 2000 were designed for different purposes (including responses to

medical malpractice insurance crises of the 1970s and 1980s and as regulatory tools to increase oversight of hospitals) and therefore may have lacked advanced data-gathering and analytic capability. However, since 2000, the number of states with authorized systems has almost doubled, and many of the original systems have been updated and refined. As state experience with reporting systems grows, the systems continue to evolve and mature.

Accountability

State systems do not punish facilities for events but do seek to hold them accountable for correcting system weaknesses. They do so by investigating events, providing expertise or information to help remedy problems, and insuring that appropriate changes are made and sustained to avoid similar problems in the future.

Patient safety improvement requires both internal and external pressure to drive change. As *To Err Is Human* observed, external reporting systems can help create an environment that encourages organizations to identify errors, evaluate causes, and take appropriate actions to improve performance.(1) As Leape and Berwick have noted, systemic nationwide patient safety improvements require, among other things, pressure on the health care industry from public outrage, reformed reimbursement policies, and regulation.(3)

Although institutions may already report errors internally and analyze them for lessons and opportunities for system change, external reporting requirements can increase the priority of patient safety within institutions. The majority of state reporting systems now require facilities to conduct root cause analyses (RCAs) and submit information about root causes and corrective action plans with their reports. This process is critical to state efforts to reduce recurring problems and can also help facilities make internal process improvements.

Transparency

In discussing the need to foster innovation and improve the delivery of care, the IOM called for public accountability by emphasizing transparency as one of ten principles that should guide the redesign of the health care system.(4) States have recognized the tension inherent in promoting transparency with regard to medical errors: although transparency can drive improvements, care must be taken to avoid penalizing institutions for honestly seeking opportunities for improvement. In response, states are beginning to encourage more transparency while providing strong protections for certain data (patient and provider identifiers). The majority of states now report aggregate data of some kind, and legislation authorizing several of the more recent systems requires the availability of facility-specific data. Minnesota has set the stage, having produced annual reports with facility-specific data for the past 3 years.(5) To date, concerns that such facility-specific reporting would lead to massive recriminations or unfair press coverage have generally not been realized. And, despite fears of litigation, there is no evidence to suggest that data available through state patient safety reporting systems have been used to generate malpractice claims. In fact, these systems often have stronger confidentiality protections than other state data (statements of deficiencies, complaints, report cards, etc.).(6)

Analysis

In addition to analyzing individual event reports, most states also aggregate data over time and/or across facilities to assess the patient safety performance of a facility, region, or state. Although small numbers can hinder some analyses, states have discovered that extracting useful data from reporting systems is not dependent on the existence of epidemiological risk-adjusted data. Simple, routine analysis using aggregated event report data identifies information that is not apparent from a review of individual incidents. Anecdotal information sharing?in the form of trends, stories, and lessons learned?can be useful in providing facilities with opportunities for improvement.(7)

New York, for example, invites hospitals to participate in expert subcommittees with local health department staff to review de-identified findings from RCAs and extract lessons that may have broader applicability for release in a hospital alert. Analysis of wrong-patient/wrong-site surgical errors led to development of the New York preoperative protocols final report in January 2001. Hospitals were expected to develop and implement procedures based on the report. Following the analysis and subsequent protocols, the number of such events decreased from 25 in 2002 to 17 in 2003.(8)

Although it is unrealistic to expect states to achieve full reporting, they can achieve a critical mass for analysis. During 2006, Pennsylvania collected the greatest number of adverse event and near miss reports (almost 196,000), which enabled opportunities for analysis in many areas.

Feedback for Improvement

Patient safety alerts and advisories provide an opportunity for state reporting systems to share timely, specific, actionable information. Pennsylvania, for example, distributes its quarterly Patient Safety Advisories electronically to an estimated 10,000 recipients around the country. Pennsylvania facility patient safety officers, in responding to a survey, reported implementing more than 500 changes in their facilities as a result of Patient Safety Advisories, including using color-coded patient wristbands to communicate clinical information, forming a skin integrity task force, restricting the use of propofol to the anesthesia department, and reducing the use of verbal orders.(9)

A growing number of states are developing Web-based systems that enable providers to access their own data and create comparative reports with their own data over time, to a peer group, and statewide. This improvement enables users to access timely information and enhances learning from the data. Utah, for example, developed a Web site that enables users to query hospital discharge data for occurrences of AHRQ Patient Safety Indicators (PSI), ICD-9 codes, and Utah's adverse drug event (ADE) indicators.(10) Users can investigate PSIs and ADEs in relation to length of stay and total charges; compare indicator trends for a hospital with hospitals in its peer group, a hospital corporate system, and aggregate state data; and stratify results by sociodemographic factors, payer, and service.

Information from reporting systems, combined with other quality data, may also be useful to purchasers and consumers. Health plans and payers may find information about adverse events useful to target their quality improvement projects and to assess overall quality of care. Tufts Health Plan in Massachusetts, for example, uses publicly available state data to monitor opportunities for improvement within its network. When appropriate, the plan follows up with a contracted facility to determine if corrective action plans submitted to the state have been implemented. Examples of follow-up may include requesting policies and procedures, reviewing training content and attendance records, and scheduling site visits.

Future Challenges

In recent years, the national call for transparency and public reporting has increased and states have gained more experience partnering with providers and outside experts to create systems that can have a meaningful impact on patient safety. As a result, the political opposition and lack of technical expertise that initially kept many states from moving forward in developing effective systems have been abating.

However, challenges remain. Lack of standardized reporting continues, although there is a growing trend of new systems adopting, unaltered or with modifications, the National Quality Forum's list of serious reportable events for adverse event reporting systems (Table 1 and Table 2).

Funding remains a persistent challenge. Although the IOM recommended that Congress provide funding and technical expertise to all state governments to establish or adapt error reporting, funding has not been made available. States have used various mechanisms to support reporting systems, including general revenue funds and facility assessments. Although some program costs can be absorbed into existing state budgets, analysis and dissemination of useful information are likely to represent substantial new costs. Pennsylvania, an exception in terms of funding level, budgeted $2.5 million, or about $17 per report, for aggregating, analyzing, and disseminating information from 150,000 reports in 2005.(7)

Patient safety issues are also complex, particularly for consumers. Disseminating information in a useful and meaningful way continues to be a challenge: What is an error, event, incident? What is a system weakness? Can the information be used to compare facilities? Are facilities with fewer numbers safer? What are effective corrective actions? Should these reports be used as stand-alone documents or are they better used in conjunction with other quality information?

There is general agreement that nationwide progress in improving patient safety is slow. Patient safety reporting represents just one tool to promote patient safety. Since we have yet to develop a nationwide system or identify one ideal system, states continue to serve a valuable role as laboratories of innovation to examine how best to monitor facilities for safety, assist with quality improvement processes, and keep stakeholders informed about progress in improving patient safety.

Jill Rosenthal, MPH National Academy for State Health Policy

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Table 1. State Reportable Events (11)(Go to table citation in commentary)

NQF's Serious Reportable Events Unaltered or with Modifications, Exclusions, or Additions	Other State-Generated List
CA, CT, IL, IN, MN, NJ, OR, VT,* WA, WY	CO, FL, GA, KS, MA, MD, ME, NV, NY, PA, OH, RI, SC, SD, TN, TX, UT

*VT update added by author.

Table 2. The National Quality Forum's List of 28 "Never Events" (11,12) Reprinted with permission from the National Quality Forum.(Go to table citation in commentary)

Surgical Events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately postoperative death in an ASA Class I patient

Product or Device Events

- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility
- Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility

Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with patient elopement (disappearance)
- Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a health care facility

Care Management Events

- Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility
- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility
- Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
- Stage 3 or 4 pressure ulcers acquired after admission to a health care facility
- Patient death or serious disability due to spinal manipulative therapy
- Artificial insemination with the wrong donor sperm or wrong egg

Environmental Events

- Patient death or serious disability associated with an electric shock while being cared for in a health care facility
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility
- Patient death or serious disability associated with a fall while being cared for in a health care facility
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility

Criminal Events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
- Abduction of a patient of any age
- Sexual assault on a patient within or on the grounds of a health care facility
- Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care facility