NATIONAL ACADEMY
for STATE HEALTH POLICY

Maximizing the Use of State Adverse Event Data to Improve Patient Safety

Jill Rosenthal
Maureen Booth

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EXECUTIVE SUMMARY

During the nearly six years since the Institute of Medicine released its first report on medical errors, there has been growing recognition of the size and scope of the problem. Many states have responded by creating or improving reporting systems for collecting hospital-based adverse events. As of September 2005, twenty-four states had passed legislation or regulation related to hospital reporting of adverse events (23 are mandatory systems, one is voluntary). Although the overriding reason for many of these systems is to ensure accountability, many state reporting systems have a learning component as well as an accountability component. The systems have the potential to improve patient safety through event report analysis and dissemination of best practices and lessons learned, which could prevent recurrences.

Improving the collection, analysis, and feedback of state reporting system data could be useful in a variety of ways. Trend data are potentially useful to state regulators, providers, purchasers, and consumers for various purposes, including accountability for health care safety, facility improvement projects, consumer education, and pressure to drive change and enhance patient safety. However, data collection, analysis, and feedback present challenges to state reporting system administrators, data analysts, and potential data users as they try to develop and use effective reporting systems to improve patient safety. Challenges include incomplete reporting, statistical hurdles, and identifying user-friendly reporting formats.

In May 2005, NASHP convened a meeting of data collectors (state officials who administer reporting systems), analysts (state officials or consultants to them), and users (providers, purchasers, and consumers) to identify mechanisms to improve reporting, tools used for event report analysis and dissemination, and opportunities for improvement. The following states were represented: Florida, Georgia, Maine, Maryland, Massachusetts, Minnesota, Nevada, New York, Oregon, Pennsylvania, and Utah.

This report reviews key findings from the meeting to assist states in improving their reporting systems and to encourage providers to improve the quality of the required reports so that data are credible and useful in shaping patient safety improvement interventions. It focuses on data integrity, event report analysis, and data feedback. It also raises a number of challenges and opportunities that states encounter as they attempt to improve their databases and the usefulness of the data for improving patient safety.

In initiating this project, NASHP assumed that states need to increase the number of reports in order to provide useful feedback from their systems to those who can use the data to improve quality of care. This situation is certainly the case in some states, and those states can use a variety of methods to increase the number of reports. However, it became apparent that extracting useful data from reporting systems is not dependent on

the existence of epidemiological risk-adjusted data. In contrast, anecdotal information sharing, in the form of trends, stories, and lessons learned can be useful in providing facilities with opportunities for improvement.

By focusing on the quality improvement aspect of reporting systems, states with existing reporting systems may be able to improve their data analysis and feedback of best practices, providing more information to providers to assist them in improving care. Providers who receive useful feedback from the systems may then have more incentive to report into them.

As states consider these tools, they will now do so in the context of several new national developments that may influence state systems, including the Patient Safety Event Taxonomy (PSET) endorsed by the National Quality Forum and the Patient Safety and Quality Improvement Act of 2005. Any national standardization is likely to affect state systems.

In addition to this paper, NASHP will disseminate project findings through a news brief and a Web-based toolbox (at www.nashp.org) that will contain tools and resources developed by states with mandatory reporting systems.

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INTRODUCTION

Medical Errors and Adverse Events

During the nearly six years since the Institute of Medicine (IOM) released its first report on medical errors,[1] there has been growing recognition of the size and scope of the problem. Medical errors rank as a leading cause of death in the United States.[2] The issue has caught the public's attention as well as the attention of those who provide, purchase, and regulate health care.

Several patient safety leaders have examined patient safety progress since the IOM released *To Err is Human*, and have found little evidence of systematic improvements in the health care system.[3] Despite the growing awareness and varied activities that have made small improvements in safety, the public does not feel safer,[4] and progress has been slow.

Not only has systematic change been slow, but it has proven difficult to measure. One of the difficulties in measuring improvements is the lack of data available to track and measure change. The IOM recommended in *To Err is Human* that identifying and learning from errors through immediate and strong mandatory reporting systems be part of a four-tiered approach to improving safety.[5]

Many states have responded by creating or improving systems for the reporting of hospital-based adverse events. Many of them have accepted this role as part of their

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[1] Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C: National Academy Press, 1999).

[2] As many as 98,000 people die annually in hospitals alone as the result of errors, many of which are preventable. Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C: National Academy Press, 1999), 26.

[3] Lucian L. Leape and Donald M. Berwick, "Five Years After To Err is Human: What Have We Learned?", *JAMA*, 293, no. 19 (May 18, 2005), 2384-2390; Drew Altman, Carolyn Clancy, and Robert Blendon, "Improving Patient Safety—Five Years After the IOM Report," *New England Journal of Medicine*, 351, no. 20 (November 11, 2004), 2041-2043; Timothy Ferris, Vida Foubister, and Lucian Leape, "Five Years After To Err is Human: Report and Recommendations to the CMWF Quality Improvement Colloquia," unpublished summary of colloquia proceedings, 2004.

[4] Kaiser Family Foundation, Agency for Healthcare Research and Quality, Harvard School of Public Health, *National Survey on consumers' experiences with patient safety and quality information* (Menlo Park, CA: Kaiser Family Foundation, July 5, 2004).

[5] Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C: National Academy Press, 1999), 6.

responsibility to address medical errors and patient safety issues as the licensing entity for health care facilities.

Project Overview

In May 2005, NASHP convened a meeting of data collectors (state officials who administer reporting systems), analysts (state officials or consultants to them), and users (providers, purchasers, and consumers) to identify the following:

- mechanisms to improve reporting,
- tools used for event report analysis and dissemination, and
- opportunities for improvement.

NASHP limited the summit to a small group of participants to encourage in depth discussion, interaction, and information sharing. (See Appendix A for a list of participants.) Issues of discussion included:

1. What type of data do states collect for analysis?
2. How do states collect and categorize reporting system data to assure it will be useful to analyze?
3. Who conducts analysis for the state? Who advises the state on the types of analysis to conduct?
4. What types of analyses are most useful to state officials, providers, consumers, and purchasers? What do the data tell you and what have you learned?
5. How do states handle issues related to small data sets?
6. What information on root causes and corrective action plans is useful for states to share with facilities?
7. Are state reporting systems moving us toward our goal? How do we define success?
8. What barriers limit the usefulness of the data and how can they be addressed?
9. What methods can states use to maximize reporting of adverse events and assess completeness of reports when limited resources are available?
10. What is the potential to integrate adverse event data with other state data systems or across states?

States that were represented at the meeting include: Florida, Georgia, Maine, Maryland, Massachusetts, Minnesota, Nevada, New York, Oregon, Pennsylvania, and Utah. Brief relevant information on the systems in these states is included in Appendix B.

The project emphasized how reporting systems can convert data into practical information within existing policy parameters. Regardless of whether state policy dictates protection or disclosure of data,[6] enhanced reporting and analysis of the data at

[6] This project deliberately avoided the debate about protection and disclosure of data in order to focus on issues related to data analysis and feedback. For a discussion of issues related to

both the state and hospital levels could potentially result in improved care for all types of hospital patients as well as patients in other care settings.

An advisory group of state and federal experts in the field guided the project. The members of that group are listed in Appendix C.

This report reviews key findings from the meeting to assist states in improving their reporting systems and encourage reporters to improve the quality of the required reports so that data are credible and useful in shaping patient safety improvement interventions.

State Reporting Systems

As of September 2005, just under half of all states (24)[7] had passed legislation or regulation related to hospital reporting of adverse events (23 are mandatory systems, one is voluntary).[8] Since the Institute of Medicine published *To Err is Human*, the National Academy for State Health Policy has tracked state progress in developing reporting systems, provided policy analysis and technical assistance to states, and issued numerous publications on this issue.[9] These publications provide information on the types of events that are required to be reported in states, the protection and disclosure of information to the public, the use of the data collected, and other factors, all of which vary across states.

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disclosure and protection, including the pros and cons, legal tools for protection, strengths and weaknesses of various approaches, and sample language, see Lynda Flowers and Trish Riley, *State-Based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues* (Portland, ME: National Academy for State Health Policy, 2001); Mimi Marchev, *Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears* (Portland, ME: National Academy for State Health Policy, 2003).

[7] CA, CO, CT, FL, GA, KS, IL, MA, MD, ME, MN, NV, NY, NJ, PA, OH, OR, RI, SC, SD, TN, TX, UT, WA. Oregon is the only voluntary system.

[8] Massachusetts has two mandatory reporting systems. This report reflects only the system administered by the Department of Public Health, not the system administered by the Board of Registration in Medicine's Patient Care Assessment Program, which requires quarterly reports.

[9] The following are available from NASHP at www.nashp.org. Jill Rosenthal, Maureen Booth, *Defining Adverse Events: A Guide for States Tracking Medical Errors* (Portland, ME: National Academy for State Health Policy, 2003); Jill Rosenthal, Maureen Booth, *How Safe Is Your Health Care? A Workbook for States Seeking to Build Accountability and Quality Improvement Through Mandatory Reporting Systems* (Portland, ME: National Academy for State Health Policy, 2001); Lynda Flowers and Trish Riley, *State-Based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues* (Portland, ME: National Academy for State Health Policy, 2001); Lynda Flowers and Trish Riley, *How States Are Responding to Medical Errors: An Analysis of Recent State Legislative Proposals* (Portland, ME: National Academy for State Health Policy, 2000); Trish Riley, *Improving Patient Safety: What States Can Do About Medical Errors* (Portland, ME: National Academy for State Health Policy, 2000); Jill Rosenthal, Maureen Booth, Anne Barry, *Cost Implications of State Medical Error Reporting Programs: A Briefing Paper* (Portland, ME: National Academy for State Health Policy, 2001).

Most states have followed the IOM's recommendation to implement mandatory reporting systems. Although the overriding purpose for these systems, as recommended by the IOM, is to hold health care organizations accountable for performance, many state reporting systems have a learning component as well as an accountability component. The purpose of the learning component is to provide information to health care organizations to support quality improvement efforts and prevent errors from occurring.

State reporting systems have the potential to improve patient safety through event report analysis and dissemination of best practices and lessons learned to prevent adverse event recurrences. For example, some states send out safety alerts when incidents with significant consequences are reported or when there is a potential to avert their recurrence elsewhere. Other states attempt to aggregate the data they collect to identify patterns and trends across facilities. They may share aggregate data with facilities in the form of newsletters that highlight trends and showcase best practices to reduce repeat incidents. Some states provide facilities with a comparison of their reporting experience with that of peer facilities or national standards. Some produce routine reports showing trends in reportable events, by size of facility and type of incident.

Despite state interest in analyzing reporting system data and providing feedback that can be used to improve patient safety, states have found barriers to analysis and feedback. States may be challenged by small numbers of reportable and/or reported events, lack of resources, and lack of clinical expertise, all of which may limit states' ability to produce reliable trend data and identify best practices. In addition, state reporting systems are in various stages of implementation and many are in the process of determining how best to analyze and share information with reporting facilities.

Improving the collection, analysis, and feedback of state reporting system data could be useful in a variety of ways. Trend data are potentially useful to state regulators, providers, purchasers, and consumers for various purposes that include accountability for health care safety, facility improvement projects, consumer education, and pressure to drive change and enhance patient safety. Currently, data collection, analysis, and feedback present a challenge to state reporting system administrators, data analysts, and potential data users as they try to develop and use effective reporting systems to improve patient safety. These challenges include incomplete reporting, statistical hurdles, and identifying user-friendly reporting formats.

DATA INTEGRITY

Consistency in reporting is essential to analysis. States need consistent, reliable data in reporting systems in order to extract useful information. During the May 2005 meeting, participants distinguished between *full data*, the reporting of every event, and *complete information for each event reported*. Reporting system administrators acknowledge that they are not likely to achieve reporting of every event. Thus, even as they attempt to increase the number of reports, they also focus on ensuring that the reports they do receive are complete and accurate so that the resulting information is as useful as possible. States clarify reporting requirements and educate facilities about reporting requirements in order to increase the number of reports and the completeness of each report.

Themes and Examples

1. Reporting systems need clear definitions of reportable events.

Most reporting systems have developed their own list of reportable events with varying definitions of events. Many states have refined their list of events, or issued additional guidance on reportable events, in the belief that clear definitions help clarify for facilities the events that need to be reported and may be important to increasing reporting rates. Clear definitions can also improve consistency in reporting which is critical to quantitative analysis.

The Institute of Medicine's Committee on Data Standards for Patient Safety has noted the need for national leadership to establish and maintain standards for patient safety databases. Its recommendations include developing standards for the collection, exchange, and reporting of data to support patient safety and standardizing report formats and terminology to capture and report data related to medical errors.[10] These recommendations led to the National Patient Safety and Quality Improvement Act of 2005, which allows the Secretary of the Department of Health and Human Services to determine common formats, including data elements and definitions, for organizations that will be included in a network of patient safety databases created and maintained by the Secretary.[11] Prior to this act, states moved forward to create clear definitions for use within their own reporting systems. Among the strategies they have employed:

[10] Institute of Medicine, *Patient Safety: Achieving a New Standard for Care* (Washington, D.C: National Academy Press, 2004), 11.
[11] http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ041.109

- The Minnesota Hospital Association (MHA) Patient Safety Registry Advisory Council has developed recommendations on definitional questions that arose related to the adverse health event reporting law. In order to create more accurate and consistent reporting across facilities, MHA has broadly shared the recommendations to provide guidance to facilities as they review potential reportable events. These recommendations have been tacitly endorsed by the state.

- New York has improved and clarified its definitions of reportable events by using an includes/excludes list developed through interpretive guidelines. *The New York Patient Occurrence Reporting and Tracking System (NYPORTS) User's Manual* also helps clarify definitions. The NYPORTS Refinement Committee reviews all proposed changes to definitions. New York also provides a comparison of NYPORTS requirements with AHRQ's Patient Safety Indicators,[12] Inpatient Quality Indicators,[13] and other indicators.

- Pennsylvania requires the reporting of both near-misses and actual adverse events, which are defined by statute. After determining that an event meets one of these definitions, the reporting entity then clarifies the event by using a taxonomy of specific clinical events or conditions. The taxonomy is classified according to three levels: the first includes nine broad categories of event types. The event types are further broken down into second- and third-level subcategories.

- Pennsylvania has also noted the critical need for consistent reporting criteria because providers are required by statute in that state to notify patients about serious events (an adverse event that results in patient harm) to which they have been subjected.

Efforts to clarify definitions are useful; however, some meeting participants claimed that efforts to refine and restrict the list of reportable events leads to more questions about what is and is not reportable and to other concerns from providers about the operations of the reporting system. The continuous need to clarify reportable events may be expected, given that the types of complex events that are reportable are not easily categorized.

[12] Patient Safety Indicators Overview. AHRQ Quality Indicators. July 2004. Agency for Healthcare Research and Quality, Rockville, MD. http://www.qualityindicators.ahrq.gov/psi_overview.htm

[13] Inpatient Quality Indicators Overview. AHRQ Quality Indicators. July 2004. Agency for Healthcare Research and Quality, Rockville, MD. http://www.qualityindicators.ahrq.gov/iqi_overview.htm

2. Reporting systems must be clear about reportable data elements in order to enhance analysis.

The types of data elements that are commonly required include the who, what, when, where, how, and why of an event: who discovered the event and who was involved (by position, not by name), type and severity of incident, patient outcome or status, the date of occurrence, the facility name, why the event occurred, and action taken.

One participant noted that data elements can be categorized into patient factors (diagnosis, procedure, co-morbidities), team factors that may have contributed to the event, such as communication, and facility or system issues that may contribute to events, such as staffing levels.

- Georgia posts its reporting form, instructions, and frequently asked questions on its Web site. Utah also includes its reporting form on its Web site.

- The Minnesota Department of Health's Adverse Healthcare Events Reporting Evaluation Tool provides criteria against which event reports can be evaluated. As reports are received, staff members review them for full descriptions of the event, completeness of root cause analysis, soundness of corrective action plans, and timeliness of event reports and follow up.

- Nevada has a space on its report form for reporting lessons learned. It is optional, but many reporters include them.

3. States categorize data using a combination of coded elements and narrative text.

The Institute of Medicine Committee on Data Standards for Patient Safety recommended that an event report include a combination of narrative and coded data elements.[14] Coding assures that the elements that are reported, and the values associated with those elements, are consistent thus permitting reports to be aggregated and compared across facilities.

Some participants noted the difficulty of translating narrative text from reported events into quantitative information. Some states have addressed this difficulty by excluding narrative text boxes from their reporting forms. Other states find that the narrative text is a critical complement to structured responses and helps in the understanding of the event and its underlying causes. According to one participant, the structured responses provide information on *what* happened for quantitative analysis, and the narrative provides

[14] Institute of Medicine, Patient Safety: Achieving a New Standard for Care (Washington, D.C.: National Academy Press, 2004), 159.

information on *how* it happened to inform the care process. For example, narrative information can enable reporting system analysts to examine all reports that contain issues related to safety culture and to categorize and study those issues by topic. In doing so, they are able to examine and assess such topics as the degree to which senior management does or does not support patient safety, the extent to which a blame-free error reporting process exists, and whether or not all levels of staffing participate in reviewing adverse events. A number of states with narrative reporting elements are interested in natural language processing, which enables computer software to understand and analyze the language within narrative texts. This software would enable states to process narrative reports electronically, rather than manually.

- Florida provides directions for completing reports, including coding instructions, on its Web site.

- Massachusetts is in the process of reviewing its coding practices to streamline data collection and analysis and enhance the system's capacity to provide systematic feedback to facilities and the public. The state is in the process of modifying and reducing its original 120 serious incident codes to 50 codes that correspond with the National Quality Forum's list of serious reportable events. The streamlining of codes is intended to clarify reportable events, lead to more consistency in selecting codes, and clarify areas for corrective action. After extensive testing, the state plans to further simplify the reporting template to inform a new Web-based reporting system.

- Earlier versions of New York's system captured inconsistent and variable data due to varying interpretations of reportable information. As a result, the data could not be analyzed easily. In modifying the system, the state created two reporting forms—a short form for complications and a long form for events that require detailed review. The state now uses the JCAHO Root Cause Analysis process[15] with narratives for root causes and corrective active plans and some click boxes for structured questions.

- Pennsylvania's reporting form includes a space for a 1,000-character narrative. Analysts claim that in about one of four reports, the additional information in the narrative changes the impression created by reading only the coded data elements.

- Minnesota, New York, Pennsylvania, and Utah require electronic reports, which can eliminate some problems with coding.

[15] For more information on the JCAHO RCA process, go to www.jcaho.org/accredited+organizations/sentinel+event/rca_assisttool.doc

4. Ongoing training and educational support for system users is essential.

Training for hospital personnel enables reporting system administrators to work toward consistency in reporting, to control the quality of reports, and to obtain buy-in from facilities. States use training as an opportunity to clarify questions about reportable events and other aspects of the system. State training efforts run into difficulty due to turnover in hospital staff and the continual need for training. Some reporting system administrators claim that new state systems have the advantage of starting with a clean slate; modifications or adaptations of legacv systems can cause confusion among hospital personnel.

- Georgia developed a decision-tree to assist hospital staff in knowing when to report.

- New York's training and education subcommittee of the NYPORTS Statewide Council coordinates and schedules regional and statewide trainings. A NYPORTS tutorial ensures that new staff are consistently trained. The state also developed a card that lists reportable codes for distribution to hospital frontline clinical staff to be used as a quick reference or cheat sheet.

- Nevada offers a PowerPoint presentation on its Web site for training hospital personnel.

- Pennsylvania conducted 16 hands-on, all-day training sessions around the state for staff designated by facilities as their patient safety officers and system users. PowerPoint slides and a comprehensive users' manual are also available on a protected Web site.

- Utah includes a user's guide for reporters on its Web site.

5. States can facilitate thorough root cause analyses (RCA) at the facility level by requiring reporting not only of the event but also of information about root causes and corrective actions.

As the IOM report *To Err is Human* noted, external reporting systems offer a mechanism for creating an environment that encourages organizations to identify errors, evaluate causes, and take appropriate actions to improve performance.[16] In fact, some observers believe that mandatory reporting has made patient safety reporting more of a priority within institutions. For example, Minnesota's system was mentioned as an impetus for "Safest in America," a collaboration of ten Minnesota hospital systems that has

[16] Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C: National Academy Press, 1999), 8.

conducted in-depth analysis of events and is committed to improving patient care by collaborating on process improvements.

Root Cause Analysis (RCA) is a tool for helping to prevent future recurrences of adverse events. RCAs describe the root causes, or basic causal factors, contributing to the event as well as the actions taken by facilities to correct the situation. The goal of an RCA is to find out what happened, why it happened, and what can prevent it from happening again. A variety of techniques and tools for conducting RCAs have been promoted through organizations such as the Veterans Health Administration's (VHA) National Center for Patient Safety,[17] the Joint Commission International Center for Patient Safety,[18] and Great Britain's National Patient Safety Agency.[19]

- The Maryland Patient Safety Center offers an RCA training to facility personnel who are responsible for overseeing RCAs. It is offered free of charge to organizations that participate in the Maryland Patient Safety Center.

- Most states involved in NASHP's project require facilities to *collect* information about root causes and corrective action plans and many require this information to be *reported* to the state for certain categories of serious events. This information, combined with data elements about the event itself, is critical to state efforts to reduce recurring problems. RCAs also help facilities make internal process improvements.

- Massachusetts analyzed the data it had collected on contributing factors and corrective actions by using a framework developed by Charles Vincent. The framework examines seven factors that influence clinical practice and contribute to adverse events: patients, tasks, individual staff, teams, work environment, organization and management, and institutional context.[20] The analysis revealed that many of the contributing factors and corrective actions had not been reported.

- Before June 2000, New York used a narrative-free investigative report for the most serious events. In June 2000, an RCA framework replaced the long form which added structure to the reports and was intended to allow for more meaningful analysis. An RCA analysis based on the new form revealed that the quality of the information submitted was variable, despite ongoing educational efforts. The state then designed a tool to evaluate submitted RCAs, both to ensure the presence of certain criteria that are expected in a thorough and credible RCA and to assure more consistency.

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[17] http://www.patientsafety.gov/faq.html
[18] http://www.jcipatientsafety.org/show.asp?durki=10365&site=180&return=9808
[19] http://www.npsa.nhs.uk/health/resources/root_cause_analysis/conditions
[20] Charles Vincent, "Understanding and Responding to Adverse Events," *New England Journal of Medicine*, 348, no. 11 (March 13, 2003): 1051-1056.

- Minnesota and New York use the VHA National Center for Patient Safety's RCA form and its contributing factors categories.

6. States use a range of methods to identify events that facilities fail to report.

Although states acknowledge that facility reporting of every reportable event is unlikely, they attempt to identify events that facilities fail to report, and they use these opportunities to notify the facility in hopes of improving reporting in the future. State officials acknowledge that complete reporting is labor intensive and that facilities cannot commit resources to identifying every potentially reportable events; nevertheless, states take seriously their role in ensuring that hospitals identify events and take corrective action when needed.

- Many states attempt to match administrative claims data from hospital discharge databases with their reporting system data to improve facilities' reporting of adverse events. Although these efforts have been successful to some degree, meeting participants noted that the codes used to categorize hospital discharge data do not match lists of reportable events, and the two systems, developed for different purposes, provide different information about events, making matches difficult. Meeting participants agreed that any revisions to administrative data that would allow for the identification of adverse events would be extremely useful.

- In addition to reviewing administrative claims data, New York uses a number of methods to capture more reportable events. These include quality reviews conducted by the Quality Improvement Organization (QIO) as part of its Medicaid utilization contract with the state. As the QIO conducts its review, it examines whether reportable events were reported to the state reporting system, and, if not, the QIO notifies the hospital. The state also identifies events through complaint reports from consumers and during on-site visits for other reasons.

- Utah is reviewing death certificate data to identify reportable events. The data include information on underlying cause of death, contributing factors, and other useful narrative information.

Tools

The following tools are available to states and others interested in examples of how states clarify reporting requirements and educate facilities about these requirements in order to improve reporting. To access these resources, go to www.nashp.org/psdataresources.

Florida reporting forms and instructions
http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Risk/reporting.shtml

Georgia reporting forms, instructions, frequently asked questions and decision-tree http://www2.state.ga.us/departments/dhr/ors (click on "Health Care Programs", then "Hospitals")

Minnesota Recommendations and Guidance for Application of the Adverse Health Event Definitions http://www.nashp.org/Files/MN_AEdefinitions.pdf

The Minnesota Department of Health's Adverse Healthcare Events Reporting Evaluation Tool http://www.nashp.org/Files/MN_MDHEvaltool.pdf

Nevada Sentinel Event Registry Report Forms and Guides:
http://health2k.state.nv.us/sentinel/formspg.htm

NYPORTS User's Manual can be accessed by authorized users or by individual requests via email to emf02@health.state.ny.us

The Pennsylvania patient safety taxonomy is explained in the 2004 report, available on the Patient Safety Authority's website www.psa.state.pa.us/psa/site . The nine broad categories are described. The second and third levels of the taxonomy are available on request via email to arabinowit@state.pa.us

Utah user's guide and reporting form: www.Health.utah.gov/psi

EVENT REPORT ANALYSIS

Event report analysis can be conducted at various levels using a variety of approaches. First, facilities can conduct internal analysis, in which they review their internal data for root causes, contributing factors, and trends. Second, state reporting systems can conduct analyses of individual event reports in order to hold facilities accountable for serious errors and to better understand and share contributing factors, (i.e., communication, safety culture, etc) so that events can be avoided in the future. States also aggregate data over time and/or across facilities to assess the patient safety performance of a facility, region, or state. The benefit of state-level aggregated data is in identifying institutional factors that may contribute to adverse events, which cannot be identified by an individual facility, and in creating a larger database with a greater numbers of events to enhance analysis of rare events.

Meeting participants noted that statistical analyses of event reporting can be problematic. The small number of events reported in most states limits the types of statistical analyses that can be conducted. The number of reported events is not a valid indicator of the incidence of events because the number of opportunities for the event to occur is usually unknown. For instance, the number of morphine overdoses during a specific period of time may be captured accurately, but the number of morphine injections given in all the hospitals in the state during that same time period will probably be elusive. Despite these problems, there are ways to use reported data that, while not yielding epidemiological trends, can enhance our understanding of the causes of adverse events and potential solutions for reducing them. Participants stressed the value of analyzing the content of individual report data and dispelled the notion that analysis must always be about aggregate numbers.

Themes and Examples

1. Reporting systems should complement, not replace, practices used by hospitals to review and analyze their patient safety incidents.

State reporting systems should complement, not replace, practices at the hospital level to review and analyze patient safety incidents.

- Maryland reviews all hospital reported events and corresponding root cause analyses on a weekly basis. If the root cause analysis is not adequate, the state contacts the hospital to discuss the RCA and, if appropriate, to obtain additional information. The state may also ask the hospital to probe further to identify potential systems failures.

- New York's requirement that an RCA be submitted for serious events is an important catalyst for hospitals to analyze their events for possible contributing factors and propose strategies for avoiding them in the future. The state will not accept a "blame and train" strategy—in which facilities blame the problem on an individual and propose to fix it through training—as a credible solution. Instead, it looks for approaches that address core problems and that can potentially serve as models to other facilities.

- Pennsylvania's reporting system requires responses to several complex questions related to root cause analysis, underlying causes and severity/frequency scales.

Some of the meeting participants noted that the role of the state should be to ensure that facilities have a rapid response system to address adverse events, and when there is evidence that such a system exists, the state should not impose additional burdens, such as requiring facilities to use specific follow up processes or complete additional reviews.

2. There was general agreement that individual event report analysis at the facility or state level can yield very useful information. Participants stressed the value of seeking out the "stories" behind a reported event.

A story—as we are defining it here—begins before an event occurs and captures the conditions that may have been present to precipitate an adverse event (including root causes). The story ends with an understanding of what should be done to avoid similar future problems. Both stories and narrative (as described in an earlier section of this paper) are built upon qualitative information. However, stories may also include quantitative data; they offer a full picture of what has occurred, and why. States use various techniques to seek out and analyze "the story":

- Many states require facilities to submit the results of an RCA within a specified time period after a serious event is reported, ranging from 30 to 60 days. These results should be as probing as possible so that the factors contributing to an event can be fully identified.

- The Minnesota Department of Health has a contract with the Quality Improvement Organization (QIO) to review all reported events and corrective action plans. It shares the QIO findings with a state users' group of hospital medical directors and clinicians for additional insights into what the data may reveal.

- Maryland notifies hospitals through clinical alerts when patterns, trends, or interesting cases emerge. The state invites comments from hospitals to encourage a dialogue.

3. Although analysis of individual events is very useful, aggregation can identify information that is not apparent from a review of individual incidents. A state can conduct simple, routine analyses using aggregated event report data.

Aggregated reports allow analysts to identify patterns—both consistencies and differences—in a group of similar events. At the state level, an analysis of aggregated data can provide useful information, especially about rare events, in spite of the biases and imperfections that may be contained in the data reported to the state. Although states cannot achieve full reporting to ensure complete data, they can achieve a critical mass for analysis.

- New York invites hospitals to participate in expert subcommittees (with representatives of the local Department of Health staff) to review de-identified findings from RCAs and to extract lessons from those findings that may have broader applicability for release in a hospital alert or other communiqué. Because the group serves as an agent of the state, its discussions and the RCAs themselves are prevented from discovery. For example, a medication error subcommittee reviewed reports submitted by hospitals for a two-year period, and the results were published in *Advances in Patient Safety*.[21] An analysis of wrong patient/wrong site surgical errors led to the development of the New York preoperative protocols final report in January 2001 which focused on strategies to reduce these events. Hospitals were expected to develop and implement procedures based on the report. As a result of the NYPORTS analysis and subsequent protocols, the number of such events decreased from 25 events in 2002 to 17 in 2003.[22]

- New York looks for patterns in the data and "holes in the pattern". For example, questions on data reporting or potentially successful prevention strategies may be raised when there are no reports of pulmonary embolism in joint surgery from a facility with a very high rate of such procedures.

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[21] Elizabeth Duthie et al., "Quantitative and Qualitative Analysis of Medication Errors: The New York Experience," *Advances in Patient Safety: From Research to Implementation, v.1* (Washington, D.C.: Agency for Healthcare Research and Quality, April 2005), AHRQ Publication No. 05-0021-CD.

[22] Ellen Flink et al., "Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems," *Advances in Patient Safety: From Research to Implementation, v.3* (Washington, D.C.: Agency for Healthcare Research and Quality, April 2005), AHRQ Publication No. 05-0021-CD.

- Pennsylvania is piloting an interactive risk prioritization using the frequency of event types reported and assigning weights to the outcome of each event to reach an aggregated severity measure.[23] The risk associated with each of the 198 event types in the taxonomy can be calculated from the sum of the events reported for each event type after weighting for the degree of harm. Pennsylvania presents the information on a spreadsheet that facilitates interactive use of the data. Facilities can cluster event types in a variety of ways (medication problems, ICU problems, communication problems, etc.) and can change relative weights. In order to conduct cost-benefit assessments of potential interventions, they can also fill in additional fields with local estimates of reporting compliance, costs of interventions, and probabilities of success with interventions.

- In the absence of valid denominators to calculate true rates, Pennsylvania is considering using "process control" measures.[24] Pennsylvania believes that process control measures will provide useful information but does not yet have sufficient experience to provide any proof of the concept. However, state analysts believe the following process control measures can reasonably be used for event reporting, keeping the caveats in mind.

    - A consistent increase or decrease in the number of reported events from a facility over five months.

    - A consistent increase or decrease in the difference between the number of reported events and the mean number of reported events over five months, indicating an increase or decrease in variability.

    - The number of reported events for a month exceeds the 95 percent confidence intervals of prior experience (considering the most recent previous ten months as the prior experience).

    - The number of reported events is above or below the historical mean consistently over five months.

[23] The weights are reported as NCC MERP harm scores, http://www.nccmerp.org/.

[24] Manufacturing uses "process control" measures for monitoring defects in the absence of a denominator. Process control measures are based on two concepts: trends and variability. Process control measures assume a steady state and make no judgment about the cause of trends or variability. For instance, an increase in the number of reportable adverse events might mean an increase in the complication rate, an increase in the number of opportunities, or an increase in the compliance of reporting. Therefore, results should always be interpreted in context. The Pennsylvania system takes the position that these measures are most appropriate around an intervention program (personal communication, John Clarke, Clinical Director, Pennsylvania Patient Safety Reporting System, September 2005).

- For rare events, the time measured between six reported events (five elapsed-time periods) increases or decreases.[25]

- States that collect near misses can calculate a near miss/adverse event ratio which is considered good if it increases as a result of either more reporting of near misses or fewer adverse events.

4. States should be cautious when drawing conclusions from their aggregate event data.

Participants underscored the limitations in conducting comparisons across facilities or within facilities over time given the small number of reports and the inability to determine whether differences were statistically significant, due to chance, or a product of poor reporting. These are not necessarily problems with the reporting systems themselves but reflect the constraints of analytic techniques and/or access to denominator data that allow for the construction of patient safety measures.

- Analyzing even large numbers of reports may be problematic since the denominators may not be known at the time of analysis (e.g., rate of perforations during colonoscopies). In other cases, the denominator may never be known (e.g., rate of insulin overdoses).

- Reporting system data provides useful quality improvement information but has more limited value in facility comparisons. This weakness may not be the result of poorly designed or implemented systems but may be due instead to the inherent complexity of the events being reported. System wide comparisons are problematic due to inconsistency in coding, differences in the diligence of detecting problems, and variations in patient risk factors.

- Comparisons are compromised by rare events, which make it difficult to determine statistical significance. For example, there is no statistically significant difference between an adverse event that occurs once in one hundred procedures versus five in one hundred procedures. This lack of statistical significance makes it difficult to identify priorities.

[25] For monitoring trends, the Pennsylvania system considers months as the smallest stable reporting interval. A constant trend up or down over five months is unlikely to be due to chance alone and can be considered statistically significant. For calculating current and past means and 95 percent confidence intervals, Pennsylvania considers a 10-month interval appropriate.

5. There are many ways to enhance state analytic capacity.

States often lack the internal resources needed to conduct rigorous analyses of event reports and look to consultants to assist them with the analysis.

- The Quality Improvement Organizations in Minnesota and New York are actively engaged in reviewing event data.

- Massachusetts and New York work closely with universities in their states to assist in analyzing data. Massachusetts does this through a three-year grant from the Agency for Healthcare Research and Quality, and New York through a long-term relationship.

- In Pennsylvania, data collection and analysis are, by law, contracted to an outside entity that administers the system under the supervision of the state's Patient Safety Authority. As a result of an open bid process, the state contracts with ECRI[26] and the Institute for Safe Medication Practices (ISMP). A team of clinicians from these two organizations headed by a trauma surgeon and comprised of nurses, pharmacists, and product engineers conducts objective, scientific analysis.

6. States should look beyond the reported data to other sources of information on patient safety.

Some states supplement information they receive from their reporting systems with information from hospital surveys, committees, and other hospital activities.

- The Massachusetts Coalition for the Prevention of Medical Errors, which often partners with the commonwealth's reporting system to identify and learn from errors, conducted a clinician survey to identify patient safety issues that "keep you up at night." The coalition created an advisory committee that examined the survey results, state data on reported adverse events, and malpractice data to identify events that were severe, more frequent, and for which there was evidence that best practices existed. The committee found that communication of critical test results and reconciling medications were major problems, findings that would not necessarily have come out of pre-coded adverse reporting forms. The coalition created a consensus group on each of the two topics, studied the literature, searched for national models for safe practices, reached agreement on recommended safe practices, and created learning collaboratives to share tools and implementation strategies among hospital teams working on the two issues.

[26] Formerly the Emergency Care Research Institute.

- Pennsylvania statute requires facilities to develop formal patient safety plans and establish patient safety committees as part of the state's overall patient safety mandate. The plans, which are required to be submitted to the state's department of health, can provide additional information on hospital patient safety activities.
- Utah's system engages hospital staff in a dialogue that encourages people to unload their secrets in a safe environment of formative learning. These informal sessions, facilitated by the state's department of health, help identify barriers that get in the way of improvements and help hospital staff share lessons learned and opportunities for improvement.

7. Analyzing patient safety outcomes is desirable, but for the foreseeable future, it will be more helpful to analyze patient safety processes rather than outcomes.

Analyzing patient safety data is complicated by a lack of standards or benchmarks against which progress can be measured. Participants in this project stressed the value of identifying evidence that links specific processes to desirable outcomes so that—in the absence of good outcomes data—process measures could be tracked over time. Participants noted that both The Leapfrog Group and the Agency for Health Care Research and Quality have developed good process measures.

Tools

The following tools are available to states and others interested in strategies for analyzing information contained within state reporting systems. To access these resources, go to www.nashp.org/psdataresources.

PA risk scores http://www.nashp.org/Files/Sampleadverseeventreport.pdf

Massachusetts' safe practices, tools, and implementation strategies on communication of critical test results and reconciling medications are available at www.macoalition.org under 'initiatives'.

The Leapfrog Group Expert Panel-Endorsed Process Measures: https://leapfrog.medstat.com/(ewxwaq55vug1mx2prlschse1)/index.aspx under process measures- specifications

Agency for Healthcare Research and Quality: http://www.qualitymeasures.ahrq.gov/

DATA FEEDBACK

The IOM's Committee on Data Standards for Patient Safety pointed out that the data collected in reporting systems is neither complete nor standardized, making it difficult to aggregate the data or identify trends or patterns.[27] Nevertheless, providing feedback on the reported data can accomplish several useful purposes.

Feedback based on an analysis of the collected data can help purchasers and consumers create external pressure to drive improvements by providing information about health care facility safety. It can also assure the public that the issue is being addressed, improving the public trust.[28] Feedback can motivate change within an institution, especially in the culture, and it can present providers with information on best practices. It can also help determine which issues are most critically in need of attention within a facility or organization.

Providers indicate that a lack of data feedback can be a disincentive to report. They tend to view reporting systems that do not provide feedback as data graveyards, a burden that provides no benefits. Reporting systems can dispel this notion by disseminating useful information that creates external pressure on the system for change. Providers may also view the opportunity to share "lessons learned" as an incentive to report.

States face the challenge of providing users with an easy and efficient way to access meaningful data. Among the challenges they face: how to identify appropriate and useful information to disseminate, how to identify user-friendly formats for disseminating information, how to target the appropriate audience, and how to determine the most useful mechanisms for disseminating the information to the intended audience.

Themes and Examples

1. Patient safety alerts and advisories provide an opportunity for state reporting systems to share timely, specific, actionable information.

Providers at the meeting indicated that they are interested in lessons learned, implementation processes, and best practices that are applicable to their needs. Others

[27] Institute of Medicine, *Patient Safety: Achieving a New Standard for Care* (Washington, DC: National Academy Press, 2004), 4.

[28] For more information on reasons to disclose data, the type of information that is disclosed, and the methods of disclosure, see Jill Rosenthal and Maureen Booth, *How States Report Medical Errors to the Public: Issues and Barrier*s (National Academy for State Health Policy, Portland ME: 2003).

mentioned that providers want stories from which to learn topic-specific information. Alerts and advisories can provide this type of information.

- One participant cautioned that providing information about best practices out of context may be problematic. Providers who attempt to apply a best practice without understanding their own current situation may become discouraged if the best practice is not effective. Information on the error, cause, best practice, and how the best practice addresses the problem can help provide context. For this reason, Maryland added a new field to data collection forms to identify why the solution worked. The form asks: "Is there a process improvement or lesson learned that could benefit other hospitals?" If the answer is yes, respondents are asked to provide some explanation.

- Nevada's reporting system has issued two alerts since it began collecting reports in January 2005. Because the system is so new, the alerts have focused on reporting procedures but state officials expect that the alerts will focus on critical patient safety issues in the future.

- New York publishes a *NYPORTS News and Alert* newsletter to educate facilities about analysis, interpretations, and system use (log-in required).

- Pennsylvania issues a scholarly quarterly and supplementary patient safety advisories on a variety of topics that provide clinical guidance to facilities about steps they can take to reduce adverse events and near misses.

2. Aggregate reports provide an opportunity to share simple analyses that states routinely conduct.

According to some participants, providers would like risk-adjusted benchmark information to set goals, but some participants cautioned that "benchmarking" should only be done compared to best practice, not the average. For example, there is no acceptable level of wrong site surgeries against which a facility should measure itself. Nevertheless, aggregate reports enable comparison of frequency distributions and experience over time as discussed in the analysis section.

- Florida, Maine, Maryland, Massachusetts, Minnesota, Nevada, New York, Oregon, Pennsylvania, and Utah issue reports with aggregate data. These reports often include information on the number of incidents reported, the number of incidents by category, trends in reporting over time and information to help readers interpret the information.[29]

[29] NASHP analyzed the contents of aggregate reports in 10 states. See Mimi Marchev, Jill Rosenthal, and Maureen Booth, *How States Report Medical Errors to the Public: Issues and Barriers* (National Academy for State Health Policy, Portland, ME: 2003).

- Florida requires its Agency for Health Care Administration to publish annually a report on its Web site that summarizes the information contained in annual incident reports as well as malpractice claims information reported to the agency.

- New York provides feedback through a Web-based system that enables providers to access their own data and to create comparative reports with their own data: over time, to a peer group, and statewide. This improvement from earlier versions of the NYPORTS system, in which facilities were dependent on the state to create data reports, enables users to access timely information and enhances learning from the data. New York claims that this feature has prompted facilities to conduct internal studies targeting areas identified through an analysis of trends and has improved patient safety as a result. For example, using the system's comparative function, one facility identified an increased risk of its patients developing deep vein thrombosis and pulmonary embolus. The facility established a risk factor assessment and prophylaxis protocol which has decreased the number of hospital-acquired thromboembolic events.[30]

- New York also publishes on its Web site annual reports based on aggregate data.

- Pennsylvania's system contains integral analytical tools that provide real-time feedback and statistical analysis to individual facilities about their own database. The system includes some statewide comparisons.

- Utah's Web site 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. 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, or aggregate state data; and stratify results by socio-demographic factors, payer, and service.

3. Information from reporting systems, combined with other quality data, may be useful to purchasers and consumers as well as providers.

Aggregate data can serve the needs of various audiences by providing legislators and the public with a monitoring device, assisting purchasers in targeting improvement projects, and assisting providers with developing internal safety improvements.

[30] Ellen Flink et al., "Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems," *Advances in Patient Safety: From Research to Implementation, v.3* (Washington, D.C.: Agency for Healthcare Research and Quality, April 2005), AHRQ Publication No. 05-0021-CD.

- Some participants noted that consumers are most interested in assurances that the health care system is being monitored and that quality is being addressed. This information may be more important to consumers than data on specific incidents.

- States that provide information to the public often do so through Web sites, and several states provide information to consumers on broader quality issues if not specifically on patient safety data. States may provide quality information by linking to national sites such as the U.S. Department of Health and Human Services' Hospital Compare Web site. The Minnesota Health Information Web site, for example, is a clearinghouse that connects consumers with information about the cost and quality of health care in Minnesota. The site includes links to numerous other sites that compare provider performance, quality, and costs; help consumers manage their health conditions; give tips on purchasing care; and offer strategies for staying healthy. The Minnesota Community Measurement Project provides information on how well Minnesota's Medicaid plans and providers meet certain proven standards, for example, the extent to which physicians adhere to clinical guidelines and evidence-based medicine.[31]

- The Maine Quality Forum has launched a Web site comparing and reporting facility performance on a range of quality indicators, some of which include patient safety. Recently the state initiated its Maine Quality Star program which publicly recognizes hospitals that are found to be implementing safe practices.

- Health plans and payors may find information about adverse events useful to targeting their quality improvement projects and assessing overall quality of care. Payors may also be interested in knowing if corrective action plans submitted to the state following an adverse event are being implemented. Reporting systems can help support payors who are seeking improvements from providers. Reporting systems can also help support providers who are seeking to demonstrate improvements to payors. Tufts Health Plan in Massachusetts uses publicly available state data to monitor opportunities for improvement within its network. When appropriate, the Plan, follow up with a contracted facility to determine if the corrective action plans submitted to the state have been implemented. The follow-up may include requesting policies and procedures, reviewing training content and attendance records, and, in select cases, scheduling a site visit.

[31] See www.mnhealthcare.org and www.minnesotahealthinfo.org.

4. Data must be effectively disseminated to appropriate audiences.

In addition to making information available, reporting systems should also be designed to disseminate information so that it reaches appropriate potential users. In some states, information is intended solely for providers; in others, it is designed for use by providers, purchasers, consumers, legislators, and other audiences. States face a number of dissemination challenges, among them: How does the information that providers receive spread through the health system? How does the feedback get disseminated from safety officers to frontline practitioners? Do personnel that operate internal reporting systems actively feed information back to data reporters?

- The New York NYPORTS Statewide Council has formed a new subcommittee to focus on dissemination. In addition, the state provides regional and statewide trend information at public forums and council meetings. At times, the state gives public recognition for patient safety practices. The NYPORTS bulletin board, accessed through a secure Web-based system, provides an opportunity for the state to post relevant information for system users, including in its *News and Alert* issues.

- Florida, Maryland, Massachusetts, Minnesota, Nevada, New York, Pennsylvania, and Utah have all developed Web sites that contain reporting system information.

- Meeting participants suggested that ultimately it would be useful to have stories, case studies, and best practices on a reporting system Web site that has the capacity to enable providers to contribute their own lessons learned.

- The Massachusetts Coalition for the Prevention of Medical Error's Web site includes safe practice recommendations, along with tools and strategies for implementing them. The site also includes information about work that has been conducted in Massachusetts on how to communicate critical test results and reconcile medications.

- Participants acknowledged that information sharing and feedback does not need to remain state-specific. Alerts and advisories may contain useful information for other states and can increase the impact of lessons learned. Sharing may be particularly useful for states with small populations and correspondingly more rare events.

- Pennsylvania distributes its quarterly Patient Safety Advisories electronically to an estimated 10,000 recipients around the country, including various national list-serves, and encourages facilities and networks to share the information.

Tools

The following tools are available to states and others interested in strategies to disseminate information contained within state reporting systems. To access these resources, go to www.nashp.org/psdataresources.

Florida website: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Risk/index.shtml

Maryland website: http://www.dhmh.state.md.us/ohcq/alerts/alerts.htm

Massachusetts website: http://www.mass.gov/dph/dhcq/cicletter/cir1298.htm

Massachusetts Coalition for the Prevention of Medical Errors: www.macoalition.org, check under the Initiatives page for communicating critical test results and reconciling medications.

Minnesota website: http://www.health.state.mn.us/patientsafety

Nevada website: http://health2k.state.nv.us/sentinel/

New York website: http://www.health.state.ny.us/nysdoh/hospital/nyports/index.htm

Pennsylvania website: www.psa.state.pa.us

Utah website with report analysis capabilities: http://health.utah.gov/psi/ADEsuccess.htm

Hospital compare: www.hospitalcompare.hhs.gov/

Challenges

Many of the challenges confronting states as they seek to maximize the use of adverse event data to improve patient safety are the result of working with small numbers, lack of denominators, incomplete data or inconsistencies in reporting, the lack of identified risk factors for adverse events, and/or incomplete knowledge of the relationships between processes of care and outcomes. Although these issues are not insignificant, they often have technical solutions. Meeting participants identified other, more persistent, challenges affecting the success of their reporting systems:

1. Although measurably improving patient safety is the long-term goal of reporting systems, participants agreed that states should establish reasonable interim measures to mark progress in their efforts to improve patient safety.

Examples of possible measures include:

- At least initially, an increase in the actual number of reports especially among facilities that historically have failed to report.
- More complete reporting with contextual information that provides a fuller understanding of the event and the environment in which it occurred.
- For serious events, higher quality root cause analyses identifying the factors contributing to an event and corrective action plans with measurable change.

2. The business case for patient safety has yet to be made and universally accepted.

Despite growing awareness among the public and purchasers about patient safety, little attention has been given to cost savings that can result when safe practices are introduced in hospitals. Lacking a business case, facilities may not have a strong incentive to focus on patient safety and implement change.

3. Changes in administration at the state level can alter commitments to reporting systems.

Although the statutory basis for many reporting systems may protect their survival during changes in elected leadership, new administrations can affect the allocation of resources to these systems or weaken the underlying leadership needed to send an unambiguous message about reporting requirements and their benefits. A previous NASHP report found that although many program costs may be absorbed into existing budgets, analysis and dissemination of useful information is likely to represent substantial new costs.[32] For example, Pennsylvania's budget for aggregating, analyzing, and disseminating information from 150,000 reports is approximately $2.5 million, or about $17 per report. The Pennsylvania system is an exception in terms of its funding level; nevertheless, states are likely to need additional staff or contractual arrangements in order to effectively collect, analyze and disseminate information.

4. The lack of national standards for patient safety currently prevents super-aggregation of data and may confuse data reporters.

Some state systems were developed prior to the national focus on patient safety and have been adapted in different ways to address emerging concerns. These systems, and others that have been established specifically to capture adverse events, are now being joined by multiple national efforts to collect, analyze and improve patient safety. These efforts include the National Quality Forum's (NQF) development of a list of serious reportable events recommended for state use, the establishment of Patient Safety Indicators by the Agency for Healthcare Research and Quality (PSIs), patient safety standards imposed by accrediting bodies such as the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), and recently promulgated CMS indicators for Medicare. Given these converging but distinct activities, states are often challenged in defining their own reporting requirements.

Some states propose adopting the NQF list of serious reportable events as the model for state reporting systems so that duplication can be minimized. NASHP's efforts to map state reporting requirements against NQF's list found that in numerous instances, states include events that are similar to the NQF list but are more broadly or narrowly defined and that many states have broader mandates to report events that are less serious than NQF events but are strong indicators of quality of care.[33] The National Patient Safety and Quality Improvement Act of 2005 may help drive standardization of reporting. It is hoped that states, especially those with experience in patient safety reporting, will be able to contribute to the development of the consensus of any national system.

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[32] Jill Rosenthal, Maureen Booth, and Anne Barry, *Cost Implications of State Medical Error Reporting Programs: A Briefing Paper* (Portland, ME: National Academy for State Health Policy, 2001), 20.

[33] Jill Rosenthal and Maureen Booth, *Defining Adverse Events: A Guide for States Tracking Medical Errors* (Porltand, ME: National Academy for State Health Policy, 2003).

5. Medicaid has not assumed a leadership position in most states' event reporting systems, in spite of its role as a major state purchaser.

Participants expressed frustration that their state Medicaid agencies had not used selective contracting, incentive programs, or other strategies to support patient safety efforts. At the same time, they noted a number of positive developments occurring elsewhere in state government. Many state agencies have joined Leapfrog, a public/private initiative to address patient safety through the contract process, among the participating agencies: the Massachusetts Group Insurance Commission, the New Jersey State Health Benefits Program, the North Carolina Teachers' and State Employees' Comprehensive Major Medical Plan, the Ohio Public Employees' Retirement System, the State of Kansas Division of Personnel Services, the State Teachers' Retirement System of Ohio, and the Washington Health Care Authority. The state of Minnesota has joined with private business and labor groups in a "Smart-Buy Alliance" to drive quality improvements and efficiencies in the health care delivery system. Alliance members purchase health care individually but have agreed to set uniform performance standards, cost/quality reporting requirements, and technology demands on health plans and providers and to favor providers and health plans that are certified for highest quality.[34]

These efforts could serve as models to state Medicaid programs which, in many states, represent one of the largest state purchasers.

6. Many states have antiquated licensure practices that fail to adequately address patient safety.

State licensure activities tend to focus on facility structure and process standards that may not necessarily contribute to high quality. Meeting participants argued that more attention should be given to training licensure personnel on care processes known to influence quality of care.

7. Event reports pick up errors but don't address the broader array of quality concerns.

As the IOM noted, the health care system not only harms too frequently but also routinely fails to deliver its potential benefits; safety is one of many quality issues in the American health care system.[35] For example, reporting systems will identify problems in errors

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[34] The Commonwealth Fund, *States in Action: A Quarterly Look at Innovations in Health Policy,* http://www.cmwf.org/publications/publications_show.htm?doc_id=276919#featured

[35] Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington, D.C.: National Academy Press, 2001), 2-3.

made in the administration of medications but will not pick up prevailing problems in the prescribing habits of physicians which can also do serious harm to patients.

Opportunities

While acknowledging that more needs to be done to assure accurate and full reporting, meeting participants were encouraged by the amount of activity currently being conducted by states as they work to use and learn from the data they already have. These developments, when combined with technological advancements and sustained national interest in transparency (the availability of information to help patients and families make informed decisions), can work to support and advance improvements in adverse event reporting.

1. States should not wait for perfect data before analyzing their event reports.

Meeting participants all agreed that major value can be found in "mining" individual event reports for the stories behind their occurrence, looking for similar events, and sharing the stories with others to prevent their reoccurrence. The more data are used and the results shared and made accessible to hospitals and the public, the more likely facilities will report.

2. Other data sources can be used in conjunction with event reports to track and trend patient safety and/or to assess the completeness of event reporting.

State mortality data, hospital claims data, and voluntary reporting of PSIs can serve as useful adjuncts to event reports. While this information can be used to enhance patient safety information, states noted many challenges to linking the diverse architecture of these databases to event reports. Without common identifiers and complex relational protocols, this mapping can be onerous and time consuming.

3. Improvement in patient safety requires transformation at the provider level and is nurtured in a collaborative atmosphere.

Participants cautioned against thinking that regulation alone could solve patient safety problems. Event reports provide states with an opportunity to work collaboratively with the provider community in addressing known problems and sharing effective practices. This is a new role for many states and may be met with initial suspicion unless staffed by persons with experience and expertise who can contribute in knowledgeable ways to the collaborative process.

4. The emergence of electronic health records and other advancements in information technology (IT) will significantly augment our understanding of the care process and its impact on patient safety.

Participants in the meeting noted that they believe that future access to information technology will not replace event report systems but will enrich the capacity of hospitals and state reporting systems to diagnose factors contributing to adverse events in a timely manner and to track changes in care processes and outcomes over time.

5. States should defend hospitals that are bold enough to report, and they should persuade the media to focus on the value of transparency.

The sensationalism surrounding medical errors can have a chilling effect on reporting and undermine the goal of reporting systems. State reporting officials can play an instructive role by convening journalists for mini-seminars on patient safety and on the value of hospital efforts in detecting, acknowledging, and addressing problems.

6. Attention and funding to bio-terrorism may be a catalyst for state event reporting systems.

States should find ways to advance their reporting systems by making use of the systems and technologies, as well as grant opportunities, that are available through bio-terrorism initiatives.

7. States can learn much from each other as their programs mature.

Meeting participants very much valued the opportunity to come together to share lessons they have learned and to discuss issues confronting their programs. They were particularly receptive to the toolbox that is planned as part of this project and that will attempt to compile in one place the policies, practices, forms, reports and methods used by state reporting systems. Up to this point, states have assisted each other mostly on a one-on-one basis, through telephone conversations and occasionally site visits. However, no mechanism exists for states to share, or learn from each other, more broadly. The lack of readily available information creates an obstacle for states that are just initiating their efforts and can also create a burden for states that are at the forefront and who are often sought out for assistance and advice. Although implementation issues are unique for each state, states can learn much from the experiences and resources of other states.

8. Recent national developments may support state reporting system efforts and should be monitored carefully for their impact on states.

The National Patient Safety and Quality Improvement Act of 2005, signed into law on July 29, 2005, has been mentioned previously and will have a number if implications for state reporting systems. In addition, on August 3, 2005, the National Quality Forum (NQF) endorsed a National Voluntary Consensus Standard for.the Patient Safety Event Taxonomy. The taxonomy was developed by the Joint Commission on Accreditation of Healthcare Organizations with the assistance of a work group and represents the consensus of more than 260 healthcare providers, consumer groups, professional associations, purchasers, federal agencies, and research and quality improvement organizations. It establishes the nation's first standardized integrative classification system for healthcare errors and other patient safety problems. Both of these developments may help to standardize reporting system data, improve consistency, and enhance analysis. However, at this point it is unknown whether they will augment and support state systems by providing consistency, validity, and confidentiality protections, or whether they will dilute and supplant state efforts by overshadowing states and creating more confusion about how, what, and where to report.

CONCLUSION

In initiating this project, NASHP assumed that states need to increase the number of reports received from health care facilities in order to provide useful feedback from their systems to those who can use it to improve quality of care. This situation is certainly the case in some states, and those states can use a variety of methods to increase the number of reports, from data matching with other databases (claims, autopsy, complaints, and other data sources) to chart audits during licensure inspections. However, it became apparent from meeting participants that extracting useful data from reporting systems is not dependent on the existence of epidemiological risk-adjusted data. Anecdotal information sharing from individual report analysis and aggregate data from the analysis of a critical mass of reports are both useful in providing facilities with trends, stories, and lessons learned that can used to improve patient safety.

States face a number of challenges in implementing their systems, from the technical issues of collecting and analyzing inherently complex information to the more persistent challenges of funding, support, and buy-in from state agencies and providers. However, they also have opportunities to improve and use their data, in combination with other sources of information, to identify and share useful information for patient safety improvements and to foster a collaborative relationship with providers.

By focusing on the quality improvement aspect of reporting systems, states with existing reporting systems may be able to improve their data analysis and feedback of best practices, providing more information to providers to assist them in improving the care process. And providers, who receive useful feedback from the systems, may have more incentive to report into them.

Each state has a unique environment in which its reporting system operates, potentially affected by state/provider relationships, public pressure for patient safety improvement, state legal authority, available funding, and the existence of other complementary patient safety initiatives. A system that is created under a regulatory framework may be perceived as punitive despite a state's intent to create a collaborative environment. In addition, a bill to establish a reporting system may look dramatically different once it wends its way through the legislative process. Although it may be impossible to control all of these variables, the information in this report may help states make the most of their systems within existing parameters. For instance, a state's required list of reportable events may be static but the methods of collecting and analyzing the data may be flexible. Each state's success, if shared, provides support for other states to improve their systems.

An electronic toolbox will be created on NASHP's Web site (www.nashp.org) to promote the dissemination of project findings. The toolbox will include policies, practices, forms, reports, and methods used across state reporting systems. It may also lay the groundwork

for the 26 states that have yet to authorize reporting systems, some of which have considered doing so during the past five years.

As states consider these tools, they will now do so in the context of several new national developments that may influence state systems, although it may be too early to ascertain the changes to come. The Patient Safety Event Taxonomy (PSET) endorsed by the National Quality Forum and the Patient Safety and Quality Improvement Act of 2005 may influence state developments. Any national standardization is likely to affect state systems and may enhance analysis, although it will likely also cause problems for states with well-established systems and those with specific requirements in state statute. The confidentiality provisions of the Patient Safety and Quality Improvement Act may be redundant for some state systems, but they may also provide incentive for states to share their information with Patient Safety Organizations (PSOs) created under the Act to facilitate enhanced data analysis. It may also enable state systems that are designated as PSOs to share information and pool resources with each other. States will watch with significant interest as the Agency for Healthcare Research and Quality carries out provisions of the bill.

Appendices

Appendix A: Data Summit Participants

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Appendix B

Profile of participating state reporting systems for hospital-based adverse events

State	Date of system implementation	Mandatory (M) or voluntary (V)	Reportable events	Manual (M) or electronic (E) data collection	Intent and use of the data from the system	Analytic support	Number of reports received in 2004	Issues periodic public reports with aggregate data	Publishes facility-specific information	Provides incident-specific information	Website
FL	1995	M	State-specific list of adverse events	M	Regulatory and QI	Licensure and certification agency staff. In the future, additional support may be provided by staff of the newly created Florida Patient Safety Corporation.	995 (preliminary)	√			http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Risk/index.shtml
GA	March 2003	M	-Unanticipated Deaths -Rape -Wrong patient or site surgery	M	Regulatory and QI	Licensure and certification agency staff	129				
MA	Required since early 1980s, but revised in 1995	M	State-specific list of adverse events	M	Regulatory and QI	Licensure and certification agency staff	825	√		√	http://www.mass.gov/dph/dhcq/cicletter/cir1298.htm
MD	2005	M	Death or serious disability	M	Regulatory and QI	Licensure and certification agency staff	117	√		√	
ME	Statute 2003, reporting 2004	M	Sentinel events list similar to JCAHO	M	QI	Sentinel event staff	36	√			
MN	Transition from MN Hosp. Assn: July 1, 2003 Full: Dec 6, 2004	M	NQF list of Serious Reportable Events	E	Regulatory and QI	State and partner with QIO	99 from Jul 1, 2003 to Oct 6, 2004	Tentative plans	√	Lists incidents by type	www.health.state.mn.us/patientsafety

State	Date of system implementation	Mandatory (M) or voluntary (V)	Reportable events	Manual (M) or electronic (E) data collection	Intent and use of the data from the system	Analytic support	Number of reports received in 2004	Issues periodic public reports with aggregate data	Publishes facility-specific information	Provides incident-specific information	Website
NV	Jan 1, 2005; acute care hospitals voluntary retroactive reporting Jul 1, 2003 to Dec 31, 2004	M	Sentinel event definition and list similar to JCAHO; developed in partnership with Nevada Hospital Association Sentinel Events Work Group	M	Regulatory and QI	State Repository for Health Care Assurance/Sentinel Events Registry staff and State Biostatistician; future partnership with QIO	N/A	√			http://health2k.state.nv.us/sentinel/
NY	April 1998	M	State-specific list of adverse events and some near misses	E	Regulatory and QI	Contract with University at Albany SPH, partner with QIO	30,842	√	Not generally		http://www.health.state.ny.us/nysdoh/hospital/nyports/index.htm
OR	Fall 2005	V	State-specific list of adverse events	M	QI	Patient Safety Commission, semi-independent state agency	N/A	√			http://www.oregon.gov/DHS/ph/pscommission/index.shtml
PA	June 2004	M	Statutory definitions of adverse event and near misses	E	QI (although reports of adverse events are also distributed to the state regulatory agency)	Contract with ECRI (with 2 subcontractors: EDS and ISMP) A dedicated team of clinical analysts, headed by a Clinical Director, includes professionals with backgrounds in medicine, nursing, pharmacy, risk management, law, health administration, product engineering and statistical analysis.	70,851	√		Yes	www.psa.state.pa.us
UT	Oct 15, 2001	M*	State-specific list of sentinel and adverse events	M & E	QI	State staff	Sentinel Events=~ 40 annually since Oct. 2001 Adverse Drug	√			Health.utah.gov/psi/

State	Date of system implementation	Mandatory (M) or voluntary (V)	Reportable events	Manual (M) or electronic (E) data collection	Intent and use of the data from the system	Analytic support	Number of reports received in 2004	Issues periodic public reports with aggregate data	Publishes facility-specific information	Provides incident-specific information	Website
							Events= ~7,000 annually				

* Utah's system is mandatory but the regulation was developed through consensus process.

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