

2007 Guide to State Adverse Event Reporting Systems

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Since the Institute of Medicine called for a nationwide, mandatory reporting system to provide for the collection by state governments of standardized information about adverse medical events, much state activity has focused on the development and refinement of these systems. The information collected can help identify health system weaknesses, complement other state functions, and help safeguard health care consumers.

The National Academy for State Health Policy (NASHP) recently collected information about all state adverse event reporting systems that were authorized as of October 2007. For purposes of this research, state adverse event reporting systems were defined as those systems authorized and operated by

state governments to collect reports from hospitals (and in some cases other types of facilities such as ambulatory surgical centers) about adverse events, with the intent of improving patient safety. The work was supported by the Commonwealth Fund.

This *State Health Policy Survey Report* provides a snapshot of the current scope and operations of state adverse event reporting systems and compares current information with information from previous NASHP work. The intent of this work is to identify trends in state policies governing these systems.

Key Findings

- Just over half the states (plus the District of Columbia) now have an adverse event reporting system. In October 2007, NASHP identified 25 states plus the District with mandatory adverse event reporting systems and 1 state with a voluntary system that met our criteria for an adverse event reporting system, a total of 27 adverse event reporting systems in place.
- Between 2005 and 2007, 15 states and the District of Columbia enacted or revised patient safety reporting systems through legislative and/or regulatory activity. Four states and the District of Columbia added mandatory reporting systems and 11 states undertook significant revisions, adding well-defined reportable event lists and often, more thorough state oversight.
- By 2007 almost half of states with reporting systems had adopted or adapted the National Quality Forum's (NQF) recommended core list of standardized reportable events, including the five most recently authorized systems.

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- In 2000, only one state had the ability to receive reports electronically via an interactive Web-based system that also could be used for analysis and feedback to data reporters. In 2007, nine states had implemented this electronic capability – and four others have Web-based systems nearing development.
- In 2000, the purpose of most state reporting systems was to improve patient safety by holding individual health care facilities accountable for preventable adverse events and perhaps secondarily to improve quality and patient safety across facilities. In 2007, most states note that their systems are intended to provide both of these regulatory and quality improvement (QI) functions.
- All but four states require that root cause analysis (RCA) results and/or corrective action plans be submitted in response to serious adverse events.
- The current trend is toward strong, comprehensive data protection in state reporting system legislation. All but 4 of the 27 adverse event reporting systems have some type of legal protections beyond general peer review protections to prevent unwanted disclosure of data.
- Disclosure of adverse events to patients and/or families is becoming more accepted and supported behavior. In 2000, only one state required health care facilities to disclose to patients and/or their families directly when an adverse event occurred. In 2007, 11 of the 27 reporting systems did so.
- All but three states have provided, or plan to provide, public reports of some of their collected data. Sixteen states post the reports on a Web site and five plan to do so when the data are available.
- Sixteen states plus the District of Columbia publicly release aggregate data that does not identify facilities and seven have released, or plan to release, facility-specific data. Those that require release of facility-specific reports are mostly newer systems.
- Funding for patient safety reporting systems is a continued concern and many state officials expressed frustration regarding their limited ability to ensure compliance with reporting guidelines, follow-up with facilities, and conduct analysis and feedback of data because of funding shortages.

With the mandatory reporting systems added between 2005 and 2007, and with improved data collection, public reporting, and transparency measures occurring in half of

the other states, there is a strong current among states to advance their role in addressing patient safety.

Introduction

One of the most sweeping improvements in health care that the United States could make would be to place patient safety at the forefront of the national agenda. Preventing medical errors would save more lives than eliminating motor vehicle or workplace accidents, AIDS, or breast cancer.¹ Considering the estimate of up to 98,000 hospitalized patients that die annually due to medical errors, in combination with errors of omission, and hospital acquired infections, as well as adverse events in nursing home and ambulatory care settings, the toll of deaths and injuries is significant.^{2,3} Medical errors also result in added costs of between \$17 billion and \$29 billion per year in hospitals nationwide.⁴ In many cases, evidence-based methods are available that can prevent these deaths and injuries from occurring.

The majority of medical errors are due to faulty systems and processes, but systems redesign requires vigilance and leadership from a variety of stakeholders, including state government. In 1999, the Institute of Medicine (IOM) called for a nationwide, mandatory reporting system to provide for the collection by state governments of standardized information about adverse events.⁵ Since that time, most state activity has focused on the development and refinement of state mandatory reporting systems, which can help improve quality and outcomes by identifying health system weaknesses, can complement other state functions, and can help safeguard the health care consumer.

PROJECT OVERVIEW

Since the 1999 IOM report, the National Academy for State Health Policy has tracked state progress and provided technical assistance to states on patient safety issues through reports,⁶ technical assistance, a patient safety discussion group for state officials, a patient safety toolbox for states,⁷

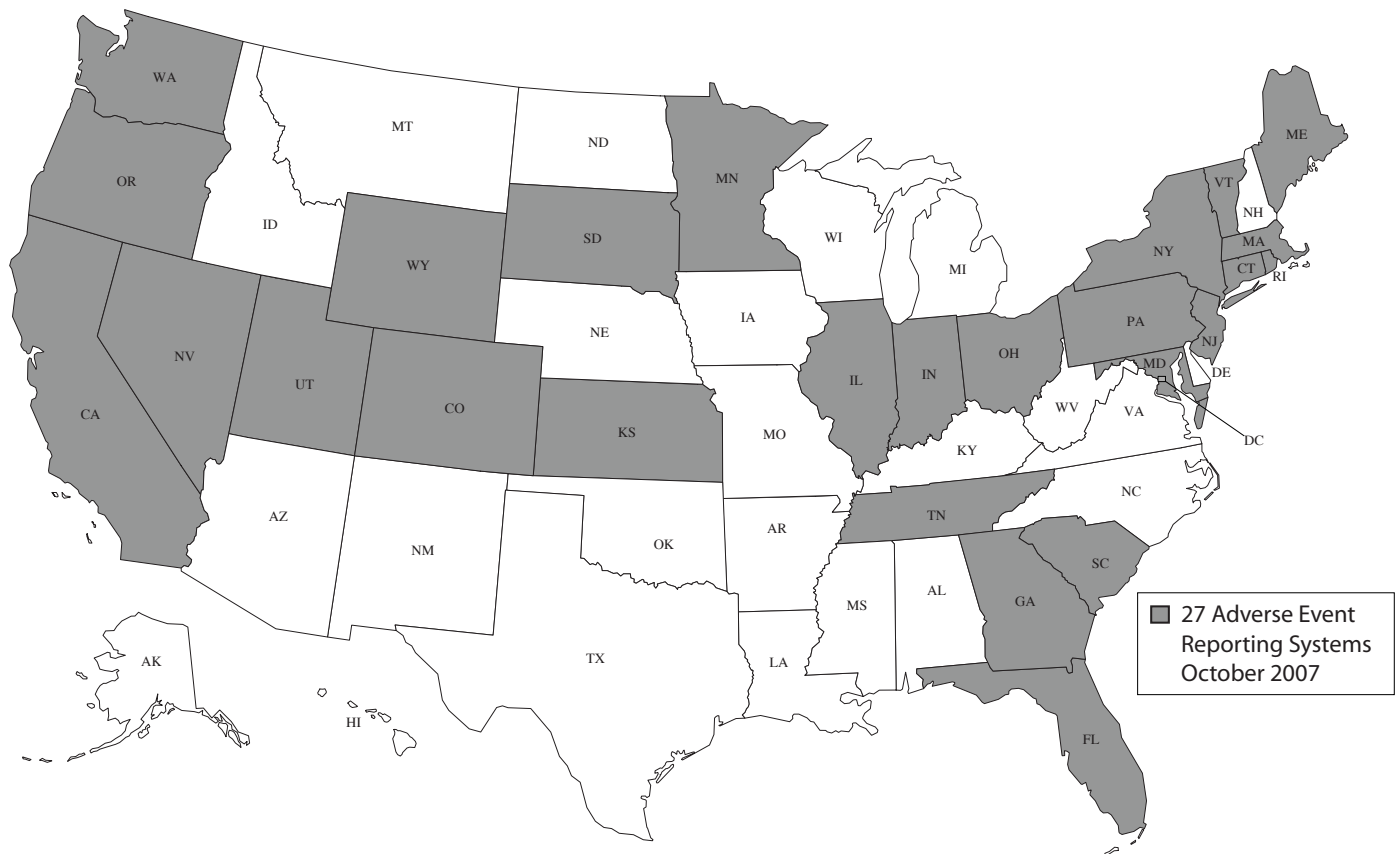
About the National Academy for State Health Policy

The National Academy for State Health Policy (NASHP) is an independent academy of state health policy makers working together to identify emerging issues, develop policy solutions, and improve state health policy and practice. As a non-profit, non-partisan organization dedicated to helping states achieve excellence in health policy and practice, NASHP provides a forum on critical health issues across branches and agencies of state government.

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FIGURE 1. AUTHORIZED ADVERSE EVENT REPORTING SYSTEMS, OCTOBER 2007

and conferences and workshops.

With the support of the Commonwealth Fund, NASHP has built on this previous work to develop this *2007 Guide to State Adverse Event Reporting Systems* to reflect recent state activity, including key characteristics of state systems. This report includes information about all state adverse event reporting systems that were authorized as of October 2007. For purposes of this research, state adverse event reporting systems were defined as those systems authorized and operated by state governments to collect reports from hospitals (and in some cases other types of facilities) about adverse events, with the intent of improving patient safety.

To augment information from NASHP's previous patient safety projects, staff first conducted a scan of relevant state Web sites and legislation. NASHP pre-completed a matrix with information about each state identified as having authorized a reporting system as of October 2007.

The pre-completed matrix was then sent for review and verification to each of the state agencies responsible for implementing patient safety reporting systems. The matrix is included as Appendix A of this *Survey Report*. The completed matrix was used to develop a snap shot of the current scope

and operations of state adverse event reporting systems, and when combined with information from previous NASHP work, to identify trends in state policies governing those systems.

Our findings are presented in five major categories:

- Reporting system criteria: Presents information on the criteria NASHP used to categorize reporting systems and how the criteria have evolved since 2000.
- Reporting system authorization: Discusses the increase in state reporting systems since 2000.
- Data flow: Examines the type of events that facilities report, which facilities report events, and how they do so.
- Use of Data: Examines how the intent of reporting systems influences the use of data, as well as how states review data, disclosure and protection practices, and publicly reported information
- Resources: Examines how states fund their adverse event reporting systems.

TABLE 1: ADVERSE EVENT REPORTING SYSTEMS AUTHORIZED IN 2000 AND 2007

<p>15 authorized adverse event reporting systems in 2000 (including several that focused solely on abuse, neglect, or clinical outcomes, not adverse/patient safety events).</p>	<p>27 authorized adverse event reporting systems in October 2007 (only those systems that focus on adverse events with the intent to improve patient safety).</p>
<p>Colorado, Florida, Kansas, Massachusetts, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington</p>	<p>California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Illinois, Indiana, Kansas, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, Wyoming</p>

Adverse Event Reporting Systems: Status and Trends

REPORTING SYSTEM CRITERIA

In order to analyze and report trends on state policies and programs, it is first necessary to develop criteria for inclusion and exclusion in the analysis. NASHP’s criteria for including state reporting systems in its tally has evolved over the past seven years as the result of state reporting system modifications, an evolving understanding of the potential of these systems to address patient safety issues, and advances in the field of patient safety related to the types and preventability of events that affect patient safety.

When NASHP first examined state reporting systems in 2000, 15 mandatory systems were identified. All sought to hold hospitals accountable for the most serious mistakes made in the provision of health care.⁸ Among these 15 states, the systems in operation in 3 (Nebraska, Ohio, and Texas) focused solely on abuse, neglect, or clinical outcomes (not adverse/patient safety events). The origins of the earlier reporting systems were often a response to a medical malpractice insurance crisis, a highly publicized tragic event, or an effort to increase oversight of hospitals.⁹ These systems would not be included in NASHP’s current categorization of adverse event reporting systems.

The criteria we used in 2007 includes only those systems authorized and implemented by state governments to collect reports from hospitals (and in some cases other facilities) about adverse events, with the intent of improving

patient safety. By October 2007, based on NASHP’s criteria, 26 states plus the District of Columbia had adverse event reporting systems in place.

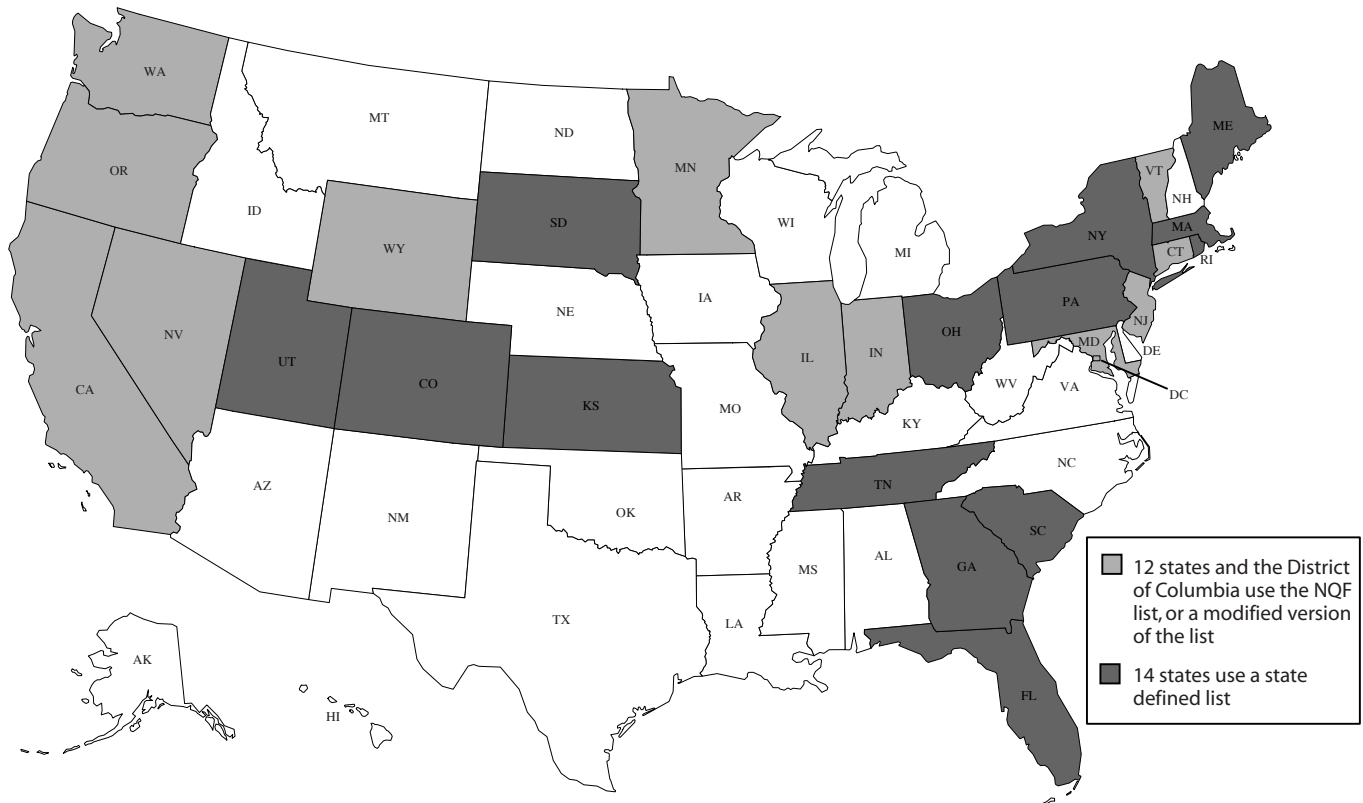
Many states operate other systems intended to focus on performance measures or, increasingly, on health care acquired infections (HAI). Information on clinical outcomes alone does not fit the NASHP criteria for adverse event reporting systems. Some states are adding requirements that facilities report HAI measures to their existing adverse event/medical error reporting systems, while other states are creating new systems to which facilities report only HAI information. Since HAI reporting systems do not address a broader range of adverse events, systems designed solely to collect information on HAI are not examined in this report.

REPORTING SYSTEM AUTHORIZATION

The number of state adverse event reporting systems increased between 2000 and 2007, even though NASHP’s criteria for these systems tightened. In 2007, NASHP identified 25 states and the District of Columbia with mandatory adverse event reporting systems and 1 state (Oregon) with a voluntary system that met our criteria for an adverse event reporting system.

In 2000, NASHP had identified 15 states that met the broader definition in use at that time. As mentioned above, the Nebraska, Ohio, and Texas systems would no longer be considered to be adverse event reporting systems as NASHP defines them. However, changes made to the Ohio system brings it in line with the current criteria. Texas also made changes to fit the criteria, but its system was discontinued in 2007 due to sunset provisions.

The increase in adverse event reporting systems illustrates growing acknowledgement of the state role in improving patient safety. Interest in improving and refining

FIGURE 2. SOURCE OF REPORTABLE EVENTS LIST USED IN ADVERSE EVENTS REPORTING SYSTEMS

adverse event reporting systems is confirmed by the amount of legislative activity that occurred over the past two years. Between 2005 and 2007, 16 states enacted or revised patient safety reporting systems through legislative and/or regulatory activity, including:

- Four states – Indiana, Illinois, Vermont, and Wyoming – plus the District of Columbia that had not previously had reporting systems added mandatory reporting systems.
- Eleven states undertook significant revisions of existing systems, such as by adding well-defined reportable event lists and often, more thorough state oversight (California, Colorado, Minnesota, New Jersey, Nevada, Ohio, Oregon, South Carolina, South Dakota, Utah, and Washington).

DATA FLOW

In its 1999 report, the Institute of Medicine recommended that states collect standardized information about adverse events that result in death and serious harm, initially from hospitals and eventually from other health care delivery settings.¹⁰ Eight years after the release of that report, states have moved toward standardization of a minimal set of reportable events, have expanded in many cases the types of

reportable events (sometimes including near misses), and have moved toward more advanced reporting mechanisms.

Reportable Events

States may identify and define reportable events in different ways. The IOM report recommended that states collect information about adverse events that result in serious harm or death, because these events are easy to identify and may be more difficult to conceal. The rationale for focusing on the most serious adverse events is that the occurrence of serious and presumably preventable injury may indicate a weakness in a health care facility's responsibility to ensure patient safety.¹¹

When states first began implementing adverse event reporting systems there was no nationally recommended list of reportable events. However, in 2002, the National Quality Forum (NQF) published *Serious Reportable Events in Health-care: A Consensus Report*. This report offered a recommended list of standardized reportable events as the basis of a national, state-based event reporting system. The NQF list was developed through a consensus process involving consumers, providers, purchasers, researchers and other health care stakeholders. The list was updated in 2006 and now identifies 28 adverse events that are serious, largely preventable, and of concern to health care providers, consumers, and all

stakeholders. The 28 events are organized into six categories – five that relate to the provision of care (surgical, product or device, patient protection, care management, and environmental) and one that includes four criminal events.¹² By 2007, almost half of the reporting systems included in this report had adopted or adapted this list (California, Connecticut, District of Columbia, Illinois, Indiana, Maryland, Minnesota, New Jersey, Nevada, Oregon, Vermont, Washington, Wyoming).

States' interest in basing their systems on a nationally recognized list of events is confirmed by two additional findings from our research in 2007. First, since the publication of the NQF list, most states that have enacted new reporting systems or made significant revisions have used the list as the basis of their reporting.

- The five with the newest reporting systems (District of Columbia, Illinois, Indiana, Vermont, and Wyoming) have all adopted NQF standards.
- Some states that continue to use a “state-defined” list of adverse events have modified their lists to include events from nationally recognized lists, such as the NQF events, CMS (Centers for Medicare and Medicaid Services), AHRQ (Agency for Healthcare Research and Quality), and Joint Commission specified events, and some have added HAIs.

Finally, six states either collect or plan to collect some range of “near miss” data. Near miss events focus on a much broader set of errors, mainly those events that do no or minimal harm but which help detect system weaknesses that can be fixed before more serious harm is done.¹³

- Three state systems (Kansas, Oregon, and Pennsylvania) collect data on some type of near misses.
- New York established a separate system in 2007 that collects information on near misses and which complements its adverse event reporting system.
- New Jersey and Washington are planning to begin collecting information about “near miss” events.

In addition, Vermont requires hospitals to establish an internal reporting system to identify, track, and analyze near misses as well as reportable events. However, near misses are not reportable to the state.

The value of near miss data is illustrated by Pennsylvania, where that data forms the foundation for a substantial portion of the education and feedback to providers in the form of patient safety alerts and special projects. For example, a near miss report of a patient who nearly died as the

result of confusion caused by color-coded wristbands led to a supplementary advisory and survey of facility procedures. The lack of standardization triggered a “color of safety” task force comprised of facilities that standardized risk reduction strategies and led to suggested policies and procedures posted on the Pennsylvania Patient Safety Authority Web site.¹⁴ Despite the potential usefulness of near miss data, states recognize that this type of analysis is resource intensive and may not be appropriate for the intended purpose and scope of their systems.

Reporting Mechanism

Reporting mechanisms have evolved with the technology. In 2000, only New York had a Web-based system that could be used for data collection as well as analysis and feedback to data reporters. The system enables providers to access and create comparative reports with their own data: over time, to a peer group, and statewide. This feature enables users to access timely information and enhances learning from the data. In 2007, nine states have implemented this electronic capability (Florida, Illinois, Indiana, Minnesota, New York, New Jersey, Ohio, Pennsylvania, Tennessee). New Jersey, Utah, Vermont, and Washington have Web-based systems nearing development.

Facilities that Report Events

In 2007, all 27 reporting systems include event reporting from acute care hospitals. Only five (Maryland, New Jersey, Ohio, Rhode Island, and Vermont) collect reports solely from hospitals, while eight collect reports from all licensed facilities, which may include psychiatric, and specialty hospitals, birthing centers, ambulatory surgery centers, clinical laboratories, or renal disease facilities (Colorado, District of Columbia, Massachusetts, New York, South Carolina, South Dakota, Tennessee, and Wyoming).¹⁵

Other types of providers from which systems now collect reports include:

- Ambulatory surgery centers (Connecticut, Florida, Illinois, Indiana, Kansas, Maine, Minnesota, Nevada, Oregon, Pennsylvania, Utah, and Washington).
- Retail pharmacies (District of Columbia and Oregon).

USE OF DATA

States use the data collected within adverse event reporting systems in various ways, including holding individual facilities accountable for correcting problems that led to errors; sharing information about common errors and best practices in prevention across facilities; and informing policy makers, consumers,

and other stakeholders about patient safety issues in order to create pressure for change or to guide decision making.

System Intent

The Institute of Medicine recommended separate reporting systems for accountability (mandatory) and quality improvement (voluntary).¹⁶ In 2000, the purpose of most state reporting systems was to improve patient safety by holding individual health care facilities accountable for preventable adverse events and perhaps secondarily to improve quality and patient safety across facilities. Most states now note that their systems are intended to provide both of these regulatory and quality improvement (QI) functions. Only a handful of states, mostly with older systems, intend their systems to serve only a regulatory function (California, Kansas, Massachusetts, and South Dakota).

The purpose of the system, in addition to other factors, influences how states use the data to hold individual facilities accountable and improve patient safety by providing relevant, useful information to a variety of stakeholders.

Review Process

In our research, states were asked about their review process for submitted data; for instance, whether the state provided clinical review, on-site investigation, root cause analysis (RCA) review, or some other reviews. We found that in 2007 most states conduct clinical reviews and triage reports as needed, in some cases conducting on-site investigations for the most serious events. Oregon is unique in having an independent review process, separate from the Patient Safety Commission's formal review, and which is conducted by the Public Health Officer to confirm the quality of reports received and overall program integrity.

States can encourage facilities to conduct thorough RCA by requiring reporting not only of events but also of information about root causes and corrective actions.¹⁷ Most states require that RCA results and/or corrective action plans (CAP) be submitted in response to serious adverse events (except California, Kansas, Ohio, and Wyoming). Several states that do not require RCA/CAP reports from facilities indicated that staffing constraints limit their capacity to review such information, and many states noted that limited feedback was due to budget constraints.

Data Disclosure and Protection Practices

State reporting systems vary in their provisions for disclosure and protection of patient safety data in terms of types of specificity of disclosed information (individual events, facility specific, statewide aggregate), sharing of data among

state agencies, and legal protections offered (including discoverability, confidentiality, and admissibility in court).¹⁸

The current trend is toward strong, comprehensive data protection in state reporting system legislation. The public policy rationale for protecting the confidentiality of information in mandatory reporting systems is to encourage honest, accurate, and full disclosure of events to the state systems. Without such protections, some believe that hospitals will not report events that expose them to legal risk or public embarrassment and regulatory agencies will not have the information that they need to adequately protect public health. All but 4 of the 27 adverse reporting systems in 2007 (California, Massachusetts, Ohio, and South Carolina are the exceptions) have some type of legal protections beyond general peer review protections to prevent disclosure of data from their systems. Of these four states, three systems were authorized by regulation as opposed to statute, which may be a factor in their lack of legal protections; most states specify legal protections in the statute that established the system.

Disclosure of adverse events to patients and/or families is becoming more accepted and supported behavior.

In 2000, only 1 state out of the 15 with adverse event reporting systems (New York) required hospitals to disclose to patients and/or their families directly when an adverse event occurred. In 2007, 11 of the 27 reporting systems have such disclosure (California, Florida, Maryland, Massachusetts, New Jersey, New York, Nevada, Oregon, Pennsylvania [for serious events], Tennessee, and Vermont). Factors that contributed to this change likely include experience that suggests disclosure is not tied to an increase in the number of lawsuits. (For example, the Veterans Affairs (VA) Medical Center in Lexington, Kentucky, demonstrated that disclosing errors to patients and families did not lead to an increase in payments for legal fees.)¹⁹

Publicly Reported Information

Public reporting is considered an effective way to spur quality improvements in health care.²⁰ The Institute of Medicine included public reporting in its call for state governments to create mandatory reporting systems. In discussing the need to foster innovation and improve the delivery of care, the IOM continued its call for public accountability by emphasizing transparency as one of ten principles that should guide the redesign of the health care system.²¹

Public reporting is influenced in part by the number of reports received by the state. Not surprisingly, given the differences among states in reporting standards and other factors, the number of individual events reported to states

varies widely. For example, in 2006, Pennsylvania received reports of 200,000 events (of these, 7,000 were serious incidents and the remaining were near misses) compared to 10 in South Dakota. Most states receive a range of from hundreds to thousands of reported events.

The number of reported events is not necessarily a valid indicator of the incidence of events for several reasons – the number varies based on the broad or narrow definition of reportable events, the number of facilities and beds in the state, and the inability to identify the number of opportunities for the event to occur. In addition, some states and facilities are more aggressive and experienced in monitoring and reporting, so that a high number of events reported in a state or a facility may be more indicative of a robust reporting system rather than delivery system flaws. The IOM report cautions that the goal of reporting programs is not to count the number of reports, but to analyze and use the information they provide and match it with the right tools, expertise, and resources to help correct the errors.²² The number of reported events has limited value for the consumer, but may be useful to note individual state trends over time.

Among the 27 adverse events reporting systems in 2007, all but 3 (Georgia, South Carolina, and South Dakota) have provided, or plan to provide, public reports of some of their collected data. Among these:

- Sixteen post public reports on a Web site (Colorado, Connecticut, Florida, Indiana, Maryland, Maine, Minnesota, New Jersey, Nevada, New York, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, and Wyoming). In addition, four states and the District of Columbia are planning to provide data on a public Web site when the data are available (California, Illinois, Vermont, and Washington).
- Most release reports on an annual basis, although some are sporadic or less frequent due to budget constraints. One (Colorado) releases information weekly on its Web site.
- Seventeen release aggregate data that does not identify facilities.
- Seven have released, or plan to release, facility-specific data (California, Colorado, Illinois, Indiana, Massachusetts, Minnesota, and New York). Those states that release facility-specific reports are mostly newer systems.²³

Resources

Funding for patient safety reporting systems is a continued concern. During our research, many state officials expressed frustration about their limited ability to ensure compliance with reporting guidelines, to follow up with facilities, and to conduct analysis and feedback of data because of funding shortages. Six states (California, Colorado, Minnesota, Oregon, Pennsylvania, and Vermont) and the District of Columbia use a facility assessment or license fees to pay for their patient safety systems; they are among those with newer systems. Five states (Illinois, Maine, Nevada, New York, and Wyoming) have a state dedicated funding stream for their systems. The majority, however, use agency general operating funds or a combination of sources to finance their operations.

It is promising to note that as states grapple with broad reform measures in health care, a robust patient safety reporting system may assume a higher profile as a state public health care priority, with patient safety initiatives included in efforts to improve quality and reduce costs. For example, Governor Edward G. Rendell's health care reform proposal, Prescription for Pennsylvania, calls for improvements in patient safety and quality to reduce overall costs. The Governor's Office for Health Care Reform Web site notes that "charges for uncompensated care for the uninsured, additional days of hospital care due to potentially avoidable hospital-acquired infections, certain medical errors, readmissions for complications and infections and avoidable hospitalizations due to inadequate care for patients with chronic diseases total \$7.6 billion per year."²⁴

Notes

- 1 Institute of Medicine. *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 2000), 1.
- 2 Institute of Medicine. *Patient Safety: Achieving a New Standard of Care* (Washington, D.C.: National Academy Press, 2004), 31.
- 3 R.A. Weinstein. Nosocomial infection update. *Emerging Infectious Diseases*, 4:416-420, 1998.
- 4 Institute of Medicine. *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 2000), 2.
- 5 *Ibid.*, p. 9.
- 6 See www.nashp.org for access to previous publications on patient safety and state reporting systems.
- 7 www.pstoolbox.org
- 8 Jill Rosenthal et al., *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives*, (Portland, ME: National Academy for State Health Policy, 2001).
- 9 *Ibid.*, p. 19-20.
- 10 **Institute of Medicine.** *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 2000), p.88.
- 11 ***Ibid.*, p. 88.**
- 12 National Quality Forum, *Serious Reportable Events in Healthcare 2006 Update* (Washington, D.C.: NQF; 2006).
- 13 Institute of Medicine. *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 2000), p. 87.
- 14 Use of Color-Coded Wristbands Leads to Unnecessary Risk, December 14, 2005, http://www.psa.state.pa.us/psa/lib/psa/press_releases/press_release_color-coded_wristbands_12-14-05_final.pdf, retrieved November 2007.
- 15 New Jersey is phasing in reporting in all health care facilities.
- 16 Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 2000), p. 86.
- 17 Jill Rosenthal and Maureen Booth, *Maximizing the Use of State Adverse Event Data to Improve Patient Safety*, (Portland, ME: National Academy for State Health Policy, 2005), p. 9.
- 18 For a more thorough discussion of disclosure and protection of data in state reporting systems, see Mimi Marchev, Jill Rosenthal, and Maureen Booth, *How States Report Medical Errors to the Public: Issues and Barriers* (Portland, ME: National Academy for State Health Policy, 2003).
- 19 S.S. Kraman and G. Hamm, "Risk Management: Extreme Honesty May Be the Best Policy," *Annals of Internal Medicine* 1999; 131:963-967.
- 20 Institute of Medicine, *Performance Measurement: Accelerating Improvement* (Washington, D.C: National Academy Press, 2006).
- 21 Institute of Medicine, *Crossing the Quality Chasm* (Washington, D.C: National Academy Press, 2001), p. 8.
- 22 Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 2000), p. 100.
- 23 Massachusetts currently releases adverse event information on a request basis and does not post to a public Web site; however, the state is in the process of developing a broader Web site to share cost and quality data with consumers. Consumers will have access to information

on performance and costs to help them compare health care providers, pharmacies, payers, and insurers. It is hoped that greater transparency and accountability will inform better decision making by providers and insurers (<http://www.mass.gov/>)

- 24 <http://www.gohcr.state.pa.us/prescription-for-pennsylvania/Rx-for-Pennsylvania.pdf>.

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APPENDIX A. STATE ADVERSE EVENT REPORTING SYSTEMS

State	Start Date	Legislative or Regulatory Authority	Mandatory or Voluntary (M/V)	Reportable Event List (NQF, Modified NQF, or State-defined)	Near Misses Reported (Y/N)	Web or Manual Data Submission (E/M)	Regulatory or QI Tool (Reg/QI)	Facilities Required to Report Events	Agency Receiving Data	Legal Protections Against Disclosure of Reported Data (Y/N)
CA	Regulation, replaced by statute enacted 2006, operational 7/07	Health & Safety Code Sec. 1279.1, 1279.2, 1279.3	M	Modified NQF (+1 misc. defined as adverse event that causes serious harm to patient, personnel or visitor)	N	M	Reg	Acute care, psychiatric, and special hospitals	CA Dept. of Public Health	N
CO	1988, Revised 4/1997, 2005	25-1-124 (CRS)25-3-109 (1),(3),(7),(8) (Article 3, Title 25, Part 6)	M	State-defined "occurrences" (such as deaths, brain injuries, burns, equipment malfunctions, abuse, anesthesia complications, select surgical and infection outcome measures)	N	M	Reg/QI	All licensed facilities	CO Dept. of Public Health & Environment, Health Facilities & Emergency Medical Services Division	Y
CT	10/02, Revised 5/04	General Statutes Section 19a-127n	M	Modified NQF	N	M	Reg/QI	Hospitals, ASCs	CT Dept. of Public Health	Y
DC	Enacted and operational 7/2007	District of Columbia Code § 7-161 (2007)	M	NQF and 1 HAI	N	M	QI	All health care facilities, businesses and any licensee doing health care business, including pharmacies, dental offices	DC Health Regulation and Licensing Administration	Y
FL	1985, Revised 1998 and 2003, with anticipated revisions in 2008	Florida Stat.Ch.395.0197 (2003)	M	State-defined (adverse events)	N	M/E	QI	Hospitals, ambulatory care centers	FL Agency for Health Care Administration	Y

State	Disclosure to Patient/Family Required	RCA/CAP Reporting Required (Y/N)	Review Process for Submitted Data (Clinical Review, On-Site Investigation, RCA Review, other)	Specificity of Publicly Reported Data	Public Report Frequency	Public Report Available on Website (Y/N)	Reporting System Website	Reporting System Funding Source (Agency General Operating Funds, Facility Assessment, State Dedicated Funding Stream, Other)
CA	Y	N	Onsite inspection or investigation within 48 hrs.; penalty for noncompliance	Aggregate and Facility-specific	Law requires first report to be issued sometime between 1/09 and 1/15	TBD-- mandated to be in place by 1/2015	To be developed (TBD)	Licensure fees
CO	N	Y	Limited staff review due to funding. Staff reviews and triages reports, may request additional information and instigate an on-site investigation for certain incidents. State-appointed advisory committee may review reports.	Aggregate and Facility-specific	Weekly (Annual with biannual bulletins)	Y	TBD	Facility assessment (Licensing fees paid by general acute care, acute psychiatric & special hospitals) (general funds)
CT	N	Y	DPH screens, formal investigation into system failures and/or inadequate standard of care	Aggregate	Annual (October)	Y	http://ct.gov/dph	Agency general operating funds
DC	N	Y	Adverse events to be reported semi-annually	Aggregate	Annual	TBD	TBD	Licensure fees
FL	Y	Y	Clinical reviews and on-site investigations in some cases	Aggregate	Annual	Y	http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Risk/index.shtml	General revenue for three FTE positions

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GA	Enacted and operational 2003	O.C.G.A. Sec. 31-7-15, 31-7-131et seq.	M	State-defined (adverse events, hospital burns, assault with injury, missing patient>8hrs, serious injury due to equipment misuse/malfunction)	N	M	Reg/QI	Hospitals, end-stage renal disease facilities, clinical laboratories	GA Dept. of Human Resources Office of Regulatory Services	Y
IL	Enacted 2005, operations delayed 1/08	Public Act 094-0242	M	Modified NQF	N	E	QI	Hospitals and ASCs	IL Dept. of Public Health	Y
IN	Executive order issued 1/05, operational 2006	Executive Order 05-10 Indiana Code 16-21-1-7	M	Modified NQF	N	E	QI	Hospitals, ASCs, abortion clinics, birthing centers	IN Dept. of Public Health	Y
KS	Enacted 1987, operational 1988	Kansas Stat. Ann. § 65-49239 (2002) Kansas Administrative Code, 25-52-1	M	State-defined "substandard standards of care"	Y	M	Reg	Hospitals and ASCs	KS Dept. of Health and Environment	Y
MA	1980s, revised 1995	105 Code of Massachusetts Regulations 130.331	M	State-defined (adverse events)	N	M	Reg	All licensed facilities	MA Dept. of Public Health's Division of Health Care Quality	N
MD	3/04	COMAR 10.07.06	M	State defined but categorized by a modified NQF	N	M	Primarily QI (Reg only for failure to report or to perform RCA)	Licensed hospitals	MD Dept. of Health and Mental Hygiene, Office of Health Care Quality	Y
ME	2004	Maine Rev. Stat. Ann. tit. 22, § 8753 (2003)	M	State-defined (sentinel events)	N	M	Reg/QI	Hospitals, ASCs, end-stage renal facilities, intermediate care facilities	ME Dept. of Health and Human Services, Division of Licensing and Regulatory Services	Y

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GA	N	Y	RCA, clinical reviews and on-site investigations in some instances	N/A	None	N	http://ors.dhr.georgia.gov (find facility, click on inspection reports by hospitals)	Agency general operation funds
IL	N	Y	Not yet determined	Aggregate and Facility-specific	Annual	TBD	TBD	Dedicated funding stream
IN	N	Y	Data collection/best practices	Aggregate and Facility-specific	Annual (August)	Y	http://www.in.gov/isdh/regsvcs/mers/index.htm	Agency general operation funds
KS	N	N	clinical review and desk audits, on-site investigation, administrative review. Mandated risk management plan must be approved	Aggregate	Annual (Fall)	N	N	Kansas health care stabilization fund administered through Agency general operating funds
MA	Y	Y	Clinical review, physician consults, on-site inspections	Aggregate and Facility-specific	Information available upon request	N	http://www.mass.gov/healthcareqc	Agency general operation funds
MD	Y	Y	RCA review with follow up when appropriate which may include further clinical review or onsite review	Aggregate	Annual (~January)	Y	http://www.dhms.state.md.us/ohcq	Agency general operation funds
ME	N	Y	Initial review, may take other action such as on-site review. Audits of non-reporting entities	Aggregate	Annual (~January)	Y	http://www.maine.gov/dhhs/dlrs/medical_facilities/home.html	State dedicated funding stream

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MN	Enacted 4/03 revising in 2007	Minnesota Statutes, Section 144.706 et seq.	M	NQF	N	E	Reg/QI	Hospitals, ASCs, regional treatment facilities	MN Dept. of Health	Y
NJ	1990, updated system enacted 4/04, operational 2/05	P.L.2004, chapter 9	M	Modified NQF	TBD	M (E TBD)	QI	Acute care hospitals now (all health care facilities to be phased in)	NJ Dept. of Health and Senior Services	Y
NV	Enacted 2003, revised 1/05	Nevada Revised Statutes (NRS) 439.800-890 Nevada Administrative Code (NAC) 439.900-920	M	NQF and state defined facility-acquired infections	N	M	Reg/QI	Acute care, psychiatric inpatient and rehab inpatient hospitals, ASCs, independent ERs, obstetric centers	NV State Health Division - Bureau of Health Planning and Statistics	Y
NY	Operational 10/85; 1998 electronic-based reporting	New York Public Health Law, sec.2805(L) New York Code of Rules and Regulations, Title 10, Section 405.8	M	State-defined adverse events	Y	E	Reg/QI	Licensed hospitals, licensed diagnostic and treatment centers (which include ASCs and other types)	NY Dept. of Health	Y
OH	1995, new law enacted 4/07	Ohio Revised Code 3727.33	M	6 measures chosen from CMS, JCAHO, NQF, AHRQ (including 5 PSIs)	N	M	QI	Hospitals	OH Dept. of Health	N

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MN	N	Y	State QIO clinical team reviews all RCA/CAP info, provide feedback until RCA/CAP are deemed complete/thorough	Aggregate and Facility-specific	Annual (~January)	Y	www.health.state.mn.us/patientsafety	Facility assessment (Fee-based funding - base and per bed fee on hospitals and surgical centers)
NJ	Y	Y	Clinical Review, no on-site investigation	Aggregate	Annual	Y	www.nj.gov/health/ps/index.shtml	State general operating funds
NV	Y	Y	Mandatory facility patient safety committee reviews all reported sentinel events and evaluates corrective actions	Aggregate	First report: 2005-2006, due to small cell size; goal is annual reporting	Y	http://health.nv.gov	State dedicated funding stream
NY	Y	Y	DOH review and follow-up, surveillance, cross-walking report with hospital discharge summary	Aggregate and Facility-specific	Annual	Y	www.health.state.ny.us/nysdoh/hospital/nyports/index.htm	State dedicated funding stream
OH	N	N	none	Aggregate	Semiannual	Not yet determined	www.odh.ohio.gov/healthStats/hlthserv/hospitaldata/hospperf.aspx	Agency general operating funds

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OR	Enacted 2003, operational 5/06 (hospitals); 7/07 (retail pharmacies, amb. surgery centers and nursing homes); 2008 (others)	Section 9, Chapter 686, Oregon Laws 2003	V	Modified NQF (customized lists for each reporting entity type all based on NQF)	Y	M	QI	Hospitals, nursing homes, retail pharmacies, ASCs, outpatient renal dialysis facilities, birthing centers	OR Patient Safety Commission	Y
PA	Regulation in 1998, revised by statute in 2002, operational 6/04	Pennsylvania Stat. Ann. tit. 40, § 1303.308 (2003) Pennsylvania Stat. Ann. tit. 40, § 1303.313 Medical Care Availability and Reduction of Error Act	M	State-defined (Serious Events [harm], Incidents [no harm], and Infrastructure Failure)	Y	E	Reg/QI	Hospital, ASCs, birthing centers, some abortion facilities, soon nursing homes for HAI.	PA Patient Safety Authority (serious events and incidents); Dept. of Health (serious events and infrastructure failure)	Y
RI	1994	Rhode Island Statutes, section 23-17-40 Rules and Regulations for Licensing of Hospitals, R23-17-40, sections 1.41, 1.42 and 34.0	M	State-defined (Hospital Incidents)	N	M	Reg/QI	Hospitals	RI Dept. of Health, Office of Facilities Regulation	Y
SC	1976; 2006 amendments	South Carolina Code of Regulations, Regulation No. 61-16, Sec. 206	M	State-defined (adverse events resulting in death or serious injury)	N	M	Reg/QI	Licensed healthcare facilities	SC Dept. of Health and Environmental Control	limited to peer review protection
SD	Regulation 1987, updated in 1995 and 2000, statute 1/06	South Dakota Codified Law 34-12-12 Administrative Rules of South Dakota 44:04:01:07	M	State-defined (unnatural deaths, accidental, suicide, abuse and neglect, missing patients)	N	M	Reg	Licensed healthcare facilities	SD Dept. of Health	Y
TN	Prior to 1999, 6/00, Revised 2002	Tennessee Health Data Reporting Act of 2002; 68-11-211.pdf	M	State-defined ("unusual events")	N	E	Reg/QI	Licensed healthcare facilities	TN Dept. of Health	Y

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OR	Y	Y	Commission determines if report is complete, makes recommendations. Commission staff use a formal review process, done internally. There is also an independent review process done by the Public Health Officer to confirm quality of reports received	Aggregate	Annual	Y	www.oregonpatientsafety.org	Facility assessment Grants In-kind Support
PA	Y for serious events	Y	PSA analysts review every serious event and incident report. Patient Safety Advisories developed, and special projects conducted, based on review. DOH surveyors have access to Serious Event and infrastructure failure reports.	Aggregate	Annual	Y	www.psa.state.pa.us/	Facility assessment
RI	N	Y	Peer-review committee reporting	Aggregate	Infrequent: 2001 last report, next 2008	Y	www.health.ri.gov/hsr/facilities/hospitals/index.php	Agency general operating funds
SC	N-hospitals Y-ASC/ hospice	Y	Regional team leaders review and determine need for investigation	N/A	N/A	N	www.scdhec.net/health/licen/forms.htm	Agency general operating funds
SD	N	Y	Complaint Intake Coordinator screens need for clinical review, on-site investigation, and/or referral to other agencies.	Internal use only	N/A	N	N	Agency general operating funds
TN	Y	Y	Dept. approves Corrective Action Report if not hearing	Aggregate	Quarterly	Y	www.health.state.tn.us/PS/index.htm	Agency general operating funds

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UT	10/01, Revised 4/07	Utah Division of Administrative Rules, R380-200, Health Care Facility Patient Safety Program Rule R380-210	M	NQF, CMS, and JCAHO for sentinel events, ICD9 codes from hospital discharge data for adverse drug events	N	M / Electronic TBD	Reg/QI	Healthcare facilities and hospitals, ASCs	UT Dept. of Health	Y
VT	Statute 7/06; Rule adopted 10/07 with an effective date of 1/08	Act 215 (2006), 18 V.S.A http://www.healthvermont.gov/hc/patientsafety.aspx	M	NQF	N	M/E	Reg/QI	All hospitals, including dtate mental health hospital, excluding VA Hospital	VT Dept. of Health	Y
WA	Regulation 1995, statute 2006	Law, Revised Code of Washington Chapter 70.56	M	NQF	Y (voluntary)	M (estimated E by July 2008)	QI	Hospitals, childbirth centers, psychiatric hospitals, correctional medical facilities (ASCs, July 2009)	WA Dept. of Health	Y
WY	Enacted 7/05	W.S. 35-2-912 Department of Health, Health Care Facility Event Reporting, Chapter 2	M	Modified NQF	N	M	Reg/QI	Licensed healthcare facilities and hospitals	WY Dept. of Health	Y

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UT	N	Y	Clinical review and on-site participation in RCA as needed and requested by patient safety coordinator	Aggregate	Annually or as needed	Y	www.health.utah.gov/psi	Combination of UDOH and Medicaid state funds, grants, civil money penalties, prescription based overdose program
VT	Y	Y	For reportable events, each hospital is required to submit an initial report, causal analysis and action plan which is reviewed by the Department. Additional information, including periodic interim reports or modifications to the causal analysis or to the corrective action plan may be required.	Aggregate	Interim report 1/08 to legislature; full report to legislature 1/09 - to include recommendations regarding expansion of the system to include health care facilities other than hospitals	TBD- website determined but data not yet available	www.bishca.state.vt.us/HcaDiv/HRAP_Act53/HRC_BISHCAcomparison_2007/index_BISHCA_HRC_compar_menu_2007.htm	State general operating funds (50%) and facility assessment (hospitals) (50%) (beginning 7/07)
WA	N	Y	RCA Review	Aggregate	Annual (begin by 1/08)	TBD	TBD	State general operating funds
WY	N	N	Surveillance only	Aggregate	Annual	Y	www.wdh.state.wy.us/PHSD/phsd/ser.html	State dedicated funding stream