

**State Reporting of Medical
Errors and Adverse Events:
*Results of a 50-State Survey***

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April 2000

*Funded by
The California HealthCare Foundation*

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We also wish to thank those who took the time to complete the survey in all 50 states and the District of Columbia. The report would not have been possible without the time and effort required to complete surveys. We hope the survey analysis contained in the report accurately reflects the information provided to us by states; any errors and omissions are those of the authors.

The authors would also like to thank Al Cardona for survey formatting and follow up to ensure a 100 percent response rate from states.

EXECUTIVE SUMMARY

The Institute of Medicine's report *To Err is Human* was released in the fall of 1999. The report details the monumental number of medical errors and adverse events that occur in the United States health care system, many of which cause serious injury and death. In fact, the report asserts that medical errors are a leading cause of death in the United States, with many of the errors being preventable.

Based on recommendations in the report, state and national policy makers have begun to focus attention on the role of states in reporting and reducing medical errors. Consequently, states, Congressional staff, federal agencies, consumer groups, and the media are seeking up-to-date information about current state error reporting systems.

A February 2000 survey of states by the National Academy for State Health Policy sought to explore current state activities to assess and address this issue. The principal purpose of the survey was to determine the extent to which states require reporting of serious adverse events attributable to error in hospital settings. A secondary purpose was to collect more general information on similar reporting requirements in other settings of care, exclusive of nursing facilities.

The survey was mailed to state licensure and certification contacts in all 50 states and the District of Columbia with a copy to state public health officers. All 50 states and the District of Columbia responded to the survey. The results provide a snapshot of activities that states are undertaking to track and reduce medical errors and adverse events.

Among the survey's findings:

- The survey confirmed the lack of universal use or interpretation of the terms "medical error" and "adverse event" as employed by the Institute of Medicine's report. No states have a definition of medical error. Two states use the term "adverse event." Six states have a standard definition of a term that is similar to adverse event, but the term and the definition vary among the states. Seven states reported they do not have a standard definition of adverse event but, instead, specify which types of events must be reported.
- Fifteen states require mandatory reporting from general and acute care hospitals of adverse events, as defined by the Institute of Medicine (IoM) or by the state in a way that encompasses part or all of the IoM definition.
- Six states (including the District of Columbia) have voluntary reporting of medical errors or adverse events.
- Six states have pending legislation to require reporting of medical errors or adverse events.
- While 12 of the 15 states that require mandatory reporting from hospitals do so for

unexpected patient deaths, much variability exists in the other types of events that must be reported, including major loss of function, wrong site surgery, and medication errors.

- Of the 15 states that require mandatory reporting from hospitals, 13 also require reporting from free standing ambulatory care settings and 12 require reporting from psychiatric hospitals.
- Most states that require mandatory reporting indicate that they protect at least some reports from legal discovery, although states vary in the types of information and reports that are protected. Five states protect data in the case of a request under the Freedom of Information Act.
- Seven states protect access to person-level reports, the most frequent method of protecting reports. Five states provide a promise of confidentiality, the second most frequent response. Various other methods of protecting data include removing certain identifying information, anonymous reporting, and destroying reports once data is extracted.
- The most frequent use of data from reports is aggregating data to identify trends, reported in ten states with mandatory reporting. Nine states administer sanctions and assure corrective action; eight states issue public reports.
- States cite under-reporting and inadequate resources as their two greatest concerns with their reporting systems.
- Using medical error reporting data to improve public safety is still an issue with which states are grappling; two states are using data to develop quality improvement projects and many others noted this area as one of their greatest technical assistance needs.

The survey provides a snapshot of what states are doing to track and reduce medical errors and adverse events. The National Academy for State Health Policy will conduct phone interviews, site visits, and expert meetings in the coming months to assist states as they explore the issues involved in reducing errors and improving patient safety.

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INTRODUCTION

Extent of the problem

In the fall of 1999, the Institute of Medicine (IoM) released a report indicating that medical errors are a leading cause of death in the United States. Health services researchers estimate that between 44,000 and 98,000 Americans die each year as a result of preventable adverse events, more than the number who die from automobile accidents, AIDS, or breast cancer, ranking as the eighth leading cause of death in the United States. The costs of preventable adverse events are estimated to be between \$17 billion and \$29 billion each year. Adverse events occur among three to four percent of hospitalized patients; about one in ten of these events results in death. Over half of these deaths are preventable.¹

The IoM Report captured the attention of the public, the media, and health policy makers. When the report was released, 51 percent of the American public closely followed the media coverage, more than the number who reported following other prominent health issues, such as the presidential candidates' health proposals or the decision by United Healthcare to allow physicians to make medical decisions without a health plan gatekeeper.² The *Philadelphia Inquirer* published a four-part series in September 1999 calling attention to the serious and widespread nature of medical errors and the fact that they are often concealed. Bipartisan interest in improving patient safety has grown as evidenced by Senate and House hearings and calls for legislation to develop policies to reduce the injuries and deaths caused by medical errors. The Senate Health and Education Committee and Appropriations Subcommittees on Labor, Health and Human Services, and Education all have held hearings on the issue. Bills have been introduced in both the Senate and the House to mandate reporting of errors, compile statistics, and develop demonstration projects to test alternative ways to report errors.

In December 1999, President Clinton directed the Quality Interagency Coordination Task Force (QuIC), an umbrella organization established to coordinate Administration efforts to improve quality, to evaluate the recommendations in the IoM Report and to respond with a strategy to identify prevalent threats to patient safety and reduce medical errors. In February 2000, based on QuIC's endorsement of IoM recommendations, President Clinton announced support for a state-based, nationwide system of reporting medical errors, with state reporting requirements adopted within three years. The President's plan calls for mandatory reporting of all medical errors that cause serious injury or death and voluntary reporting of less serious errors.³

¹Institute of Medicine. *To Err is Human*. National Academy Press, Washington, D.C., 1999.

²Kaiser/Harvard Health News Index, 2000.

³Report of the Quality Interagency Coordination Task Force (QuIC) to the President. *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and their Impact*. February 2000.

As Congress and the Administration focus attention on the role of states in reporting and reducing medical errors, states, Congressional staff, federal agencies, and the media are seeking up-to-date information about current state error reporting systems. Clearly, a need exists for accurate information on state systems that are designed to collect, report, and use data on medical errors and adverse events. While systematic reporting and tracking of safety problems is a key strategy to improving quality, states currently collect, analyze and use safety-related data in a variety of ways. Their systems vary significantly depending on requirements for reporting (voluntary vs. mandatory), the type of events reported, who is responsible for reporting, the proposed use of reporting, and the organization responsible for maintaining and using the data.

Emphasis on hospitals

States bear chief responsibility for licensing and monitoring health care providers and, as regulators and as large purchasers, have a key role in improving patient safety and reducing medical errors. They are front and center in the federal recommendations to create mandatory reporting of the most serious errors that result in serious harm or death. Studies in the early 1990s first called attention to the issue of medical errors in hospital settings, due to the ready availability of data. The IoM focused its attention primarily on hospitals as well. The focus on hospitals has raised anew issues of state regulatory roles with regard to hospitals. While states are accountable for public safety and provider licensing, they have, over the past few decades, delegated many of their hospital oversight duties to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

The shift in hospital oversight responsibility away from states can be partially attributed to enactment of the Medicare Act in 1965, which required hospitals to meet certain minimum health and safety requirements to participate in the program. Within the Act, Congress provided that hospitals accredited by what is now JCAHO were deemed to be in compliance with the Medicare conditions of participation. As the largest accreditor of hospitals, accrediting about 80 percent of the nation's 6,200 hospitals, JCAHO is responsible for the majority of the nation's external reviews of hospital quality.⁴

Accreditation is a voluntary assessment process whereby industry experts define operational standards an organization must meet to be accredited and then systematically review the organization's performance against those standards. It is a form of self-regulation for which hospitals pay a fee. Accreditation is grounded in a collegial approach to oversight, one that focuses on education and improved performance as opposed to investigation and enforcement of minimum requirements. JCAHO's triennial surveys form the core of its accreditation process.⁵ For their part, states have typically accepted compliance with these accreditation standards as fulfilling state licensure requirements.

⁴ June Gibbs Brown, Inspector General. *The External Review of Hospital Quality: A Call for Greater Accountability*. July 1999, OEI-01-97-00050.

⁵ *Ibid.*

In 1996 JCAHO implemented its “sentinel event” policy for dealing with serious adverse events in hospitals. The policy stresses voluntary and timely self-reporting both of the events and of hospitals’ analyses of events and emphasizes confidentiality for self-reporting hospitals. JCAHO’s policy seeks quality improvement in health care by treating errors as opportunities to improve systems rather than as a means to find and punish individuals or institutions. For hospitals that comply with the self-reporting format, JCAHO does not release any information on errors.⁶ During March 1999, JCAHO conducted a survey of state agencies to identify state requirements related to sentinel event reporting. The survey is being repeated in 2000.

Hospitals wishing to participate in Medicare without accreditation must go through a Medicare certification process. The Health Care Financing Administration (HCFA) relies on survey and certification agencies in the 50 states and the District of Columbia to conduct surveys at these hospitals to determine compliance with the Medicare conditions. Hospitals pay no fee for this process. States currently certify 1,442 nonaccredited hospitals nationwide. With no mandated minimum cycle for surveys, nonaccredited hospitals are subject to limited external review other than those triggered by complaints and adverse events. State response to complaints and adverse events is a high priority for HCFA, above routine hospital surveys, as reflected in its priorities for state agencies’ survey and certification budgets. The results of state investigations are available to the public.⁷

In 1972, Congress enacted amendments giving HCFA responsibility for overseeing JCAHO Medicare certification activities. To assess JCAHO’s performance, HCFA relies mainly on validation surveys, conducted by state agencies at HCFA’s expense. HCFA obtains limited information on the performance of JCAHO or the states, provides limited feedback on performance, and makes little information available to the public.⁸

As states have become aware of the serious problem of medical errors and adverse events, many are reviewing their roles as regulators to determine if more can be done to identify, track, and prevent medical errors and adverse events. Mandatory reporting to states of errors and adverse events is one step recommended by the IoM and the Administration, one in which a number of states already have some experience.

The National Academy for State Health Policy (NASHP) surveyed all 50 states and the District of Columbia in February 2000 to learn about current state activities to track, report, and respond to medical errors and adverse events and to identify the assistance states need to improve their

⁶ June Gibbs Brown, Inspector General. *The External Review of Hospital Quality: The Role of Accreditation*. July 1999, OEI-01-97-00051

⁷ June Gibbs Brown, Inspector General. *The External Review of Hospital Quality: A Call for Greater Accountability*. July 1999, OEI-01-97-00050

⁸ *Ibid.*

systems aimed at eliminating errors and restoring public confidence in the health care system. All 50 states and the District of Columbia responded to the survey. With such a significant response, the results provide important information on current state activities to assess and address the issue of medical errors and adverse events.

The survey addressed the following: which states require mandatory reporting systems, what type of data is reported, how states use the data, who has access to data, and the type of assistance states need to improve their systems. NASHP plans to provide further information on best practices in the future through site visits and phone interviews with states.

SURVEY METHODS AND FOCUS

The NASHP survey was developed with the assistance of several frameworks designed to examine medical errors, including the IoM study and JCAHO's Sentinel Event State Survey. The survey was reviewed by national experts, pretested by several states, and modified for clarity.

The survey was mailed in February 2000 to state licensure and certification contacts in all 50 states and the District of Columbia with a copy to state public health officers. After two weeks, follow-up calls were made to states that did not respond to identify appropriate contacts and retrieve information.

Medical errors and adverse events cover a broad range of reporting requirements across multiple settings of care. The NASHP survey was intended to be as simple and focused as possible, with the recognition that more detailed information would be obtained through phone interviews and site visits. The principal purpose of this survey was to determine the extent to which states require reporting of serious adverse events attributable to error in hospital settings. Given the complexity of capturing state reporting requirements for various settings of care in a brief survey instrument, the hospital was selected as the most compelling setting given the IoM's recommendation that it be the starting point for reporting.⁹ A secondary purpose of the survey was to collect more general information on similar reporting requirements in other settings of care, exclusive of nursing facilities.

Survey areas of focus included:

- Legislative/regulatory requirements
- Uniformity and standardization of data
- Protection from legal discovery
- Use of data
- Technical assistance needs

⁹ Institute of Medicine. *To Err is Human*. National Academy Press, Washington, D.C. 1999.

Challenges in survey design/analysis

One of the first methodological challenges in constructing the survey was in defining terms. The IoM Report defines "medical error" and "adverse event" as follows:

- ▶ *Medical error*: failure of a planned action to be completed as intended or use of the wrong plan to achieve an aim.
- ▶ *Adverse event*: serious injury or death resulting from medical management, not the underlying condition of the patient.¹⁰

The terms "medical error" and "adverse event" have specific meaning in the IoM Report but are otherwise not broadly understood by the public or used identically by states in establishing their reporting requirements. Rather than rely on a single definition, the NASHP survey enumerated multiple incidents that alone and in combination could be considered to represent adverse events or medical errors. The enumeration of specific incidents increased the likelihood of an "apples to apples" comparison across states. In their response to the survey, states either identified which of these incidents were required to be reported and/or supplied the legislation defining a reportable incident. In the case of the latter, the authors of this report frequently needed to make a judgment call in order to assign a state's reporting requirement to one or more of the survey's categories of incidents. Judgments generally fell into three areas:

- Reporting requirements exclusive to nursing facilities were omitted.
- Reporting requirements only for incidents unrelated to the medical management of a patient were omitted. Examples typically included reporting systems for epidemic outbreaks, prevalence of communicable diseases, disappearance or loss of a patient, physical or sexual assaults, and patient abuse or neglect.
- When states described or attached their definitions in lieu of completing several survey questions, survey responses were identified that most closely approximated a state's definition. For example, "brain or spinal cord injury" was interpreted to fit the survey category of "major loss of function."

¹⁰ *Ibid.*

KEY FINDINGS

Please see Appendix 1 for detailed question-by-question analysis of findings.

I. How do states define reportable incidents?

As noted in the discussion on survey methodologies, the terms “medical error” and “adverse event” may be interpreted differently by different people and vary from state to state. Definitions, however, are important when attempting to track trends over time, across facilities, and states.

The survey confirmed the lack of universal use or interpretation of the terms “medical error” and “adverse event” as employed by the IoM report.

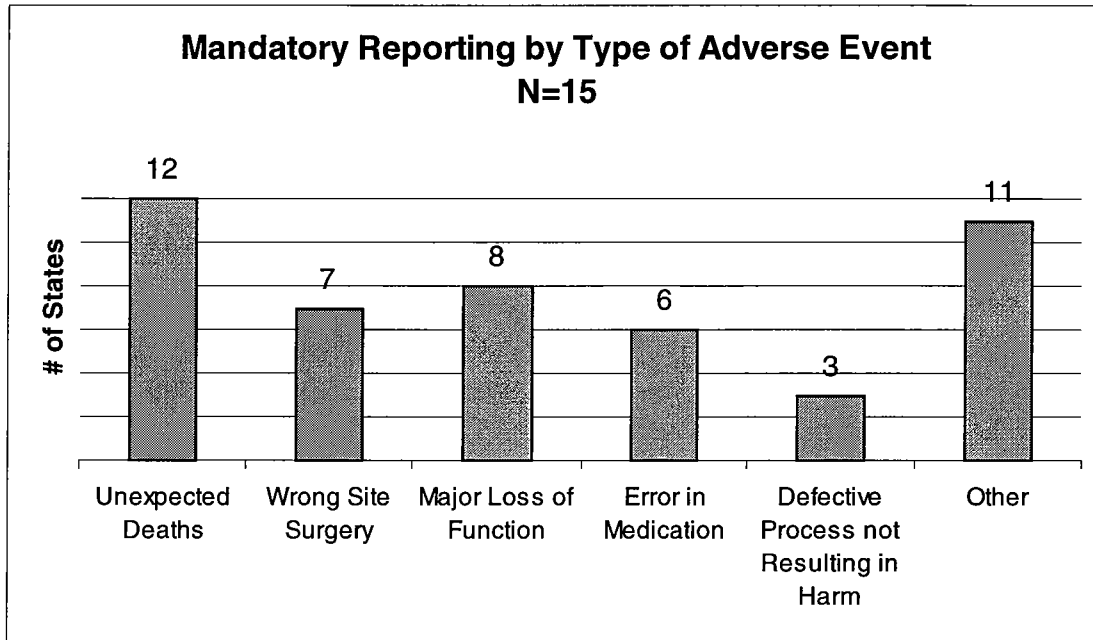
- No states have a definition of medical error.
- Two states use the term “adverse event.”
- Six states have a standard definition of a term that is similar to adverse event but the term and the definition vary among the states. (See Table 1 on the following page.)
- Seven states reported they do not have a standard definition of adverse event, but instead specify which types of events must be reported. As noted in the methodology section above, interpretations were made to categorize states’ reportable incidents as “adverse events,” as defined by IoM.

Table 1: Terms and definitions in the six states with a standard definition

State	Definition
CO	Occurrence: any occurrence that results in death of a patient or resident of the facility [...] as arising from an unexplained cause or under suspicious circumstances; any occurrence that results in any of the following serious injuries to a patient or resident: brain or spinal cord injuries; life-threatening complications of anesthesia or life-threatening transfusion errors or reactions; second or third degree burns involving 20% or more of the body surface areas of an adult patient or resident and 15% or more of the body surface of a child patient or resident (Colorado Department of Public Health and Environment, 3.2.1).
KS	Reportable incident: an act by a health care provider which: (1) Is or may be below the applicable standard of care and has a reasonable probability of causing injury to the patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency (Kansas Risk Management Statutes, 65-4921).
MA	Serious injury: injury that is life threatening, results in death, or requires a patient to undergo significant additional diagnostic or treatment measures. Accidents: falls, burns, electrocutions, and other misadventures not related to patient treatment. Other serious incidents that seriously affect the health and safety of patients: incidents that result in patient injury. These include, but are not limited to, poisonings occurring within the facility; reportable infectious disease outbreaks; equipment malfunction or user error; medication errors; and other incidents resulting in serious injury not anticipated in the normal course of events (Massachusetts 105 CMR 130.331).
PA	Events which seriously compromise quality assurance or patient safety: include, but are not limited to, deaths due to injuries, suicide, or unusual circumstances; deaths due to malnutrition, dehydration, or sepsis; deaths or serious injuries due to a medication error; elopements; transfers to a hospital as a result of injuries or accidents; complaints of patient abuse, whether or not confirmed by the facility; rape; surgery performed on the wrong patient or on the wrong body part; hemolytic transfusion reaction; infant abduction or infant discharged to the wrong family; significant disruption of service due to disaster such as fire, storm, flood or other occurrence; notification of termination of any services vital to the continued safe operation of the facility or the health and safety of its patients and personnel, including, but not limited to, the anticipation or actual termination of electric, gas, steam heat, water, sewer and local exchange telephone service; unlicensed practice of a regulated profession; receipt of a strike notice (Pennsylvania Title 28, Part IV, Subpart A, Chapter 51.3).
TN	Incidents and accidents of an unusual nature: include but not limited to a fire in the hospital, burning of a patient, suspected abuse of a patient by an employee, another patient, or any other person, or an accident that causes injury to a patient (Tennessee 1200-8-1-01).
WA	Events: unanticipated death or major permanent loss of function, not related to the natural course of a patient's illness or underlying condition; a patient suicide while the patient was under care in the hospital; an infant abduction or discharge to the wrong family; sexual assault or rape of a patient or staff member while in the hospital; a hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; surgery performed on the wrong patient or wrong body part; failure or major malfunction of a facility system which affects any patient diagnosis, treatment, or care service within the facility; a fire which affects patient diagnosis, treatment or care area of the facility (WAC 246-320-145).

II. What types of events must be reported?

- Twelve states require mandatory reporting for unexpected patient deaths, the most common reporting requirement. Only three states include “defective processes that do not result in serious harm,” which could be considered a proxy for medical error. (See the chart that follows for more detail.)



III. How common is reporting?

The survey asked whether a state has current or pending legislation or regulations concerning the mandatory or voluntary reporting of specific types of adverse events. Among the findings:

- Fifteen states (Colorado, Florida, Kansas, Massachusetts, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington) require from hospitals mandatory reporting of adverse events, as defined by the IoM or by the state in a way that encompasses part or all of the IoM definition. This figure does not include reporting from nursing facilities.
- Six additional states (Georgia, New Mexico, North Carolina, Oregon, Wyoming, District of Columbia) have voluntary reporting of medical errors or adverse events.
- Six additional states (Iowa, Kentucky, Maine, Missouri, North Dakota, New Hampshire) have pending legislation to require reporting of medical errors or adverse events.
- Two additional states (Indiana and Minnesota) have legislation that requires mandatory reporting from hospitals of adverse events, but the types of events are significantly different from the IoM and from the other states, and are mentioned but not included in the analysis of this report.¹¹

¹¹ Indiana requires mandatory reporting only for murder, suicide, kidnapping, infectious outbreaks/food poisonings, and disruptions of services exceeding four hours. Minnesota's mandatory

- One state (Michigan) has legislation that requires mandatory reporting of adverse events but does not require reporting from general and acute care hospitals. It is also mentioned but not included in the analysis.¹²

Table 2: States with mandatory, voluntary, and/or pending legislation

	C	D	F	G	I	I	K	K	M	M	M	M	M	N	N	N	N	N	N	O	O	P	R	S	S	T	T	W	W		
	O	C	L	A	A	N	S	Y	A	E	I	O	N	C	D	E	H	J	M	Y	H	R	A	I	C	D	N	X	A	Y	
Mandatory	✓		✓			* ✓	✓		✓		* ✓		* ✓			✓		✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	
Voluntary		✓		✓										✓					✓			✓									✓
Pending					✓			✓	✓		✓			✓		✓															

* Not included in the analysis due to significant differences in definitions and reporting requirements.

The survey findings that follow apply only to the fifteen states that require mandatory reporting from general and acute care hospitals of medical errors and adverse events, as defined by the IoM or by the state in a way that encompasses part or all of the IoM definition.

IV. What entities are required to report?

- Most states require reporting of adverse events from hospitals (15), free standing ambulatory care centers (13), and psychiatric hospitals (12). Fewer require reporting from outpatient mental health centers (4), home health agencies (4), laboratories (2), individual health professionals (2), or pharmacies (0). (See chart on the following page.)

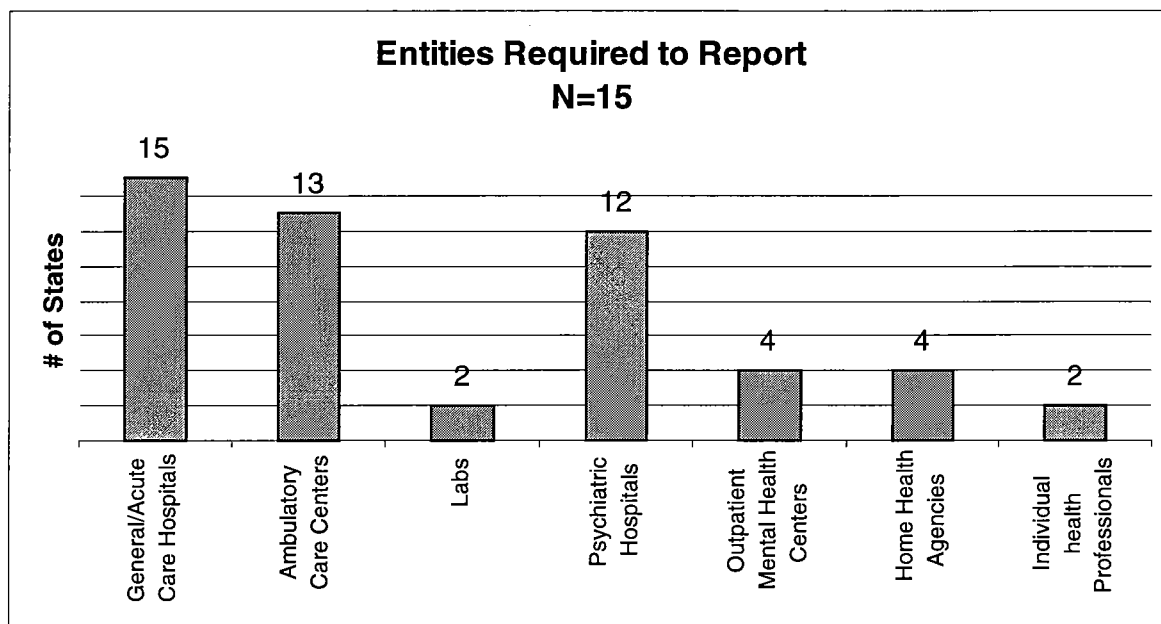
Other entities of state government, notably professional licensing boards, have jurisdiction over individual practitioners; review of their work was beyond the scope of the project. State emphasis on hospital reporting conforms to the IoM’s recommendations and reflects the fact that the largest number of medical errors -- 48 percent -- result from surgical treatment.¹³ State emphasis on reporting from free standing ambulatory care centers seems well placed as well, given the trend toward more procedures being conducted at ambulatory surgical centers that are

reporting requirement is limited to abuse and neglect which is not the result of an accident or therapeutic conduct.

¹² Michigan does not require reporting from general and acute care hospitals.

¹³ Andrea Gerlin, “For a systematic problem, no easy fix,” *Philadelphia Inquirer*, 13 Sept 1999.

largely unregulated. (For example, two independent surveys estimate the late 1990s mortality rate from liposuction at about 20 per 100,000, or 1 in every 5,000 procedures, compared to a 16.4 per 100,000 fatality rate of U.S. motor vehicle accidents.¹⁴)



- Most states require quick reporting of events, but there is much variability in timing. Standards include immediate reporting, within 24 or 48 hours, or within 5, 10, 30, or 90 days.

V. What reporting is protected from legal discovery?

Opinions vary on whether, how, and to what extent data submitted to reporting systems should be protected from disclosure, especially when litigation is involved. Some believe that all information should be protected from disclosure in order to encourage full reporting and discourage medical malpractice cases. Others believe that some, if not all, information should be disclosed because the public has a right to know and providers should be held accountable for medical errors that result in serious injury or death.

Fear of legal discoverability or litigation is believed to contribute to underreporting of medical

¹⁴ Grazer, F.M. and de Jong, R.H., Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons, Vol 105 (1), January 2000.

errors and adverse events. Access to detailed information about medical errors and adverse events could greatly help a plaintiff's lawyer to build and prove a case, which creates a strong disincentive to collect and report such information. Protection from liability may play a critical role in encouraging health care providers to report medical errors and adverse events.

According to the IoM report, plaintiffs can seek information from three components of a reporting system: 1) the original reporter; 2) the recipients of the information who receive, investigate, or analyze the reports; and 3) the reported information itself as it resides in the data bank. Two avenues are available to protect each of these targets: laws that prevent discovery and practical methods that render the reporter unfindable or the data not useful to the plaintiff.¹⁵

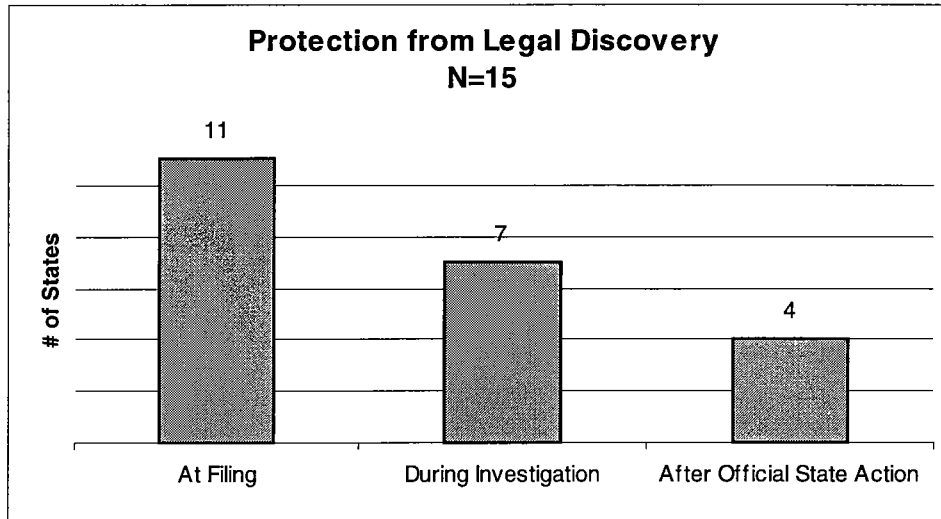
Legal protections are the only way to protect reporters, report recipients, and the reports from discovery. Anonymous reporting and de-identification (removal of identifying information after receipt of the report) can provide some, but not complete, protection. Existing law often protects data about errors within an institution, but not when the data is transmitted elsewhere. Some fear that reporting to state government is particularly likely to be made public given "sunshine" laws requiring public accountability and the capacity to seek public records through requests under the Freedom of Information Act. At issue is when reported documents are protected and when they are discoverable.

Issues that involve disclosure and discovery were addressed in the survey through questions concerning when and how data is protected, whether protection extends to requests under the Freedom of Information Act, and incentives used to encourage reporting.

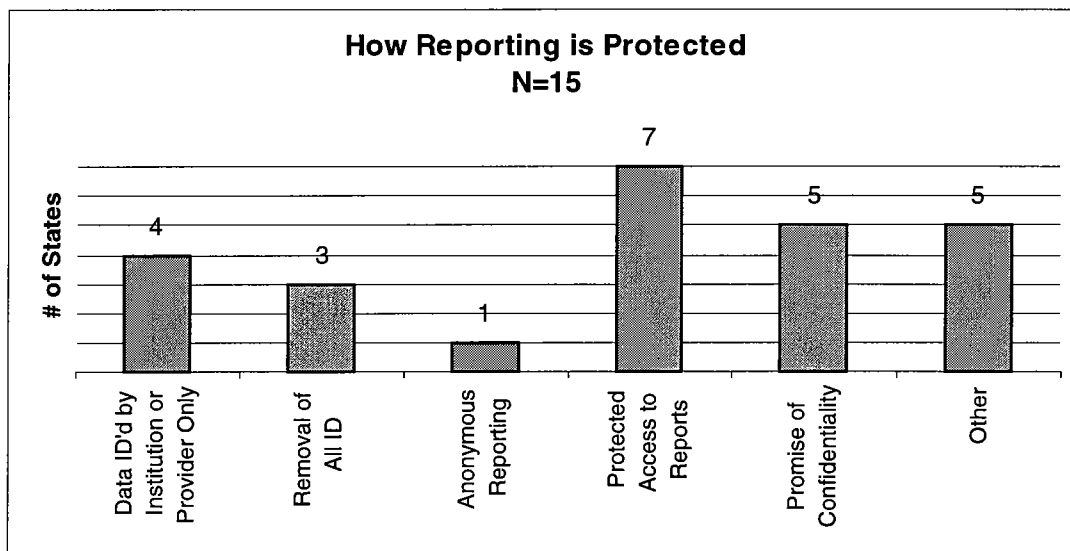
Analysis of survey results is difficult due to considerable variation in the events that must be reported and in the definitions used. More attention will be focused on this issue in future NASHP studies.

- Most states (13) indicated that they protect at least some reports from legal discovery although they vary in the types of information and reports that are protected. For example, Colorado protects investigative reports but creates public summaries. Massachusetts does not protect data but redacts some patient and peer review information. New Jersey protects anesthesia but not cardiac data. In Tennessee, only patient and complainant names are undiscoverable. Pennsylvania, South Carolina, South Dakota, and Texas release data only by court order.
- States indicated that reports generally become protected at filing (11) or during investigation (7) as opposed to after official state action (4). (See the following chart.)

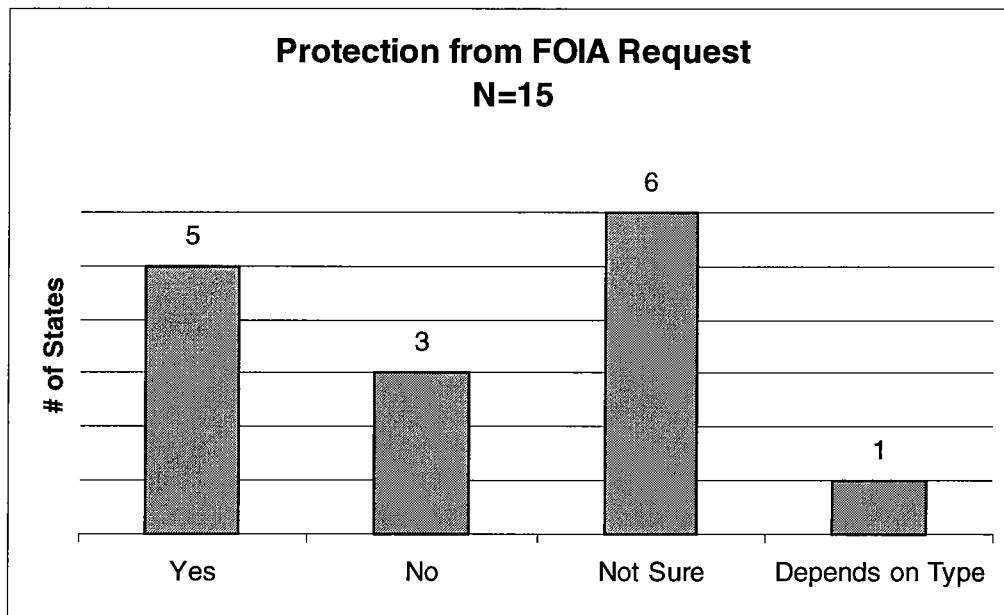
¹⁵ Institute of Medicine. *To Err is Human*. National Academy Press, Washington, D.C., 1999.



- Seven states noted that they protect access to person-level reports, the most frequent method of protecting reports. Five states provide a promise of confidentiality, which was the second most frequent response. Various other methods of protecting data include removing certain identifying information, anonymous reporting, and destroying reports once data is extracted. (See the chart that follows for more detail.)

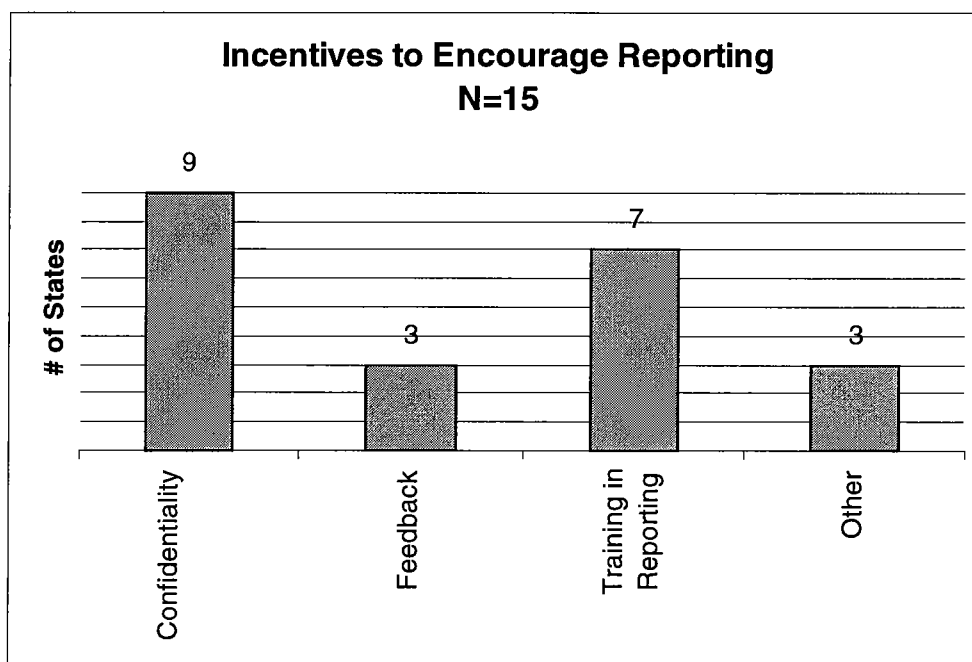


- Five states report that data is protected in the case of a Freedom of Information Act (FOIA) request; three report that data is not protected in this situation. Six others are not sure whether their legal protection applies in this situation. In one state, protection depends on the type of incident.



VI. How is reporting encouraged?

- Many states encourage reporting of events by guaranteeing confidentiality (9) or providing training in event reporting (7). Few states (3) provide feedback to data reporters.



According to the IoM, reporting systems generally focus primarily on accountability or on safety improvement. It is difficult to design one system to do both. The purpose influences the design in terms of who is required to report and whether data is confidential or released to the public. Systems designed to hold health care organizations accountable often impose mandatory reporting, usually focus on specific cases that involve serious harm or death, may result in fines or penalties, and may share information about the events with the public. Voluntary systems, which usually focus on a much broader set of errors and aim to detect system weaknesses before serious harm occurs, may be designed to be confidential.¹⁶

The IoM report emphasizes that medical errors and adverse events largely result from systems problems. Health care delivery entails numerous interactions among complex systems, technology, and multiple health care practitioners. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy to do the right thing. Building a safer system means designing processes of care to ensure that patients are safe from accidental injury. While people must be held accountable for their actions, blaming an individual does little to make the health care system safer and prevent others from committing the same error. Thus, reporting systems are not ends unto themselves.

Both mandatory and voluntary reporting systems can play a role in reducing medical errors and adverse events. According to the IoM report, a nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. The report recommends that reporting should initially be required of hospitals and eventually extended to other institutional and ambulatory care delivery settings. The report asserts that mandatory reporting of serious adverse events is essential for public accountability; the public has the right to be informed about unsafe conditions.

The committee also recommended that the scope of mandatory reporting systems be narrowly defined to ensure timely analysis and follow-up of events. A narrow focus was seen as increasing the likelihood of a successful system.¹⁷

Voluntary systems are also an important part of an overall program for improving patient safety and should be encouraged, according to the IoM. Voluntary systems report events that result in less serious harm or no harm at all. Errors that do not result in harm may represent an important opportunity to identify system failures with the potential to cause serious harm in the future.

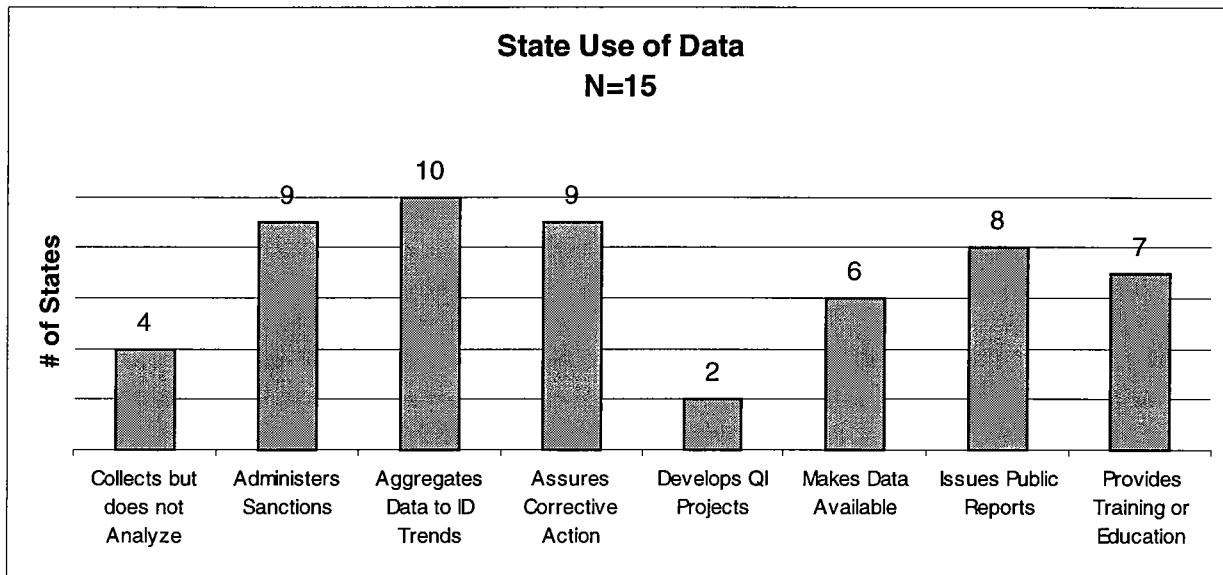
¹⁶ *Ibid.*

¹⁷ *Ibid.*

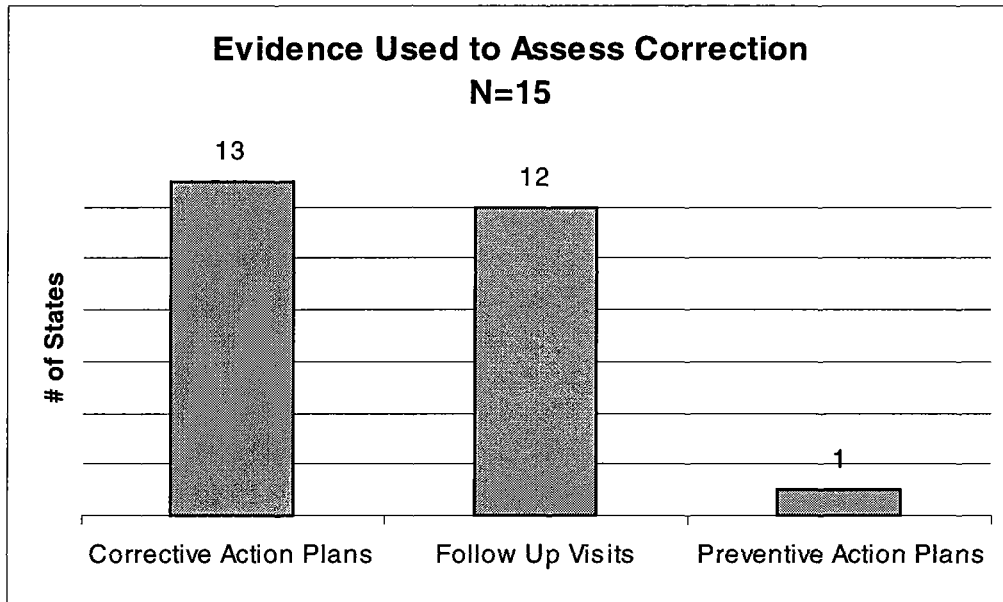
VII. How is data used?

The survey included questions on the use of data. Those questions focused on identification of the state agency with responsibility for maintaining the data; how the agency uses the data; how the agency assesses if problems have been corrected; if data is accurate; if reporting is complete; and the number of reports received.

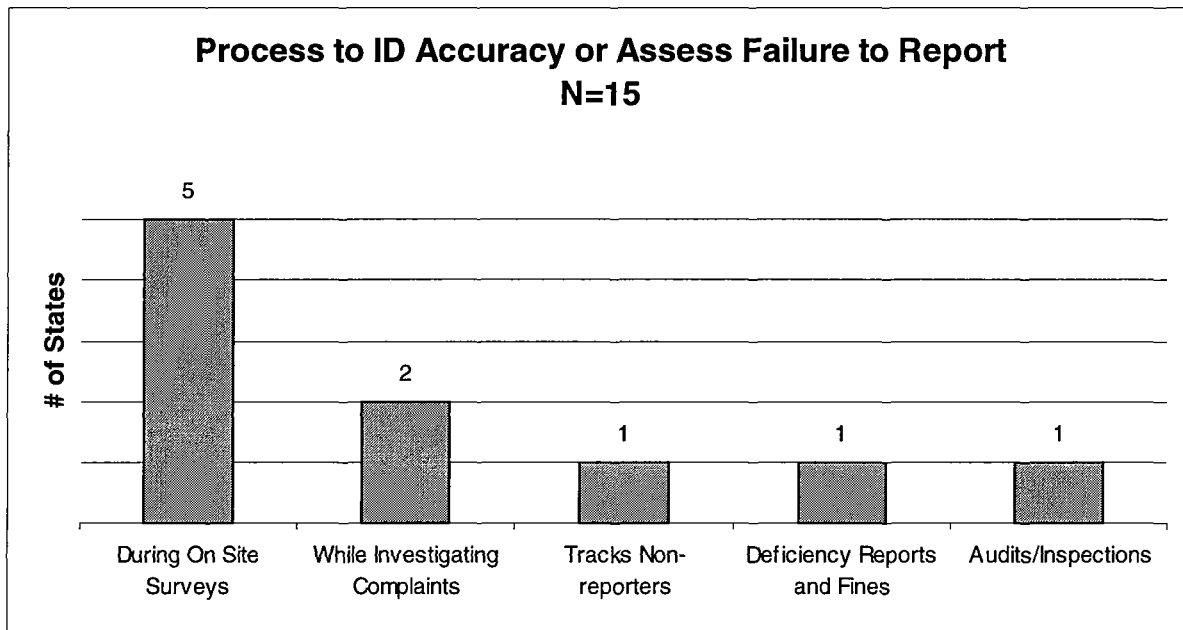
- States use data in a variety of ways, the most frequent being aggregating data to identify trends (10), administering sanctions (9), assuring corrective action (9), and issuing public reports (8). At this point, only two states, Massachusetts and Ohio, report using data to develop quality improvement projects. (See chart below.)



- States use corrective action plans (13) and follow up visits (12) as evidence to assess whether or not corrections have been made.



- Ten states indicated that they have processes in place to identify the accuracy of hospital reports or to assess failure to report. The most common methods were reviewing files while conducting on-site licensure and certification surveys (5) or while investigating complaints (5). (See chart below.)



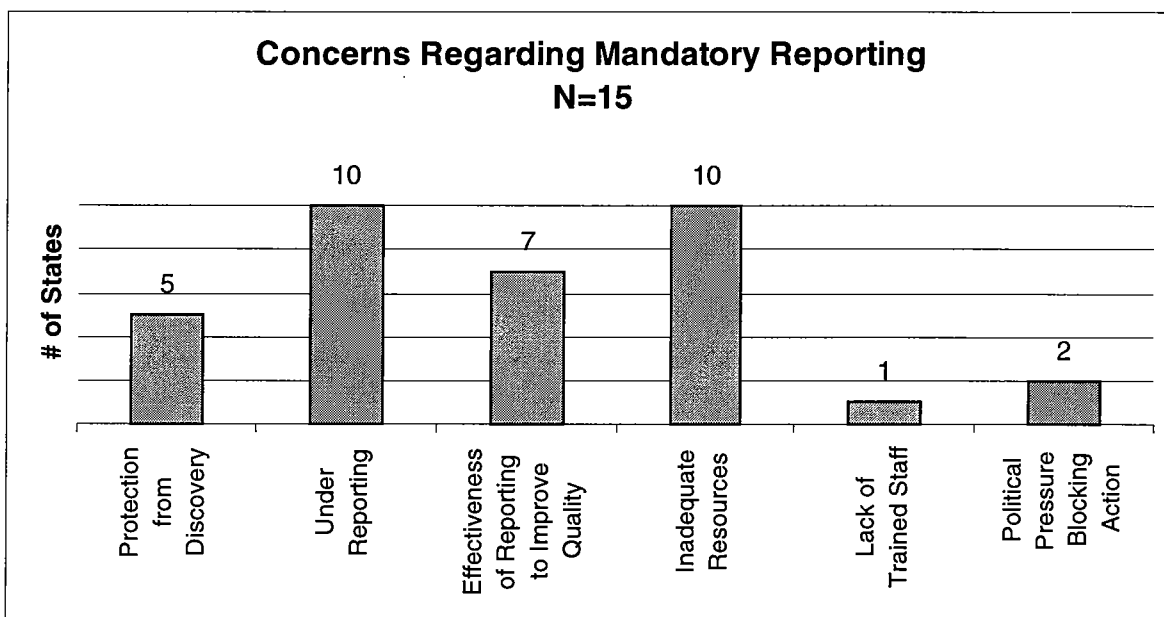
- Little coordination exists across state agencies responsible for provider and professional oversight. Only three states reported any coordination with other state or national reporting programs.

VIII. What do states need to improve mandatory reporting systems?

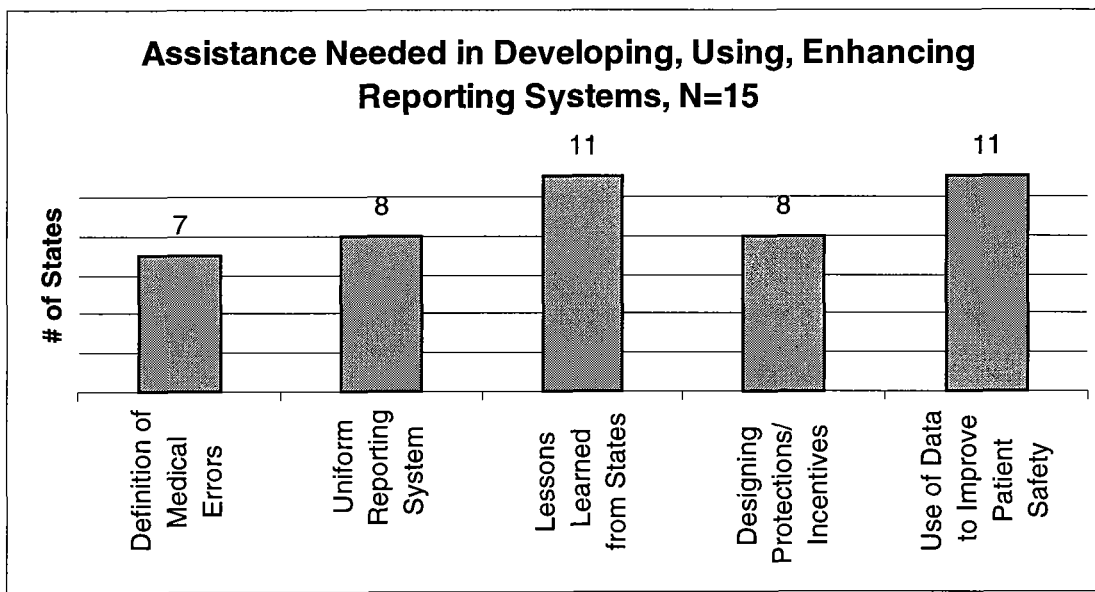
Many states are in the initial stages of improving their reporting systems for medical errors and adverse events. As they examined their needs and resources, they identified areas for technical assistance.

Questions regarding technical assistance needs focused on areas of greatest concern, areas of assistance that would be of greatest use, and identification of factors considered critical for a successful reporting system.

- States cite under-reporting (10) and inadequate resources (10) as their two greatest concerns with their reporting systems. (See chart that follows.)



- When asked what technical assistance would be useful, states reported lessons learned from other states (11) and use of data to improve patient safety (11) would be of most interest. Eight states expressed interest in development of a uniform reporting system and designing protections/incentives for reporting. Most of the seven states that indicated interest in definitions of medical errors and related terms currently do not have standard definitions. (See chart that follows.)



The survey provided an open-ended opportunity for states to identify what they believe to be factors critical to a successful mandatory reporting system. Many responses addressed ensuring full reporting through mechanisms such as training, strong confidentiality guarantees, and feedback to reporters. Others addressed improved timeliness, quality, and objectivity of peer review, credentialing, and investigative processes. Others suggested on-site, non-punitive follow up for reported errors.

The following page contains a list of the factors that states identified as critical to a successful mandatory reporting system.

Critical Success Factors

Reporting/Protections

- Ability to obtain and evaluate preventive plans to eliminate reoccurrence
- Accuracy of reporting
- Maintaining confidentiality
- Standardized definitions
- Stronger sanctions for trying to block investigations
- On-line confidential reporting systems

Staffing/Resources

- Increased involvement of professional licensing agencies
- Independently employed risk managers
- Training on reporting
- Education
- Restructuring peer review and credentialing processes to assure fairness and objectivity

External Factors

- Media awareness of true nature of adverse outcomes and errors
- Reducing malpractice litigation

Follow up

- Corrective action plans that are non-punitive
- Ability to demonstrate improved outcomes
- Ability to share information
- Timely investigations with sound plans of correction
- On-site follow up
- Ability to investigate all reports
- Better understanding of systems vs. practitioner issues
- Providing feedback to improve patient safety
- Encouraging facilities with low utilization to discontinue some procedures to be safer and economically beneficial on a national and regional level
- Matching errors to site specific UR rates

CONCLUSIONS

Reducing medical errors and adverse events and improving patient safety is clearly emerging as an issue of national prominence with a critical role to be played by states. The survey results and the 100 percent response rate to the survey by states make clear that states are interested in this issue, and many have begun to address reporting and follow-up through existing and emerging systems.

The survey also points to the complexity of the issue, with states using different terminology and approaching the issue from many perspectives. States included in the analysis have taken the first critical step in developing systems to collect and analyze data on medical errors and adverse events. However, using the data to improve public safety is still an issue with which states are grappling; ten states are analyzing reported data to identify trends, two states are using data to develop quality improvement projects, and many others noted this area as one of their greatest technical assistance needs.

NEXT STEPS

The survey provides a snapshot of what states are doing to track and reduce medical errors and adverse events. The National Academy for State Health Policy will assist states as they explore the issues involved in reducing errors and improving patient safety, including issues identified in the survey, finding commonality among state definitions, and identifying cost implications of developing reporting systems. In the next several months, the issues raised in the survey will be more fully explored and described through a series of in-depth telephone interviews, discussions with an expert panel, and case study reports of state site visits to further explore how states operate medical errors and adverse events reporting systems and other patient safety initiatives.

Appendices

Appendix 1: States with mandatory reporting of medical errors and/or adverse events

Appendix 2: Survey instrument

Appendix 1: States with mandatory reporting of medical errors and/or adverse events

	CO	FL	IN	KS	MA	MI	MN	NE	NJ	NY	OH	PA	RI	SC	SD	TN	TX	WA	Total	
OVERVIEW																				
MANDATORY REPORTING (not including long-term care facilities)	•	•	• (a)	•	•	• (b)	• (c)	•	•	•	•	•	•	•	•	•	•	•	•	18*
Unexpected patient death	•	•			•	•			•	•	•	•	•		•		•	•		12
Wrong site surgery or retention of foreign object		•			•					•		•	•	•				•		7
Major loss of function from treatment or surgery	•	•			•				•	•			•	•				•		8
Error in medication					•					•	•	•	•	•						6
Defective process not resulting in serious harm					•					•								•		3
Other	•			• (d)	•			• (d)	•		•	•		•		• (d)	•	•		11
STANDARD DEFINITION																				
Medical Error																				0
Adverse Event	• (e)	•		• (e)	• (e)					•		• (e)				• (e)		• (e)		8
ENTITIES REQUIRED TO SUBMIT																				
General/Acute care hospitals	•	•		•	•			•	•	•	• (f)	•	•	•	•	•	•	•	•	15
Ambulatory care centers	•	•		•	•			•	•	•	•	•		•	•	•	•	•		13
Labs										•							•			2
Psychiatric hospitals	•	•		•	•	•		•	•	•			•	•	•		•			12
Outpatient mental health centers	•									•				•			•			4
Home health agencies					•			•				•					•			4
Pharmacies																				0
Individual health professionals		•				•														2
Other	• (g)				•						• (g)	• (h)		• (i)			• (i)			6
*The remainder of Appendix I focuses on 15, not 18, states. See notes a, b, and c for an explanation of the mandatory reporting provisions in Indiana, Michigan, and Minnesota.																				

	CO	FL	IN	KS	MA	MI	MN	NE	NJ	NY	OH	PA	RI	SC	SD	TN	TX	WA	Total	
GENERAL/ACUTE CARE HOSPITALS ONLY																				
TIME FRAME FOR REPORTING																				
Within 24 hours										.			.							2
Within 1 week																				0
Within 30 days								.												1
Within 90 days				.																1
Within 180 days																				0
Other	• (j)	• (k)			• (l)				• (m)		• (n)	• (o)		• (p)	• (q)	• (r)	• (s)	• (t)		11
STANDARD FORM FOR MANDATORY REPORTING	•	•		•	•			•	•	•	•								•	9
COORDINATION WITH OTHER REPORTING SYSTEMS	• (u)				• (v)					• (w)										3
LEGAL DISCOVERY																				
PROTECTION FROM DISCOVERY	• (x)	•		•				•	• (x)	•	• (x)	• (y)	•	• (y)	• (y)			• (y)	•	13
WHEN IN THE PROCESS REPORTS ARE PROTECTED																				
At filing		•		•				•	•	•	•	•	•		•			•	•	11
During investigation	•	•		•					•		•							•	•	7
After official state action		•			•						•							•		4
Other									• (z)											1
HOW REPORTING IS PROTECTED																				
Data identified by institution or provider only	•			•							•	•								4
Removal of all identification									•									•	•	3
Anonymous reporting									•											1
Protected access to reports		•		•					•	•		•						•	•	7
Promise of confidentiality				•				•		•		•							•	5
Other					• (aa)				• (bb)				• (cc)	• (dd)				• (bb)		5
PROTECTION IN FREEDOM OF INFORMATION CHALLENGE	(ee)	•		(ee)				(ee)	• (ff)	•	(ee)		•		(ee)	•	•	(ee)		6
INCENTIVES TO ENCOURAGE REPORTING																				

	CO	FL	IN	KS	MA	MI	MN	NE	NJ	NY	OH	PA	RI	SC	SD	TN	TX	WA	Total
Confidentiality guarantees		•		•					•	•		•	•			•	•	•	9
Feedback to data reporter		•								•	•								3
Payment																			0
Training in event reporting	•	•		•	•					•	•				•				7
Other					•(gg)								•(hh)	•(dd)					3
USE OF DATA																			
AGENCY MAINTAINING RECORDS FOR MANDATORY REPORTING																			
Health	•			•	•			•	•	•	•	•	•	•				•	11
Licensure		•			•			•					•	•	•	•	•		8
Insurance																			0
STATE USE OF DATA																			
Collects but does not analyze									•				•		•	•			4
Administers sanctions	•	•			•			•	•		•	•	•				•		9
Aggregates data to identify trends		•		•	•					•	•	•	•	•			•	•	10
Assures corrective action		•		•	•				•		•	•	•				•		9
Develops quality improvement projects					•						•								2
Makes data available on request		•			•					•	•	•				•			6
Issues public reports	•	•		•	•				•	•	•					•			8
Provides training or education	•	•		•	•					•	•						•		7
Other					•(ii)													•(jj)	2
EVIDENCE STATE USES TO ASSESS CORRECTION																			
Corrective action plans		•		•	•				•	•	•	•	•	•	•	•	•	•	13
Follow up visits		•		•	•				•	•	•	•	•		•	•	•	•	12
Preventive action plans	•																		1
Other		•(kk)																	1
PROCESS IN PLACE TO ID ACCURACY OF HOSPITAL REPORTS OR TO ASSESS FAILURE TO REPORT	•(ll)	•(mm)		•(nn)	•(oo)					•(oo)	•(pp)	•(nn)	•(nn)	•(nn)			•(nn)		10

Endnotes

(a) Indiana requires mandatory reporting only for murder, suicide, kidnapping, infectious outbreaks/food poisonings, and disruptions of services exceeding four hours.

(b) Michigan does not require reporting from general and acute care hospitals; thus it is not included in the analysis.

(c) Minnesota's mandatory reporting requirement is limited to abuse and neglect which is not the result of an accident or therapeutic conduct.

(d) "Other" responses include: an act by a health care provider which is or may be below the applicable standard of care and has a reasonable probability of causing injury to the patient or may be grounds for disciplinary action by the appropriate licensing agency (KS); reporting of payment due to acts or omissions of a health care professional (NE), or a fire in the hospital; burning of a patient; suspected abuse of a patient by an employee, another patient, any other person; an accident that causes injury to a patient (TN).

(e) A standard definition is used to define a term with similar meaning as adverse event (serious incident, reportable incident, occurrence, adverse occurrence).

(f) Ohio does not require mandatory reporting from hospitals but certain services provided by hospitals are required to report.

(g) All licensed facilities

(h) Special hospitals, birth centers, cancer treatment centers, ambulatory surgical facilities

(i) Renal dialysis facilities

(j) One business day

(k) Within 24 hours for serious patient injuries of a volatile nature; fifteen days for individual serious adverse incidents, annual report for all incidents identified at a facility throughout the year

(l) Certain types must be reported immediately, others within one week

(m) Anesthesia within 24 hours, cardiac annually

(n) Data is aggregated

(o) Immediate notification in writing

(p) Ten days

(q) Forty-eight hours

(r) Five business days

(s) As soon as possible

(t) Once confirmed by QI/PI review

(u) Colorado refers appropriate occurrences to HCFA and other regulatory agencies and licensing boards.

(v) Massachusetts refers to other state boards of registration when appropriate.

(w) In New York, if an adverse event is reported to another reporting system within the state, it is not reported in this system.

(x) Some, but not all, mandatory reports are protected from legal discovery.

(y) Protected other than by court order

(z) If the matter is in litigation, any protections could be exercised from the beginning of litigation

(aa) Patient name and some peer review information may be removed.

(bb) By statute

(cc) Peer review

(dd) Report destroyed once required data is extracted

(ee) Not sure

(ff) Protection in FOIA depends on the procedure

(gg) Circular letters, reminders, on-site review of files to ensure reporting requirements are fulfilled

(hh) Citation for failure to report

(ii) Best practices/coalition safety alerts

(jj) May conduct own investigation

(kk) Extended case studies

(ll) Generate reports on which facilities have not reported and address either by letter or onsite

(mm) Deficiency reports and fines on repeat violations

(nn) Review files for on-site licensure and certification survey

(oo) Review files during complaint investigation

(pp) Conduct audits and inspections

(qq) 1997 data

(rr) Includes only abuse, neglect, and exploitation

(ss) Not tabulated yet. Still receiving reports.

(tt) Reported since April 1, 1998

(uu) Bill went into effect March 10, 1999

(vv) Media intensity and inaccuracy

(ww) How to solve specific “systems” problems– fragmented tracking and trending programs, distorted and disappearing medical records, peer review processes that cannot provide an objective analysis, boards not acting on their responsibility.

Voluntary reporting of medical errors or adverse events:

GA, NM, NC, OR, WY, DC

Pending legislation on reporting of medical errors or adverse events:

IA, KY, ME, MO, ND, NH

Appendix B

Survey Instrument

NATIONAL ACADEMY
for STATE HEALTH POLICY

Medical Errors State Survey
February, 2000

State: _____
Agency: _____
Position: _____

Respondent: _____
Email: _____
Phone: _____

A recent Institute of Medicine (IoM) study identified preventable adverse events as a leading cause of death in the United States. The IoM defined medical error and adverse event as follows:
 ♦ Medical error: failure of a planned action to be completed as intended or use of the wrong plan to achieve an aim.
 ♦ Adverse event: serious injury or death resulting from medical management, not the underlying condition of the patient.
 The purpose of this survey is to gather information on whether and how States are collecting and reporting data on medical errors and adverse events. We are particularly interested in mandatory reporting for hospitals.

Overview

1. Does your state have a standard definition for **medical error**?

Yes Please attach or describe below No

2. Does your state have a standard definition for **adverse event**?

Yes Please attach or describe below No

3. Does your state have current or pending legislation or regulations concerning the mandatory or voluntary reporting of

(Please check all that apply)

	Mandatory	Voluntary	Pending
Unexpected patient deaths	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wrong site surgery or retention of foreign object	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Major loss of function due to treatment or surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Error in the dose or method of using a drug, resulting in serious complications	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Defective process not resulting in serious harm but could signal a system failure (burns, falls, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: (Please specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

◆ If your state has **no** legislation or regulation concerning reporting, please stop and return survey.
 ◆ If your state has legislation or regulations, please attach copies.

4. What entities are required to submit mandatory reports? (Please check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> General and acute care hospitals | <input type="checkbox"/> Psychiatric hospitals or residential psychiatric centers |
| <input type="checkbox"/> Free standing ambulatory care centers | <input type="checkbox"/> Outpatient mental health centers |
| <input type="checkbox"/> Laboratories | <input type="checkbox"/> Home health agencies |
| <input type="checkbox"/> Other: (Please specify)
_____ | <input type="checkbox"/> Pharmacies |
| _____ | <input type="checkbox"/> Individual health professionals
type: _____ |
| | _____ |

FOR QUESTIONS 5-17, PLEASE RESPOND FOR GENERAL AND ACUTE CARE HOSPITALS ONLY

5. If your State requires hospitals to report such events, what is the time frame within which reports must be submitted?

- | | |
|--|--|
| <input type="checkbox"/> Within 24 hours | <input type="checkbox"/> Within 90 days |
| <input type="checkbox"/> Within 1 week | <input type="checkbox"/> Within 180 days |
| <input type="checkbox"/> Within 30 days | <input type="checkbox"/> Other: (Please specify) _____ |

6. Does your state have a standard form or format for hospital mandatory reporting?

- Yes Please attach
- No

7. Does your state coordinate hospital mandatory reporting with other state or national programs (e.g. JCAHO, HCFA, MERP, National Practioner Databank, state professional boards, etc.)

- Yes Please attach or describe below
- No

Protections from Legal Discovery

8. Are mandatory reports from hospitals protected from legal discovery?

- All Some None

Please describe:

9. If reports from hospitals are protected, when in the process are they protected?

- At filing
- During investigation
- After official state action
- Other (Please specify):

10. How is hospital reporting protected from legal discovery? (Please check all that apply)

- Data identified or aggregated by institution or provider, not by patient
- Removal of all personal and organizational identification from data
- Anonymous reporting
- Protected access to individual reports
- Promise of confidentiality
- Other: (Please specify)

11. Does protection from legal discovery apply in a Freedom of Information challenge?

- Yes No Not sure

12. What incentives has your state provided to hospitals to encourage reporting? (Please check all that apply)

- Confidentiality guarantees
- Feedback to data reporters (if your state provides feedback, how and on what?)
- Payment
- Training in event reporting
- Other: (Please specify)

Use of Data

13. What primary state agency is responsible for maintaining mandatory reports from hospitals:

- Health
- Insurance
- Licensure
- Other: (Please specify)

14. How does your state use data from hospital mandatory reports? (Please check all that apply)

- | | |
|--|--|
| <input type="checkbox"/> Collects but does not analyze data | <input type="checkbox"/> Makes data available on request from public |
| <input type="checkbox"/> Administers sanctions | <input type="checkbox"/> Issues public reports |
| <input type="checkbox"/> Aggregates data to identify trends | <input type="checkbox"/> Provides training or education |
| <input type="checkbox"/> Assures corrective action | <input type="checkbox"/> Other: (Please specify) |
| <input type="checkbox"/> Develops quality improvement projects | _____ |
| | _____ |
| | _____ |

15. What evidence does your state use to assess whether problems have been corrected?

- Corrective action plans
- Follow up visits by the state or its agents
- Preventive action plans
- Other: (Please specify)

16. Do you have a process in place to identify the accuracy of hospital reports or to assess the failure to report?

- Yes Please attach or describe below
- No

17. How many hospital events were reported in 1998? How many hospital events were reported in 1999?

Technical Assistance Needs

18. What are your biggest concerns regarding mandatory reporting? (Please check all that apply)

- | | |
|---|---|
| <input type="checkbox"/> Liability | <input type="checkbox"/> Inadequate resources |
| <input type="checkbox"/> Protection against legal discovery | <input type="checkbox"/> Lack of trained staff to interpret information |
| <input type="checkbox"/> Underreporting | <input type="checkbox"/> Political pressure from the industry that blocked action |
| <input type="checkbox"/> Effectiveness of reporting programs to improve quality | <input type="checkbox"/> Other: (Please specify) |

19. What areas of assistance would be most helpful to your state in developing, using, or enhancing your reporting system? (Please check all that apply)

- Definition of medical errors and related terms
- Development of a uniform reporting system
- Lessons learned from states
- Designing protections/incentives for reporting
- Use of data to improve patient safety
- Other: (Please specify)

20. If there were no constraints on resources what do you believe would be the critical success factors of a mandatory reporting system?

21. Additional comments, insights, and lessons learned are welcome.

Please remember to attach legislation and regulations that will help us to better understand your programs.
Thank you.

Thank you for completing this survey. Please mail, fax or email by **February 28, 2000** to:
Al Cardona, Program Assistant,
National Academy for State Health Policy,
50 Monument Square, Suite 502 Portland, ME 04101 Tel: (207) 874-6524; Fax (207) 874-6527
Email: acardona@nashp.org

