How States Report Medical Errors to the Public: *Issues and Barriers*

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INTRODUCTION

The 1999 Institute of Medicine (IOM) report *To Err is Human* brought the issues of medical errors and patient safety to state agendas by documenting that medical errors may cause up to 98,000 preventable deaths in U.S. hospitals each year. As part of a comprehensive strategy to improve patient safety, the IOM recommended the creation of external reporting systems to identify and learn from errors so as to prevent future occurrences. Two types of reporting systems were discussed: mandatory reporting systems, intended to hold providers accountable for improvements, and voluntary reporting systems, to detect system weaknesses before serious harm occurs.

The IOM report noted that provisions for protecting and disclosing reported data would be different for the two types of systems. Voluntary systems were envisioned as confidential, having full protection and existing solely to improve patient safety and quality. They would not necessarily be run by the state, and would collect and aggregate information about a broad set of errors that result in no harm or very minimal harm in order to detect system weaknesses before serious harm occurs.

State-based mandatory reporting programs would gather information on serious adverse events. State government would be responsible for collecting the data that would be linked to systems of accountability and made available to the public. The IOM maintained that the public has a right to be informed of unsafe conditions and that, in the case of serious adverse events, disclosure to the public is an appropriate and desirable practice. It further considered that confidentiality and protection from liability may be inappropriate in the case of serious error.[1]

Table 1 Comparison of IOM recommendations for mandatory and voluntary systems

	What is the purpose of the system?	Who administers the system?	What data are collected?	Are data on individual incidents disclosed?
Mandatory System	Accountability	State	Serious adverse events	Yes
Voluntary System	Quality improvement	Private	Near misses	No

[1]Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C: National Academy Press, 1999), p. 102.

The Institute of Medicine continued its call for public accountability in its 2001 report, *Crossing the Quality Chasm*. In discussing the need to foster innovation and improve the delivery of care, the report stressed that transparency should be one of ten general principles guiding the redesign of the health care system. According to the report's authors, the health care system should make complete and understandable information available to patients and their families, information that enables them to make informed choices about their care settings and treatments. The information should include descriptions of systems' performance on safety, evidence-based practice, and patient satisfaction.[2]

Since the release of *To Err is Human* in 1999, the National Academy for State Health Policy has issued several publications on patient safety and state reporting systems.[3] As those reports detail, 21 states currently have mandatory reporting systems, but releasing adverse event and medical error data to the public continues to be sporadic and inconsistent across the systems. Some states are prohibited from releasing certain data by statute. Others are free to release certain data but refrain from doing so due to concerns that data collected are incomplete and unreliable and may be easily misinterpreted, or in order to alleviate hospitals' and practitioners' fear that reporting and public disclosure of error information will lead to increased claims of medical malpractice. For many states, the question of how best to release medical error data to the public in order to further the goals of improved patient safety and accountability remains unanswered. This report is designed to assist states in their efforts to disclose important information to the public as envisioned by the IOM.

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[2]Institute of Medicine, *Crossing the Quality Chasm* (Washington, D.C: National Academy Press, 2001), p. 4

[3]Jill Rosenthal, Maureen Booth, *Defining Adverse Events: A Guide for States Tracking Medical Errors* (Portland, ME: National Academy for State Health Policy, 2003); Sharon Conrow Comden and Jill Rosenthal, *Statewide Patient Safety Coalitions: A Status Report* (Portland, ME: National Academy for State Health Policy, 2002); Jill Rosenthal, Maureen Booth, *How Safe Is Your Health Care? A Workbook for States Seeking to Build Accountablity and Quality Improvement Through Mandatory Reporting Systems* (Portland, ME: National Academy for State Health Policy, 2001); Lynda Flowers and Trish Riley, *State-based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues* (Portland, ME: National Academy for State Health Policy, 2001); Lynda Flowers and Trish Riley*, How States Are Responding to Medical Errors: An Analysis of Recent State Legislative Proposals* (Portland, ME: National Academy for State Health Policy, 2000); Trish Riley, *Improving Patient Safety: What States Can Do About Medical Errors* (Portland, ME: National Academy for State Health Policy, 2000); Jill Rosenthal*,* et al. *, Cost Implications of State Medical Error Reporting Programs: A Briefing Paper* (Portland, ME: National Academy for State Health Policy, 2001).

Table 2 Definition of terms

Disclosure	Protection
Making reported data available: < to the public/media/legislature < upon request/through distribution of reports/on web sites < either in aggregate or incident-specific	Establishing in state law or regulation provisions that enable the state < to keep reported data confidential and < to prevent the *compulsory* release of data through the legal process.

Issues Pertaining to Protection and Disclosure

The issues related to the protection and disclosure of data in state mandatory reporting systems are multifaceted and complex. Determining when and how to disclose and protect reported data necessitates a precarious balancing act of competing rights and interests. The IOM clearly articulated the interest in holding healthcare facilities accountable for preventable adverse events through a system that publicly disclosed information about errors. Moreover, the IOM claimed the public has a right to information concerning the safety of the health care system. Public reporting can increase transparency so that patients and their families can make informed choices and change the nature of accountability. It creates a level playing field, where competitors share an equal incentive to invest in better care.

At the same time, however, valid arguments can be made for protecting data from public release, arguments that focus on fairness and due process. The fear that publicly released data will lead to an increase in malpractice suits may act as a substantial deterrence to reporting. Under reporting or the inability to adjust for risk may result in data that are misleading to the general public.

In determining the proper equilibrium between protection and disclosure, states must guard against leaning too far one way or the other in order to avoid the unintended consequences outlined in Table 3.

Table 3 Balancing protection and disclosure

What are the potential dangers of too much protection?	What are the potential dangers of too much disclosure?
< Lack of public trust < Lack of transparency < Data are not useful for the public; consumers have no way to make choices about their care or to learn about problems < No way for purchasers to provide incentives for quality < Providers who don't meet standards of care may be protected from the consequences of their actions	< Disclosure of useless information can scare the public by providing information without interpretation < Potential exists for an environment that fosters under reporting < Fear of malpractice < Lack of due process for reporters < Potential for harm to reputations

Overview and Purpose of the Report

In earlier work, the National Academy for State Health Policy examined the origins and operations of mandatory reporting systems for medical errors and adverse events. Findings showed that most states developed their reporting systems in response to crises in medical malpractice insurance, a highly publicized tragic event, or as part of broader initiatives to enhance quality oversight of hospitals. Because many of these systems were established considerably earlier than the IOM report, their data disclosure provisions were not necessarily designed with public reporting in mind.

The purpose of this paper is to explore how data from mandatory reporting systems are (or can be) disclosed to the public. Based upon detailed interviews with states that have mandatory reporting systems, we have identified critical junctures in the design of reporting systems that influence the ultimate use of data. By examining and mapping out these critical junctures, the parameters of existing reporting systems can be better understood, and the intent of new reporting systems can be made more explicit and viable.

To guide the work of this project, NASHP convened a work group composed of officials from state agencies, attorneys general offices, legislators, and consumer representatives to explore the issues and barriers related to the public disclosure of data gathered in state mandatory systems. Work group members helped in the formulation of the interview protocol and in the assessment and interpretation of findings. Most importantly, the work group kept this project grounded by balancing the vision of the IOM with the reality and constraints of state-based systems. (See Appendix A for list of work group members.)

Telephone interviews were conducted with 19 of the 21 states with mandatory reporting systems.[4] The purpose of the interviews was to assess whether and how states protect and disclose data obtained from state-based mandatory reporting systems of adverse events and medical errors. Interviews were conducted with persons responsible for administering the reporting system and, as appropriate, other staff with knowledge of its use and dissemination. (The interview protocol can be found in Appendix B.)

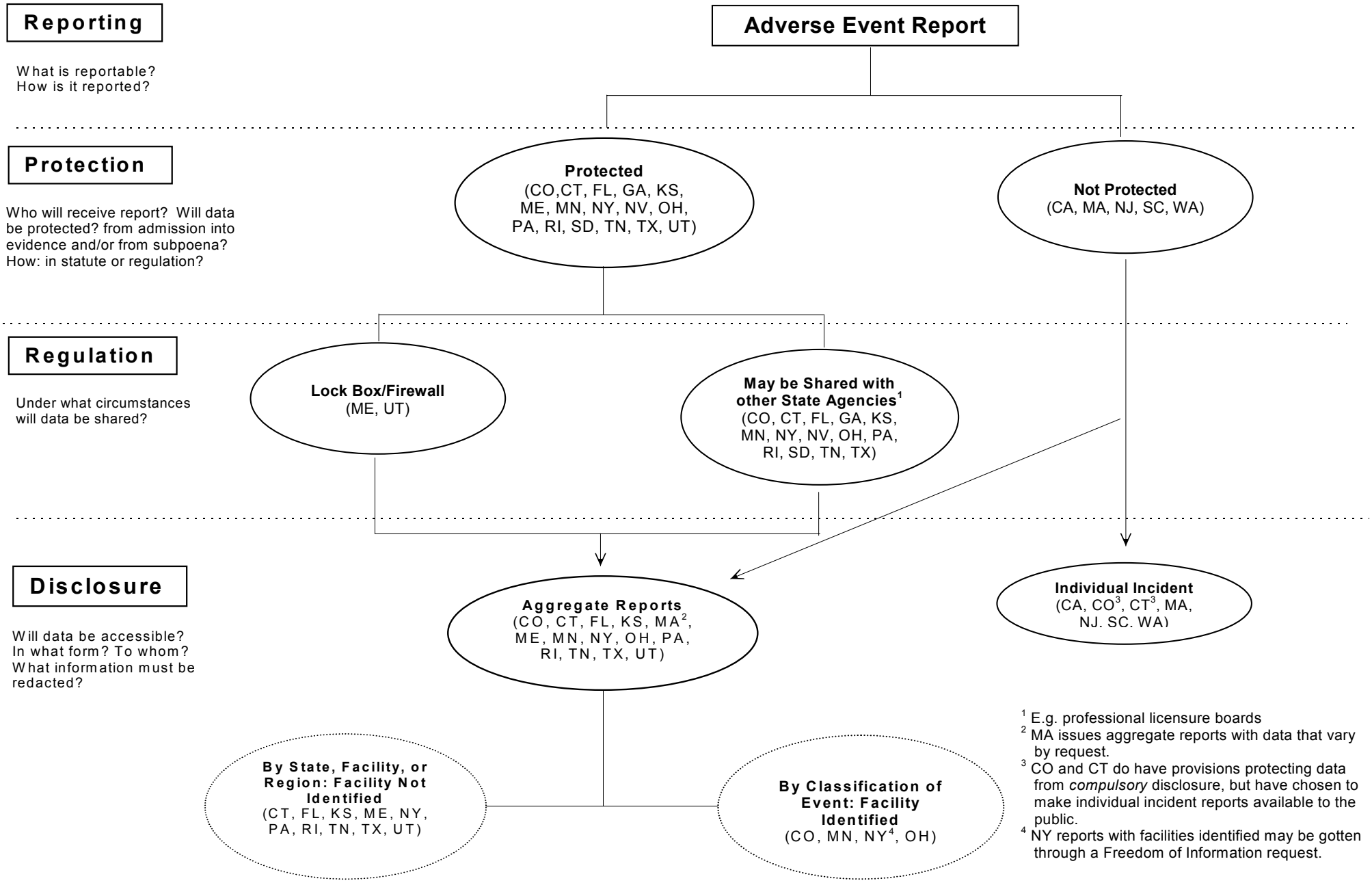
This report examines the information received during interviews pertaining to the protection and disclosure of mandatory reported data with a focus on:

- When and how states publicly disclose reported data,
- When and how states protect reported data,
- The perceived relationship between reporting and malpractice litigation, and
- Other factors relevant to data disclosure.

The paper is organized around the decisions a state typically makes when setting up a mandatory reporting system. This process is graphically represented in Figure 1: Decision tree for disclosure of adverse event data. The decision tree follows the data chronologically through the system from receipt of the event report, through protections, and up to the point of disclosure. The paper begins by looking at what a state might disclose and then examines the barriers that exist to disclosure and how these barriers might be overcome with appropriate data protections.

[4]The two states that were not interviewed were Minnesota, whose statute establishing a mandatory system was passed in 2003 following the initiation of this project and is not yet operational, and South Carolina. Information on these two states—available from independent sources such as statutes and regulations—may be included in selected tables in this report, but that information has not been verified with officials in those states.

Figure 1 Decision Tree for Disclosure of Adverse Events



Decision Tree for Disclosure of Adverse Event Data

Figure 1 illustrates the types of decisions a state makes in relation to disclosure and protection of data when designing a mandatory reporting system. It includes the options that states typically consider when deciding whether and when to disclose adverse event data to the public and how much data to disclose. The decision tree is designed to illustrate the sequential decisions that are integral to all state systems, and it provides details on where states with current systems fit in the model. It is also intended to guide states that have not yet developed systems, to help them identify the decisions to be made at each step in the process.

As the decision tree illustrates, that process begins with the receipt of an event report by the state. It is at that point that a state must determine whether the data in the event report will be protected or unprotected, whether it will be kept confidential or made available to the public.

In deciding that the individual event reports can be released to the public, a state should consider:

- What information will be redacted or de-identified from the report before release, such as the name of the patient?
- When is it appropriate to release the event report? For example, should only those events that have been substantiated be released?
- What is the state policy for releasing investigation reports, in both the case of substantiated and unsubstantiated events?

If a state decides to keep event reports confidential, decisions must be made that assure that data are protected in ways that support the state's intent.

- How will data be protected? By statute or regulation?
- To what extent will data be protected? Will data be discoverable or admissible under court order? Will data be exempt from disclosure under state sunshine laws?
- Will data be confined for use by the mandatory reporting system (lock box/firewall) or are there circumstances under which an event report will be shared with other state agencies?
- What state agencies may have access to the data? How will data protections be extended to other state agencies?

Reports with aggregate data are released by both systems that protect individual incident data and systems that do not protect such data, but vary in the level of detail that is included. Questions to be considered include:

- At what level will reports be aggregated? Reports generated from confidential data may be aggregated by state, region, or peer facilities, with steps taken to assure that individual facilities cannot be identified.
- In a system that does not protect data and so may generate reports by facility, have steps been taken to assure that individual patients cannot be identified? Prior to the release of the report, a state may provide advance copies to the reporting facilities for information or

for the addition of explanatory text.

- When releasing reports to the public, has the state provided narrative descriptions that assist the reader in understanding the data and how they should be interpreted?

DATA DISCLOSURE PRACTICES

The decision tree follows data through a state mandatory reporting system in the chronological order of 1) the receipt of an event report; 2) the protection of reported data; 3) the sharing of data with state agencies, and 4) the disclosure of data. However, in determining the design of a system, it may make sense to first think about what information a state wants to disclose and then establish the level of protection that will enable the state to achieve the desired goal. In the process of determining what the state ultimately will disclose it must make a number of decisions about what information from its mandatory reporting systems will be kept confidential and protected, will be protected from *compulsory* disclosure but released at a time of the state's choosing, or will remain unprotected and available to the public. These decisions include what information will be available, and how, to whom, and under what circumstances it will be disclosed. The decision tree highlights some of the questions states may need to consider when designing a mandatory reporting system; these questions will be addressed in this section.

Why Disclose Data?

The reasons that a state may choose to publicly release data are varied and include assuring accountability for health care safety, providing information to consumers about health care facility safety, improving public trust, and creating pressure to drive change and enhance patient safety.

Data released for the purpose of holding facilities accountable

When designing systems and considering data disclosure, states should be clear as to whether they intend facilities to be held accountable to the state acting on behalf of the public, or to the public at large. The decision has implications for data disclosure, in identifying who needs access to the data to fulfill the state's policy goals, and what information they need. Some systems were not designed with the consumer in mind; rather, their primary purpose was for regulatory agencies to learn more about what was happening in hospitals in order to guarantee a

> *"The general assembly hereby finds that an increasing number of people are faced with the difficult task of choosing a health care facility for themselves and their family members. This task may be made less difficult by improved access to reliable, helpful, and unbiased information concerning the quality of care and the safety of the environment offered by each health care facility. The general assembly further finds that it is appropriate that the department, in keeping with its role of protecting and improving the public health, solicit this information from health care facilities and disseminate it to the public in a form that will assist people in making informed choices among health care facilities."* (Colorado Statute 25-1-124)

minimum level of health care delivery performance on behalf of the public. Releasing data to the public may not be a priority in a system that is designed in this fashion.

Table 4 How purpose of reporting system determines disclosure

	Purpose of System	Disclosure
CO	"...to improve access to reliable, helpful, unbiased information concerning the quality of care and the safety of the environment offered by each health care facility."	State discloses facility-identified and individual incident data
UT	"...to help the Department and health care providers to understand patterns of systems' failures in the health care delivery system."	State limits access to identifiable health information that facilities report to the Department in order to enhance compliance and use data for state and system-wide improvement

Data released for the purpose of informing consumers

Release of data to the public enables consumers to search for the safest options, to be aware of possible dangers, and to ask the appropriate questions of their health care providers.

Data released for the purpose of driving change and improving patient safety

Release of data may reveal that a problem is widespread rather than an isolated occurrence and provide an incentive to institute prevention strategies. Facility comparisons may motivate facilities to improve quality in order to improve their ranking and achieve a greater market share by attracting consumers and payers. Purchasers may use the information to identify high performing facilities for contracting.

> *"The Rhode Island Department of Health proposes to use individual hospital reports for licensure investigations, and to provide the public with aggregated information for all hospitals to allow the tracking of trends. As more experience in interpreting the incident and event reports is gained, it is envisioned that these data would be incorporated into the health care quality reporting system."* (Hospital Surveys and Incident and Event Reporting, Final Report to the Rhode Island General Assembly, November 2001, p.16.)

While each mandatory reporting system examined in this report has made a decision regarding what data will be publicly disclosed, the disclosure provisions differ in that they reflect the particular goals and purposes of each state. For example, Colorado's reporting system was implemented to "improve access to reliable, helpful, unbiased information concerning the quality of care and the safety of the environment

offered by each healthcare facility."[5] In order to achieve this goal, Colorado makes facility-identified individual incident data available to its citizens. The state of Utah, in contrast, explicitly instituted its system of mandatory reporting "to help the Department and health care providers to understand patterns of system failures in the health care delivery system and, where appropriate, to recommend statewide improvements to reduce the incidence of patient injuries" and in keeping with this purpose, "limits access to identifiable health information that facilities report to the Department" and publicly releases only aggregate reports.[6] While some states spell out the purpose of disclosure in their establishing statute, others, such as Rhode Island, state their intent in the public report.

What Information is Disclosed?

States with mandatory reporting systems must determine what information to make available from their systems. Typically, these decisions revolve around whether to release individual incident-specific information, aggregate information that does not identify facilities, or aggregate information that does identify facilities.[7] If incident-specific information is to be released, further decisions must be made about whether to release the incident report itself, the state's investigation report, any deficiencies issued by the state as the result of investigation, and the facility's plan of correction. Table 5 identifies the level of data disclosure planned or currently implemented in the 21 states with mandatory reporting systems.

It is important to note that in their licensing capacity states act on behalf of the public to guarantee a minimum level of quality health care. For most of the states with mandatory reporting systems, reported data are shared with the regulatory branch that has the power to license facilities and investigate complaints. Regardless of what data are released through the mandatory reporting system, all states release some degree of information regarding complaints and deficiency decisions.

[5]CO Statutes Title 25-1-124(1).

[6]Utah Administrative Code R380-210-1.

[7]All patient information is confidential and protected under HIPPA.

Table 5 What type of information is disclosed?

Type of report	CA	CO	CT	FL	GA	KS	ME	MA	MN	NV	NJ	NY	OH	PA	RI	SC	SD	TN	TX	UT	WA
Periodic aggregate reports		T	T	T		T	1		1	1		T	T	1	T			T	1	T	
Facility specific aggregate information		T							1			2	T								
Information on individual incidents	T	T	T					T			T					T					T

1: Planned but not yet implemented; Maine system not yet funded.

2: 1999 report (released in 2001); only data for the facilities with lowest reporting rates.

States issuing aggregate reports have to decide the level and categories of aggregation. If they choose to aggregate by state or region and thus to protect the identity of individual facilities, care must be taken to assure that facilities are not identifiable through other information included in the aggregate report. In the situation where a report aggregates types of errors by identified facility, care must be taken that patients cannot be identified. In all cases of aggregate reports, the state must determine that the information in the report is sufficient to be analyzed meaningfully, whether there are sufficient resources and expertise to analyze and risk-adjust the data, and whether there is enough information provided in the report to interpret the data accurately.

Table 6 Comparative advantages of aggregate and individual incident reports

Aggregate reports	Incident-specific reports
• show trends • enable consumers to see broad range of possible problems and thus ask appropriate questions about given procedures	• hold individual facilities accountable • give consumers information that will facilitate choosing safest facility • provide sufficient detail to allow thorough analysis of case

Seven state mandatory reporting systems do disclose data at the individual incident level.[8] This may be either because the reporting systems were set up without specific protections in place for individual incident data or because of a choice to disclose data at the individual level for specific reasons relating to the purpose of the system. While disclosing at the individual incident level may be useful in terms of accountability, a decision to make individual incident reports accessible to the public requires states to make a number of decisions before disclosing the data.[9] These include: Which data elements on the report can remain identifiable or should be redacted? Even with identifiers removed, is the identity of the patient sufficiently protected? Should the report be verified or substantiated before release? To whom will the data be released, and what steps will be required to access the data?

In contrast to systems that release individual incident data, fourteen of the states in this study issue periodic reports with aggregate data or plan to do so.[10] Four states (Colorado, Minnesota, New York, and Ohio) have provided or plan to provide facility-specific aggregate information, although New York's report only identified facilities with low reporting rates to create pressure to increase reporting. Table 7 elaborates on what information is released in aggregate form in the states that currently collect information in this way. (See Appendices C, D, and E for examples of states' public reports.)

As noted on page 15, other types of patient safety information—besides mandatory reporting information—may be available through state agencies. In all states, the public can access statements of deficiencies issued as the result of a survey or complaint investigation conducted as part of the state licensing and/or Federal certification process.[11] In some states the public can access hospital discharge data. Some states have quality information that might include performance reports and patient satisfaction (such as report cards, licensure surveys, complaints), but these tools are not focused on safety per se. Patient safety reporting is not intended to replace these other sources of data which may be less protected and part of the public record.

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[8] California, Colorado, Connecticut, Massachusetts, New Jersey, South Carolina, and Washington.

[9] Many states distinguish between access to reports submitted by facilities versus substantiated investigation reports.

[10] These fourteen states are: Colorado, Connecticut, Florida, Kansas, Maine, Massachusetts, Minnesota, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Texas, and Utah. Massachusetts is unique in that aggregate reports can be generated on request, but the state does not produce a report unless requested.

[11] The Centers for Medicare and Medicaid Services State Operations Manual, Section 3314 and 42 CFR 431.115.

Table 7 Content of reports in states that currently publicly release aggregate data

Content	CO	CT	FL	KS	MA	NY	OH	RI	TN	UT
Background information										
Description of the system	T	T	T			T		T		T
Authority for reporting system		T	T			T	T	T	T	T
Definition of reportable events		T	T			T	T	T	T	T
Analysis of incidents										
Number of incidents reported		T	T			T	T	T	T	T
Number of incidents reported by category		T	T			T	T	T		T
Number of incidents reported by region			T			T			T	
Trends in reporting over time, total and by category			T			T		T	T	T
Number and types of incidents by facility	T						T			
Category percentage of total incidents reported		T	T							
Incidents compared to total discharges (by region in FL and NY) (not by facility). NY: cases/100,000 discharges. CO: per number of procedures			T			T				T
Number of incidents by facility per 10,000 discharges for lowest reporting hospitals						T				
Information on malpractice claims and comparison to adverse incident reports			T							
Implications										
Under-reporting identified as a problem						T		T	T	T
Comparison to other databases						T			T	
Interpretative information: larger numbers do not necessarily equate with poorer quality of care		T	T							T
Recommendations/plans by state to improve the system		T				T		T	T	T
Examples of how the data have led to quality improvements/best practices						T			T	

Notes on Table 7:

Colorado	Occurrence summary reports, 2000-2003.
Connecticut	Data are released six months after being reported. A March 2003 report released data on October and November 2002. The first annual report to the General Assembly was released June 2003. This chart refers to the annual report.
Florida	Data from 1995-2000. Some reports are not yet available due to database changes.
Kansas	Data from 2001. 2002 is not yet available. Information on details of Kansas public reports was not available at the time of printing
Massachusetts	Data are available by request. Massachusetts does not issue a standard report.
New York	Report with 2000-2001 data was issued on August 29, 2003.
Ohio	Reports are available for four types of services (adult cardiac catheterization, adult open heart, bone marrow transplantation, and obstetric/newborn care services). Plans exist to post these reports on the Ohio Department of Health website; until then, interested parties should request the reports.
Rhode Island	2001 report with data from 1994-2000. No plans for future reports at this time.
Tennessee	2003 report with data from 2002.
Utah	Annual reports on sentinel event data. The 2002 report includes the first year of reported data from October 2001 (date of implementation) to October 2002. Quarterly adverse drug (ADE) reports on ADEs identified through hospital discharges for 1995-2001.

How Is Information Released?

Data may be made available on request or through public reports. In the states that make information available on individual incidents, reports tend to be made available by request only. The exception is Colorado, where information on individual incidents can be found on the state's website.[12] Most states that make aggregate analyses available do so on their website or in formally issued public reports. As mentioned previously, public reports in Massachusetts are available only on request.

Requests for data are handled in accordance with state freedom of information or public disclosure statutes. In many states, requests must be made in writing, and consumers must know specifically what to ask for, making it difficult for consumers to access the information. The data may be in raw form without analysis and may be difficult to interpret. Table 8 provides details on how states release information.

Questions for state to consider related to how to disclose data:

- Will information be available on request? On a website? Through public distribution?
- Who will handle requests for information?
- How will requests be made?
- How will potential users be informed of the availability of information?

(For more on this topic, see *How Safe is Your Healthcare?* A NASHP workbook for states seeking to build accountability and quality improvement through mandatory reporting systems.)

The NASHP work group recommended that wholesale release of individual incident-specific data is not necessary to fulfill the IOM's vision of improved patient safety. Aggregate reports with interpretive guidance would be more helpful, with information by type of event, by region, and perhaps by facility, although concern was raised about the impact of under reporting if facility-specific information is included. Providing numbers with no details or context may make it impossible to draw conclusions about the significance of the information and may provoke fear in the public. For example, a newspaper in one state accessed and reported on an incident-specific report but found that the report lacked key information that would have been helpful to the public's understanding of the event, such as: What were the circumstances of the event? Was the event investigated? How will the health department reassure the public that its interests are being protected?

[12] Colorado's website provides information on the facility name, date, type of occurrence, a description of the occurrence, facility action, department findings, and use of information. It provides the date that the state sent its findings to the facility and the date the information was released to the public. See www.cdphe.state.co.us/hf/hfd.asp. Search by facility name.

Table 8 How information is released in states that currently release data

Type of report	CA	CO	CT	FL	KS	MA	NJ	NY	OH	RI	SC	TN	UT	WA
Information available only on request	T		T			T	T		T		T			T
Information available on website		T	T	T				T		T		T	T	
Information available in a publicly distributed report			T		T			T		T		T	T	

Notes on Table 8:

Colorado	www.cdphe.state.co.us/hf/hfd.asp Search by facility name. In Connecticut, incident-specific information is by request only; aggregate public reports are distributed to the legislature. www.dph.state.ct.us
Florida	www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Risk/annual_report.shtml
New York	www.health.state.ny.us/nysdoh/commish/2001/nyports/nyports.htm
Ohio	Plans to post reports on its state website, but the reports are not yet available.
Rhode Island	www.health.ri.gov/hsr/facilities/hospital/hospitals2001.pdf
Tennessee	www.tennessee.gov/health
Utah	www.health.utah.gov/psi

To Whom are Data Disclosed?

Since most states that release incident-specific information do so by request only, it is only available to those that request it. Usually no analysis accompanies the data and the report is not targeted to any specific type of audience. Requests typically come from consumers or the media. Consumers may use incident-specific information to find out about an incident that occurred during their own or a loved one's care, information that is otherwise not available. Facilities may be interested in learning how other facilities have handled similar events.

Aggregate reports, in contrast, are often targeted to specific audiences: the state legislature, the public at large (including the media), and other facilities.[13]

[13] For more discussion about potential users and uses of publicly available data, see Lynda Flowers and Trish Riley, *State-Based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues* (Portland, ME: National Academy for State Health Policy, 2001), and Jill Rosenthal and Maureen Booth, *How Safe Is Your Health Care? A workbook for states seeking to build accountability and quality improvement through mandatory reporting systems* (Portland, ME: National Academy for State Health Policy, 2001).

Targeting the public at large

As previously discussed, some states make aggregate reports available to the public at large by posting them on their websites or releasing them to the media. The purpose for doing so may be to assure the public that the state is addressing the issue.

Few states note a public outcry or interest in the information. However, the media in several of the states included in this report play the role of government watchdog, holding state government accountable for its role of facility oversight. Some states (e.g., New York, Massachusetts, and Utah) stress efforts to educate the media in order to assure that the media correctly interprets the information, dispelling conclusions that the number of reported events necessarily means poorer quality of care. For example, Utah issues press releases when their reports are distributed in order to frame the message they want the public to receive. Utah explained in its January 2003 patient safety update that with better awareness and tracking, the rates of reported adverse events is likely to increase in the first few years, not as a result of an increase in events but as a result of improved reporting.[14]

Consumers may use the information to select facilities. However, research suggests that patients choose physicians and hospitals primarily on the basis of personal stories or advice rather than outcome measurements.[15] In addition, consumers often do not have a choice of providers in emergency situations or when decisions are controlled by their health plans. Nevertheless, consumers note that patient safety reports can empower patients by helping them to identify the questions that they should raise in discussing care with their providers and making choices in their care. Informed consumers can exert pressure on hospitals to meet safety goals. Consumer advocacy organizations can also use the information to develop tips to help consumers use the data.

Targeting facilities

Some states target aggregate reports to facilities in order to provide information that may be useful to them for bench marking and quality improvement initiatives. Facilities may use the information to identify areas of substandard performance in comparison to other facilities and to focus their improvement activities in those areas. Kansas, for example, sends a copy of its report to all hospitals, risk managers, health organizations, and licensing agencies. It is not available on a website, and the state does not publicize its availability. However, anyone can request a copy.

Targeting the legislature

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[14]Utah Patient Safety Update, Vol. 1, No. 2, January 2003, www.health.utah.gov/psi.

[15]Lynda Flowers and Trish Riley, *State-based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues* (Portland, ME: National Academy for State Health Policy, 2001).

In some states, statutes require that reports be sent for legislative review and identification of policy issues. For example, in Rhode Island,"[t]he department shall issue an annual report by March 31 each year providing aggregate summary information on the events and incidents reports by hospitals as required by this chapter. A copy of the report shall be forwarded to the governor, the speaker of the house, the senate president, and members of the health care quality steering committee..."[16] Rhode Island's 2001 report to the legislature was the result of special funding intended to examine hospital care in the state, including information on its reporting system. A Tennessee law in 2002 required aggregate reporting to the legislature and to the board for licensing health care facilities.

Work group members noted that reports intended to inform the public—however the public is defined—should provide findings in a consumer friendly manner. Some states have not been able to conduct a systematic review of incident reports; in these cases, the information provided to the public is not provided in a usable format.

[16]Rhode Island Public Law Chapter 23-17-40 (h) (2002).

BARRIERS TO DISCLOSURE

As suggested earlier in the paper, several significant barriers to disclosure were frequently mentioned by the states:

- concern that data would be invalid and misleading because of under reporting;
- facility fear of malpractice litigation and resulting strong opposition to disclosure;
- the desire of the states to establish a collaborative relationship with facilities and not to be seen as punitive.

Under Reporting

Under reporting is a problem for several reasons. If all facilities are not reporting to the same extent, the compliant facility runs the risk of appearing to be less safe. Thus facilities are hesitant to report unless they can be reassured that all facilities in the state will be equally forthcoming. Under reporting may also make it difficult to determine whether a given problem is widespread or an isolated occurrence, and this poses a major barrier to identifying patient safety trends.

All states with mandatory systems—representing a variety of events reported and a range of protection (from very limited to very comprehensive)—recounted a problem with under reporting. The following were among the reasons cited for under reporting:

- A lack of effective internal systems within hospitals to identify incidents;
- Unclear definitions or requirements for what must be reported;
- Reporting burden and a lack of perceived usefulness by facilities;
- Fear of liability and negative publicity creates a culture of non-reporting; and
- A lack of enforcement at the state level.

Many states noted that they provide data protection in the interest of achieving a high level of compliance. However, since all of the states with mandatory reporting systems describe under reporting as a problem, the connection between protection of data and under reporting is not an easy one to draw.

Fear of Malpractice Litigation

Fear of malpractice litigation is often cited as a reason for under reporting. The release of the 1999 IOM report, *To Err is Human*, coincided with yet another spike in malpractice insurance premiums. These two events and the publicity given both has resulted in a high level of awareness of and concern about medical malpractice lawsuits. This, in turn, has led to a reluctance on the part of facilities to report adverse events to the state.

As detailed below, the protection of data may be worthwhile for a variety of reasons, including the desire to create an environment that encourages reporting. However, states cite many possible reasons for under reporting, and fear of litigation may not be the primary concern.

When asked about any connections between their mandatory reporting systems and medical liability litigation, the majority of states reported that their system had not resulted in an increase in the number of malpractice suits. No relationship between mandatory reporting and an increase in malpractice claims was identified through the interviews. States observed that because egregious cases resulting in deficiencies must be disclosed, plaintiff attorneys do not have to rely on mandatory reporting data for their information. Although it is not a common occurrence for attorneys to look for new cases through the reporting system, those with existing medical malpractice cases may file a complaint and use a state's subsequent investigation and conclusions as another means of determining the strength of their case.

While the *fear* of litigation is real, it is an open question whether reporting of medical errors in the absence of protection, would actually lead to a dramatic increase in litigation. Patients who have suffered harm from the types of serious errors subject to mandatory reporting are very likely to be aware of the harm independent of reporting, and there is some indication that full disclosure to patients decreases the likelihood of litigation.[17]

Desire for Collaborative Relationships

Another barrier to disclosure is the desire to establish a collaborative relationship with facilities in order not to be perceived as punitive. For the most part, states have approached accountability as a regulatory as opposed to punitive function. Although most states have the ability to impose fines or cite a facility or practitioner for deficiencies, usually a state's primary interest is to uncover error and require both a root cause analysis and plan of correction from the facilities. For example, in most cases of reported error, New York will not issue a citation or impose a fine, but rather will request the provider to submit a root cause analysis and provide risk reduction strategies to the state reporting system. The state will share lessons learned and identify common root causes across categories of occurrences. However, since most states do link their systems to the regulatory branch, they are often considered punitive by the facilities.

Considerations to the contrary notwithstanding, the state work group saw the appropriate and effective protection of reported data as essential to addressing these barriers to disclosure. The protection practices typically used by states are detailed in the following section.

[17]Amy B. Witman et al., "How Do Patients Want Physicians to Handle Mistakes?" *Archives of Internal Medicine* 156 (Dec 9/23, 1996): 25652569.

DATA PROTECTION PRACTICES

After a state has identified the goals and purposes of its mandatory reporting system and determined what, if any, information to disclose to the public in order to meet these goals, it must then ensure that the information it does *not* want disclosed is protected. A well designed system will allow a state to disclose everything it wants to disclose while protecting the rest from *compulsory* disclosure. Although most states readily acknowledge the public's right to know about the safety and quality of the health care system to help individuals make informed decisions, the majority of states with mandatory systems argue that protecting some data from disclosure is necessary to foster a non-punitive culture of safety that leads to improved reporting by hospitals. Currently the balance between disclosure and protection appears to be tipped toward protection, with the fear of malpractice acting as a thumb on the scale.

This section discusses the protection questions that state policy makers are likely to consider in designing a reporting system and explores the data protection practices of the states with mandatory reporting systems already in place.

Why Protect Data?

States have various reasons for protecting data. Chief among them is a desire to create an environment that encourages full compliance. Providers and facilities maintain that they are hesitant to report incidents of medical error in the absence of legal protection due to concerns about the legal consequences of disclosure. In addition to threats of litigation, facilities are also concerned about loss of business and damage to reputations if reported data are disclosed. Fairness and considerations of due process lead states to protect unverified reports, and issues of privacy result in the protection of individual's identity.

Since there are competing interests at play, and individuals, members of the press, or attorneys may attempt to gain access to data through the legal process, information that the state does not want disclosed must be expressly protected. In the absence of specific system-related protections, even data that the state treats as confidential may be vulnerable to the legal process.

The state work group recommended that in order to be effective and reliable, protections should be:

- comprehensive: in order to cover the many ways that confidentiality can be challenged;
- statutory: to better withstand legal challenges; and
- specific to the reporting system: in order to make legislative intent clear.

What Information is Protected?

Although states interviewed for this report recognize the benefits of an informed public, they do not all agree that the public has the right to know incident-specific or facility-specific information. The reasons why a state might choose to protect data, as stated above, can usually be satisfied by protecting individual incident and facility-specific information. Fifteen state mandatory reporting systems protect incident-specific information as it comes into the system and disclose data only in aggregate form after investigation and/or analysis. The reasons not to disclose do not often apply to de-identified or aggregate data. As the decision tree suggests, states that protect data tend to do so at the point that the data enter the system as an individual incident report identified by a facility. As the data move through the system and are investigated and verified or analyzed and aggregated, the protections tend to diminish or disappear.

When is Information Protected?

If a state has clearly considered what data should be disclosed and protected and has established strong comprehensive protections, then the decision of when to protect is theirs. Data can be completely protected as it enters the system and only released under very limited circumstances.

In developing protections, states must first determine if the mandated information will be reported to the regulatory branch or a separate entity. States such as Utah and Maine that report to a separate entity have created a "lock box" or a "firewall" separating the reported data from the state's regulatory entity. Reporting to a separate entity is thought to create an extra level of protection, one designed to alleviate concerns of regulatory consequences and to foster greater compliance. States that design their systems in this way must determine under what circumstances data may be released to other agencies. They must also consider how to hold accountable providers who commit and report egregious medical errors. In Utah, for example, if a facility fails to report, analyze, or submit an approved plan of correction, the state reporting system can act and require the facility to comply.

Other states protect data as they enter the system, but use them in regulatory oversight. In these states, incident data are used only after verified by investigation and only where there is a deficiency. If a state system provides for reporting to the regulatory entity, it must clarify if and under what circumstances data may be shared with other agencies or boards within the state. If data are shared among agencies, the extent of the confidentiality protections must be specified.

Protection from What?

U.S. laws and practice most often presume openness, as exemplified in the Federal Freedom of Information Act and state public disclosure laws that require documents and records obtained while conducting official government business to be made available to the public upon request. The right to due process in a legal proceeding may give parties the ability to compel disclosure of

material that is relevant to a particular case. The following are legal provisions under which an attempt to gain access to data considered confidential by the state could be made.

- Freedom of Information or Open Records request: The state equivalent of the Federal Freedom of Information Act (FOIA) requires the disclosure of records requested in writing by any person.

- Subpoena: A written court order requiring the production of a paper, document, or other object relevant to the particular investigation, proceeding, or lawsuit. A subpoena is issued by someone authorized by law, usually by the attorney for a party to a lawsuit.

- Legal discovery: A mechanism whereby one party in a lawsuit may compel the opposing party to disclose all relevant material which is within his or her possession.

- Admission into evidence in a civil or administrative proceeding. Admissible evidence is that which a court allows to be heard or received by the trier of fact, be it judge or jury. Each jurisdiction has established rules of evidence to determine questions of admissibility. Relevant evidence may be considered inadmissible if it is found to be privileged, unduly prejudicial, cumulative, or for a variety of other reasons.[18]

How are Data Protected?

Just as there are various approaches to accessing reported data through the legal process, diverse strategies exist for protecting reporting system data.

- System Design Features: The design of mandatory reporting systems can minimize concerns about public disclosure and legal discovery of data. De-identification of data and anonymous reporting are two system design strategies that may make data less useful for discovery.

- Exemptions from Public Disclosure Laws: To accommodate public policy considerations that override this basic right of access, as in the case of reporting systems, states may create statutory exemptions to their public disclosure law.

- Confidentiality Protections specific to Reporting Systems: These protections address provisions of legal process as listed above and specifically protect data against subpoena, discovery, and admissibility in civil or administrative proceedings. Protections included as an integral part of the reporting system, as opposed to general protections of health information, are more resistant to legal attack because the legislative intent to protect the mandatorily reported data is clear.

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[18]Steven H. Gifis, *Law Dictionary* (NY: Barron's Educational Series, Inc., 1975).

- Peer Review Privilege: All states, with the exception of New Jersey, have a peer review privilege under state law. This privilege is designed to encourage participation in the process under which physicians analyze errors within their institutions so as to find the causes and avoid repetition.

Most of the states with mandatory reporting systems provide some protection to reported data, either through regulation or statute, although the level of protection varies substantially. (See Table 8.) Data protections are most common for the following:

- Patient identifiers as per HIPAA regulations[19] or other confidentiality laws;
- Individual incident reports, substantiated or unsubstantiated;
- Provider identifiers, individual or institutional; and
- Material generated from the peer review process.

As was discussed previously, the release of the IOM report and the latest malpractice crisis has led to both an increase in the number of mandatory reporting systems and a demand from providers for strong protections of reported data. Whether or not a connection can be shown between reporting and an increase in litigation, the fear is real and has contributed to the trend of more recently instituted reporting systems having strong, comprehensive system-related statutory protection of data.

Several states with mandatory reporting systems rely solely on their existing peer review provisions to protect reported data. While offering protection, peer review is more vulnerable to requests for disclosure through the legal system, wherein a judge will balance a litigant's need for relevant information with the policy goals served by the protections. On occasion, peer review protection has been held by courts to be trumped by the rights of individuals to information relating to a personal law suit.[20]

For these reasons, none of the recently established reporting systems rely on existing peer review protections alone. Before 1999 and the release of *To Err is Human,* states tended to rely on general protection and confidentiality provisions not specifically related to their mandatory reporting systems. Almost all mandatory reporting systems established after 1999 have included comprehensive protections as an integral part of the system and have included them in the authorizing statute. (See Table 9.)

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[19] The Health Insurance Portability and Accountability Act of 1996.

[20] *Adams v. St. Francis Regional Medical Center,* 955 P.2d 1169 (1998).

Table 9 Trend toward greater protection

	System established pre-1999	System established post-1999
Comprehensive protections are specific to the reporting system	Colorado Florida Kansas New York	Connecticut Georgia Maine Minnesota Nevada Pennsylvania* Tennessee Texas
Data received by reporting system are unprotected, or relies on peer review provisions or other general protections not specifically related to the reporting system	California Ohio Massachustts New Jersey Rhode Island South Carolina South Dakota Washington	Utah**

* In Pennsylvania the original reporting system (known as Chapter 51 system) had reporting protections that were strengthened when their new system was established in 2002.

** The UT system was established by regulation in 2001, but the data are protected by reference to existing general protections for health data that were established prior to 1999.

Table 10 Legal protections against disclosure of reported data in state confidentiality statutes/regulation

State	CA	CO	CT	GA	FL	KS	ME	MA	MN	NV	NY	NJ 2	OH	PA	RI	SC	SD	TN	TX	UT	WA
Data excluded from disclosure under open records provisions		T	T	T	T	T	T			T	T 3		T						T	T	
Data not discoverable		T	T	T	T	T	T		T	T	T			T	4			T	T	T	
Data not subject to subpoena			T				T		T	T	T				4			T	T	T	
Data not admissible as evidence in civil proceedings			T	T	T		T		T	T				T	4			T	T	T	
Data not admissible as evidence in administrative proceedings (except disciplinary)			T	T 1	T		T		T	T				T	4			T	T	T	
Data confidential			T	T	T		T		T	T	T		T	T			T	T	T	T	
Peer review protections *only*	T							T							T	T					T

Notes

Colorado: CO Revised Statutes, §25-1-124(4)(1999)

Connecticut: CT Public Act 02-125 §3(g) (19–)

Florida: FL Statutes Chapter 395.0197 (6)(c); (8)(h) (1999)

Georgia: O.C.G.A. §31-7-15/ §31-7-133 & §31-5-5. #1-Georgia protections include an exception for use of peer review material in licensure actions against hospitals where the effectiveness of the peer review system is at issue (O.C.G.A. §31-7-133(b)).

Kansas: KS Statutes Annotated §65-4925 (1999)

Maine: 22 M.R.S.A. ch. 1684 §8754(3) (2002)

Minnesota: MN Statutes 2002 §145.64 (2003)

Nevada: NV Rev. Stat. Ann. 439.840 and 860 (2003)

#2-New Jersey does not have a peer review protection at this time

New York: NY Civil Practice Law and Rules, art. 31 (2000); NY Public Health Law, §2805-m (1999). #3-NY can release facility specific aggregate information (annualized data) under a Freedom of Information Act request.

Ohio: OH Statutes §3702.18

Pennsylvania: 40 PS §311(a) and 28 PA Code §51.3 (i)

Rhode Island: RI Statutes Ch 23-17-40(g); #4-reporting system incorporates peer review protections by reference.

South Dakota: SD Statutes CH 34-12-17 (----)

Tennessee: TN Code Ann Ch 11 §__(d)(1)

Texas: Sub Ch H §241.204

Utah: R. 380-210-5 and R 380-200-6; UC 26-3-7

States may *choose* to release data in spite of strong protections in their mandatory reporting systems that prevent *compulsory* disclosure of data. For example, Colorado and Connecticut protect their reported data from the legal process and also make it possible to access individual incident reports. Other states have not provided for an exception to their open records laws which may subject reported data to compulsory disclosure.

In some states, the reported data are subject to release but are extremely difficult to access. For example, in one state all reports are submitted on paper. In order to access a report, a person must go to the Department of Health office and leaf through the files by hand. In other states, data are available on the website, but the sites are so difficult to navigate that the data are only theoretically available.

New Jersey is the state with the least amount of protection, but legislation has been introduced in 2003 that will create a statutory reporting system with system-specific comprehensive protections.

OTHER FACTORS AFFECTING DISCLOSURE OF DATA

State officials interviewed for this report noted several other factors that influence and shape the disclosure of mandatory reporting system data. Since the publication of the IOM Report recommending that states develop mandatory systems for the reporting of serious adverse events, no cohesive national effort has been made to promote and support states in assuming this role. Without the leverage of federal mandates and resources, adverse event reports are unlikely to achieve the same level of compliance and public interest that characterize nursing facility reporting.

Lack of Resources

Resources, or the lack thereof, are a major concern of all states with mandatory reporting systems. The effectiveness and utility of the systems depends on the availability of resources to collect, analyze, and disclose data. Resource constraints may be financial (the dollars needed to invest in system improvements such as electronic reporting), or they may be related to staffing (the staff time needed to assess patient safety trends, provide feedback to providers, disseminate findings to the public, and work collaboratively to address system failures). In several states, statutes have been enacted to create reporting systems, but the systems have yet to be implemented due to lack of funding. This creates an additional problem; the public may mistakenly believe that the state is taking action when in fact it is not. Other states reported that they had lost ground and were forced to cut back on aspects of the program due to the current budget climate.

Lack of Clear Definitions

The lack of clear, consistent definitions of adverse events thwarts efforts to compare and evaluate results. A few states advocated for greater national standardization of definitions while others placed the focus on improving their own reporting specifications. This poses a potential problem for states in which reportable events are defined in statute, since any proposed changes in definitions must return to the legislature for approval.[21]

[21] For a detailed discussion of state reportable events, compared to the National Quality Forum's recommended list of reportable events, see Jill Rosenthal and Maureen Booth, *Defining Adverse Events: A Guide for States Tracking Medical Errors* (Portland, ME: National Academy for State Health Policy, 2003).

Potential Federal Concerns

The Health Insurance Portability and Accountability Act (HIPAA) has surfaced in some states as an impediment to data reporting or disclosing. While HIPAA provisions should not impede compliance with reporting requirements, they create hurdles that must be addressed. For example, it may become necessary for states to provide education and training to provider reporters about exceptions to HIPAA in order to eradicate the perception that HIPAA is more prohibitive than it is. Another issue that will arise is how to protect the identity of an individual who has been the victim of a reported medical error when the case has been widely publicized or when the individual is a public figure.

In addition, the impact of the Centers for Medicare and Medicaid Services (CMS) new automated tracking system for complaints and incidents has raised some concerns. The ASPEN Complaints/Incidents Tracking System (ACTS) is intended for state use to report to CMS any complaints and adverse incidents that are reported to state survey agencies as part of their Medicaid and Medicare certification contract with CMS. The purpose of the ACTS system is to provide more comprehensive tracking and greater consistency in reports by providing clearer guidance to states. However, states have concerns about how their mandatory reporting systems will interface with the ACTS system. The definition of reportable incidents for the ACTS system has not been clarified, the transfer of data between mandatory reporting systems and the ACTS system may impose an administrative burden, and there exists the potential for violation of confidentiality provisions of state mandatory reporting systems if data are shared with CMS.

Despite these concerns, states generally express confidence that the most egregious incidents are reported and/or are otherwise brought to the attention of the state. In this respect, they believe they are in some part satisfying the regulatory responsibility of their systems to protect public safety. However, states that strive to add a learning component to their system express frustration with the level of reporting, the inability to conduct more extensive analyses on patterns, and a lack of resources to more fully engage providers and consumers in collaborative improvement initiatives.

CONCLUSION

Interviews with officials in states with mandatory reporting systems suggest that states continue to face a number of challenges in their efforts to report medical errors to the public. The challenges are complex and multifaceted, often pitting the public's right and need to know against privacy concerns. Among the key findings of this report:

1. There is no evidence to show what level of data disclosure advances the patient safety agenda. More research is needed in order for state officials to be able to make informed decisions and not act simply on gut feelings, anecdote, and/or pressure from interest groups.

2. Under reporting is a serious issue. State systems are not as useful as they could be because under reporting limits the accuracy of data analysis and may result in public reports that are misleading. States are hesitant to release data that the public might misunderstand or that unfairly punishes compliant reporters.

3. The reasons for under reporting are numerous and include facilities' lack of internal systems to identify events, uncertainty about reporting requirements, a culture of non-reporting, a lack of enforcement at the state level, bureaucratic burden, competition and market share, fear of publicity, and fear of liability. It is simplistic to assume reporting would increase if data were protected; however, some degree of protection may be necessary to create an environment conducive to reporting.

4. The trend among states introducing new mandatory systems is to: a) establish them in statute, as opposed to regulation, b) offer strong comprehensive protection of reported data, and c) release data only in aggregate form.

5. Seven of the 21 states with mandatory reporting systems release incident specific data. Fourteen states currently issue or plan to issue aggregate reports. Of these, five states have or plan to issue aggregate reports with individual facilities identified.

6. Recognizing that there will probably always be some level of under reporting and consumers may not be able to make selections based on the data, the state work group believed public reporting can still fulfill a variety of goals, including regulatory accountability and the detection of trends.

7. States may choose not to disclose their mandatory reporting data or may not make data easily accessible to the public. Incident-specific data are most commonly provided on a request only basis. In several states, where information is available to the public, it is often difficult to access or requires an intricate understanding of how and where to request the information in order to access it. The data may be provided in a raw form without accompanying analysis to assist with interpretation.

8. Patient safety event data require careful analysis and interpretation before they are useful to the public.

9. Besides mandatory reporting information, other types of patient safety information may be available through state agencies. Patient safety reporting is not intended to replace these other sources of data which may be less protected.

10. States need resources to improve their systems in order to meet public expectations of a patient safety system. While the Institute of Medicine recommended that funds be provided to states to create reporting systems, funds are not now available. In some states data that would otherwise have been analyzed and released to the public have not been because of a lack of resources. In other states, reporting systems have been established by law but are not operating due to lack of funds.

APPENDIX A LIST OF WORK GROUP PARTICIPANTS

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APPENDIX B INTERVIEW PROTOCOL

Public Disclosure of Adverse event Data		
1	Does your state routinely issue public reports of adverse event data?	
	a) If so:	b) If not, why not?
	What type of reports are routinely issued?	What patient safety/quality information could a person get if they so desired? How? What would need to be in place so that you would be able to issue public reports?
	How is information reported? Aggregate data? Data elements?	
	Do you have special report capacity? If so, what restrictions apply to the release of special reports?	
	How are public reports accessed? Are reports published?…available on the state web site?…available only upon request?	
	In addition to these reports, what other patient safety/quality information could a person get? How?	
	Does the state release hospital specific data? In what form?/Why not?	
2	The IoM report "To Err is Human" suggests that data reported under a mandatory system be released to the public. Is your state moving toward this goal?	
3	What information do you think the public has a right to know?	
4	What are the considerations, pro and con, in deciding whether or not to publicly disclose adverse event data?	
Barriers to Reporting/Disclosing		
5	Is there a high level of reporting compliance among hospitals or is there a problem with under reporting? What factors influence compliance?	
6	Does the fact that you [do/don't] publicly disclose data have an effect on hospital reporting? Why/Why not?	
Protection of Data/ Legal Discovery and Liability		
7	What legal protections are in place for reported adverse event data? 11. Confidentiality? 12. Discoverability? 13. Admissibility? 14. Use for research purposes? 15. Exemption from "right to know" laws?	
8	Are protections in statute, regulation, or policies? (Please give citation)	
9	Have protections been challenged? If so, what was the outcome?	
10	Do providers trust protections? Do weaknesses in protection provisions, whether real or perceived, impede full reporting?	
11	Does the state conduct its own investigation of reported events? Can data reported under the mandatory system be used in the state licensure and certification survey process? Can state surveyors act on data collected through mandatory reporting systems (e.g., target specific facilities for in-depth reviews)? In these cases do the results of the state investigation enjoy the same protections?	
12	Are there peer review protections associated with the reporting system? Separate from reporting system? Do you think your state's peer review laws need to be modified to protect patient safety data?	

13	Is data routinely de-identified when reported?
14	Do you have any evidence of a relationship between the reporting system and numbers of liability claims filed?
15	Has there been any initiative to change protections, either creating or abandoning?
General Assessment	
16	Has your mandatory reporting system fulfilled the purpose for which it was established? What works well? What is not working? What changes would improve the system?
17	Is there an appropriate balance between protection (to encourage reporting) and disclosure (to meet the public's right to know)? Is anyone advocating change to your system? If so, is there resistance to proposed changes?
18	Are there other ways that NASHP could support your efforts to improve patient safety?

Appendix C: Colorado Public Report
www.cdphe.state.co.us/hf/hfd.asp

Appendix D: Florida Public Report
http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Risk/annual_report.shtml

Appendix E: Utah Public Report
http://health.utah.gov/psi/