

8. Will Incident Reports and Findings Be Disclosed?

8.1 Disclosure versus protection of data

- ▶ ***What are the arguments for and against disclosure of reporting system data?***
 - ▶ ***Who may want access to reporting system data?***
 - ▶ ***What issues should be considered when debating disclosure of data?***
 - ▶ ***How do data protections affect use of data?***
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Strong arguments exist both for and against releasing reporting system data. States often refer to the practice of making reporting system data available as the *disclosure* of data and of limiting the availability of data as the *protection* of data. The debate is complex and involves several embedded questions, such as who should have access to data, how data can be protected, and how it might be disclosed. The decisions are not cut and dry but rather influence, and are influenced by, other system design features. Earlier NASHP reports provide a more comprehensive analysis of issues related to protection and disclosure of mandatory reporting system data.²⁵

Opponents of making information publicly available claim that releasing data may discourage providers from reporting incidents for fear of inappropriate blame, misinterpretation by the public, or malpractice litigation, although no empirical evidence exists to support the claim that disclosure of information increases litigation. The occurrence of adverse events may be portrayed as a failure of the facility or as a failure of the regulatory agency. Underreporting may harm facilities that comply with reporting requirements by giving the perception that they experience more adverse events. Some also claim that disclosing information may increase litigation between the state and data reporters if the state publishes erroneous information.

Proponents of disclosing data claim that since mandatory reporting systems are intended to be

²⁵ 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); Jill Rosenthal, et al., *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives* (Portland, ME: National Academy for State Health Policy, 2001), 58-67.

part of a public system for holding health care organizations accountable for performance and maintaining safety, the information needs to be available to the public. According to this view, withholding information may create an environment of mistrust and erode public confidence in the health care system. The IOM recommends that information within state-based mandatory reporting systems be available to the public and not protected from legal discovery.²⁶ Some believe that data disclosure is necessary to drive safety improvements.

Consumers, health care facilities, state agencies, and attorneys may be interested in mandatory reporting system data for different reasons and may have different concerns about release of data.²⁷ *Consumers* may seek information about an incident if they or their family members were personally involved. This information may help them come to terms with the event and advocate patient safety improvements. Consumers may seek aggregate data to identify quality of care differences among facilities and may use this data in selecting settings of care. Although some evidence suggests that consumers do not maximize the use of quality information in making health care choices, some consumer advocates suggest this may be partially attributed to lack of salient data and difficulty obtaining data. They believe that publicly available data is a necessary check on the health care industry. However, potential negative consequences of releasing data to the public do exist. Care must be taken to avoid scaring or providing false assurances to consumers through incomplete data. Consumers may also lose trust in government oversight if adverse events continue to occur.

Health care facilities may use reported data to compare their performance to others, identify areas in need of improvement, and learn from others' experiences. They may identify institutions with whom to partner to learn improvement strategies. Some claim the very existence of publicly available patient safety information can spur managers to improve systems. Despite the benefits of benchmarking data, facilities may be reluctant to share this information for several reasons, including liability concerns and questions about usefulness of data.

State reporting system officials may share data with various *state agencies*. Most states share information from individual incidents with surveyors to inform licensure inspections and with professional licensing boards to identify individual practitioners who may not meet standards of care. Aggregate data may be useful for state purchasers, such as Medicaid and state employee purchasing agencies, to develop purchasing strategies that can improve quality of care. In most states, purchasers are not currently accessing or using this information, citing lack of confidence in data completeness and other barriers to action. Some reporting systems share data with other state agencies that are better suited to conduct data analysis and produce reports. (See 9.2, Partnerships with Other Quality Improvement Initiatives.)

²⁶ Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 1999), 102.

²⁷ For a thorough discussion of potential data users, 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), 23-30.

Attorneys may seek access to incident reports to obtain information for initiating or supporting lawsuits against facilities. Attorneys are likely to be aware of incidents since serious incidents are often identifiable to facilities, patients, and families, but release of details of investigations may provide information that may not be easily obtainable otherwise. By using information available to the public, attorneys can limit costs of obtaining information. Attorneys may also use incident reports for soliciting clients or use aggregate data with facility identifiers to prove hazardous conditions. Even if information is protected, attorneys may find ways to gain access to information.

Examples from existing systems

- ▶ **Colorado** shares copies of some incident reports with professional licensing boards, the attorney general's office, and other relevant state agencies.
- ▶ **Florida's** statute makes reports confidential and not subject to discovery or admissible as evidence in civil lawsuits. Data cannot be shared with other state agencies. Aggregate data are available upon request but names of facilities and individuals are not available.
- ▶ **Massachusetts** does not have any legal data protections for reported incidents. However, patient specific information and some peer review protected information may not be released. All information in the reporting system, including formal narrative reports, deficiency statements, and facility personnel interviewed during investigations, is available to the public upon request.
- ▶ **New York's** system includes a report generation function that allows facilities to track and trend their own incidents and to compare their performance against peer facilities, within their regions, and statewide.

Worksheet #8.1: Disclosure vs. Protection

Clarification of goals

Be explicit about whether your goal is to hold facilities accountable to the state agency that runs the reporting system or to the public at large. How you respond to this question has implications for whether data are disclosed to the public. Identify who needs access to reporting system information in order to fulfill your policy goals, and what information they need. Consider whether release of data will unnecessarily frighten or provide false assurances to consumers or discourage information sharing for safety improvements.

Management checklist

- Consider how to balance stakeholders' demand for information with efforts to ensure that the information released is accurate and easily interpreted.
- Determine whether the media can present the data using a balanced approach. If information will be released, develop a strategy for presenting information to the media so that it will be accurately represented.
- Examine whether you can modify your policies on release of data as the system develops and data improve.
- Identify opponents and supporters of publicly disclosed information.
- Identify ways to release information that may lessen perceived or real threats of litigation and the integrity of the data. *(See 8.3 Mechanisms to Disclose Information.)*

Resource checklist

- Identify the availability and resources of legal counsel.

Key question

Will data be protected or released?

	Pro	Con
Protected	<p>Supported by health care providers</p> <p>May discourage lawsuits against the state</p> <p>Releasing incomplete data may be misleading and of limited utility to all users</p>	<p>Denies users access to data</p>
Released	<p>May promote trust in government oversight</p> <p>Provides a public mechanism for facility and government accountability</p> <p>Can provide incentives to poorly performing facilities to make improvements</p> <p>May be useful to several stakeholder groups interested in improving quality</p>	<p>Raises concerns about loss of business, damaged reputations, and real or perceived threats of litigation</p> <p>May discourage reporting which undermines tracking and trending</p> <p>High levels of adverse events may raise questions about whether the government is doing its job</p> <p>Facilities may experience poor public relations consequences</p>

Other issues for consideration _____

Making the decision

Check all that apply

- The reporting system will be designed to provide some information to the public
- The reporting system will be designed to provide feedback to health care facilities
- Information from the reporting system will be shared with other state agencies.
Specify: _____
- Some information from the reporting system will be protected from legal discovery

8.2 Mechanisms to protect data from disclosure

- ▶ ***How do states protect reporting system data?***
 - ▶ ***What forms of data protection are subject to legal challenge?***
 - ▶ ***Will data be protected by system design features, confidentiality provisions, exemptions from public disclosure, peer review statute, or a combination of methods?***
-

Three types of legal protections have implications for state reporting systems: confidentiality protections, exemptions from public disclosure requirements, and peer review/quality review privileges and immunities.²⁸

Confidentiality provisions prohibit disclosing information to nonlegal entities such as the general public and the media. States may include confidentiality provisions specifically in reporting system laws or regulations to avoid arguments about whether and how reports are intended to be protected. Confidentiality protections can provide legal protection for data in a number of ways, including protection from legal discovery, subpoena, search warrant, state's public disclosure laws, and evidence in civil or administrative proceedings. They can also protect data reporters in a number of ways. These statutes and regulations may be legally challenged, however, because government agencies are generally required to make documents and records in their possession publicly available through freedom of information laws. Five states have confidentiality protections for incident reports. (See Appendix I for details of state data protections.)

To reduce the possibility of legal challenges, states may also create *statutory exemptions to public disclosure* requirements for certain records. States can create exemptions to override freedom of information requirements when public policy considerations override the basic right of access to information. Public disclosure exemptions may be created as part of a state's general public disclosure statutes or in statutes specific to mandatory reporting. Statutory public disclosure exemptions provide limited protection for data as well, because courts may limit the scope of their application and state officials may have discretion to disclose records. However, they can be strengthened by creating or referencing them in confidentiality or peer review laws that protect reporting system information. Five states have created a public disclosure exemption

²⁸ For a thorough discussion of mechanisms to protect 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), 38-46.

for reported information. (See Appendix I for details of state data protections.)

Medical peer review/quality review privileges and immunities are legal protections provided to health care providers, their entities, and the records generated during evaluation of facility medical personnel and procedures. State legislatures have provided this protection to encourage open and honest evaluation by physicians who feared that such review would expose them to liability and malpractice litigation among other issues. *Medical peer review* statutes protect peer review committees which are generally comprised of physicians. *Quality review statutes* may protect non-medical personnel as well. *Immunities* protect individuals involved in the review process; *privileges* protect documents and materials used during the process.²⁹

Forty-nine states have statutes that protect some aspect of peer review processes but they vary in the protection offered. Committee reports, records, proceedings, testimony, and participants are usually protected. In some states, peer/quality review privileges and immunities provide health care facilities with a basis to withhold from the state information about incidents. In other states, facilities may be required by law to allow the state to access peer review information. Typically in these cases, the state is prohibited from releasing this information; language to this effect may be included in freedom of information statute, peer review statute, or both.

Since peer review protection statutes can vary in strength, mandatory reporting laws can reduce ambiguity by stating that all of the system's activities related to oversight and administration are considered quality improvement activities. This language can be included in peer review statute as well. States can also amend peer review statutes to extend protections to facilities that share error-related information for quality improvement purposes. Reporting system officials advise ensuring that findings from peer review actions are available; this is the case in four states. Hospitals in two states have claimed peer review protections to withhold information from incident reports or to bar access to information during on-site investigations. (See Appendix I.)

In addition to legal protections, *system design features* can also be used to minimize concerns about public disclosure and legal discovery of data. Systems can be designed to de-identify data (remove patient, provider, or facility identifiers) or accept anonymous reports. If reporting systems do not receive or if they destroy identifying information, reports will be less useful to attorneys seeking clients. However, de-identification may not be necessary since state personal privacy or public disclosure laws may already prohibit the release of patient identifiers. Reporting system officials suggest that provider-specific and facility-specific identifiers be maintained in order to enable follow up of events and tracking of data. Anonymous reporting is not recommended because it prohibits the state from using the information to hold facilities accountable for patient safety.

The above-mentioned data protections can be based in statute or regulation. Of the five states

²⁹ Jill Rosenthal, et al, *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives* (Portland, ME: National Academy for State Health Policy, 2001), 58-65.

with confidentiality provisions, four are based in statute. (See Appendix I.) Health care organizations prefer confidentiality provisions to be based in statute in order to provide stronger protections that are less likely to be successfully challenged in court.

Examples from existing systems

- ▶ **Colorado** statute makes any report submitted strictly confidential, except that information in any report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions. The information shall not be made public upon subpoena.
- ▶ **Florida** statute protects documents and records from the legal process. The statute states that records are not available to the public under the state's public disclosure law.
- ▶ **Kansas** statute protects reports, statements, memoranda, proceedings, findings, and other records submitted to or generated by peer review committees or officers.
- ▶ **Washington** incident reports are subject to public disclosure but names of individuals are redacted.

Worksheet #8.2: Protecting Data from Disclosure

Clarification of goals

- Make sure that design features intended to protect data do not interfere with the ability to meet policy goals (e.g. identification required for follow up of individual incidents and linkages to other databases).
- Examine how to balance your policy goals with the risks of releasing information.

Management checklist

- Identify peer review protections that may be necessary to encourage information sharing among providers without prohibiting the reporting system from obtaining necessary information.
- Evaluate the strength of existing data protections and peer review statutes to determine needed changes.

Resource checklist

- Identify the availability and resources of legal counsel.

Key question

What data protections will a state adopt and why? (See table on next page for detail.)

Other issues for consideration

Making the decision

Check all that apply

- De-identify data
- Collect anonymous data
- Protect data through confidentiality provisions
- Protect data through exemptions from public disclosure provisions
- Protect data through peer/quality review privileges and immunities
- Protect data through statute
- Protect data through regulation

Type of Protection	Pro	Con
De-identified or Anonymous Reporting	<p>Reduces need for legal protections by not collecting or maintaining identifying information</p> <p>May encourage reporting by minimizing threat of legal exposure</p> <p>Protects identifying information but not incidents</p>	<p>No follow up or institution-specific reports if reporting is anonymous</p> <p>Cannot hold facilities accountable through threat of exposure</p> <p>Does not provide consumers with information for making choices</p>
Confidentiality Provisions	<p>Designed specifically for reporting systems, so not susceptible to court interpretation</p> <p>May encourage reporting by minimizing threat of legal exposure</p>	<p>May not protect follow-up information</p>
Exemptions from Public Disclosure	<p>May strengthen confidentiality protections</p> <p>May strengthen peer review protections</p>	<p>Courts may limit application</p> <p>May not provide strong protection from the legal process</p> <p>May give state officials discretion to release exempted information</p>
Peer/quality Review Privileges and Immunities	<p>May provide strong legal protections for reports and reporters</p> <p>May be protected from varying court interpretations through clear legislative intent</p>	<p>May be subject to limited application</p> <p>Courts may exclude certain documents</p> <p>May not protect information produced by states</p>

8.3 Mechanisms to disclose information

- ▶ ***Will information be available on a request basis, through public reports, or both?***
 - ▶ ***Who handles the requests and decides how to provide information?***
 - ▶ ***How will potential users be informed of released data?***
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Information from mandatory reporting systems may be made available by request only or by issuing public reports. State investigations of individual incidents are available on request in most states. One state makes investigation reports available on the Internet. States generally limit publication of aggregate data, making them only available upon request, especially if facility identifiers are included. Requests are handled in accordance with state freedom of information or public disclosure statutes. States redact information that is not specific to the incident and patient identifiers. Many also redact identification of other individuals, such as providers and witnesses, as well as facility identifiers. (See Appendix A for state-specific provisions for public release of data upon request.)

Only a limited number of states routinely publish reports. States are cautiously approaching public reporting for fear of losing the ground they have gained in getting facilities to comply with reporting requirements. However, under pressure to publish, many states are looking to find reporting formats that are meaningful to consumers and providers alike. No ideal model or format exists for public reporting that provides useful information to consumers without creating misleading comparisons.

Examples from existing systems

- ▶ **Colorado** regularly posts summaries of all reported incidents by facility on the Internet. Hard copies are available upon request. Despite this ambitious effort, awareness of the summary reports is limited among those outside state government.
- ▶ **South Carolina** incident report information is available upon request. Names of patients are not available.
- ▶ All information in **Massachusetts'** reporting system, including formal narrative reports and deficiency statements, is available upon request. Patient identifiers are not available, but names of involved facility personnel and individuals interviewed during investigations are released. Annual reports are also available on a request basis. Requests are handled by the Public Information Office.

Worksheet #8.3: Disclosure Mechanisms

Clarification of goals

- Determine whether public reports are critical to policy goals.
If the goal is to provide users with information as a tool to hold facilities accountable, public reports may be useful. However, states may make a distinction between the public's right to know and the state's duty to tell.

Management checklist

- Evaluate the state's history and experience with publishing reported data and the lessons learned from those experiences.
- Identify specific identifiers or other information that must be released and/or protected according to freedom of information laws.
- Decide whether you will publicize the availability of data.
- Determine how to present data in a user-friendly manner.

Resource checklist

- Assess the resources needed to develop and distribute public reports.
- Assess resources necessary to respond to requests for information.

Key question

Will information be readily available through public reports or available only on request?

	Pro	Con
Disseminate Public Reports	Can preempt requests for information Can present the information consistently with analysis and interpretation May enhance public trust	Development and distribution may be costly
Make Information Available Upon Request	Eliminates need to develop special reports	Depending on requests received, may be more or less time intensive than public reports Limits the distribution of information

Other Issues for consideration _____

Making the decision

Check all that apply

- Make data available by request only.
Specify request format: _____
- Make data available by issuing public reports.

Notes

8.4 Type of information to be protected or disclosed

- ▶ ***Will information from individual incident reports be disclosed?***
 - ▶ ***If information about individual incidents is disclosed, at what point in the process should it be made available?***
 - ▶ ***Will aggregate data be disclosed?***
 - ▶ ***If aggregate data are disclosed, will facilities be named?***
 - ▶ ***What are potential uses of reporting system data?***
-

Although the IOM report recommends that information from mandatory reporting systems be publicly available, it does not provide specific recommendations about what information should be available, to whom, or how it should be accessed. It does suggest that the mere filing of a report should not, by itself, trigger release of information. It recommends that results of analyses of individual reports should be made available but should not be released until after an investigation has been completed to ensure that released information is accurate.³⁰

Several states provide information from individual incident reports to the public. All reporting systems reviewed during site visits protect patient specific information. Reporting system officials unanimously support protecting patient confidentiality. (See 2.3, Content of Reports and 5, How Will Information on Incident Reports Be Stored?)

Some states release aggregate data that does not identify the facilities or patients involved in the incidents (de-identified data). (See Appendix A for specific states.) Data elements may include the most common injuries, the average number of incidents per facility, or the total number of incidents reported.

States less commonly provide aggregate data that identifies incidents by facility name, in part because underreporting leads to incomplete data that could be misleading. However, some states have considered releasing information on the number, type, frequency, and causes of errors by facility. To do so requires risk adjustments for age, relative illness, and other complex factors so that users can interpret the data accurately. States continue to struggle with risk adjustment

³⁰ Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 1999): 87, 110.

methodologies that take into account relevant factors that may help explain the frequency of adverse events.

The decisions regarding release of data and the type of data to release are influenced by the quality of the data. If data are not validated or underreported, aggregate data may be harmful to consumers, facilities, and state agencies. Consumers may be misled or provided false assurances regarding the safety of care. Facilities may suffer from negative public relations. The effectiveness of state oversight may be questioned.

States may choose to change their approach to disclosure over time. Some may choose to release de-identified aggregate data in the early stages of the system's development and move toward facility-specific data as the system matures, reporting increases, and a risk-adjustment technique is identified.

Examples from existing systems

- ▶ ***Kansas*** prepares an annual report using aggregate data by facility size for the average number of incidents reviewed, the total number of reportable events, and the total number of reportable events reported to each professional board.
- ▶ In 2001, ***New York*** prepared its first annual report that identifies hospitals with reporting rates significantly below what is anticipated: www.health.state.ny.us/nysdoh/commish/2001/nyports/nyports.htm
- ▶ In ***Washington*** incident reports are disclosed.

Worksheet 8.4: Type of Information to be Protected or Disclosed

Clarification of goals

If the goal of the system is strictly to investigate and ensure corrective action for individual incidents, the availability of aggregate data may not be necessary. If you plan to release information, identify the purpose for doing so, and ensure that the type of information you plan to release is consistent with the purpose of disclosure.

Management checklist

- If aggregate data that identify facilities will be released, determine how the system will address issues of underreporting and ensure the integrity of the data.
- Consider how to present the data as a tool for improvement as opposed to blame.
- Determine whether patients and/or providers will be identifiable if small facilities report incidents.

Resource checklist

- Identify the availability and resources of legal counsel.

Key question

Who benefits from specific disclosure policies? (See table on next page for detail.)

Other issues for consideration

Making the decision

Check all that apply

- Protect patient identifiers
- Release analysis of incident reports
- Release aggregate data with facility identifiers
- Release aggregate data without facility identifiers

	Incident Reports	Aggregate Data with Facility identifiers	De-identified Aggregate Data
Consumers	learn about personal and family incidents	shop for facilities based on quality ensure state fulfills accountability function, <u>but</u> possibility of skewed and misleading data	ensure state fulfills accountability function <u>but</u> provides least detailed information
Reporting Facilities	learn how other facilities have managed similar situations	compare to others and identify gaps in performance identify facilities to learn from <u>but</u> unfair comparisons can lead to underreporting	learn for quality improvement may encourage reporting if facilities find data useful for quality improvement <u>but</u> patients and/or providers may be identifiable by small facility size
State Agencies	validate reports inform licensure surveys identify professionals below standards of care	purchase for quality identify facilities with certain types of problems <u>but</u> possibility of skewed and misleading data may raise questions as to whether government is doing its job	identify patterns and trends in errors <u>but</u> provide least detailed information may raise questions as to whether government is doing its job
Attorneys	use legal discovery to find evidence find new cases	prove a pattern within a facility identify trends to solicit clients through advertisements	identify trends to solicit clients through advertisements

Resources

- ▶ 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, March 2001).
- ▶ Jill Rosenthal, et al., *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives* (Portland, ME: National Academy for State Health Policy, 2001).
- ▶ Institute of Medicine. *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 1999).
- ▶ NYPORTS: The New York Patient Occurrence and Tracking System Annual Report 1999, (www.health.state.ny.us/nysdoh/commish/2001/nyports/nyports.htm).
- ▶ Appendix I, Overview of State Reporting System Legal Protections and Challenges
- ▶ Appendix A, Mandatory Reporting Systems in Site-Visited States

9. How Can States Learn from Patient Safety Data to Improve Quality?

9.1 Analyzing and using aggregate reporting data

- ▶ *How can states use incident reports for broader learning?*
 - ▶ *What are the impediments to analyzing and disseminating aggregate data?*
 - ▶ *How can states enhance their capacity to analyze reporting data?*
-

The discussion so far in this report has been on the state's role in collecting and responding to individual incidents. While the primary purpose of a mandatory reporting system is to hold a facility accountable for patient safety, reporting can serve a broader goal by sharing lessons learned so that all facilities and patients can benefit. Insufficient experience, resources, and expertise limit states in analyzing their data, tracking trends, and disseminating information. The lack of useful analysis and feedback to facilities on their performance and the sharing of best practices is the most commonly cited complaint about mandatory reporting systems.

Despite constraints, states are progressing in their efforts to use and share their data more effectively to improve collective knowledge and action.

- ▶ *Alerts and tips*
States send out alerts when incidents with significant consequences or in alarming numbers are received or when there is a potential to avert their recurrence elsewhere (e.g., storage of potassium chloride, use of blood-cell saver devices).
- ▶ *Showcase good practices*
Several states publish regular newsletters highlighting trends and describing practices in use to reduce repeat incidents that may have been reported.
- ▶ *Facility feedback*
Some states provide facilities with a comparison of their reporting experience with that of peer facilities or national standards.
- ▶ *Trend analyses*
Many states produce routine reports showing trends in reportable events, by size of facility and type of incident. These may be published in newsletters or shared with patient safety coalitions for establishing priorities and system-wide interventions. (See 9.2, Partnerships with Other State Quality Improvement Initiatives.)

States share common challenges in using reporting data to better understand what action can be taken to address system problems across facilities. These challenges include:

- ▶ ***Overcoming small numbers***
States, especially in the early stages of implementing mandatory reporting systems, indicate that they lack a sufficient number of incidents to produce reliable trend data. This problem may always plague small states and large states alike for certain types of incidents with low prevalence. The problem of small numbers is a strong argument in favor of developing regional or national repositories of data submitted under a state-based mandatory reporting system. The National Quality Forum, in recommending standardized definitions, recognized that single state data are not likely to be large enough to yield credible inferences. Unfortunately, few acknowledge the significant funds that would be needed to support such regional or national infrastructures.
- ▶ ***Enhancing analytic capacity***
No state agency is likely to have all the internal resources necessary to conduct rigorous analyses of reporting system data. Some states look to other state agencies or external contractors whose existing roles parallel closely those required to use patient safety data more effectively. The national system of Peer Review Organizations (PROs), state data repositories, and university-based health services research programs have significant experience in working with large health data bases, standardizing data, and adjusting for risk.
- ▶ ***Interpreting the data for clinical relevance***
Understanding what the data tell us about systemic problems and/or solutions requires clinical expertise and a consensus process. Most states lack clinical experts and credibility to fill this role on their own. The emergence of patient safety coalitions can provide an ideal forum to evaluate aggregate data and to determine how best the system can respond to future threats.

Examples from existing systems

- ▶ ***Colorado*** has established an Occurrence Advisory Committee, composed of providers, consumers, and state representatives, to assist the state in making better use of data that are reported.
- ▶ ***Kansas*** publishes newsletters highlighting trends and describing practices to reduce repeat incidents in those areas.
- ▶ ***Massachusetts*** provides data to the Massachusetts Coalition for the Prevention of Medical Errors to determine approaches for alerting and informing facilities about the risk of errors and practices for addressing identified problems.

Worksheet 9:1: Analyzing and Using Aggregate Reporting Data

Clarification of goals

A mandatory reporting system that looks to move beyond accountability into overall quality improvement faces issues of resources, commitment, and leadership. Reporting system officials have found that success in creating and sustaining quality improvement can only happen when they are part of a broader community of stakeholders. Patient safety is ultimately not a regulatory function but one that must be embraced by practitioners, purchasers, and patients alike. Coalitions also provide a credible authority for intervening in a non-punitive approach to identified problems.

Management checklist

- Identify or establish a committee to advise reporting system officials on content of routine aggregate reports and on dissemination strategy.
- Identify confidentiality restrictions on sharing or reporting data.

Resource checklist

- Identify analytic resources within the mandatory reporting system unit to conduct special reports and statistical tests for reliability.
- Assess the capacity of the mandatory reporting system database to generate routine reports for sharing with facilities and other stakeholders.

Key question

Will data analysis be conducted internally or by a contractor?

	Pro	Con
Internal Staffing	Control of product and timing	Reduces external buy-in Costly option for small programs
Contractor	Allows state to choose appropriate experts State can focus on program administration	Confidentiality considerations May reduce state control

Other issues for consideration

Making the decision

Check all that apply

- Develop internal analytic capacity.
Specify _____

- Contract with external contractors.
Specify _____

Notes

9.2 Partnerships with other state quality improvement initiatives

- ▶ ***How should mandatory reporting link to other state reporting systems?***
 - ▶ ***What other state-based patient safety initiatives augment mandatory reporting?***
 - ▶ ***How can mandatory reporting support consumer and provider patient safety initiatives?***
-

The IOM advocates for a multifaceted and comprehensive strategy to improve patient safety. The complexity of the problem demands that the different components of the health care system work together to better understand and reduce medical errors and adverse events. This section reviews other state-based or private patient safety activities and their relationship to the mandatory reporting system.

- ▶ ***Other state-based reporting systems***

Professional licensing boards protect the public through licensing and regulation of healthcare professionals. Through licensure of individual practitioners, boards ensure that providers have the appropriate education and training and that they comply with standards of professional conduct. Information to the contrary is furnished to the boards through complaints from consumers, malpractice data, information from healthcare organizations, and reports from government agencies. When a board receives information that might indicate a violation of professional standards, the board has the authority to investigate, hold hearings, and impose discipline. Some mandatory reporting officials refer to professional licensing boards any incident report on a medical error or adverse event that clearly demonstrates negligence on the part of an individual practitioner. Similarly, professional licensing boards may refer to a state's mandatory reporting system evidence that could suggest systemic problems in a facility.

Some states have specialized reporting systems that may duplicate or complement data submitted under mandatory reporting systems. These may include outcomes reporting on cardiac procedures, perinatal care, or transfusion/blood bank incidents. States have to individually negotiate whether or how to link findings from these reporting systems to any mandatory reporting system. (See 2.5, Linkages to Other Data Sets.)

▶ *Other state-based patient safety initiatives*

Coalitions are forming in many states to combine the knowledge and resources of various stakeholders in a coordinated approach to reduce medical errors. Often these are legislatively authorized and include representation from consumers, purchasers, providers, and regulators. They vary in degree of formality, governing structure, and diversity of membership but generally offer a forum for aggregate data collected through mandatory reporting systems to be reviewed and disseminated for system improvement.

▶ *Private patient safety initiatives*

Hospital associations have developed patient safety initiatives that include building overall awareness, prevention and assessment strategies, and participation in statewide patient safety partnerships. Consumers are gradually becoming more active and making their voice heard on state coalitions, in hearings on pending patient safety legislation, and in public advocacy roles to ensure patient rights and informed decision making. Purchaser alliances advocate that employers and employees use patient safety data as criteria in their healthcare purchasing and use patterns.

States alone play a leadership role in creating mandatory reporting systems and holding facilities accountable for taking appropriate action on identified problem areas. But states alone cannot create the learning environment that uses data to improve care. Such efforts require data to be shared with the many stakeholders that purchase, use, provide, and regulate health services delivery so that the clinical, cultural, legal, and resource barriers that cause adverse events and medical errors can be broken down.

Examples from existing systems

- ▶ The **Massachusetts** Board of Registration in Medicine is unique among boards in requiring that each healthcare facility have a functional patient care assessment (PCA) unit that is responsible for integrating the facility's quality assurance, risk management, peer review, utilization review, and credentialing activities. The PCA must submit quarterly reports to the Board on deaths and serious injuries that are not ordinarily expected, based on a the patient's presenting condition. The Board's PCA function and the state's mandatory reporting system collect information on similar types of events but differ in data protections, timeliness of reporting, and use of data.
- ▶ The **Pennsylvania** Patient Safety Collaborative, initiated and staffed by the state hospital association, was created to identify and correct the root causes of medical errors.
- ▶ The mission of the **New York** City-based Center for Medical Consumers is to promote safety, ensure quality, and cultivate informed decision-making. The Center has a history of working with the state on a number of programs, including the design and implementation of its mandatory reporting system. The director of the Center serves on the NYPORTS Statewide Council.

Worksheet #9.2: Partnerships with other state quality improvement initiatives

Clarification of goals

A broader quality improvement goal will require that reporting system officials reach out to other stakeholders in an effort to understand and act on patient safety data from multiple sources.

Management checklist

- Review state-based and other patient safety activities occurring in the state.
- Examine the relationship of these activities to the mandatory reporting requirements to determine whether they complement, compete or duplicate, or have no impact on each other.
- Identify opportunities for coordination or collaboration.

Resource checklist

- Assess how resources from other patient safety initiatives can aid in understanding and using data collected from the mandatory reporting system.
- Consider joint meetings, publications, legislative actions that maximize the use of existing resources.

Key question

What partnerships may be useful for focusing on quality improvement efforts?

	Pro	Con
Other State-based Reporting Systems	Specialized review and understanding of particular types of events.	Potential for duplicative reporting Sharing data may be complicated by different confidentiality provisions Provider confusion, frustration and burden
Private/public Patient Safety Initiatives	Increases awareness of patient safety issues Promotes external buy-in Opportunities for collaboration Enhances expertise and resources to address problems Can be considered "neutral" environment for action	Reduces state control of QI agenda Confidentiality considerations

Other issues for consideration

Making the decision

Check all that apply

- Carve-out duplicative reporting requirements from mandatory system.
Specify _____
- Share findings with other reporting systems.
Specify _____
- Develop collaborative patient safety activities.
Specify _____

Resources

- ▶ Jill Rosenthal et al., *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives* (Portland, ME: National Academy for State Health Policy, 2001).
- ▶ Massachusetts Coalition for the Prevention of Medical Errors, www.mhalink.org/mcpme_welcome.htm
- ▶ Institute of Medicine. *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 1999).
- ▶ Center for Medical Consumers, www.medicalconsumers.org/#Main_Index

CONCLUSION

States must make a number of decisions when designing mandatory reporting systems, many of which are driven by the intended goals of the system. The overriding purpose for establishing a mandatory reporting system is to hold healthcare facilities accountable for preventable adverse events. A secondary purpose may be to improve overall quality and patient safety throughout regulated facilities. As a result, mandatory reporting systems range from no-frills versions that are developed strictly to ensure that individual incidents are reported and corrected to systems that also provide quality improvement opportunities for a wide range of facilities.

Setting goals for the system will be influenced by political and environmental realities in the state, including legal authority to establish reporting requirements, political will, provider support, and the existence of other patient safety initiatives. States struggle to balance the legitimate interests of consumers who seek a public accounting of adverse events with concerns that the data generated by mandatory reporting systems will be used to punish rather than support facilities in their efforts to improve.

Subsequent decisions at each stage of system design are driven in part by the specific goals established for the system. A number of other factors influence decisions at each stage including management and resource considerations and the environment in which the system will operate. Decisions in one area often dictate options in another area. (See the decision tree at the end of this section.)

Despite room for variability, some clear recommendations emerge from reporting system officials:

- ▶ At a minimum, mandatory reporting systems should require reporting of adverse events that result in death and serious illness.
- ▶ Reportable events should be well defined and states should undertake efforts to help facilities understand the reporting requirements.
- ▶ Incident reports should include certain basic data elements necessary for holding facilities accountable (name of facility, type of incident, date of incident).
- ▶ Data should not be collected unless they will be used.
- ▶ State regulatory agencies must have access to the data to meet the goal of accountability.
- ▶ States should consider how they will ensure that corrective actions have been taken to prevent recurrences.
- ▶ States must develop systems to store and protect confidential data.

- ▶ States should develop policies for validating data and reviewing incident reports to determine which events require follow up or investigation.
- ▶ If data will be disclosed, states should consider how to present information in a format that is not misleading or punitive for facilities that comply with reporting requirements.

Appendix J provides summary sheets for states to use in documenting their own decisions with respect to each of the issues raised in this report.

Even with meticulous system design, unresolved implementation issues are likely to arise. Reporting system officials generally believe that events are underreported. Efforts to increase reporting levels may include involving providers in system design and providing meaningful feedback to facilities that report. Nevertheless, states must be cautious about compromising goals to meet provider demands, especially in the area of data protection and disclosure.

Decisions may not be cut and dry, and it may be necessary to reconsider decisions as the system matures, data become more reliable, and reporting system officials gain experience. As a result, states should consider how they will evaluate the system as it is being developed.

