Patient Safety and Medical Errors: A Road Map for State Action

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**EXECUTIVE SUMMARY**

Medical errors have been cited as the nation’s fourth leading cause of death, at a total cost of $29 billion annually. States, which are responsible for protecting the public’s health and safety, provide a laboratory for innovation to make the healthcare system safer. To do so requires state collaboration with providers, consumers, and purchasers; leadership to establish clear goals; understandable benchmarks to measure progress; and coordination across all agencies and members of state government to meet goals and strategies.

**The Road Map**

Many roads can lead to a safer healthcare system. To arrive there, however, all stakeholders need to agree on the destination and the best route to follow. State governments can substantially help chart the course through the commitment of executive and legislative branch officials.

**How can states estimate the size of the problem?**

State data agencies and purchasers have hospital discharge, claims, and other sources of data that can be used to help estimate how many reported deaths in the state are likely due to medical errors. By working with data agencies, hospitals and their associations, and researchers, states can identify mechanisms to estimate the number of medical errors. Although nearly one-third of the states now administer mandatory reporting programs for hospital adverse events, the Institute of Medicine recommends that all states do so.

**Who could be responsible for patient safety at the state level?**

Many agencies within state governments have a role in patient safety. Departments of health are charged with protecting public health; licensing and certification agencies and boards conduct oversight; Medicaid, state employee and retirement benefits plans, and others purchase health care; public health and mental health departments may directly provide care; data agencies collect information; and insurance departments oversee health insurance and health plans. In general, there is no vehicle around which to organize state activities on patient safety although at least one state has established a Center on Patient Safety to coordinate fragmented state activities. Other states have created task forces and commissions to craft coordinated strategies.
What can state governments do to improve patient safety?

This report provides a framework for state governments, in their various roles as purchasers, providers, regulators, educators, conveners, and policymakers, to use in their efforts to address patient safety and reduce medical errors. However, the report makes it clear that states cannot meet their responsibility to be accountable for public health and improve the safety of the healthcare system without recognizing the importance of collaboration with key stakeholders—providers, consumers, and purchasers—to create an environment that enhances safety. This report can be used to help state policy leaders establish plans throughout state government to meet that goal.
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WHY SHOULD STATES CARE ABOUT MEDICAL ERRORS?

Nationally, medical errors cause as many as 98,000 deaths in hospitals alone, at a total cost of up to $29 billion each year. Medical errors are estimated to be the fourth leading cause of death in the U.S., translating to 39 deaths per 100,000 people. More people die as a direct result of medical errors in a given year than die from motor vehicle accidents, breast cancer, or AIDS. If it were possible to count deaths due to medical errors occurring in such settings as ambulatory, long term, home health, retail pharmacy, and others, that number would likely be higher.

These shocking statistics, released last year by the **Institute of Medicine** in its report *To Err is Human*, provide a call to action. But who should answer the call? Responsibility for healthcare quality and patient safety is diffuse, spread across the federal government, state governments, and private and public providers. Moreover, the oversight that exists tends to focus more on assigning blame and punishment for individual behaviors and less on systems improvements. The Institute of Medicine makes it clear that solving the problem of medical errors requires a comprehensive, systematic approach, one that creates a culture of safety and continuous identification, understanding, and timely responses to problems in order to alleviate the conditions that create the opportunity for error and develop responses that improve patient safety. Finding fault and pointing fingers does nothing to solve the problem.

Within days after the release of the IoM report, President Clinton directed the **Quality Interagency Coordination Task Force** (QuIC) to “evaluate the recommendations in *To Err is Human* and respond with a strategy to identify prevalent threats to patient safety and reduce medical errors.” A comprehensive report on actions the federal government could take to address medical errors and patient safety was written, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and their Impact*. The President accepted the report, and implementation of the report’s recommendations began.

However, the federal government alone cannot solve the problem, particularly since the delivery of health care is largely a local issue. Through state licensure, states have more oversight authority over healthcare facilities and providers than the federal government does. States regulate private health insurance, purchase significant amounts of health care, and assume responsibility for protecting the public’s health and safety. However, most states have not yet fully embraced their responsibility to reduce medical errors and improve patient safety.

Patient safety, defined as freedom from accidental injury, is a hot topic. Regulators want to ensure that they have the information they need to monitor patient safety. Consumers want to know how to ensure that the care they receive, and where they receive it, is safe. Providers want information about best practices and technical assistance to help address the heightened expectations of consumers. Purchasers want information about the quality of care they purchase. The media wants information to
educate the public. There are examples of state leadership, including task forces, commissions, and centers for patient safety that have been formed to study and address the issue, and mandatory reporting of adverse events exists in some states. A meeting of state leaders on patient safety and medical errors suggested that states have a growing interest in patient safety, but there is confusion about how to proceed (Riley 2000).

This report provides state executive and legislative branch officials with a framework for considering how they might address medical errors and patient safety in their states. Modeled after the federal QuIC report, state officials can use it to develop their own state “QuIC-like” documents. Although errors that occur in ambulatory care settings will likely receive increased attention in the future, the examples that are included in this report focus on hospitals because more information is available for that setting; much of the information could be applied to other settings as well.

Each section of this report includes a narrative of the issues and a boxed list of questions and potential actions that might be helpful in your state. The boxes also include relevant resource materials. The potential actions suggested reflect both industry experience and recommendations from the Institute of Medicine. They are included as suggestions for states’ consideration and are not offered as best practices.

Throughout the body of the report, references are bolded. More information about these references is included in the resources list at the end of each section and in Appendices A and B.

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**Resources**


THE BASICS: WHAT, WHO, AND HOW?

What are errors and adverse events and why do they happen?

Medical errors may result in no harm, limited harm, serious injury, or death. The following terms are used in the Institute of Medicine report and throughout this paper:

- **adverse event**: an injury or death resulting from medical management, not the underlying condition of the patient.
- **medical error**: the failure of a planned action to be completed as intended, or use of the wrong plan to achieve an aim.
- **preventable adverse event**: an adverse event attributable to error.
- **patient safety**: freedom from accidental injury.

Some adverse events are unavoidable and others are the result of errors. Using an example from the Institute of Medicine report, if a patient has surgery and dies from post-operative pneumonia, an adverse event has occurred. Whether an error occurred during the event is often unknown until after the incident is investigated. If it is discovered that the patient developed pneumonia due to poor hand washing or poor instrument cleaning techniques by staff, the adverse event was preventable, and is classified as a medical error. If it is determined that the patient simply had a difficult surgery and recovery, but no error was committed, then the adverse event was unavoidable and not the result of error.

Not all medical errors result in harm. In the example above, if the staff used improper instrument cleaning techniques but caught the error before coming into contact with the patient, an error occurred, but since no injury resulted, the error did not lead to an adverse event. A medical error that causes no harm is sometimes referred to as a “near miss.”

The Institute of Medicine contends that most errors are not the result of bad or negligent providers but instead are a result of complex systems. However, the complexity of the problem cannot be used to excuse or ignore it. The Institute of Medicine proposed a solution that requires building safety into the healthcare system by focusing on ways to prevent errors rather than blaming individuals for past errors, while simultaneously holding individuals and facilities accountable for their actions.

Who should be at the table when states address medical errors and patient safety?

As referenced in the Institute of Medicine report, patient safety can be improved through internal changes within the healthcare system as well as through external changes, such as regulation and
legislative action, and through economic and other incentives or disincentives. Regulation and legislative action can serve as a call to action to healthcare organizations to improve quality and can provide public information about safety. Purchasers and consumers can use economic and other incentives to direct their business to organizations with the best safety records. Professional groups and providers set and follow norms and standards of practice. Thus, each party has a stake in patient safety and a role to play, and it will be helpful for state governments to recognize that.

State governments

State governments have a responsibility to protect public health and insure public safety. There are numerous actions state governments can take independently, as public agencies, and in partnership with providers, consumers, and purchasers.

Different strategies can be used to address different types of medical errors, and therefore, a wide array of state stakeholders should be involved. There is often no focal point for state efforts to address medical errors and patient safety. State responsibility for patient safety tends to be spread across an array of professional licensing boards, licensing and certification agencies, and other departments, often leading to a fragmented approach to the issue. Like the federal government response, a first step might be to convene all the state agencies that play a role in patient safety in order to develop a unified state approach. Table 1 lists some of the key state government players and primary responsibilities in addressing medical errors and patient safety. State governments are structured differently, but this matrix provides one way to initiate state-based discussion and examine which organizations play what roles in patient safety.
Table 1: Key state government players with a role in medical errors and patient safety

<table>
<thead>
<tr>
<th>Entity</th>
<th>Regulator</th>
<th>Provider</th>
<th>Purchaser</th>
<th>Educator/Data Provider</th>
<th>Convener</th>
<th>Policy Maker</th>
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<td>Licensure and certification agency</td>
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<td>Medicaid agency</td>
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<td>Public employee/retiree health plan purchasers</td>
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<td>Corrections department</td>
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<td>Mental health agency</td>
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<td>State universities/health professions schools</td>
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Private partners

States alone cannot fix medical errors and improve patient safety; healthcare facilities and those who deliver the care are in the front line as informed consumers, purchasers, and regulators demand improvement. Table 2 lists the key private stakeholders that could become involved in strategies to improve patient safety and reduce medical errors.
Table 2: Key private stakeholders with a role in improving patient safety and reducing medical errors

| Health providers and their associations (medicine, nursing, pharmacy, others) |
| Health facilities and their associations (hospitals, ambulatory care clinics, pharmacies, long-term care facilities) |
| Health plans, other health insurers, and their associations |
| Consumer advocates |
| Business coalitions |
| Trial attorneys |
| Health system researchers |
| Quality experts |
| Peer Review Organizations |
| Journalists |
| Hospitals’ and other non-profit health organizations’ boards of trustees |

The role of the legislature

The potential actions listed throughout this paper may be useful to policymakers, administrators, and providers alike. However, as mentioned above, some strategies may require statutory change, and others may rely on the oversight role of state legislators to commission studies and hold hearings. Responsibility for addressing medical errors and patient safety is scattered across a number of state agencies. Given the lack of a single authority responsible for patient safety, legislators may play a role in ensuring accountability of the executive branch in a fragmented system. Just as the Institute of Medicine recommended a national Center for Patient Safety to set national goals, track progress, develop knowledge and understanding of errors, and disseminate funding, such centers may also prove to be useful at the state level. Centers may fall under a larger umbrella agency responsible for quality, for example, the Center for Quality Improvement and Patient Safety, under the auspices of the Agency for Healthcare Research and Quality (AHRQ). Centralizing functions in this manner avoids adding another layer of bureaucracy.

At least 15 state legislatures introduced 45 pieces of legislation related to medical errors in early 2000 (Flowers et al. 2000). Legislative strategies to address medical errors fell into several categories, including increasing consumer confidence through public reporting systems, published report cards, or other mechanisms; conducting system-wide analysis; addressing the issue of insufficient nursing staff; tracking and reducing medication errors; and requiring training, quality assurance, quality improvement, and risk management programs. Three of the legislative approaches are described below. The
National Academy for State Health Policy (NASHP) will continue to track and disseminate information on state legislation that addresses patient safety.

The Center for Patient Safety in the New York State Department of Health was created by the legislature in 2000 to focus on issues of patient safety and medical errors. The center is responsible for improving the quality of health care by improving systems of data reporting, collection, analysis, and dissemination, and public access to information. The center will evaluate reporting requirements and develop legislative recommendations to consolidate and supplement data collection and eliminate duplicative and unnecessary reporting requirements.

The Florida Legislature established the Commission on Excellence in Health Care in 2000 to explore whether data collected through the hospital reporting system is the appropriate data to collect, how it should be used, and how to make sure information gets distributed in a useful manner. The commission is chaired by the secretaries of the Department of Health and the Agency for Health Care Administration and includes 42 members who have been appointed to represent professional associations and boards, health lawyers, medical schools, health insurance carriers, consumer advocates, and legislators.

The Washington State Department of Health is required to report to the legislature in 2001 with strategies to address medication errors. As a result, the state has initiated a task force to develop recommendations. The task force includes professional boards that represent providers with prescribing authority, state reporting system officials, and a legislative liaison.

Directing state government attention to medical errors raises issues about what information should be made public and what should remain confidential. To create a culture of trust that breeds improvement in patient safety, rather than blame, suggests that information be shared only within and among health providers and facilities. But to assure the public that there is external oversight and accountability suggests that some information should be widely available. What information to share, and when and how to share it, are key policy deliberations for legislators. As a result, legislators may want to review their state’s statutory legal protections for data. The legislature can play a role in balancing the interests of injured parties, for example, in accessing information about medical errors with providers’ interests in keeping that information confidential. Since peer review statutes that protect information from disclosure vary significantly across states, legislators may want to review their state’s peer review privilege to determine what information is protected from discovery and compare that to other states.

The following questions may prove useful for legislators as they assess whether to enact policy to address medical errors and patient safety. As reflected in the questions, states may want to consider the numerous approaches to improving patient safety before moving too quickly to legislative action.
What are the key questions for legislators to ask?

6 What legislative committee or committees have jurisdiction over medical errors and patient safety?

6 Does the legislature know about executive branch activities (as regulators, purchasers, and providers) aimed at improving patient safety? Who in the executive branch is responsible for reporting on executive branch initiatives?

6 Does the legislature know about and understand private initiatives underway in the state to address medical errors and patient safety?

6 What vehicle(s) exists in the state for all stakeholders to play a role in patient safety?

6 What measures exist to provide information to the legislature on the status of medical errors and patient safety over time?

6 What information should be publicly available, in what form, when, and for what purpose?

6 What does state law say about protection of data, including peer review privilege?

6 Do state licensing and credentialing laws assure sufficient accountability for safety?

6 What is known about malpractice and the impact of reporting on liability?

6 What legislation has been effective in other states?

6 What are the pros and cons of particular legislative efforts? Are the costs worth the benefits?

6 Will proposed strategies address legislative goals? How will progress toward meeting goals be measured?

The New York Center for Patient Safety website is currently under development.


HOW BIG IS THE PROBLEM IN MY STATE?

When key players convene, they will most likely want to set goals for improving patient safety.

Where can you start?

6 How safe is the healthcare system currently?
6 What can we realistically expect to achieve?
6 What methods work?

The first step will be to find out what data exist in the state and how they are used to set goals, measure progress, and decide which agencies should be involved at the state level. Although medical errors occur in all settings, the information presented in this report focuses on hospitals since most studies have focused on the hospital setting and more information is available on it as a result.

There are no easy answers to the questions posed above nor agreed-upon methods to assess patient safety and make improvements. There are no definitive data to determine the scope of the problem in each state because no nationwide reporting system exists to collect data about medical errors. About one-third of the states have adverse event reporting systems. Even with a reporting system, establishing a baseline can be difficult because if the system is successful, the number of reports should increase in the short term as the reporters of the adverse events come into compliance. Given the limits of the data, some states may want better data before launching patient safety efforts. However, even though state data about medical errors may not be readily available, there may be data sources that provide some indication of the extent of the problem.
How can you begin to determine the size of the problem?

6 Explore what data sources are currently available in your state, how they are being used, and the potential for using them to assess medical errors and patient safety issues. Data may be housed in a variety of state or private agencies. Most likely, the data will not be categorized as medical errors data, but several proxies exist for states to consider, as described in the following section.

What types of data may help in documenting the problem?

Extrapolating data from the Institute of Medicine report

Background: In two large samples of hospital admissions data referred to in the Institute of Medicine study, the percentage of hospital admissions with documented adverse events, defined as injuries caused by medical mismanagement, was 2.9 and 3.7, respectively. In the first of these studies (the most extensive study ever done of adverse events), data from more than 30,000 randomly selected 1984 discharges from 51 randomly selected hospitals in New York State were examined. A 1992 study of adverse events in Colorado and Utah, which used data from a random sample of 15,000 discharges from a representative sample of the hospitals in the two states, had similar findings. The proportion of adverse events attributable to error (preventable adverse events) was 58 percent in New York and 53 percent in Colorado and Utah. In New York hospitals, 13.6 percent of preventable adverse events led to death; in Colorado and Utah hospitals, 8.8 percent led to death. The Institute of Medicine extrapolated the number of preventable adverse events nationwide based on each study, arriving at an estimate of 44,000 to 98,000 deaths in hospitals each year as a result of medical errors. States can use these same studies to develop a state-based extrapolation.

While some researchers (McDonald et al. 2000) claim that the Institute of Medicine report exaggerated the number of errors, the Institute of Medicine considers the numbers conservative. The criticism suggests that the original studies upon which the Institute of Medicine report relied did not include information about the baseline risk of death, making it impossible to determine whether adverse events caused death. The rebuttal (Leape 2000), while recognizing limitations in the study methodology, clarifies the issue by stating that the original research did, in fact, take into account patients’ underlying risk of death and that the total number of errors was likely underestimated, for several reasons: 1) although it is unlikely that the reviewers found adverse events that did not exist, they probably missed some that did occur because the errors were not recorded in medical records; 2) the
study looked only at hospital patients, although more than half of all surgeries now occur on an outpatient basis; and 3) evidence suggests that record-review studies seriously underestimate the extent of medical injury.

*Keep in mind:* While an extrapolation provides a starting point, it will be a only a rough estimate that is most likely an underestimate of the real number of deaths due to medical errors, based on the reasons stated.

**How can you get a snapshot of the size of the problem in your state?**

6 Identify the number of annual admissions to general and acute care hospitals in the state and extrapolate to get an estimate for

- the number of adverse events statewide (2.9 to 3.7 percent, according to the New York and Colorado studies);
- the number of preventable adverse events (53 to 58 percent of adverse events, according to the New York and Colorado studies); and
- the number of preventable adverse events resulting in death (8.8 to 13.6 percent of preventable adverse events, according to the New York and Colorado studies).
The following is the state extrapolation for Maine, using hospital inpatient discharge data for 1999, provided as an example:

```
Maine hospital discharges for 1999: 158,294 *

! The estimated number of adverse events would be 4,590 to 5,857 per year.

    158,294 x 0.029 = 4,590 lower estimate
    158,294 x 0.037 = 5,857 upper estimate

! The estimated number of preventable adverse events would be 2,433 to 3,397 per year.

    4,590 x 0.53 = 2,433 lower estimate
    5,857 x 0.58 = 3,397 upper estimate

! The estimated number of preventable adverse events that result in death would be 214 to 462 per year.

    2,433 x 0.088 = 214
    3,397 x 0.136 = 462

* Maine hospital discharge data are available at www.healthweb.state.me.us.
```

Even without access to hospital discharge data, states can extrapolate to get the estimated number of adverse events. The following example from Alabama was completed using state population data and using the high estimate of 98,000 deaths annually.
State-based extrapolation without hospital discharge data

| ALABAMA |
|-----------------|--------|
| U.S. annual deaths as a result of medical errors: | 98,000 |
| U.S. population: | 250,000,000 |
| Annual deaths as a result of errors per 100,000 population: | 39 |
| (98,000 x 100,000 / 250,000,000) |
| Alabama’s population: | 4,181,866 |
| Alabama annual deaths as a result of medical errors: | 1,630 |
| (4,181,866 x 39/ 100,000) |

Hospital discharge data and E-codes

Background: Since the late 1980s, some states have collected statewide hospital discharge data with external cause of injury codes to set priorities and assess the effectiveness of injury prevention activities. The International Classification of Disease, Injuries, and Causes of Death, 9th Revision, Clinical Modification (ICD-9-CM) classifies all medical conditions using a series of numerical codes. A subset of conditions has additional codes, known as E-codes, that describe the possible external cause of the injury. Some E-codes capture factors directly related to the medical management of patients, called medical misadventures. For example, the code for a foreign object left in the body during a procedure (E871) is generally considered to represent a medical error.

According to an American Public Health Association report, 42 states and the District of Columbia currently have statewide hospital discharge data systems in place; 36 of these routinely collect some level of E-codes. Twenty-three of the 36 states have mandated E-coding; however, due to pressure from hospitals that sought to avoid a mandate on some codes, some states specifically exclude from the E-code requirement the categories of codes (E870-E879) that are most relevant to the tracking of adverse events and medical errors.

Access to data may depend on whether the data system is maintained by a public agency or is proprietary. Sixteen of the 42 states with hospital discharge data systems maintain the systems at state health departments. Another 11 states and the District of Columbia base their hospital discharge data systems in their state hospital associations, and the remainder are at various other entities. Those states with mandated E-coding are more likely to base the data systems at state health departments. Eighteen of the 36 states that routinely collect E-codes also publish reports of E-coded data.
Table 3 lists the states that have hospital discharge data systems, where the systems are housed, and whether the systems routinely include E-code data.

**Table 3: States that have hospital discharge data systems**

<table>
<thead>
<tr>
<th>States that have hospital discharge data systems</th>
<th>Where data systems are housed</th>
<th>E-codes routinely collected</th>
<th>States that have hospital discharge data systems</th>
<th>Where data systems are housed</th>
<th>E-codes routinely collected</th>
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Keep in mind: The use of E-codes to assess medical errors has its drawbacks, including chronic under-reporting of E-codes on hospital claim forms and the lack of access to hospital discharge data in some states. Since E-codes were not designed to capture errors, some E-codes may not be specific enough to indicate whether the injury was the result of an error. For example, some E-codes, such as the code for medication overdose, could be reporting an intentional act by a patient or could be reporting a medical error, but the codes are not precise enough to arrive at one (correct) conclusion. The timeliness of availability of hospital data, running as much as three years behind schedule in some states, restricts how useful the data might be in providing real-time correlation. Nevertheless, for states that collect the data, examining those codes that most closely correlate with errors may be a useful start and provide at least a minimal snapshot of potential problems.

Another potential source for hospital discharge data is The Healthcare Cost and Utilization Project (HCUP), a federal-state-industry partnership to build a standardized, multi-state health data system. HCUP is maintained by AHRQ and managed in the Center for Organization and Delivery Studies. HCUP’s all-payer databases currently provide data for 1988-97, and data for 1998-99 are currently being processed. HCUP databases contain discharge information compiled in a uniform format with privacy protections in place; no individual identifiers or dates are released. The Nationwide Inpatient Sample (NIS) is based on State Inpatient Databases (SID) and includes inpatient data from over 1,000 hospitals to approximate a 20% sample of U.S. hospitals. The State Ambulatory Surgery Databases (SASD), the project’s newest restricted-access public release, contain data from ambulatory care encounters in nine states. The State Inpatient Databases cover inpatient care in community hospitals in 22 states that represent more than half of all U.S. hospital discharges. SID data for 2000 will include up to 31 states. Of the 22 states that currently participate, 15 allow HCUP to release their data. SID data reflect state hospital discharge data that HCUP converts to a uniform format, which is especially useful if you are interested in comparing your data to that of other states.
What can you learn from hospital discharge data?

6 Is there a state health data agency that collects and analyzes hospital discharge data? Does the data include E-codes? If so, what specifically is required and how are the data analyzed?

6 If the state collects E-codes, does the state have the authority to audit medical records to verify E-code reporting? If so, are audits conducted?

6 What steps could be taken to improve the data, such as requiring relevant E-codes through state law or mandates if not currently required?

6 Does the state participate in the HCUP project? If so, what data are available?

Claims data

Background: State purchasers may have claims data that can be used to get a sense of the number of medical errors occurring in the populations they cover. Claims data will be similar to hospital discharge data but will be available for ambulatory care settings as well as hospital inpatient settings. This data source may be most helpful to state agencies that do not have access to hospital discharge data. Medicaid agencies or state employee purchasing agencies may require contracted health plans to track sentinel events in hospitals with which the health plans contract.

Keep in mind: Claims data may not include the clinical detail found in discharge data. Some purchasers may be reluctant to provide claims data. Claims data need to be sorted and combined so that multiple claims for the same patient are not overcounted. Some claims data are hidden within managed care data; if reimbursement is made on a per member per month basis, the actual service provided may not be evident from the claims information. Although data will only be available on the populations covered under that plan, it is a starting point for building a state estimate.
What can you learn from claims data?

6 What claims information is available from state purchasers?

Malpractice data

Background: According to the **Kansas Health Care Stabilization Fund**, which has tracked state funds, nine states have medical professional liability coverage funds to pay for judgments, awards, or settlements in medical malpractice claims that exceed the basic limits of coverage provided in professional liability insurance policies. These funds, often called healthcare stabilization funds or patient compensation funds, were generally established during malpractice crises to provide a source of insurance for providers when insurers were leaving the market. Certain providers, which vary from state to state, are required by law to pay into these funds. Claims submitted can be considered to be alleged medical errors although funds may settle cases with provider consent even when the incident is determined to be unavoidable. The agencies that administer these funds compile information regarding alleged medical errors in preparation for defending against potential litigation. Aggregate data may be useful in assessing the types of medical errors and their causes, depending on how the data are categorized, stored, and retrieved. Some liability coverage funds will be able to analyze data by type of injury and setting in which it occurs, among other variables.

*Keep in mind:* All medical errors do not result in malpractice cases, and not all malpractice cases are due to medical errors. Liability coverage funds vary in the amount of coverage provided, who is required to participate, and the minimal amount that triggers involvement of the fund. For example, the Kansas Health Care Stabilization Fund provides coverage only for claims that are greater than $200,000, and only physicians and hospitals are covered. The number of cases on which the funds have data depends on these factors. Confidentiality provisions vary from state to state. Since funds were not established to collect patient safety data, some will not collect this type of information. Some states may be able to provide aggregate data that may be more useful for research purposes than for estimates of medical errors. The funds will have information only about those errors that result in malpractice cases.

The advantage of having such a fund for collecting information is that it provides one source from which to gather information. The same information is collected by private insurance companies. If private insurance companies are required by state law to report to state insurance departments, the data may be available there as well and would include information on cases that did not trigger coverage from the fund.
What can you learn from malpractice data?

6 Does your state operate a medical professional liability coverage fund? If so, what information can the fund provide about types and settings of injuries that may be useful in assessing medical errors?

6 What can the department of insurance tell you about the type of malpractice data that are available in your state and what do/don’t the data tell you?

Complaints

Background: The Health Care Financing Administration (HCFA) contracts with states to conduct a number of activities related to hospital oversight on behalf of the federal government. According to the HCFA contract, state agencies are the front-line responders to complaints and to major adverse events in hospitals. HCFA requires that certain steps be taken and certain information be collected each time there is an allegation of improper care or treatment against a Medicare or Medicaid certified facility. Some states rely on complaints to provide information about potential quality problems and to review hospital risk management programs. Those states that deem Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation and do not conduct separate state licensure surveys may be especially reliant on information gathered through complaints. The results of state agency investigations, which are based on the Medicare conditions of participation, are available to the public.

Keep in mind: The number of complaints that are registered does not necessarily correlate to the number of errors that have occurred. Some complaints are not due to errors, and not all errors result in complaints. Also, the number of complaints may be partly a result of how well the public is informed about how to file a complaint and how serious the errors or its consequences are.
What can you learn from complaint information?

6 How does the state facility licensure and certification agency handle complaints? Can the agency provide information on the number and types of complaints received?

Death Certificates

*Background:* All death certificates are sent to the state medical examiner’s office for coding using ICD-10 codes. Medical errors may be coded using the medical misadventure codes. Autopsies are performed in certain situations, for example, if the cause of death is suspicious, as regulated by state law. Many states sort death records into categories such as natural, accidental, or violent deaths. Some states are considering adding a category for medical misadventure. The state medical examiner’s office or office of vital statistics may be able to provide aggregate data on death certificates that may indicate a medical error. Death certificate data are likely to be more useful than autopsy data in assessing medical errors since all deaths will be included in the database.

*Keep in mind:* Medical errors on death certificates are most likely under-reported, as they are not required to be reported. Certain types of medical errors may not be reported as such; for example, medication errors may be reported under the category for poisonings. Death certificate data do not always correctly identify the cause of death and the limitations of E-codes apply to death certificate coding as well. Medical examiners may miss some cases when they interpret information from the death certificate for coding.

What can you learn from death certificates and autopsies?

6 How does the state analyze death certificates and autopsy data? Can the medical examiner’s office or vital statistics agency provide information on the number and types of errors reported on death certificates?
State adverse event reporting systems

Background: State adverse event reporting systems are usually mandatory reporting systems that require certain facilities to report a defined set of events to licensure and certification agencies within a specified time period after the events occur. The state reviews, responds to, and follows up on the reports with on-site investigations and plans of correction, if deemed necessary. Some states are using the incident reports to share information with other state agencies, track trends within and across hospitals, produce feedback for hospitals, and provide information to the public (Rosenthal et al. 2001).

States that require reporting of adverse events, as defined by the Institute of Medicine or by the state in a way that encompasses part or all of the Institute of Medicine definition, from general and acute care hospitals are listed in Table 4 (Rosenthal et al. 2000). Others states are considering developing reporting programs. Check with the state facility licensure and certification agency to determine whether a program is being developed in your state and what kind of data are or will be collected and made available.

Table 4: States with mandatory reporting by hospitals of medical errors and/or adverse events

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*a Nebraska requires reporting of payment due to acts or omissions of a healthcare professional.

*b Ohio does not license hospitals and, as a result, does not have specific reporting requirements for hospitals. However, the state requires reporting of clinical outcomes for nine specific services that are generally provided by hospitals.

*c Tennessee requires reporting of incidents and accidents of an unusual nature, including, but not limited to, fires, burning, suspected abuse, or accidents that cause injury to patients. Incidents are currently being further defined.

*d Texas requires reporting of abuse and neglect.

Keep in mind: The definitions and types of adverse events that must be reported vary significantly
across states. Some states do not analyze the data to determine whether medical errors were involved; some limit the data to cases of abuse and neglect or collect data only about specific procedures, which may be less useful for assessing medical errors. Under-reporting is considered a problem in most states. Mandatory reporting systems, as recommended by the Institute of Medicine, collect data on a limited set of adverse events that cause death or serious harm. Such a system may prove useful in gathering information and providing a minimal level of accountability but will not provide information on errors that cause minimal or no harm.

**Does your state have a mandatory reporting system?**

6. Does your state have a mandatory reporting program for adverse events? What information is available from the program?

**What if I can’t find any relevant data?**

The sources listed above provide multiple mechanisms to begin to assess the extent of the medical error problem. Even though the estimates cannot be combined and only provide a relative sense of the problem, using multiple assessment methods will help define the scope of the problem.

If you investigate data sources and identify data gaps that exist, you may want to consider opportunities to improve adverse event and medical error data. One opportunity would be to design a mandatory reporting system, as recommended by the Institute of Medicine. See the section titled “Regulating healthcare facilities,” later in this report, for more details.

There are large gaps in information about medical errors and ways to reduce the risk of their occurrence, and a great deal of research is underway on the topic. However, lack of data need not hinder initial efforts to address medical errors and patient safety. It is clear that a sizable problem exists, and even without completely accurate estimates, states can move forward on some initiatives that will likely improve patient safety. Many patient safety proponents point out that all of the workable strategies that we know are effective have yet to be put into practice. The following chapter describes some industry experiences and suggestions from the Institute of Medicine report and provides ideas for moving forward that states can consider in their roles as purchasers, providers, regulators, educators, and conveners.
Resources


Clement J. McDonald, MD; Michael Weiner, MD, MPH; and Siu L. Hui, PhD, “Deaths Due to Medical Errors are Exaggerated in Institute of Medicine Report,” *Journal of the American Medical Association* 284, no. 1 (July 5, 2000).

Lucian L. Leape, MD, “Institute of Medicine Medical Error Figures are not Exaggerated,” *Journal of the American Medical Association* 284, no. 1 (July 5, 2000).

American Public Health Association, Data Committee, Injury Control and Emergency Health Services Section, *How States are Collecting and Using Cause of Injury Data* (September 1998).


Kansas Health Care Stabilization Fund, information on state medical professional liability coverage funds, www.hcsf.org/jan01page.htm.


WHAT CAN STATES DO?

States as PURCHASERS: Are you getting the most for your dollars?

States purchase health care for a sizable share of the market through programs such as Medicaid, which covers one in ten Americans; state employee, retiree, and university system health plans; the State Children’s Health Insurance Program (SCHIP); and other state programs for uninsured and vulnerable populations, including individuals with mental health and developmental disabilities and those who are incarcerated. State purchasers have the potential to improve quality of care through purchasing strategies while at the same time reducing the financial cost of errors.

The state of Minnesota used the Institute of Medicine report to extrapolate state costs that resulted from medical errors and potential savings that could be realized by reducing such errors. Minnesota’s extrapolation of costs is based on data from the Minnesota Department of Human Services, HCFA, and a group purchaser.
MINNESOTA

Total spending for direct health care in the state of Minnesota equals $17,259,371,000 per year. The current expenditure borne directly by the state for direct health care is $1,903,300,000 annually (1998 data).

Nearly two billion dollars spent by the state on health care can be broken down in the following way: $163,400,000 by the state as an employer, $47,700,000 by the University of Minnesota as an employer, $1,467,000,000 for Medicaid, $91,200,000 for MNCare, and $134,000,000 for GAMC (General Assistance Medical Care). This represents approximately 11 percent of total healthcare expenditures in the state.

Extrapolating from the cost estimates in the Institute of Medicine report, the cost of medical error in the state of Minnesota is calculated to be $153,829,648 per year. The cost borne directly by the state is roughly 11 percent of this, or $16,963,768 annually.

The Institute of Medicine report estimates that each year, $8.8 billion is spent nationally on direct healthcare costs as a result of medical error. Extrapolating from the United States population to Minnesota’s population, Minnesota’s share of this cost is approximately $153,829,648.* Based on state expenditures of $1,903,300,000 and total healthcare expenditures in the state of $17,259,371,000, as noted above, the state spends approximately $16,963,768 per year on healthcare costs resulting from medical error.

The QuIC report recommends striving to achieve a reduction in medical errors of 50 percent over the next five years. Assuming a ten percent reduction in medical errors per year for five years and a commensurate ten percent decrease in associated costs, projected cost savings to the state of Minnesota amount to $6,946,833 over five years.

* Minnesota calculated its costs using the US population of 270,299,000. The calculation is as follows: 8.8 billion dollars x 4,725,000 (MN population) / 270,299,000 (US population) = $153,829,648. To get the most recent census figures for the US and states, go to www.quickfacts.census.gov.

State purchasers may be able to use claims data to get a sense of the extent of the medical errors problem (see section titled “Claims data,” earlier in this report).

A state’s leverage as a purchaser depends partly on how good a payer it is. If the state has low reimbursement rates and adds contracting demands, providers may leave the state programs. As a result, states may want to join forces with other purchasers to increase their leverage. As a first step, agencies may want to review the contract expectations and performance measures each imposes on providers. By consolidating and coordinating requirements, the state can speak with one voice for patient safety and reduce conflicting or duplicative requirements placed upon providers.

Private purchasers are becoming increasingly interested in patient safety issues and may provide opportunities for collaboration and examples of ways in which public purchasers can use economic incentives to improve patient safety. General Motors, a leader in the private market in considering
ways to focus purchasing on patient safety issues, used the Institute of Medicine report to personalize the issue of medical errors by examining the impact of errors on the company (Bradley 2000).

Impact of medical errors on a private purchaser

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<td>U.S. annual deaths as a result of medical errors:</td>
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<td>U.S. population:</td>
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<td>Annual deaths as a result of errors per 100,000 population:</td>
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<td>(98,000 x 100,000 / 250,000,000)</td>
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<tr>
<td>General Motors annual deaths as a result of medical errors:</td>
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<td>(39 x 1,251,282 / 100,000)</td>
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<td>General Motors deaths as a result of medical errors per day:</td>
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<td>(488 / 365)</td>
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The Pittsburgh Regional Healthcare Initiative, under the leadership of the Jewish Healthcare Foundation, is a coalition of civic, corporate, and healthcare leaders who joined forces with major stakeholder groups to improve quality and outcomes of care. The Initiative is focusing on eliminating medication errors and hospital-acquired infections by challenging area hospitals to take certain actions to improve patient safety, such as collecting and sharing data, on a community-wide basis, on medication errors and nosocomial infections.

Over the past three years, a group of coalitions that belong to the National Business Coalition on Health (NBCH), known as the V8, has been working to develop common health plan specifications. Through the use of the standardized NBCH Request for Information (RFI), project participants seek to lessen the response burden of health plans; provide a single, consistent set of specifications to improve performance on specified measures; and permit the compilation and analysis of comparable health plan performance information so that best practices can be identified. Business coalitions interested in using the RFI can complete the Participation Agreement form and access the RFI Toolkit on NBCH’s website, www.nbch.org.

The Leapfrog Group is an initiative of Fortune 500 companies and other large healthcare purchasers to mobilize employer purchasing power to create breakthrough improvements in the safety and overall value of health care. Three state agencies, the Maine State Employee Health Plan, The Commonwealth
of Massachusetts Group Insurance Commission, and the Washington State Health Care Authority, have joined the group. The Minnesota departments of Human Services and Employee Relations participate as liaisons. The Leapfrog Group aims to alert the healthcare industry that big leaps in patient safety and customer value will be recognized and rewarded. The group developed a set of purchasing principles that include using a comparative rating process, applying substantial incentives to reward delivery systems with higher value ratings, and focusing on delivery system improvements that are likely to yield the largest safety “leaps.” Initially, Leapfrog will promote the use of three methods, which research indicates will lead to a significant reduction in avoidable danger, to improve patient safety:

![Computerized physician order entry (CPOE) systems: Certain types of computerized prescription systems have been shown to reduce serious prescribing errors.](image)

![Evidence-based hospital referrals: Referrals to institutions with extensive experience treating certain conditions offer the best survival odds.](image)

![ICU physician staffing: Hospital intensive care units should be managed by physicians certified (or eligible for certification) in critical care medicine.](image)

Although the Leapfrog Group based its recommendations on evidence, there is some skepticism among policy leaders about whether these strategies will be successful and controversy about whether the evidence is substantial enough. The Leapfrog imperative may be problematic for some hospitals because implementation of CPOE is expensive and has raised technology-based, logistical problems. For example, some hospitals have had problems with software vendors that have delayed implementation. Some question whether there are enough critical-care certified physicians to implement the third recommendation. AHRQ has contracted with the Center for Primary Care and Outcomes Research, which is in the process of gathering the literature on this issue and a number of other areas in order to issue a compendium that documents the evidence to support each method. The Institute for Safe Medication Practices (ISMP) is involved in several initiatives to evaluate CPOE systems, including a project with First Consulting Group to identify safety features and test criteria for CPOE systems. The project results are targeted to be available by summer on the Leapfrog Group’s website, www.leapfroggroup.org.

The Leapfrog Group plans to support a series of “regional roll-outs” over the next couple of years. The roll-outs will be led by healthcare purchasers in seven healthcare markets where there is significant Leapfrog purchaser participation and where market characteristics are favorable for transitioning Leapfrog from a purchaser-driven movement to a community-wide collaboration. Purchasers, hospitals, health plans, physicians, unions, consumer groups, and others will be invited to participate. The regional “lead frogs” are Michigan General Motors, Minneapolis Buyers Health Care Action Group (BHCAG), California Pacific Business Group on Health (PBGH), Seattle/Tacoma Boeing, Atlanta Georgia Health Care Leadership Council, Knoxville/Chattanooga HealthCare21 Business Coalition, and St. Louis Gateway Purchasers for
Health.
What are key questions for states as purchasers?

6 Can the state extrapolate from the Institute of Medicine report to project possible cost savings of reducing medical errors?

6 Have all state purchasers analyzed and compared claims data to see if they can learn anything about patient safety issues? Have they analyzed requirements on providers to improve patient safety?

6 Have state purchasers provided information to employees and beneficiaries about quality and safety issues to aid those employees in making informed choices in the selection of healthcare coverage?

6 Are patient safety issues considered in contracting decisions? Are there ways to provide incentives to healthcare organizations that demonstrate continuous improvements in patient safety?

6 Are there joint purchasing agreements among state agencies that provide the state with more leverage to force quality improvements?

6 Are state-contracted health plans required to track sentinel events that occur in those hospitals with which it contracts? If so, is there a uniform set of specifications that define sentinel events so they can be analyzed? Are health plans encouraged to feed the information back to providers to supply them with comparison data and to drive quality improvements?

6 Do state purchasers communicate concerns about patient safety issues to accrediting bodies to support stronger oversight?

6 Can state purchasers create awards for safety leaders and champions?

6 Have state purchasers reviewed the Leapfrog Group’s principles and considered joining? Will there be a Leapfrog regional roll-out?
in your region?
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<tr>
<td>Pittsburgh Regional Healthcare Initiative, website under development.</td>
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<tr>
<td>The Leapfrog Group, <a href="http://www.leapfroggroup.org/about2.htm">www.leapfroggroup.org/about2.htm</a>.</td>
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States as PROVIDERS: Are YOUR healthcare facilities as safe as they can be?

States provide health care in a variety of settings, including publicly owned and funded hospitals, health clinics, and prisons. The state is responsible for quality and patient safety as a provider of care delivered in these settings. States can improve their own patient safety programs and use their leverage to help those facilities that they regulate and fund.

The Institute of Medicine made several recommendations to create safety systems in healthcare organizations. These recommendations apply to both private and public providers and include making continuously improving patient safety a serious goal by establishing patient safety programs with defined executive responsibility. According to the Institute of Medicine, patient safety programs should provide strong, clear, and visible attention to safety; include nonpunitive systems for reporting and analyzing errors within organizations; incorporate well-understood safety principles, such as standardizing and simplifying equipment, supplies, and processes; and establish interdisciplinary team training programs such as simulations that incorporate proven methods of team management. A meaningful safety program should include senior-level leadership; defined program objectives, plans, personnel, and budget; and monitoring through regular progress reports to the executive committee and board of directors. Healthcare facilities should develop a culture of safety by focusing on systems improvements, as opposed to finding and attaching blame to individuals. As an example, the QuIC report indicates that the Department of Veterans Affairs has implemented these recommendations by increasing the number of hours of training that focus on patient safety, implementing patient safety awards programs, and posting patient safety checklists in operating rooms. The National Quality Forum (NQF), a private organization that establishes standard quality measurement tools to help purchasers, providers, and consumers evaluate the quality of services, plans to identify a set of patient safety practices critical to the prevention of medical errors.

Improving patient safety is likely to require initial investments of time and funding to implement state-of-the-art medical errors reduction strategies, but these strategies can lead to savings in the long term. A look at adverse drug events (ADEs), defined as an injury resulting from medical intervention related to a drug, provides an example of potential safety improvements and cost savings.

ADEs are one of the most common types of adverse events that occur in hospitals, and one-third to one-half are due to errors (Leape 2000). The Institute of Medicine notes that for every dollar spent on ambulatory medications, it is estimated that another dollar is spent to treat new health problems caused by medications.

Patients who experience ADEs have longer, more expensive hospitalizations than patients who do not suffer ADEs. Hospitals are likely to absorb the extra expenses related to ADEs. One study referenced in the Institute of Medicine report found that preventable ADEs result in an average increased length of hospital stay of 4.6 days and an average increased hospital cost of nearly $4,700 per admission.
Research shows that computerized systems can prevent a large number of medication errors. CPOE systems, which eliminate handwriting and transcription errors and enable automatic checking of doses, dose-dose interactions, allergies, and patient characteristics such as age, weight, underlying condition, and renal function, can decrease serious errors.

According to a report by the National Coalition on Health Care and the Institute for Healthcare Improvement, the most expensive system to allow doctors to write orders at computer terminals may require an initial investment of $2-$3 million, but such a system has been proven to reduce medication errors by 50-80 percent within 1-2 years, meaning hospitals should quickly recover their investments. For example, Brigham and Women’s Hospital launched an inpatient computerized physician order-entry system in 1993. It is estimated to have saved the 726-bed hospital between $5 million and $10 million and reduced medication errors by 55 percent.
What the key questions for states as providers?

6 Have internal policies and procedures for reporting and investigating errors been reviewed and internal nonpunitive reporting systems been implemented? Have providers been educated about how and what to report? Is information about incidents that occur within the institution reviewed regularly to identify opportunities for improvement?

6 Do facilities have senior management teams that review patient safety recommendations and track progress in implementing changes?

6 Have proven medication safety practices been implemented and staff educated about up-to-date medication information? Consult the Food and Drug Administration and ISMP’s Medication Safety Self Assessment.

6 Has team training been implemented?

6 Is reporting of serious adverse drug reactions to FDA’s MedWatch program or U.S. Pharmacopeia’s (USP) Medication Errors Reporting Program (MER) encouraged? MedWatch reports can be submitted through the FDA’s Website at www.fda.gov/medwatch or by calling 1-800-332-1088. Reports to MER can be submitted through USP’s website at www.usp.org or by calling 1-800-23-ERROR.

6 Have policies been implemented to prepare staff to talk with patients about adverse events and medical errors?

6 Have facilities considered implementing the Leapfrog Group’s three initial delivery system improvements?

6 Have internal systems for identifying and handling marginally competent providers been developed?
Resources


- Department of Veterans Affairs, www.va.gov.


States as REGULATORS: How can states monitor patient safety?

States have the unique role of licensing medical facilities and health professionals, and in this capacity, they set performance standards and expectations. Regulators are responsible for holding providers accountable for safety. One role of a regulator is to identify practitioners that do not meet professional codes of conduct and ensure that action is taken to protect the public. Although errors are usually not the result of the carelessness or misconduct of individuals, regulators are responsible for ensuring that individuals who commit violations are rehabilitated, sanctioned, or removed from practice. This role does not have to be punitive; remedial training can be used to help providers maintain their credentials. In addition, errors can be addressed by regulators from a systems perspective by ensuring that latent factors that contribute to errors (those factors that tend to be removed from direct control of the caregiver, such as faulty equipment maintenance, bad management decisions, and poor communication), are detected and corrected, reducing the chance that similar errors will occur in the future. Regulators can call attention to the need for change in organizational and professional cultures and provide clear performance standards that emphasize systems improvements.

Regulating healthcare facilities

State Licensure

All states license hospitals or the services provided by them. States require hospitals to comply with licensure and periodic re-licensure requirements as a condition of providing patient care. The purpose of states’ licensure requirements is to ensure that hospitals maintain minimum health, safety, and quality standards.

Through licensure laws, states impose various quality management requirements aimed at preventing the incidence of adverse events and medical errors or, when they occur, assuring that systems are in place to prevent their reoccurrence. For example, states may require hospitals to establish risk management programs to identify and correct internal problems related to the delivery of patient care. Other, more general, requirements may relate to provider credentialing provisions or certification processes to assure that only the most qualified providers can perform specific procedures.

Forty-five states recognize the accreditation of hospitals by JCAHO as full or partial compliance with state licensure requirements (JCAHO December 1999). Accreditation by JCAHO is a voluntary form of regulation for which hospitals pay a fee. In these cases, the states either do not conduct their own licensure surveys or conduct only partial surveys to ensure compliance with state licensure requirements that fall outside the scope of JCAHO’s review. The information that states receive
following a JCAHO survey varies from minimal to a copy of the full findings. In a series of reports, The External Review of Hospital Quality, the United States Office of the Inspector General argues that JCAHO’s accreditation process is unlikely to detect substandard patterns of care, and some states have echoed this opinion, claiming that JCAHO does not adequately identify quality of care and patient safety problems. However, JCAHO recently approved a new set of safety standards for hospitals to be implemented July 1, 2001. In order to maintain accreditation, hospitals will be required to have a patient safety program that focuses on improvement as opposed to blame. Hospitals must use patient safety-related information to identify and reduce risks, effectively communicate patient safety issues throughout the organization, and improve performance. The new accreditation standards also require hospitals to inform patients and their families about the results of care, including unanticipated outcomes. States will have to review these standards and definitions, assess their enforcement, and examine their access to the information JCAHO collects to determine whether or not the standards meet state policymakers’ concerns for accountability and patient safety.

According to the QuIC report, the federal government plans to develop resources to identify standards for healthcare facilities that could prove useful to states. HCFA plans to publish regulations that will require all hospitals that participate in Medicare to have ongoing medical errors reduction programs. While recognizing that performance standards for, and expectations of, health professionals fall under state jurisdiction and oversight, federal agencies plan to provide technical assistance to states and professional agencies seeking to ensure a basic level of knowledge of safety issues, promote model patient safety programs that include evidence-based best patient safety practices, and help agencies encourage cultural change.
What are the key questions for states as regulators?

6 What quality management and patient safety requirements are included in hospital licensure and re-licensure requirements in your state? Are routine hospital surveys required? How often?

6 Are providers required to implement meaningful patient safety programs as part of state licensure? Do states have appropriate incentives and sanctions to enforce requirements? The Institute of Medicine recommends that after a reasonable period of time for facilities to implement internal patient safety programs, regulators should require them as a minimum standard. See “States as providers of healthcare services,” earlier in this report, for ideas.

6 Does your state deem or otherwise consider JCAHO accreditation in either full or partial compliance with state licensure requirements? Does the state have any additional risk management requirements beyond JCAHO accreditation requirements?

6 What information does the state receive from JCAHO following a hospital survey? If needed, can you work with JCAHO to get access to more of the information it collects during its surveys?

6 What are HCFA’s plans for Medicare and how will they influence industry and state government?

Handling Complaints
As mentioned previously, states investigate complaints on behalf of HCFA. In order to be in compliance with the newly released Medicare conditions of participation, states have recently heightened efforts to ensure that hospitals notify patients about complaint procedures. According to the conditions of participation, hospitals must inform patients that they may lodge a grievance with the state agency directly, regardless of whether they have first used the hospital’s grievance process. The hospital must provide patients with a phone number and an address for lodging a grievance with the
state.

**How can you use complaint data?**

6. Have patients been informed about how to file a complaint? How are complaint data stored and analyzed? Are data referenced during state surveys? Does the state have the capacity to respond?

**Reporting Systems**

Mandatory reporting requirements for adverse events may complement the state’s existing oversight functions by providing a publicly accountable form of oversight that focuses specifically on medical errors and patient safety. The Institute of Medicine report recommends that, beginning with hospitals, all states create mandatory reporting systems to collect data about a limited set of adverse events that cause death or serious harm. These events should be reported because they may indicate that something is wrong with the system of care. As envisioned, mandatory reporting systems would protect the public by assuring that errors are reported and responded to and would induce providers to invest in and improve patient safety. Mandatory reporting would be complemented by voluntary reporting systems to identify system weaknesses before serious harm occurs. Of the state mandatory reporting programs that currently exist (see Table 4 earlier in this report), some were created through regulation, using the state health agency’s broad statutory mandates to protect the health of its citizens, and others were created through statutes that specifically mandated reporting programs.

As mentioned previously, the types of adverse events that must be reported vary significantly across states, and some states use the data for purposes other than analysis of medical errors. Although states have expressed the need for flexibility in creating reporting systems that are responsive to local needs, some have also stated the need for some standardization in order to increase the usefulness of data nationwide, as long as standardization is limited to a core set of reportable incidents upon which the state can expand. The Institute of Medicine report calls for a nationwide mandatory reporting system that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. The report urged Congress to designate NQF as the entity responsible for establishing and maintaining a core set of reporting standards to be used by the states. NQF is in the process of assembling a list of serious, egregious adverse events for reporting purposes.
The design of a reporting system is largely a function of the intended use of the system. What data are collected, who can access them, and how they will be used are dependent on the purpose for which the system was designed. For instance, the Institute of Medicine recommends that for the purpose of accountability, mandatory reporting systems be created to collect information about events that cause serious injury or death. In order to hold hospitals accountable, the report recommends that results of analyses of individual reports be made available to the public. However, issues concerning the protection and disclosure of data and the identification of the specific data, if any, to be released has proven to be very controversial. Some people claim that fear of disclosure leads to under-reporting and others claim that without this information, the public cannot assess whether regulatory agencies are doing their jobs.

If you choose to develop a reporting system, you may want to ask:

6 What is the purpose and intended use of the system?

6 How will you define “reportable incident?” What standards already exist?

6 What specific data will be collected about the incidents/events?

6 What types of facilities will be required to report?

6 Of the reported data, what will be confidential, and what will be disclosed, and to whom?

6 How will the data be analyzed and used?

6 What feedback will be provided to those who report?

6 What incentives and sanctions exist to promote reporting?
If your state has reporting requirements, you may want to ask:

- Does the state reporting program cross-reference and share information with other programs that may have similar information in order to develop more complete facility profiles?
- Do the medical facilities that are required to report know and understand what and how to report? Are there educational programs to ensure that facilities can comply?
- Does whistleblower protection for reporters need to be developed or modified?
- How does the program ensure that corrective action plans are implemented?
- What kind of feedback is provided to reporters?

Licensing healthcare professionals

States are responsible for licensing healthcare professionals through professional licensure boards, which ensure that providers have the appropriate education and training and comply with standards of professional conduct. Many boards are quasi-governmental agencies that are appointed by governors but operate autonomously.

Boards may receive complaints from consumers, malpractice data, information from hospitals and other healthcare organizations, and reports from government agencies that notify them of potential violations of professional standards. 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, ranging from requiring continuing education and rehabilitation to suspension or revocation of a professional license. Professional boards develop their own requirements for collecting information about providers who may have violated professional standards. There is great variation in professional licensure standards, both within states, due to individual licensing boards for each regulated profession.
and among states.

Professional boards can also use the National Practitioner Data Bank (NPDB) to find out about professional standards violations. Hospitals are required to report disciplinary actions, taken against members of their staff, that are above a certain threshold to NPDB, a national mandatory reporting system maintained by the federal government to collect information about malpractice judgments and settlement payments, disciplinary sanctions, and license suspensions and revocations. However, according to a recent report by the United States General Accounting Office, the information in the data bank may not be as accurate, complete, or as timely as it should be. Problems include inaccuracies in the way reported data were coded, duplicate reports, lack of criteria for what must be reported, and inability to ensure that inaccurate and erroneously reported information is removed. Although the information is available to credentialing organizations, it must be kept confidential and is not available to the public.

In addition to identifying marginally competent providers, professional licensing boards have opportunities to encourage system changes in the ways that healthcare professionals are regulated that would ensure competent providers (Leape et al. 1999). Investigating some of the issues that follow may help regulators move in that direction.
What are key questions about healthcare professional licensure?

6 What professional boards exist in the state and who do they license? What types of reporting programs do they maintain, and what information is available to the public about individual providers?

6 What kinds of information-sharing arrangements have been made among facility licensing agencies and professional boards to identify systems issues, as opposed to problems specific to individual healthcare professionals?

6 Have licensing boards set performance standards and expectations that focus attention on patient safety? Are they enforced and monitored? Are periodic re-examinations and re-licensing of key providers based on both competency and knowledge of safety practices? Are there continuing education credits that focus on patient safety? If not, what would be needed to implement these practices?

6 Have licensing boards worked with certifying and credentialing organizations to develop effective methods of identifying unsafe providers and taking relevant action?

6 What are the specific procedures in your state for handling complaints against providers, such as the process for investigating and resolving complaints? Are cases handled in a timely manner?
Resources

Joint Commission on Accreditation of Healthcare Organizations, *State Recognition of Hospital Accreditation/External Review as Meeting State Licensing, Contracting, or Other Requirements* (December 31, 1999).


States as EDUCATORS: The power of information

Providers, purchasers, and consumers are searching for information on best practices and safe care. States can assist by publicizing the availability of resources and helping to develop needed new resources.

According to a 1999 survey conducted by the Henry J. Kaiser Family Foundation and AHRQ, Americans see a role for government in promoting, monitoring, or providing information about the quality of health care. Almost 75 percent of the people surveyed believe the government should require healthcare providers to report all serious medical errors to make sure that this information is publicly available, and they reject concerns about protecting the privacy of patients and medical staff as reasons to withhold this information.

One question for states to consider is how to present information to the public. The state must balance the public’s demand for information with efforts to ensure that the information released is accurate and easily interpreted. States need to consider how to responsibly collect, validate, and present information to the public and policymakers without attacking the system, unnecessarily frightening consumers or providing false assurances, or placing inappropriate blame and discouraging information sharing for safety improvements.

Some states provide hospital performance reports, or report cards, on specific procedures, such as risk-adjusted mortality rates for heart attacks, strokes, or hip surgery. This information may be useful to consumers in making decisions about where to get care, for purchasers in deciding where beneficiaries should get care, and to providers by identifying opportunities for quality improvement. Again, risk adjustments for age, relative illness, and other factors can be very complex, and reports may need to explain in detail how the numbers were calculated and the shortcomings in using the data so that readers can understand and use it appropriately.

An increasing number of states have passed laws that require state agencies to provide internet-based practitioner profiles with practice information such as practitioners’ education and training, specialties, hospital affiliations, disciplinary actions, closed malpractice cases, and hospital disciplinary proceedings. Different states use different approaches to gather information; some may indicate on their websites that information is self-reported by practitioners and not verified by licensing boards. Health Care Choices provides information on state legislation for physician profiling on its website (www.healthcarechoices.org).

There are ready-made resources available to assist in educating the public about patient safety issues.
AHRQ has developed several patient fact sheets that describe how consumers can take a proactive approach to managing the quality of their care. These include *5 Steps to Safer Health Care*, which is being used by all QuIC agencies, and *20 Tips to Help Prevent Medical Errors*. The agency has also developed a guide to help consumers avoid medication errors; it explains how to get and follow an appropriate treatment plan, take medications safely, and get help when it is needed. Alternatively, states may want to follow the lead of those states that have developed state-specific information. While no national clearinghouse currently exists for this information, states may contact AHRQ for information about QuIC initiatives or use the patient safety LISTSERV administered by NASHP to share this type of information.

States can help private providers learn where to access best practice information by publicizing information about current research and sponsoring forums to inform providers. They can also provide educational programs for health professions students at public universities and for licensed practitioners through continuing education credits for licensure and accreditation. AHRQ is currently sponsoring research that focuses on the causes of medical errors, reporting strategies, patient safety interventions, the use of appropriate technologies to reduce errors, the impact of work conditions on patient safety, and provider education strategies.
What are key questions for states as educators?

6 Has the state identified an entity responsible for providing consumers with information about patient safety issues?

6 Have consumers been educated about how to actively monitor the safety of the healthcare services they receive? Are practitioner profiles available?

6 Has information about systems improvements been provided to the media, so that it can educate the public responsibly, shift away from a culture of blame, and provide information on programs and procedures in place to reduce medical errors?

6 Does the state have an ombudsman program to advocate for patients? Does the program have appropriate access to information and authority to act?

6 Do health professions schools and continuing education programs include curricula and provider education about patient safety issues?

6 Have facilities been educated about reporting requirements and best practices?
Resources


States as CONVENERS: Taking a collaborative approach

With few exceptions, state responsibility for patient safety is spread across a number of state agencies. States can act as conveners on two levels: they can convene their own agencies to create a unified approach to patient safety, and they can also facilitate the discussion of roles and responsibilities with other stakeholders.

In many states, coalitions are forming so that stakeholders can share knowledge and resources and develop strategies to reduce medical errors and improve patient safety. Coalitions may act in an advisory capacity to the state in the development and implementation of reporting requirements. Providers may furnish recommendations on quality and patient safety measurement/data collection as they relate to defining reporting requirement terms, developing consensus about what should be reported, and considering how to improve the quality and consistency of reports. Coalitions may be useful in increasing awareness of error prevention and mitigation strategies and identifying and implementing best practices. (Refer to Tables 1 and 2, earlier in this report, for potential coalition partners.)

The Massachusetts Coalition for the Prevention of Medical Errors, for example, was founded in 1997 by the Department of Public Health, the Massachusetts Hospital Association, and the Massachusetts Medical Society to develop and implement a statewide initiative to improve patient safety and minimize medical errors. The coalition has circulated medication best practices, issued safety alerts, sponsored educational programs for providers, and issued a consumer pamphlet. It may serve as a model for other states that are interested in developing similar partnerships.

Coalitions require staffing and support. To assure coalition members are able to advance collaborative projects to improve patient safety and share information, clear goals and measures of progress will be needed.

In addition to state partners, there are regional governmental agencies and private entities that may be interested in forming partnerships. According to the QuIC report, the network of 53 Peer Review Organizations (PROs), which contract with HCFA to monitor and improve utilization and quality of care for Medicare beneficiaries, are working to reduce errors of omission through their performance-based contracts. The PROs are working toward preventing failures and delays in delivering services for breast cancer, diabetes, heart attack, heart failure, pneumonia, and stroke. These PRO efforts have already decreased mortality for heart attack victims. HCFA also plans to develop a pilot project through the PRO program for up to 100 hospitals that volunteer to implement penalty-free, confidential, mandatory reporting systems using NQF’s recommendations for reporting. The pilot projects will
assist hospitals in changing their medical delivery systems to reduce or eliminate errors.

**AHRQ** is developing Patient Safety Indicators (PSIs) through the Healthcare Cost and Utilization Project to help identify potential in-hospital patient safety problems. A team of clinical and methodological staff developed the PSI algorithms that examine ICD-9-CM codes that may, in combination, reflect complications in care. PSIs were developed for sutures of lacerations (stitches) in elective surgical cases, perforation diagnoses in elective surgical cases, post-operative infections in elective surgical cases, transfusion reactions, foreign bodies left during procedures, infections due to procedures, iatrogenic conditions, wound disruptions, miscellaneous misadventures, obstetrical misadventures, and birth traumas. A summary measure indicating the presence of any of these PSI events was also developed. PSIs are being internally and externally reviewed and validated prior to public release, which is anticipated by fall 2001. The resultant PSIs should provide an efficient means to identify potential in-hospital patient safety problems. States will be able to use the PSIs, which will be available on AHRQ’s website, free of charge, to run algorithms against their own data to identify problems and potentially prevent hospitalizations.

**What are key questions for states as collaborators?**

6 Are there opportunities to co-host forums and invite experts to describe the problem and discuss lessons learned?

6 Is the PRO in your area actively engaged in medical errors reduction strategies? Can you partner with them?

6 Has the state considered convening a task force to bring together various state agencies? Are the task force goals clearly delineated? How will progress be benchmarked and measured?

6 Are there opportunities to initiate or join coalitions with providers, purchasers, and consumers? Are the coalition goals clearly delineated? How will progress be benchmarked and measured?
Resources

HOW CAN STATES PAY FOR PATIENT SAFETY IMPROVEMENTS?

Some state activity on patient safety, such as coordinating fragmented state activities, analyzing existing databases, convening a meeting with key stakeholders, or providing general education to the public about medical errors, can occur at little or no cost. However, sustained activity takes resources.

The state of Minnesota’s extrapolation from the Institute of Medicine report suggests that improving patient safety can lead to cost savings (see “States as Purchasers,” earlier in this report). But these savings may not be realized directly by the state and may be some time in coming. Funds for start-up activity and staffing are needed now, but no discrete funding is available.

Both the federal government and state governments fund activities for hospital oversight. States receive federal funding for a variety of activities, including conducting annual surveys of ten percent of non-accredited hospitals and validation reviews for five percent of accredited hospitals. States may provide funding for state licensure activities, although in some states funding is scant, and non-accredited hospitals are only surveyed every 7-10 years. As a result, states claim that the funding is insufficient to adequately monitor patient safety, let alone fund additional state patient safety improvement projects. In support of this argument, annual funding for nursing facility surveys is nearly three times higher than funding for hospital survey activity on a per facility basis.

The Institute of Medicine report recommends that funding and technical expertise be provided to all state governments to establish error reporting systems or adapt their current systems. However, federal bills introduced during the 2000 congressional session called for the establishment of national voluntary reporting systems and did not provide concomitant resources to the states.

States can think broadly in terms of funding sources. AHRQ is releasing a series of Requests for Applications (RFAs) on the following topics:

1. Health System Error Reporting, Analysis, and Safety Improvement Demonstrations;
2. Centers of Excellence for Patient Safety Research and Practice;
3. Developing Centers for Patient Safety Research and Practice;
4. Clinical Informatics to Promote Patient Safety;
5. Effect of Working Conditions on Patient Safety; and
6. Patient Safety Research Dissemination and Education.
The RFAs for the first three topics listed above were all released by February 2001. The application deadline for the second and third RFAs had passed prior to publication of this report (January 2001); applications for the first RFA are due April 27, 2001, with a letter of intent due by April 2, 2001. Although these RFAs focus on research to add to the body of knowledge about patient safety and medical errors, additional funding will be required for implementation. States may be interested in teaming up with academic institutions for the analytic and research components of these RFAs.

Other federal sources of funding may become available as agencies implement strategies outlined in the QuIC report, and states may want to watch agencies such as HCFA and the Centers for Disease Control and Prevention (CDC) for funding opportunities.

Some states have secured additional state or federal funding to study patient safety issues and to organize staff to systematically address medical errors.

- Iowa received a $549,000 grant from CDC for a study by the Iowa Department of Public Health and the University of Iowa College of Public Health to examine health system characteristics that contribute to errors, to solicit strategies for improvement, to identify current data being collected in hospitals and long-term care institutions, and to hold conferences and meetings to discuss patient safety issues.

- The Florida Legislature appropriated $91,000 for the work of the Commission on Excellence in Health Care (see “The role of the legislature,” earlier in this report, for details).

- The newly created New York Center for Patient Safety received an approximately $3 million appropriation from the New York Legislature in FY 2000 that was re-appropriated in FY 2001 along with an additional $5 million (see “The role of the legislature,” for details).
Resources


* The Centers for Disease Control and Prevention, (Division of Healthcare Quality Promotion within the National Center for Infectious Diseases), www.cdc.gov.


* The websites for New York Center for Patient Safety and the Iowa research initiative are currently under development.

CONCLUSIONS

The events that result in medical errors are not likely to disappear without serious attention from all stakeholders. While states are currently struggling with lack of state-specific data, they can assemble the appropriate agencies to assess existing information and begin moving forward to develop mechanisms to establish state estimates and focus on known steps that have the most potential for impact in their state environments.

States may discover other opportunities to address patient safety issues and medical errors that are not listed in this report. For example, some states have considered granting funding to providers and researchers to encourage innovation. Other considerations may include such questions as, Can states secure funding and play a role as a grantor? Can states address patient safety concerns through other state venues, such as Certificate of Need (CON) policies? Can states use their national venues to play a role in advocating state needs to the federal government?

A comprehensive approach that addresses multiple roles will be required in order to be effective. Research continues on understanding the epidemiology of medical errors and practices that most improve patient safety. New data sources will continue to emerge. Funding opportunities, as recommended in the Institute of Medicine report, may emerge as well through Congressional action or a variety of federal agencies, such as AHRQ, HCFA, and CDC. In the meantime, states have an opportunity to identify patient safety champions, unify state agency approaches, and partner with private purchasers and providers to address the issue. States can share strategies and learn from each other through national conferences and other forums, such as NASHP’s LISTSERV for state patient safety leaders. States have an opportunity to try creative approaches in a variety of settings and become laboratories of innovation to inform the national health policy debate about patient safety.
APPENDIX A: DOCUMENTS REFERENCED IN THE REPORT

American Public Health Association, Data Committee, Injury Control and Emergency Health Services Section. 1998. *How States are Collecting and Using Cause of Injury Data.*


McDonald, Clement J., MD; Michael Weiner, MD, MPH; and Siu L. Hui, PhD. July 5, 2000. *Deaths Due to Medical Errors are Exaggerated in Institute of Medicine Report.* Journal of the American Medical Association 284, no. 1.


APPENDIX B: ORGANIZATIONS REFERENCED IN THE REPORT


The Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333, (404) 639-3311, (800) 311-3435, www.cdc.gov.


The Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (888) INFO-FDA, (888) 463-6332), www.fda.gov.

Health Care Choices, P.O. Box 21039, Columbus Circle Station, New York, NY 10023, info@healthcarechoices.org, www.healthcarechoices.org.


The Institute for Healthcare Improvement, 135 Francis Street, Boston, MA 02215, (617) 754-4800, info@ihi.org, www.ihi.org.


The Leapfrog Group, c/o the Academy, 1801 K Street, NW, Suite 701-L, Washington, DC 20006

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