In October 1999, the Institute of Medicine (IOM) released *To Err Is Human: Building a Safer Health Care System*, a report that put the issues of patient safety and medical errors in front of the American public and on the agendas of healthcare institutions, provider associations, consumer groups, the administration, and the Congress seemingly overnight. The national news networks and other media outlets broadcast the startling finding that up to 98,000 people die in hospitals each year as a result of medical errors and countless more are seriously harmed. And, whereas other industries have worked systematically to improve error rates and adverse outcomes over the past several decades, the healthcare industry appears to have made woefully few improvements in patient safety and has essentially maintained high medical error rates over the past 15 years.

Despite its shock value and the media attention it received, the IOM report does not include new information about the prevalence of medical errors. It explains the etiology of errors in the healthcare system and describes ways that other industries have successfully tackled this problem. It also includes detailed analyses of systems failures in the delivery of care to (primarily) hospitalized patients and identifies steps that healthcare institutions can take to reduce their error rates.

The report is essentially a call to action for policymakers, providers, and the American public to create a groundswell for change. The report’s real take-away message is that medical errors are infrequently the result of the lone individual. On the contrary, medical errors are the result of a complex series of system-related problems. In the report’s language, the authors call for the healthcare system to “systematically design safety into processes of care.” Thus, error reduction and improved patient safety focus more on designing systems to reduce the likelihood of error and less on identifying the person or persons responsible for the mistake.

This chapter describes the findings in the IOM report and summarizes some of the published literature upon which the findings were based. It also describes public- and private-
sector responses to the IOM report and the ways in which various groups have positioned themselves on this issue.

ERRORS, ADVERSE EVENTS, AND NEGLIGENCE: SOME COMMON TERMINOLOGY

With all of the talk about errors coming from a variety of different sources, it is important to designate a set of definitions that can be used to distinguish the types of events that take place within healthcare environments that apply to patient safety. The IOM report defines medical error as “the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim.”

Despite the popular appeal of discussing “errors” in health care, most of the literature on this subject, and most of the information in the IOM report, describes adverse events or potential adverse events rather than errors. An adverse event is defined as an injury caused by medical management rather than by the underlying disease or condition of the patient. A potential adverse event carries the potential for injury. Many, but not all, adverse events are preventable. Those that are preventable, or those that are preventable and result only in the potential for harm, are considered errors. Thus, errors may or may not result in adverse events, and adverse events may or may not be the result of errors.

An example commonly used to illustrate the distinction between preventable and non-preventable events is an adverse event related to the administration of a new antibiotic to a patient who subsequently has a severe allergic reaction. This case could be the result of medical error, or it could be an unavoidable adverse reaction. If the medical record showed a prior allergic reaction to the type of antibiotic, or the healthcare team failed to ask the patient whether he or she had any allergies to drugs, the adverse event (i.e., the allergic reaction) would have resulted from medical error. If, on the other hand, the patient was asked about allergic reactions and it was clear that there was no history of allergy to this type of medication, the result would be an adverse event that was not the result of medical error.

Medical errors can result from virtually all processes involved in healthcare delivery. Some of the most common sources are the following:

- Drug-related errors, such as those resulting from prescribing the wrong medication or dosage, misinterpreting the correct prescription or prescribing instructions, and using incorrect routes of administration
- Diagnostic error, such as misdiagnosis leading to an incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretations of test results, and failure to act on abnormal results
- Equipment failure, such as defibrillators with dead batteries or intravenous pumps whose valves are easily dislodged or bumped, causing increased doses of medication over too short a period of time
- Blood-transfusion-related injuries, such as giving a patient blood of an incorrect type
- Misinterpretation of other medical orders, such as failing to give a patient a salt-free meal as ordered by a physician

MEDICAL ERRORS AND PATIENT SAFETY: WHAT DOES THE LITERATURE SHOW?

The estimates of deaths of inpatients resulting from medical errors come from two separate studies. The first, published in two parts in 1991 in the New England Journal of Medicine, was conducted by Lucien Leape, Troyen Brennan, and colleagues, and is referred to as the Harvard Medical Practice Study. It estimates the number of adverse events occurring or discovered in New York hospitals in 1984 and identifies those that resulted from medical negligence. The second, by Eric Thomas and colleagues published in Inquiry in 1999, esti-
Additional findings from the Harvard Medical Practice Study are as follows:

- Rates of adverse events increased strongly with increasing age of the patient. This could be a result of the fact that older individuals tend to require more complex care with multiple services, drugs, and therapies. Each of these increases the risk of an adverse event.

- The authors found no significant differences in adverse events between patient sexes, although they did find significant differences across diagnosis-related groups (DRGs). For example, the rate of adverse events in vascular surgery DRGs (16%) was about 25 times higher than that for neonatal DRGs (less than 1%). Rates of negligence, however, did not vary across DRGs.

- Approximately 20% of the adverse events caused by negligence occurred during outpatient care before the index hospitalization but were discovered during the index hospitalization.

- Nearly half of the adverse events (48%) resulted from operations. Wound infections were the most common surgical adverse event, accounting for 29% of surgical complications and nearly one seventh of all adverse events identified in the study.

- Drug complications were the most common single type of adverse event (19%).

- There was wide variation in the type of care that resulted in negligence. For example, 17% of the adverse events related to operations were due to negligence, ranging from 13% of the wound infections to 56% of the surgical failures. Negligent care was identified as causing 75% of the adverse events resulting from problems in diagnosis and 77% of those resulting from a therapeutic mishap.

- Drug-related complications were the most common type of adverse event for patients in all age groups except those aged 16 to 44 years, among whom drug
complications ranked second to wound infections. Children had the lowest rates in all categories.

- The largest number of adverse events resulted from treatment provided in the operating room. Emergency rooms, intensive care units, and labor and delivery rooms were each the site of about 3% of the adverse events. However, 70% of the adverse events associated with the emergency room were considered to result from negligence, compared with 14% of adverse events in the operating room.
- The most common class of error for physicians, accounting for 35% of all errors, involved the performance of a procedure or operation. Errors in prevention (i.e., failure to take preventive measures) were the next most common (22%). Errors in diagnosis and prevention were the most likely to be considered negligent (75% and 60% involved negligence, respectively).

The Utah and Colorado Study

Eric Thomas and colleagues reviewed medical records of 14,732 randomly selected 1992 discharges for 28 hospitals in Utah and Colorado to estimate the costs of all types of patient injuries. Using methods very similar to those used in the Harvard Medical Practice Study, they found that adverse event rates in Utah and Colorado were similar to those in New York. In addition, they found that the total costs (in discounted 1996 dollars) were $662 million for adverse events, of which $508 million was for preventable adverse events. In the case of preventable adverse events, 46% of the costs were attributable to healthcare costs. Extrapolating these figures to the 33.6 million admissions in the United States, the authors estimated the national costs of adverse events to be $37.6 billion, of which $17 billion is for preventable adverse events.11

Furthermore, the results of the Utah and Colorado study imply that at least 44,000 Americans die each year as a result of medical errors. Even when using this lower estimate (in lieu of the 98,000 estimate from the New York study), deaths caused by medical errors exceed the number attributable to the eighth leading cause of death. More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).

Other Selected Studies

The health services literature is rich with studies that together portray a healthcare system that abounds with medical errors. Many of these studies address the issue of medication-related errors. For example:

- Each year, medication-related errors, occurring in or out of the hospital, are estimated to account for over 7,000 deaths. This is higher than the number of Americans who die each year from workplace-related injuries.12
- In a 1995 study of medication-related problems at a university hospital, an average of three clinical outcomes associated with medication-related problems were detected per patient.13
- A 1991 study of iatrogenic cardiac arrests in a university teaching hospital found that during a 1-year period, 28 of 203 arrests in which resuscitation was attempted followed an iatrogenic complication. Seventeen of the 28 patients (61%) died. The authors found that the most common causes of potentially preventable arrest were medication errors and toxic effects, as well as suboptimal response by physicians to clinical signs and symptoms.14
- In a study by Cullen and associates that looked at preventable adverse drug events in intensive care units, the authors found that the rate of preventable or potential adverse drug events was twice as high in intensive care units as in general care units. This difference was due to the quantity of drugs prescribed, and not to a high-stress environment.15
To Err Is Human: The IOM Report and Recommendations

The purpose of the committee’s work on patient safety is fourfold:

1. To establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.
2. To identify and learn from errors through immediate and strong mandatory reporting efforts, as well as to encourage voluntary efforts, both with the aim of making sure the system continues to be made safe for patients.
3. To raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups.
4. To create safety systems inside healthcare organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

The IOM recommendations fall under the four categories just listed and call for a comprehensive effort on the part of all sectors of the healthcare system and its healthcare workforce to make patient safety a priority of the industry. The report challenges the healthcare industry to reduce medical errors by half over a 5-year period. At a minimum, this requires systemwide changes in the way health care is delivered, the relationships among health professionals, and the way health professionals interact with each other and their institutions. It also requires a profound culture shift within healthcare institutions to identify and root out errors and their underlying systemic causes. It requires an explicit commitment from CEOs, boards of trustees, medical and nursing staff, and a host of other healthcare participants to view error identification not as the beginning of punitive action, but as an opportunity to learn how to redesign systems so that they are much safer for patients.

The IOM recommends that the federal government establish a new “Center for Patient Safety” that would be housed at the Agency for Healthcare Research and Quality (formerly

• David Bates and colleagues evaluated the incidence and preventability of adverse drug events in an urban tertiary care hospital over a 37-day period. The rate of drug-related incidents was 73 in 2,967 patient days, with 27 incidents judged as adverse drug events, 34 as potential adverse drugs events, and 12 as problem orders. Fifty different drugs were involved, and physicians were primarily responsible for 72% of the incidents. More than half of the events were judged to be preventable.

These studies demonstrate with remarkable consistency the vulnerability of the healthcare system and the pervasiveness of medical errors. Although they tend to concentrate on hospitalized patients, most of the studies are careful to point out that errors are by no means confined to hospitals. Hospitals tend to provide more accessible records and also demonstrate a longer and more concentrated period of time caring for a patient. They have been a valuable laboratory for research on medical errors.

Hospitals, however, may carry higher error rates than other healthcare institutions, although this is not determinable in the literature. Most researchers cite the complexity of an institution or healthcare process as being a risk factor for error. Hospitals are among the most complex healthcare delivery sites and therefore are likely to carry with them significant risk for error. They also are appropriate sites to begin designing systems for error reduction.

TO ERR IS HUMAN: THE IOM REPORT AND RECOMMENDATIONS

In June 1998, the IOM formed a Quality of Health Care in America Committee to develop a strategy to result in a “threshold” improvement in quality over the next 10 years. The report on patient safety was the first in a series that will address issues of quality in the healthcare system.
the Agency for Health Care Policy and Research) to set national goals for patient safety, track efforts, report to the American public, develop a research agenda, and fund projects designed to improve patient safety and reduce medical errors. In what is perhaps its most controversial recommendation, the IOM calls for a mandatory reporting system for the collection of standardized information by state governments about adverse events that result in serious harm or death. (See the chapter appendix for a complete list of the IOM recommendations.) The IOM also recommends setting up voluntary reporting systems to encourage the reporting of less serious adverse events.

The IOM calls for Congressional legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed for the purposes of designing safer systems. Currently, information developed outside of peer review protections is open to discovery as part of a lawsuit. Thus, calling for mandatory or even voluntary reporting of serious adverse events would require a more protected legal environment to encourage individuals who commit errors (either individually or as part of a system or group process) and those who become aware that errors have occurred to report them without fear of punishment by supervisors or retribution by peers. This appears to be an extremely challenging goal, even in the presence of legal protections, but it is certainly one that could never be achieved without some sort of protection.

It is important to note that these legal protections do not preclude use of information that is “discoverable” through other sources. In other words, the legal protections suggested previously preclude use of information developed through the patient safety reporting process. In the case of negligence or otherwise inappropriate care, information developed pursuant to a legal action outside of the patient safety reporting system would be unaffected by these protections.

Within days of the IOM report, then-President Clinton publicly underscored the administration’s commitment to improving patient safety and asked a healthcare quality task force to study the report and make recommendations about how to move forward with a patient safety agenda. The task force, known as the Quality Interagency Coordination (QuIC) Task Force, which originally had been formed in 1998 to focus federal efforts on improving healthcare quality, was chaired by Department of Health and Human Services Secretary Donna Shalala and Department of Labor Secretary Alexis Herman.20 In December 1999, it was asked to concentrate on patient safety and medical errors.

The QuIC issued a report in February 2000 that supported virtually all of the IOM’s recommendations. The QuIC’s report included details about ways that federal agencies could assist in the effort to improve patient safety, as well as specific proposals for the Veterans’ Administration and the Department of Defense. The most important feature of this report and the president’s acceptance of its recommendations was that it supported the original IOM recommendation to create a mandatory reporting system for the collection of standardized information by state governments about adverse events that result in serious harm or death. (See the chapter appendix for a complete list of the IOM recommendations.) The IOM also recommends setting up voluntary reporting systems to encourage the reporting of less serious adverse events.

The QuIC’s recommendations tended to place the monitoring components (a mandatory reporting system along with incentives to encourage voluntary reporting of lesser events) within state systems, and the research, evaluation, and advisory components within federal agencies. Some of the latter efforts would likely involve collaborative efforts between one or more federal agencies and nonprofit organizations that are experienced in the issue of patient safety.
LEGISLATIVE PROPOSALS ON PATIENT SAFETY

There appears to be a significant amount of interest in patient safety on Capitol Hill, despite the relatively few bills introduced in Congress as of late 2000 specifically on this issue. Many Hill watchers believed that with so much legislation getting bogged down in election-year politics, Congress might take a “wait and see” attitude and revisit the medical errors issue after the November 2000 elections. Since the subject has bipartisan appeal, however, it seems safe to assume that there will be some legislative action aimed at reducing medical errors in upcoming sessions of Congress.

Several of the bills that were introduced in the 106th session kept these issues in front of Congress.21 Maryland Congresswoman Morella introduced legislation that would provide for the voluntary reporting of medication errors. Senators Grassley, Lieberman, and Kerry sponsored the “Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000,” proposed legislation that largely mirrored the recommendations in the IOM’s and the QuIC’s reports. The purpose of the legislation was to develop a nonpunitive error reduction system22 with “pragmatic” reporting requirements and adequate legal protections to support the collection of information under such systems. Among other provisions, the legislation would have extended existing confidentiality and peer review protections to a set of “additional required reports of error” that would have had to be reported in some systematic way. These additional required reports essentially broadened the definition of what a mandatory, reportable event would be.

Senators Specter and Harkin drafted legislation that would establish a mechanism to award grants to states to implement data collection systems so that national trends could be determined and analyzed. Like the Grassley proposal, information collected through the Specter–Harkin proposal would also be confidential and protected from discovery.

The legislation called for the establishment of 15 research and demonstration projects throughout the nation that would test three models for reporting medical errors: Five sites would be required to inform the Department of Health and Human Services (DHHS) (through the Agency for Healthcare Research and Quality) of any medical errors occurring at the facility; five would be required to inform the DHHS as well as the patient or the patient’s family (or both) of any medical errors; and five would be asked to voluntarily inform the DHHS of any medical errors.

Both of these proposals called for larger federal investment in research that addresses the reasons behind medical errors and ways to design systems to decrease their prevalence. The two sides of the argument differed on whether to institute a mandatory or a voluntary reporting system for serious adverse events. The IOM committee, the Clinton administration, and the Grassley bill clearly favored a mandatory system. The Specter legislation would have studied and evaluated various reporting models, leaving open the possibility of a voluntary system. Specter and colleagues are not alone, however, in coming down on the side of a voluntary system, as discussed in the following sections.

CURRENT REPORTING REQUIREMENTS

State Requirements

A recent report by the National Academy for State Health Policy (NASHP) provides information on the types of reporting systems that are currently in place in the 50 states and the District of Columbia.23 According to that report, the majority of states do not have formal mandatory or voluntary systems for reporting errors or adverse events.

Fifteen states require mandatory reporting from general and acute care hospitals of adverse events, as defined by the IOM or by the state in a way that encompasses part or all of the IOM definition.24 These states are Colorado, Florida, Kansas, Massachusetts, Ne-
information gathered through these reports through nationwide bulletins known as Sentinel Event Alerts.

A sentinel event is “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.” The definition was revised in May 1998 and includes a subset of adverse events that signal the need for immediate action. Action is needed if:

1. The event has resulted in an unanticipated death or permanent loss of function, not related to the natural course of the patient’s illness or underlying condition.
2. The event is one of the following, even if the outcome was not death or major permanent loss of function:
   - Suicide of a patient in a setting where the patient receives around-the-clock care (e.g., hospital, residential treatment center, crisis stabilization center)
   - Infant abduction or discharge to the wrong family
   - Rape
   - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
   - Surgery on the wrong patient or wrong body part

Under the policy, these events are subject to review by the Commission and may be reported to the Commission on a voluntary basis. If the Joint Commission becomes aware that a sentinel event has occurred (either through voluntary reporting or through other means), the healthcare organization is required to prepare and submit to the Commission a root-cause analysis and action plan within 45 calendar days of the event. Thus, though not required to report a sentinel event, organizations that choose to report to the Commission are required to meet various reporting deadlines and criteria once the report has been made. Furthermore, following a report, The Joint Commission may decide
to conduct a “for cause” survey to determine whether there is a real or potential ongoing threat to patient safety. The Commission indicates that these surveys occur infrequently.

The Commission has elected to stay out of the debate on mandatory versus voluntary reporting systems. The Joint Commission supports the development of an “effective medical/healthcare reporting system, whether mandatory or voluntary.” It strongly supports the IOM’s call for protection of information reported for the purpose of patient safety analyses. In testimony to Congress in 2000, the Joint Commission stated that the sentinel event program had received relatively few reports, in large part because of a lack of statutory protections from disclosure of information. The testimony stated: “We will not be successful in attaining our goals if Congress does not pass federal protections that will encourage the surfacing, evaluating, and sharing of . . . information.” The Commission also responded to the IOM report.

THE RESPONSE FROM THE AMERICAN HOSPITAL ASSOCIATION

The American Hospital Association (AHA) has been very engaged in the issue of medical errors. Shortly after the release of the IOM report, the AHA sent out a Quality Advisory to its full membership, indicating that it was in the process of developing an initiative to improve patient safety. Over the next several months, the AHA contacted hundreds of its members and worked through its regional structure to approve a series of policies on patient safety.

The AHA is working with the Institute for Safe Medication Practices (ISMP) to develop tools for hospitals to improve patient safety, especially regarding the issue of medication safety. ISMP developed a Medication Safety Self-Assessment tool that the AHA sent to all of its members. Hospitals were asked to complete the self-assessment tool and send the results back to the ISMP for analysis purposes. The tool, however, has generated a fair amount of concern among risk managers, who question how the information will be used and whether there are guarantees of confidentiality.

The AHA does not support several of the key recommendations included in the IOM report. First, the AHA supports a voluntary reporting system (except in cases where the state already requires reporting of such events). AHA officials strongly believe that a voluntary system is necessary to foster open communication and error identification and reporting. Second, the AHA does not support the recommendation that the Agency for Healthcare Research and Quality (AHRQ) serve as the appropriate reporting agency. Instead, it recommends that device-related errors continue to be reported to the FDA, that medication errors go to the ISMP, and that other types of errors be reported to other currently existing expert organizations. The AHA does not consider multiple reporting entities to be a drawback.

The Institute for Safe Medication Practices agrees with the AHA in its preference for a voluntary rather than a mandatory reporting system. Its strong belief is that a voluntary system is more likely to produce the culture change necessary for encouraging individuals to come forward and report medical errors.

The AHA supports the IOM’s recommendations concerning legal protections for information developed through error reporting. It also supports federal and other efforts to raise awareness about medical errors and provide additional research dollars to study appropriate mechanisms to improve patient safety.

OTHER RESPONSES

Not surprisingly, several health-related associations and professional groups have issued policy statements or have testified about medical errors. Most often, differences among these parties center on the questions of whether a reporting system should be voluntary or mandatory (or some form of both) and which entity should receive those reports.

A partial list of these organizational responses follows.
The American Medical Association (AMA) supports the AHRQ’s role in developing information and funding research on patient safety and medical errors. It also supports the extension of peer review liability protections to those involved in patient safety improvement initiatives and confidentiality protections for individually identifiable information reported for health system safety and quality improvement purposes. The AMA does not support a nationwide mandatory error reporting system. The AMA insists that a mandatory reporting system could have unintended consequences and elicit less information than a well-designed, well-run voluntary program. The AMA also believes that Congress should help create a “culture of safety” within healthcare organizations by allowing medical professionals to convene to discuss patient safety problems and potential solutions without having their discussions, findings, or recommendations become the basis for class action or other lawsuits.

The American Nurses Association (ANA) supports the creation of a mandatory reporting system but would extend it beyond so-called sentinel events to include a broader range of errors and adverse events. The ANA is particularly concerned about how staffing affects patient safety and would like to see studies that address the extent to which understaffing of nurses is a detriment to patient care.

The Anesthesia Patient Safety Foundation (APSF) urges the nation to move cautiously before instituting the type of mandatory reporting system called for in the IOM report. Instead it urges further study and consultation with expert groups to deliberate the benefits of a mandatory system. The APSF believes that a voluntary system can be set up immediately and, if designed appropriately, can have an enormous impact on patient safety.

REASONS FOR OPTIMISM:
SUCCESSFUL STRATEGIES

Much of the rhetoric about the epidemic of medical errors is accompanied by stories of successful interventions to reduce errors, save lives, and improve patient care. Safety advances in other industries (most notably, the aviation industry) are held up as examples of successful systems redesign that have resulted in vastly improved safety outcomes. Other oc-
Other programs highlighted in the IOM report include the following:

- Efforts at Dana-Farber Cancer Institute in Boston, Massachusetts, to make chemotherapy safer
- Encouraging physicians to use computers to write prescriptions at Brigham and Women’s Hospital in Boston, Massachusetts
- Engaging the participation of a pharmaceutical company (Bristol-Myers Squibb) to redesign medication packaging and develop guidelines for naming new pharmaceuticals
- Focusing on managing a few high-risk drugs at Fairview Health Services in Minneapolis, Minnesota
- Using simulation technology at the VA/Stanford Simulation Center in Palo Alto, California, to mimic complex and realistic clinical crisis scenarios

In each of these cases, encouraging results have been shown through the interaction of technology, leadership, and a strong “corporate” commitment to error reduction and patient safety. There have also been efforts across the sites to work with teams of health professionals to stimulate a culture of change and trust—one that welcomes error detection and reporting as an opportunity for improved patient care.

According to the American Hospital Association, the Agency for Healthcare Research and Quality, and other interested organizations, hospitals and other healthcare institutions can begin a program addressing medical errors with little up-front investment other than commitment to the cause. For example, the AHA suggests that organizations review their policies and procedures for reporting and investigating errors. It also encourages hospitals to access information from organizations such as the Institute for Safe Medication Practices, the Institute for Healthcare Improvement, the Food and Drug Administration, and others who have worked for years on this issue.

cupational safety measures also serve as models for health system redesign for safety.

Examples of safety improvements in healthcare organizations that have resulted in marked (albeit smaller-scale) advances in patient safety also exist. Several quality-related organizations have published *Reducing Medical Errors and Improving Patient Safety: Success Stories from the Front Lines of Medicine*, a glossy report that details eight different approaches to error reduction. Among them are reports about the strides in anesthesiology safety, which has reduced death rates from anesthesiology from roughly 1 in 3,000 to 4,000 in the 1950s, to 1 in 10,000 in the 1970s, and to 1 in 200,000 to 300,000 by 1990. The Anesthesia Patient Safety Foundation attributes this dramatic improvement to the field’s attention to identifying safety problems early, promoting research, disseminating information, and promoting an emphasis on patients in clinical practice. According to the APSF, the most important feature of these efforts has been the elevation of patient safety to coequal status with more traditional concerns, such as determining the molecular mechanisms of anesthesia, developing specialized drugs, or managing critically ill patients.

Also showcased in the report are efforts through the Patient Safety Improvement Initiative at the U.S. Department of Veteran Affairs (VA). The VA set up the National Center for Patient Safety, headquartered in Ann Arbor, Michigan, and run by a physician and former astronaut, James Bagian. The first accomplishment under the new initiative was field-testing a bar-coding system to reduce medication errors at two VA hospitals in Kansas. The results were dramatic, with a 70% reduction in error rates over a 5-year period. The VA planned to have the bar-coding system in place at all VA hospitals by the end of 2000. A similar bar-coding system is planned for blood products used in transfusions. Other initiatives include changes in the way medications are stored and in the use of physical restraints, and improvements in the use of data on medical errors.

Other programs highlighted in the IOM report include the following:

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- Encouraging physicians to use computers to write prescriptions at Brigham and Women’s Hospital in Boston, Massachusetts
- Engaging the participation of a pharmaceutical company (Bristol-Myers Squibb) to redesign medication packaging and develop guidelines for naming new pharmaceuticals
- Focusing on managing a few high-risk drugs at Fairview Health Services in Minneapolis, Minnesota
- Using simulation technology at the VA/Stanford Simulation Center in Palo Alto, California, to mimic complex and realistic clinical crisis scenarios
The AHRQ has developed helpful lists for improving patient safety from the hospital, health professional, and patient perspective. For example, the AHRQ found through its own funded research programs that the following procedures can help reduce medical errors:

- **Computerized adverse drug event monitoring:** Although chart review has been found to be more accurate than computer tracking and voluntary reporting in identifying adverse drug events, it required five times more personnel time. Researchers concluded that the computerized method was the most efficient means of tracking drug errors.
- **Computer-generated reminders for follow-up testing:** Some diagnostic tests require repeat tests to follow up certain conditions. A computerized physician-reminder system for timing of repeat tests was suggested as a useful adjunct to these procedures to prevent patients from being subjected to unnecessary repeat tests.
- **Standardized protocols:** An AHCPR-sponsored study of ICU patients with severe respiratory disease found a fourfold increase in survival rates with computerized treatment protocols.
- **Computer-assisted decision making:** In a study of trauma cases, computerized decision algorithms were tested against physician-generated management plans and evaluated by a panel of trauma surgeons. Overall, the panel rated the computer-supported decisions as more acceptable than those based on judgment alone.

**CONCLUSION**

With very few exceptions, the healthcare industry has been united in its support for a comprehensive effort to reduce medical errors across all sites of care. Nevertheless, as noted earlier in this chapter, there is considerable difference of opinion about the ways that systems of error detection and reporting should be designed. Some of the parties feel strongly that even in the presence of added protections of error-related information, current malpractice law places providers (most often physicians) at risk of legal action. Furthermore, this risk is increased by taking error reporting outside the bounds of the healthcare institution and placing it in an external repository of information on medical mistakes.

Despite the goodwill that exists on both sides of the debate, the success of future efforts to improve patient safety may rise or fall on issues essentially unrelated to the technical design of safer systems. A redesigned healthcare delivery system can be successful only with the buy-in from the leadership at the top of healthcare institutions and from healthcare professionals at the bedside, both of whom have their reputations on the line when it comes to patient care. Any changes to strengthen patient care by exposing medical errors—albeit for study and redesign purposes only—will have to be balanced by clear and fair protections that encourage full disclosure, regardless of the mandatory or voluntary nature of the reporting system.

**APPENDIX: IOM RECOMMENDATIONS**

1. Congress should create a Center for Patient Safety within the Agency for Health Care Policy and Research. This Center should
   - set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety; and
   - develop knowledge and understanding of errors in health care by develop-

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1. The development of a national agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

2. A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about the adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should:
   - designate the Forum of Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;
   - require all healthcare organizations to report standardized information on a defined list of adverse events;
   - provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it, and conduct follow-up action as needed with healthcare organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and
   - designate the Center for Patient Safety to:
     1) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and
     2) receive and analyze aggregate reports from states to identify persistent safety issues that require more intensive analysis and/or broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers, or others).

3. The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should:
   - describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
   - convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
   - periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage healthcare organizations to participate in voluntary reporting programs; and
   - fund and evaluate pilot projects for reporting systems, both within individual healthcare organizations and collaborative efforts among healthcare organizations.

4. Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by healthcare organizations for internal use or shared with others solely for purposes of improving safety and quality.

5. Performance standards and expectations for healthcare organizations should focus greater attention on patient safety:
   - Regulators and accreditors should require healthcare organizations to implement meaningful patient safety
programs with defined executive responsibility.

- Public and private purchasers should provide incentives to healthcare organizations to demonstrate continuous improvement in patient safety.

6. Performance standards and expectations for health professionals should focus greater attention on patient safety.
   - Health professional licensing bodies should:
     (1) implement periodic reexaminations and relicensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and
     (2) work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.
   - Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should:
     (1) develop a curriculum on patient safety and encourage its adoption into training and certification requirements;
     (2) disseminate information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;
     (3) recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies, and drugs;
     (4) work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and
     (5) collaborate with other professional societies and disciplines in a national summit on the profession-al’s role in patient safety.

7. The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and postmarketing processes through the following actions:
   - develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;
   - require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names; and
   - work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through postmarketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.

8. Healthcare organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. Patient safety programs should:
   - Provide strong, clear, and visible attention to safety;
   - Implement nonpunitive systems for reporting and analyzing errors within their organizations;
   - Incorporate well-understood safety principles, such as standardizing and simplifying equipment, supplies, and processes; and
   - Establish interdisciplinary team training programs, such as simulation, that incorporate proven methods of team management.

9. Healthcare organizations should implement proven medication safety practices.
References


2. Ibid.


4. The studies upon which the IOM error estimates are based discuss medical negligence, which is a term generally left out of the IOM study. Negligence is a legal term that relates to care that falls below the standard expected of healthcare professionals (generally physicians) in their community. Some medical errors may not rise to the level of medical negligence.


6. The authors define adverse event as an injury caused by medical management (rather than underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both.

7. These estimates, along with ones from Thomas and colleagues, were used to form the basis of the national estimates included in the IOM report. The Harvard Medical Practice Study estimates set the higher range in the estimate of 40,000 to 98,000 deaths per year.


9. The Harvard Medical Practice Study identified adverse events and negligence from hospital medical records only. Some of these events occurred as a result of outpatient treatment or from hospitalization prior to the study period. All of the events occurred or were discovered during the study period hospitalization but could have resulted from prior treatments in or out of the hospital.


11. The authors used 1993 data from the American Hospital Association to estimate national admission rates.


17. The committee was chaired by William C. Richardson, president and CEO of the W.K. Kellogg Foundation. Members of the committee included representatives from health systems, academics, experts in patient safety and quality of care, major industries, consumer organizations, and medical groups. For a complete list of committee members, see page iii of the IOM report.

18. IOM, To Err Is Human, p. ix.

19. Ibid., p. 5.

20. The Clinton administration pointed out, in its public materials on this subject, that its efforts in patient safety and quality predated the IOM report. That may be true, but clearly the impetus for the administration’s increased activity specifically on medical errors was the release of the IOM report.

21. In addition, Senators James Jeffords (R-VT), Patrick J. Kennedy (D-RI), Christopher Dodd (D-CT), and William Frist (R-TN) were drafting legislation that would begin to implement
the recommendations of the presidential QuIC.
22. See the April 3, 2000, version of the Grassley bill.
24. Some states require hospitals to report other types of events, such as violence and infectious outbreaks. These do not fall within the IOM’s definitions of error and are not included here.
27. The AAHP’s stance came as a surprise to some analysts watching this debate unfold. Some of the more skeptical in the group suggested that the AAHP position was advanced to deflect attention from the Patients’ Bill of Rights.
28. The Anesthesia Patient Safety Foundation was formed in 1985 to improve the safety of anesthesia administration and reduce adverse effects. The field of anesthesia is the sole area of medicine that can point to dramatic decreases in error rates over the past two decades. These efforts are discussed in a later section of this chapter.
29. The report is the work of Accelerating Change Today (A.C.T.) for America’s Health, a collaborative initiative of the National Coalition on Health Care and the Institute for Healthcare Improvement.
30. The July 5, 2000, issue of *JAMA* includes an article under the section called Controversies that claims that the data referenced in the IOM report concerning deaths due to medical errors are exaggerated. This claim is refuted by one of the principal authors of the Harvard Medical Practice Study. See McDonald, C. J., Weiner, M., Hui, S. L. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA* 2000;284:93–94; and Leape, L. L. Institute of Medicine medical error figures are not exaggerated. *JAMA* 2000;284:95–97.