Issue Brief

Medical Errors: Five Years After the IOM Report

SARA BLEICH

ABSTRACT: Five years after publication of the Institute for Medicine's landmark 1999 report, *To Err Is Human*, notable advances have been made. They include the development of performance standards, an increase in error reporting, integration of information technology, and improved safety systems. But the IOM notes that efforts are still needed to improve safety and reduce errors, including development of data standards for patient safety information, establishment of a national health information infrastructure, and comprehensive patient safety programs in health care organizations.

★   ★   ★   ★   ★

Introduction

The 1999 Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health Care System*, placed the issue of patient safety high on the nation's health care agenda. Most salient was the finding that preventable medical errors caused 44,000 to 98,000[1] preventable deaths each year, with an associated cost of $17 to $29 billion.[2,3] Even using the conservative estimate, this placed medical errors among the leading causes of death in the U.S. Although the accuracy of the estimates created heated debate,[4,5,6,7,8] widespread agreement that medical errors were a serious problem galvanized a movement toward patient safety. In the 108th Congress, the House and Senate passed legislation to encourage a national voluntary medical error reporting system. The bills did not go to conference.
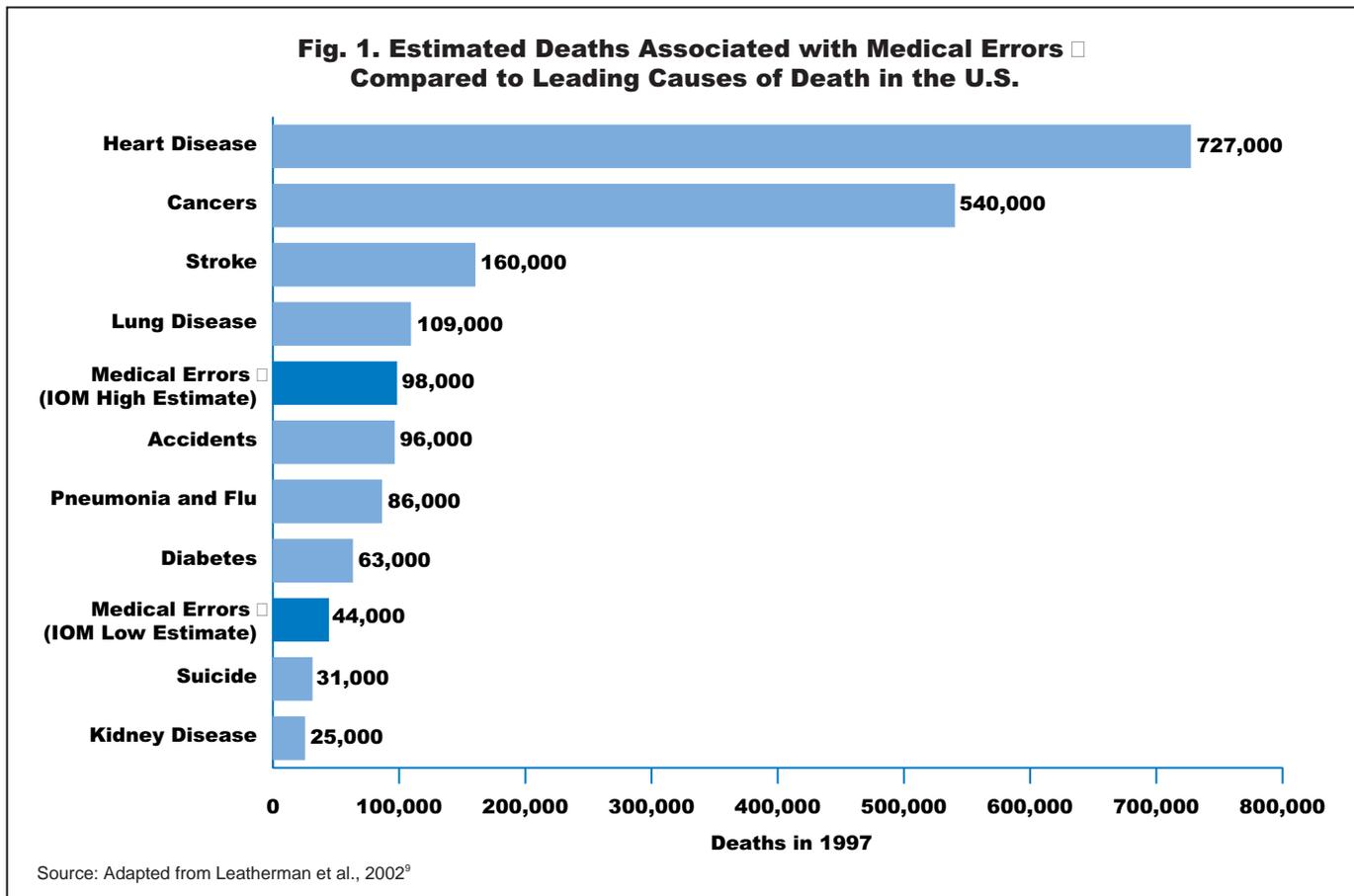
IOM Recommendations

The IOM report provided a blueprint for reducing medical errors, naming four key factors that contribute to the epidemic of errors. First, fragmentation and decentralization of the health care system may create unsafe conditions for patients and impede patient safety efforts. Second, licensing and accreditation processes give insufficient attention to preventing errors. Third,

**Fig. 1. Estimated Deaths Associated with Medical Errors
Compared to Leading Causes of Death in the U.S.**

Cause	Deaths in 1997
Heart Disease	727,000
Cancers	540,000
Stroke	160,000
Lung Disease	109,000
Medical Errors (IOM High Estimate)	98,000
Accidents	96,000
Pneumonia and Flu	86,000
Diabetes	63,000
Medical Errors (IOM Low Estimate)	44,000
Suicide	31,000
Kidney Disease	25,000

Deaths in 1997

Source: Adapted from Leatherman et al., 2002[9]

the medical liability system, which discourages physicians from admitting mistakes, impedes systematic efforts to uncover and learn from errors. Fourth, third-party purchasers of health care offer little incentive for health care organizations and providers to improve safety and quality.

The report called for a fundamental transformation in the delivery of health care, emphasizing the culpability of the entire medical system rather than individual physicians.[10] It also recommended a strategy by which government, health care providers, industry, and consumers could reduce medical errors. Commission members called for a 50 percent reduction in the number of errors by 2004, and outlined a four-tiered strategy:

- *Patient Safety Center at AHRQ*
  Congress should create a Center for Patient Safety within the Agency for Healthcare Research and Quality (AHRQ). The center

should enhance the current knowledge base on patient safety by developing a research agenda, disseminating grants for research on patient safety, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.[11]

- *Error-Reporting Systems*
  Nationwide mandatory and voluntary reporting systems should be developed to help identify and learn from errors. Under the mandatory system, commission members stipulated that state governments should collect standardized information about adverse events that result in death or serious harm.[12] Voluntary reporting systems should complement mandatory systems by focusing on errors that cause minimal harm and should help detect system weaknesses that can be fixed before serious harm occurs.

- *Performance Standards*
  Oversight organizations, professional groups, and group purchasers of health care should help raise performance standards. Commission members urged these groups to set and enforce explicit performance standards for patient safety through regulatory mechanisms such as licensing, certification, and accreditation, as well as defining minimum performance levels for health professionals.

- *Safety Systems within Health Care Organizations and Patient Responsibility*
  Health care organizations should implement safety systems to ensure safe practices at the delivery level. The report stressed the need for strong leadership on the part of clinicians, executives, and governing bodies. It also noted that patients should take responsibility for their own safety by knowing what medications they take and notifying their doctors about side effects.[13]

Five-Year Appraisal: Progress toward IOM Recommendations

Patient Safety Center at AHRQ

Within months of the IOM report, Congress instructed the Agency for Healthcare Research and Quality (AHRQ) to establish a Center for Patient Safety and lead a national effort to combat medical errors and improve patient safety. The Healthcare Research and Quality Act (P.L 106-129) took effect in December 1999 and required AHRQ to build capacity to study and eliminate medical errors, develop systems to detect errors, and identify and develop systems to enhance safety. The law authorized appropriations for five years. In the first three years, the center received $165 million. In FY 2004, the center received $80 million.[14] The funding of this center represents the federal government's single largest investment in patient safety.[15] Some experts argue that it is not enough.[16]

AHRQ's efforts to reduce medical errors have focused largely on developing centers of excellence in patient safety research, awarding training grants, and collaborating with professional

Table 1. AHRQ Patient Safety Budget

Fiscal Year	Appropriation
FY 2001	$50 million
FY 2002	$55 million
FY 2003	$55 million
FY 2004	$80 million
FY 2005	$84 million

Note: Of the $80 and $84 million in fiscal years 2004 and 2005, respectively, $50 million is earmarked for information technology development and the remainder is for patient safety research.
Source: Patient Safety Mechanism Summary, 2004, Agency for Healthcare Research and Quality, Budget Office.

organizations. Charged with the job of disseminating evidence-based best practices,★ AHRQ commissioned the University of California Evidence-Based Practice Center (EPC) to review the scientific literature regarding safety improvement. The center identified 73 interventions likely to improve safety. Of these, 11 are considered highly effective but not performed routinely in hospitals and nursing homes. In general, they are clinical interventions[17] that decrease the risks associated with hospitalization, critical care, or surgery. Table 2 outlines these practices in descending order of effectiveness, beginning with the most highly rated.

Identifying these interventions enabled AHRQ to create a set of guidelines for health care providers to encourage improvements in patient safety.[17] Information about these best practices has been widely disseminated through interactive workshops, satellite broadcasts, and summary documents.[18]

The Agency for Healthcare Research and Quality has also developed three sets of Web-based Quality Indicators (QI's), which hospitals and other health care providers can download free of charge: Preventive Quality Indicators (PQIs), Inpatient Quality Indicators (IQIs), and Patient Safety Indicators (PSIs).[19] All three use readily available hospital inpatient administrative data. The PQIs focus on hospitalizations that could have been avoided with timely access to outpatient care or conditions that could be less severe with early

---

★ Evidence-based best practice is the use of current, best evidence to make decisions about health care delivery.

Table 2. Most Highly Rated Patient Safety Practices

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk.

- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality.

- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections.

- Appropriate use of antibiotic prophylaxis in surgical patients to prevent postoperative infections.

- Asking that patients recall and restate what they have been told during the informed consent process.

- Continuous aspiration of subglottic secretions (CASS) to prevent ventilator-associated pneumonia.

- Use of pressure-relieving bedding materials to prevent pressure ulcers.

- Use of real-time ultrasound guidance during central line insertion to prevent complications.

- Patient self-management for warfarin (Coumadin™) to achieve appropriate outpatient anticoagulation and prevent complications.

- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients.

- Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections.

Source: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. 2001. Evidence Report/Technology Report: Number 43. Agency for Health Care Quality.

interventions.[20] The IQIs measure the quality of care in hospitals and include inpatient mortality for certain procedures and medical conditions; utilization of procedures for which there are questions of overuse, underuse, and misuse; and volume of procedures for which there is some evidence that a higher volume of procedures is associated with lower mortality.[21] The PSIs detect potential adverse events such as surgical complications and iatrogenic conditions associated with hospitalization.[22] The Quality Indicators (QIs) have been adopted for use by many hospitals and provider organizations across the country interested in performance measurement.[23]

Error-Reporting Systems

Perhaps the most controversial of the IOM recommendations dealt with error-reporting systems. Research suggests that health professionals are reporting errors more truthfully than in the past.[24] However, evidence also suggests that when physicians do disclose errors, some craft their statements to avoid admission of guilt or explicit discussion of the error.[25] Doctors cite the fear of malpractice litigation as the principal reason why their error disclosure often falls short of being truthful and comprehensive. Physicians also state that greater legal safeguards are necessary for a mandatory reporting system to be successful.[26] Advocates of voluntary reporting argue that the current fault-based system, which places blame on the individual, will result in underreporting and functions as a significant disincentive to disclose error. Proponents of mandatory reporting argue that voluntary reporting will not produce complete information, making it less valuable for identifying trends, ensuring corrective action, and issuing public reports.[27]

Experts differ regarding the most effective reporting system. Some suggest that voluntary systems combined with strict confidentiality may be the best method to encourage health professionals to report mistakes.[28] Others argue that mandatory systems are most effective, given research showing that hospitals report fewer care-related injuries in states with voluntary systems than in states that mandate reporting.[29]

Prior to the IOM report, 15 states had mandatory reporting systems.[30] These states varied in their definitions of adverse events. The IOM report defined an adverse event as a serious injury resulting from medical management, and not from the underlying condition of the patient.[31, 32] Numerous bills dealing with these issues remain deadlocked in state legislatures.[33] Currently, 22 states have mandatory reporting systems, covering 63 percent of the U.S. population.[34] However, the release of medical error data is sporadic across the

various systems. Generally, states that introduce mandatory systems establish them in statute, rather than regulation. These systems protect collected data and only release data in aggregate form. Of the 22 states, seven release incident-specific data. Fourteen states issue or plan to issue aggregate reports. Of these, five issue or plan to issue aggregate reports with individual facilities identified.[35]

Performance Standards

Both public and private health care systems have tried to elevate performance standards since release of the IOM report. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)★ has begun to enforce a broad set of standards focusing on patient safety.[36] These include revisions to existing standards in order to support error-reduction programs in accredited organizations as well as to develop new safety standards.[37] JCAHO incorporated these standards into its survey process, which evaluates safety and quality for nearly 5,000 hospitals. As part of its accreditation program, JCAHO also requires hospitals to conduct root-cause analyses of adverse events, a process to get at the factors leading to errors. JCAHO encourages, but does not require, hospitals to report adverse events. Recently, JCAHO began developing program-specific patient-safety goals for each of its accreditation and certification programs. JCAHO also surveys health care organizations that use new medication management standards.[38,39]

The Patient Safety Task Force within the Department of Health and Human Services coordinates a joint effort among HHS agencies to improve existing systems and integrate data on medical errors.[40] The task force has initiated two strategies to create a coordinated reporting system. The first relies on the Agency for Healthcare Quality and Research to support a series of demonstration projects to identify the causes of

errors and to develop evidence-based systems for their reduction. In FY 2001, AHRQ awarded $25 million to 24 demonstration projects. The second strategy is to develop national benchmarks for patient safety promotion. In the short term, the goal is to develop accurate assessments of adverse events. In the long term, this project aims to collect reliable rates of patients' error risk to be used to compare progress in error reduction across health care facilities.[41]

Most notable in the private sector for improving performance standards has been the Leapfrog Group, a consortium of several Fortune 500 companies and other private and public health care purchasers. The Leapfrog Group encourages large employers to reward health plans and hospitals that make breakthrough improvements in patient safety and quality. Several U.S. purchasers established the organization in 2000 to develop a common set of purchasing standards to promote patient safety and care quality. The consortium also asks hospitals to report publicly on how they meet four standards, or "leaps," proven to reduce preventable medical errors: computerized physician order entry, evidence-based hospital referral, ICU physician staffing, and the National Quality Forum's safe practices.[42]

Safety Systems within Health Care Organizations

The IOM report placed medication errors among the most common preventable mistakes in hospitals, contributing to more than 7,000 deaths annually.[43] One recent study found that medication errors occur in nearly one of every five doses in hospitals and skilled nursing facilities.[44] To reduce medication error, the American Hospital Association (AHA), Health Research and Education Trust (HRET), and the Institute for Safe Medication Practices (ISMP) have formed a partnership to promote safety. Since publication of the IOM report, the partnership has distributed the ISMP Medication Safety Self Assessment to

---

★ JCAHO is an independent, not-for-profit government organization that accredits and evaluates more than 15,000 health care programs and organizations.

1,400 hospitals in 2000 and 1,600 hospitals in 2004. The assessment reviews medication safety practices in hospitals, heightens awareness of key characteristics of a safe medication system, and provides hospital leaders with an inventory of successful practices for reducing errors. In response to the medication safety gaps identified in the first round of surveys, AMA, HRET and ISMP developed Pathways for Medication Safety, a set of educational tools for hospitals to improve safety.[45]

Error-Reducing Technology
Increasingly, information technology is being used to reduce errors. Computerized physician order entry (CPOE) can reduce errors by 55 to 86 percent.[46] However, upfront costs associated with implementation, both financial and administrative, have been major deterrents.[47] As a result, CPOE implementation has been slow; approximately 10 percent of hospitals have made CPOE completely available and approximately 7 percent of hospitals have made CPOE partially available to physicians.[48] The limited number of CPOE systems means that most patient safety reports cannot be generated automatically, making data collection mechanisms cumbersome, expensive and sporadic. The lack of standardization also makes it difficult to aggregate data or identify trends.[49] Only a fraction of hospitals have implemented electronic health record systems. However, many hospitals have made progress implementing computerized laboratory results.[50]

Patient Responsibility
JCAHO and the Centers for Medicare and Medicaid Services (CMS) launched a national program, Speak Up, to urge patients to take a role in preventing health care errors. The program distributes brochures, posters, and buttons on patient safety topics. For example, one brochure, *Help Prevent Errors in Your Care: For Surgical Patients*, offers tips to help patients prepare for surgery and to ensure that they have the correct procedure performed at the correct site on their body.

Another, *Preparing to Be a Living Organ Donor*, gives basic facts about organ donations.[51]

Recent Patient Safety Activity

Veterans Administration Activity
Prior to the IOM report, the Veterans Administration identified patient safety as a high priority issue and began a Patient Safety Improvement Initiative. The VA launched a National Center for Patient Safety to lead its patient safety effort. The VA has also supported its patient safety and quality improvement activities with a computerized patient record system and other clinical information systems. The VA requires all of its hospitals to implement a bar code medication administration system to prevent errors in drug dispensing and blood transfusion. Pilot tests indicated that the technology reduced the medication error rate by 70 percent over a five-year period.[52,53] The VA also partnered with the National Aeronautics and Space Administration to apply the aviation error and near-miss reporting process to its health care delivery system. Together, the VA and NASA developed the Patient Safety Reporting System (PSRS), a voluntary, confidential, and nonpunitive program for the reporting of events and concerns related to patient safety. PSRS, designed to identify broad system vulnerabilities, serves as a complement to the VA's mandatory internal reporting system.[54] Recently, the Agency for Healthcare Quality and Research partnered with the VA's National Center for Patient Safety (NCPS) to create the Patient Safety Improvement Corps, a training program for state health officials and their hospital partners. The Corps offers training based on NCPS patient safety programs. In the first year, 50 organizations from 14 states participated.[55] NCPS also has served as an example for patient safety activities internationally, training patient safety representatives from around the world to apply the NCPS program structure and principles to efforts in their respective countries.[56]

Military Health Care System Activity

The Department of Defense is implementing a range of electronic systems for recording and accessing patient health information. DOD's Composite Health Care System II (CHCS II) has a long-term goal of incorporating nine million military personnel and their dependents into the system by 2006. A medical and dental clinical information system, CHCS II generates, maintains, and provides secure online access to comprehensive health records. The Theater Medical Information Program gives deployed military physicians immediate access to health data for troops, allowing them to track trends across health care facilities. TRICARE Online enables military beneficiaries to schedule appointments online with primary care physicians, search through medical information, locate details about medical providers, and check for drug interactions. DOD recently launched an integrated pharmacy system for beneficiaries, with the goal of allowing DOD physicians to track prescriptions as they are filled in pharmacies worldwide. To strengthen its safety program, the DOD implemented an error reporting system modeled after the VA's.[57]

While both the VA and DOD have implemented safeguards to protect their own patients, some patients receive medications and services from both agencies, and coordination problems may mean they are less well protected. Concern about medication safeguards for shared patients has led to a joint venture between the VA and DOD to address medical safety problems regarding dually eligible beneficiaries.[58]

Medicare Activity

The Centers for Medicare and Medicaid Services recently initiated the Hospital Quality Initiative, which aims to create a standard set of quality measures for hospitals. One component is the quality incentive demonstration program in collaboration with Premier Inc., a nationwide organization of not-for-profit hospitals. The demonstration involves 278 hospitals and uses financial incentives to encourage quality care. Participating hospitals that provide high quality care are rewarded with increased payments for Medicare patients. Hospitals also receive bonuses based on quality measures for selected clinical conditions, such as heart attack, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacements. However, because the dollars are budget neutral, some hospitals may be paid less than they would have been had there been no demonstration.[59]

Private Sector Activity

Kaiser Permanente, the nation's largest private sector health care delivery system, recently began a 10-year, $3 billion national information technology program, KP Health Connect. The goal is to computerize medical records for Kaiser's 11 million members, with the long-term aim of giving Kaiser doctors and nurses nationwide online access to patients' medical information. Early indicators show that electronic medical records are accessed 10 times more frequently than paper records.[60]

State Activity

Seventeen states have formed, or are developing, statewide public/private patient safety coalitions. These programs focus on disseminations of best practices, mandatory and voluntary error reporting, education of policymakers and consumers, professional accountability, development of information technology, and systems improvement.[61] Of the states with patient safety coalitions, Massachusetts and Florida have made notable progress toward medical error reduction and patient safety.

In 1998, Massachusetts founded the first state patient safety coalition, the Massachusetts Coalition for the Prevention of Medical Errors. The move was prompted by the death of a Boston Globe medical reporter, Betsy Lehman, in 1994, following a chemotherapy overdose. The Coalition has been in the forefront of national activities to promote a systems-oriented approach to improving

patient safety.[62] The Massachusetts Department of Public Heath (MDPH) was awarded a three-year, $4.5 million grant from the Agency for Health Care Research and Quality to study the root causes of medical errors and devise appropriate prevention strategies. MDPH has worked on several initiatives, including improved systems for reporting errors and best practices to prevent common errors. Recently, the MDPH created a Patient Safety Center to coordinate state agency initiatives, promote ongoing collaboration between the public and private sectors, and coordinate state and federal patient safety programs.[63]

In 2003, Florida passed the nation's most comprehensive patient safety legislation, the Medical Incident Bill. The objectives are to create a near-miss reporting system, establish quality indicators for consumers' use in selecting hospitals, and create the Florida Patient Safety Authority—an organization established to analyze patient safety data, identify best practices, provide continuing education to practicing health care providers, and institute statewide electronic infrastructure.[64] Meanwhile, a pilot project in Pennsylvania, a state that requires near-miss reporting, found that 96 percent of the medical error reports submitted were for near-misses. A Commonwealth Fund–supported project in Pennsylvania and Minnesota is currently assessing whether near-miss reporting is associated with improvements in hospitals' underlying "culture of safety." [65]

Liability Activity
In response to criticisms of the medical liability system, the Institute of Medicine proposed demonstration projects in 2002 to experiment with alternative models for tort reform. These projects aimed to create injury compensation systems outside of the courtroom that would provide timely, fair compensation to injured patients and promote nonadversarial discussions between patients and clinicians. They were also intended to create an environment that encouraged providers

to report and analyze medical errors, involve patients in safety improvement activities, and reward providers who put effective programs in place to reduce medical injuries.[66] The existing literature on medical liability and patient safety suggests that increased efforts toward tort reform are still necessary.[67] Experts are calling for reform that will reduce the need for litigation by improving risk management, communication with patients, and fair compensation if injury occurs.[68]

Legislation in the 108th Congress[69]
The House and Senate passed similar but different versions of the Patient Safety and Quality Improvement Act in the 108th Congress. The legislation did not go to conference. Both bills would have:

- Created a national, voluntary database of non-identifiable patient safety data to track trends and identify systems-based causes of medical errors that resulted in minor injuries or "near misses."[70]

- Identified patient safety organizations (PSOs) to collect and assess confidential safety data.

- Made patient safety data privileged to prohibit it from being used against providers in litigation or administrative proceedings.

- Developed standards for communication of health information using IT.

The main differences between the House and Senate bills focused on definitions of patient safety data, legal protections for patients, the role of the Agency for Healthcare Quality and Research, and FDA standards. The House bill defined patient safety data as any documents and communications developed by providers for reporting purposes. It did not include information that is part of traditional medical record keeping, such as medical or billing records. The Senate legislation defined patient safety data as any information, reports, records, memoranda, analyses, or statements that

could result in improved patient safety or quality of care.

Under the House legislation, patient safety information would be protected from use in civil and administrative proceedings as well as from Freedom of Information Act requests. The legal protections in the Senate bill would shield patient safety information from use in civil, and administrative proceedings as well as criminal action unless a judge determines that it contains evidence of an intentional act to harm the patient directly.

The House legislation authorized the Agency for Healthcare Quality and Research to establish a national database to receive and analyze information submitted by patient safety organization as well as develop voluntary national standards to promote health information technology systems. The Senate bill instructed the Agency for Healthcare Quality and Research to maintain a network of databases to receive and analyze data reported by patient safety organizations and providers as well as establish common standards for reporting the data. Finally, the House legislation directed the FDA to issue standards for unique product identifiers, such as bar codes, on the packaging of drugs and biological products. The Senate bill did not include provisions for unique product identifiers.[71]

Are Patients Safer Five Years Later?

The IOM report called for a 50 percent reduction in medical errors by 2004. Unfortunately, it is not possible to quantify the number of errors today and therefore impossible to determine if the goal has been met.[72] Recent research suggests errors remain high and there are many issues around substandard quality in addition to error.[73, 74] Further-more, the 1999 IOM report focused primarily on errors in hospitals, but errors occur in other settings, such as ambulatory care and nursing homes.[75, 76] The IOM's 2001 publication, *Crossing the Quality Chasm: A New Health System for the 21st Century*, highlighted the overuse, misuse, and underuse of care, and

called for a "fundamental change" in the health care delivery system.[77] As a summary statistic, the average patient receives only 55 percent of the services that would benefit that individual.[78]

While the 1999 and 2001 IOM publications catalyzed a national movement toward error reduction and patient safety, physicians and the public have not demonstrated a similar urgency. In 2001, more than one of five Americans reported they or a family member had experienced a medical error. Some researchers believe that the IOM figures regarding medical errors may represent the tip of the iceberg.[79] In 2002, 35 percent of physicians and 42 percent of the public reported errors in their own or a family member's care. Neither group, however, placed errors among the most important problems in health care. In fact, a majority of both groups believed that the number of in-hospital deaths due to preventable errors is lower than IOM estimates.[80] Today, most Americans don't believe the nation's quality of care has improved. A 2004 study found that 40 percent of people said the quality of care had gotten worse in the past five years, while 17 percent said quality had gotten better and 38 percent said it had stayed the same.[81]

Business Case for Quality

Quality has become one of the most pressing issues facing the health care industry. That medical care appears to obtain less value from the resources it uses, relative to other industries, has been a key catalyst for the recent movement toward a business case for quality.[82,83] One study found that unjustified variation in the use of certain services has been largely responsible for excessive costs in the Medicare program.[84] Another concluded that low quality care is responsible for 30 percent of all health expenditures by public and private purchasers.[85]

Research exploring the business case for quality focuses on aligning financial incentives with better quality care. The breadth of research in this area is quite expansive, including hospital

quality, purchasing, pharmaceutical management, corporate wellness, tobacco cessation, and diabetes management.[86] Despite this evidentiary base, few purchasers or consumers demand higher quality.[87] Most purchasers use their purchasing power to obtain lower prices rather than higher quality.[88] Survey data indicate that consumers want a wide choice among doctors and hospitals, low cost, and unimpeded access to their caregivers. Most consumers do not ask for information about quality, health outcomes, or error rates.[89]

Conclusion

Five years after the landmark 1999 IOM report, *To Err Is Human*, presented its dramatic findings of preventable death and injury in U.S. hospitals, notable advances have been made. They include the development of performance standards, an increase in error reporting, integration of information technology, and improved safety systems. The 2001 IOM report, *Patient Safety: Achieving a New Standard for Care*, suggests that efforts are still needed to improve safety and reduce errors. The report focuses on the development of data standards for patient safety information, the establishment of a national health information infrastructure, and a need for comprehensive patient safety program in health care organizations.[90] A successful approach to reducing medical errors and improving patient safety is likely to reflect recommendations from both IOM reports.

NOTES

[1] Estimates were obtained from the Harvard Practice Study, a 1991 study that looked at over 30,000 patient records from 51 New York hospitals as well as a study from Utah and Colorado that researched 15,000 hospital records. These estimates are low since they only include deaths that occur in hospitals and do not account for the number of people who are injured, but do not die, as a result of medical errors. See: Brennan, T.A. et al. 1991. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. *New England Journal of Medicine*. 324: 370–376; Leape, L.L. et al. 1991. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. *New England Journal of Medicine*. 324 (6): 377–384; Thomas, E.J. et al. 2000. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. *Medical Care*.

[2] Institute of Medicine. 1999. *To Err Is Human: Building a Safer Health Care System*. Washington, DC: National Academy Press.

[3] Medical errors were not a new issue in 1999. The body of research describing the problem of medical errors began to emerge in the 1990's, but did not gain national attention until after the publication of the IOM report. Also, the final report of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, released in 1998, identified medical errors as one of the four major challenges facing the nation in improving heath care quality. Based on recommendations from that report, the Quality Interagency Coordination Task Force (QuIC) was established in HHS in 1998 to coordinate quality improvement activities in Federal health care plans. See: National Health Policy Forum. March 15, 2000. *Issue Brief: Improving Quality and Preventing Error in Medical Practice*; Department of Health and Human Services. March 25, 2002. *Fact Sheet: Improving Patient Safety and Preventing Medical Errors*.

[4] Brennan, T.A. 2000. The Institute of Medicine Report on Medical Errors—Could It Do Harm? *New England Journal of Medicine*. 342: 1123–1125.

[5] Hayward, R.A. et al. 2001. Estimating Hospital Deaths Due to Medical Errors: Preventability Is in the Eye of the Reviewer. *JAMA*. 286: 415–420.

[6] Jencks, S. 2000. Public Reporting of Serious Medical Errors. *Effective Clinical Practice*. 3: 299–301.

[7] McDonald, C.J. et al. 2000. Deaths Due to Medical Errors Are Exaggerated in the Institute of Medicine Report. *JAMA*. 284: 93–95.

[8] Leape, L.L. 2000. IOM Medical Error Figures Are Not Exaggerated. *JAMA*. 284 (1): 95–97.

[9] Leatherman, S. et al. 2002. *Quality of Health Care in the United States: A Chartbook*. New York, NY: The Commonwealth Fund.

[10] Institute of Medicine. 1999. *To Err Is Human: Building a Safer Health Care System*. Washington, DC: National Academies Press.

[11] Ibid.

[12] The report recommended that adverse event reporting should initially be required of hospitals and eventually mandatory for other institutional and ambulatory delivery systems.

[13] Institute of Medicine. 1999. *To Err Is Human: Building a Safer Health Care System*. Washington, DC: National Academies Press.

[14] *AHRQ's Patient Safety Initiative: Building Foundations, Reducing Risk*. Interim Report to the Senate Committee on Appropriations. AHRQ Publication No. 04-RG005. December 2003. Agency for Healthcare Research and Quality, Rockville, MD. Retrieved from: http://www.ahrq.gov/qual/pscongrpt/.

[15] Fact Sheet: Improving Patient Safety and Preventing Medical Errors. 2002. United States Department of Health and Human Services. http://www.hhs.gov.news/press/2002pres/safety.html.

[16] Learning from Mistakes: Toward Error-Free Medicine. 2004. Investigator Awards in Health Policy: Research in Profile. 11: 1-4.

[17] Making Health Care Safer: A Critical Analysis of Patient Safety Practices. 2001. Evidence Report/Technology Report: Number 43. Agency for Health Care Quality.

[18] Fact Sheet: Improving Patient Safety and Preventing Medical Errors. 2002. United States Department of Health and Human Services. Retrieved from: http://www.hhs.gov.news/press/2002pres/safety.html.

[19] PQIs were released in November 2001. IQIs were released in May 2002. PSIs were released in March 2003. See: http://www.qualityindicators.ahrq.gov/index.htm.

[20] Prevention Quality Indicators Overview. AHRQ Quality Indicators. 2004. Agency for Healthcare Research and Quality, Rockville, MD. Retrieved from: http://www.qualityindicators.ahrq.gov/pqi_overview.htm.

[21] Inpatient Quality Indicators Overview. AHRQ Quality Indicators. 2004. Agency for Healthcare Research and Quality, Rockville, MD. Retrieved

from: http://www.qualityindicators.ahrq.gov/iqi_overview.htm.

[22] *Patient Safety Indicators Overview*. AHRQ Quality Indicators. 2004. Agency for Healthcare Research and Quality, Rockville, MD. Retrieved from: http://www.qualityindicators.ahrq.gov/psi_overview.htm.

[23] As of October 2004, there were 2,612 downloads of the IQI software, 1,760 downloads of the PQI software, and 2,006 downloads of the PSI software. As a federal agency, AHRQ is limited in the ways it can obtain and track information about users of quality indicators. Therefore, only limited case studies and anecdotal information is available about specific uses of the QIs. Conversation with Dr. Denise Remus, Senior Research Scientist, AHRQ.

[24] Lamb, R.M. et al. 2003. Hospital Disclosure Practices: Results of a National Survey. *Health Affairs*. 22: 73-83.

[25] Gallagher, T.H. et al. 2003. Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Records. *JAMA*. 289 (8): 1001–1007.

[26] Robinson, A.R. 2002. Physician and Public Opinion on Quality of Health Care and the Problem of Medical Errors. *Archives of Internal Medicine*. 162: 2186–2190.

[27] Roscoe, L.A. et al. 2002. Reporting Medical Errors: Variables in the System Shape Attitudes Toward Reporting Adverse Events. *Bulletin of the American College of Surgeons*. 87 (9): 12–17.

[28] Finkelstein, J.B. July 2004. Senate Passes Patient Safety Bill with New Error Reporting System. Retrieved from: http://www.ama-assn.org/amednews/2004/08/09/gv110809.htm.

[29] Williams, L.K. et al. 2003. Differences in the Reporting of Care-Related Patient Injuries to Existing Reporting Systems. *Joint Commission Journal on Quality and Safety*. 29: 460–467.

[30] States with mandatory reporting systems: CO, FL, KS, MA, NE, NJ, NY, OH, PA, RI, SC, SD, TN, TX, WA. States with voluntary reporting systems (including the District of Columbia): DC, GA, NC, NM, OR, WY. See: Rosenthal, J. et al. 2000. *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey*. Portland, ME: National Academy for State Health Policy.

31 Rosenthal, J. et al. 2000. *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey*. Portland, ME: National Academy for State Health Policy.

32 Institute of Medicine. 1999. *To Err Is Human: Building a Safer Health Care System*. Washington, D.C.: National Academies Press.

33 106 medical–error related bills have been introduced in state legislatures since 1999. See: National Academy for State Health Policy. Fast Facts. Retrieved from: http://www.nashp.org/_catdisp_page. cfm?lid= 59d44f84-32b5-11d6-BCEA00A0CC558925.

34 States with mandatory reporting systems at the end of 2003: CA, CO, CT, GA, FL, KS, MA, MD, ME, MN, NJ, NV, NY, OH, PA, RI, SC, SD, TN, TX, UT, WA. See: Marchev, M. 2003. http://www.nashp.org.

35 Rosenthal, J. 2003. *How States Report Errors to the Public: Issues and Barriers*. Portland, ME: National Academy for State Health Policy.

36 In 2001, JCAHO enforced patient safety standards in hospitals. These standards were extended to include behavioral health care and long–term care organizations in 2003. In 2004, they were expanded to home care organizations. See: Facts About Patient Safety. Joint Commission on Accreditation of Healthcare Organizations, http://www.jcaho.org/ accredited+organizations/patient+ safety/ facts+about+patient+safety.htm.

37 *Comprehensive Accreditation Manual for Hospitals*. 2001. Joint Commission on Accreditation of Healthcare Organizations.

38 Joint Commission on Accreditation of Healthcare Organizations. 2003. *National Patient Safety Goals*. Retrieved from: http://www.jcaho.org/ accredited+organizations/patient+safety/facts+about +patient+safety.htm.

39 Rich, D.S. 2004. New JCAHO Medication Management Standards for 2004. *American Society of Health-System Pharmacists*. 61(1): 1349–1358.

40 HHS departmental agencies included in the Patient Safety Task Force: Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS).

41 Patient Safety Task Force Fact Sheet. Department of Health and Human Services. See: http://www. premierinc.com/all/safety/resources/patient_safety/ downloads/05_AHRQ_factsheet.pdf.

42 See: http://www.leapfroggroup.org/.

43 Institute of Medicine. 1999. *To Err Is Human: Building a Safer Health Care System*. Washington, DC: National Academy Press.

44 Barker, K.N. et al. 2002. Medication Errors Observed in 36 Health Care Facilities. *Archives of Internal Medicine*.162: 1897–1903.

45 *2004 ISMP Medication Safety Self Assessment for Hospitals*. Institute for Safe Medication Practices. Retrieved from: http://www.ismp.org/PDF/ 2004Hosplrg.pdf.

46 Selected References: Dexter, P.R. et al. 2001. A Computerized Reminder System to Increase the Use of Preventive Care for Hospitalized Patients. *New England Journal of Medicine*. 345: 965–970; Teich, J.K. et al. 2000. Effects of Computerized Physician Order Entry on Prescribing Practices. *Archives of Internal Medicine*. 160:2741–2747; Bates, D.W. et al. 1997. Does the Computerized Display of Charges Affect Inpatient Ancillary Test Utilization? *Archives of Internal Medicine*. 157: 2501–2508; Bates, D.W. et al 1999. A Randomized Trial of a Computer-Based Intervention to Reduce Utilization of Redundant Laboratory Tests. *American Journal of Medicine*. 106: 144–150; Bates, D.W. et al. 1998. Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors. *JAMA*. 280: 1311–1316; Bates, D.W. et al. 1999. The Impact pf Computerized Physician–Order Entry on Medication Error Prevention. *Journal of the American Medical Informatics Association*. 6: 313-321.

47 Kuperman, G.J. 2003. Computer Physician Order Entry: Benefits, Costs and Issues. *Annals of Internal Medicine*. 139: 31–39.

48 Ash, J.S. et al. 2004. Physician Order Entry in U.S. Hospitals: Results of a 2002 Survey. *Journal of the American Medical Informatics Association*. 11: 95–99.

49 Institute of Medicine. 2004. *Patient Safety: Achieving a New Standard for Care*. Washington, DC: National Academies Press.

50 Brailer, D.J. January 2003. Use and Adoption of Computer-Based Medical Records in the United States: A Review and Update. Presentation to the IOM Committee on Data Standards. Retrieved from: http://www.iom.edu/Object.File/Master/ 10/988/0.pp.

51 See: http://www.jcaho.org/accredited+organizations/ patient+safety/facts+about+patient+safety.htm#9.

52 United States General Accounting Office. 2000. Testimony of Cynthia A. Bascetta before the Subcommittee on Oversight and Investigations, Committee on Veteran's Affairs, House of Representatives. *VA Patient Safety: Initiatives Promising but Continued Progress Requires Culture Change*. GAO/T-HEHS-OO-167.

53 Findlay, S., ed. 2000. *Reducing Medical Errors and Improving Patient Safety: Success from the Front Lines of Medicine*. Washington, DC: National Coalition on Health Care and Institute for Healthcare Improvement.

54 See: http://psrs.arc.nasa.gov/web_docs/ PSRS_Brochure.pdf.

55 See: http://www.patientsafety.gov/NewsRels/PSIC.doc.

56 Stalhandske, E. et al. 2002. Department of Veterans Affairs Patient Safety Program. *American Journal of Infection Control*. 30 (5): 296–302.

57 See: http://www.ha.osd.mil/.

58 United States General Accounting Office. 2002. Report to Chairman, Subcommittee on Defense, Committee on Appropriations, U.S. Senate. *VA and Defense Health Care: Increased Risk of Medication Errors for Shared Patients*. GAO-02-1017.

59 See: http://www.cms.hhs.gov/quality/.

60 This study was conducted at Kaiser's Colorado region. Data indicate that before implementation of electronic medical records, paper charts were retrieved 90,000 per month. After implementation, electronic medical records patient charts were accessed one million times per month. Statement of Andrew M. Wiesenthal, M.D., Associate Executive Director, Kaiser Permanente. June 17, 2004. Testimony Before the Subcommittee on Health of the House Committee on Ways and Means.

61 The 17 states with patient safety organizations are: AR, CA, CO, FL, GA, IA, MA, MD, MI, MN, OH, PA, TN, TX, VA, UT, WI. See: Comden et al. 2002.

Statewide Patient Safety Coalitions: A Status Report. Portland, ME: National Academy for State Health Policy.

62 See: http://www.macoalition.org/.

63 MDPH Creates a New Patient Center to Reduce Medical Errors. January 12, 2004. See: http://www.mass.gov/dph/media/2004/pr0112.htm.

64 The legislation also included provisions focused on medical negligence. See: http://umdas.med.miami.edu/ MPSC/the_projectsahca.html.

65 Commonwealth Fund grant to ECRI, "Promoting Hospitals' Culture of Safety: Assessing the Merits of State Adverse Event and Near-Miss Reporting," approved Nov. 9, 2004. See: http://www.cmwf.org/ grants/grants_show.htm?doc_id=248527.

66 Institute of Medicine. 2003. *Fostering Rapid Advances in Health Care: Learning from System Demonstrations*. Washington, DC: National Academies Press.

67 Sage, W. 2003. Understanding the First Malpractice Crisis of the 21st Century. *Health Law Handbook*. ed. Alice Gosfield, West Law.

68 Sage, W. 2003. Medical Liability and Patient Safety. *Health Affairs*. 22 (4): 26–36.

69 This legislation is also discussed in the background brief, *International Innovations in Health Care: Quality Improvement in the UK*, by Gillian SteelFisher. Further, both briefs share language pertaining to the legislation. In addition, both rely heavily on: Redhead, C.S. November 26, 2003. *Patient Safety: Legislation to Promote Voluntary Reporting of Medical Errors*. CRS Report for Congress. Washington, DC: Congressional Research Service.

70 Neither bill addressed mandatory reporting to state agencies of errors that result in serious injury or death.

71 Redhead, S.C. 2003. *Patient Safety: Legislation to Promote Voluntary Reporting of Medical Errors*. Congressional Research Service.

72 Robert Wachter, M.D., a leading authority on medical errors based at the University of California San Francisco Medical Center, believes that the nation's response to the IOM's call to action rates only a 'C+'. See "The End of the Beginning: Patient Safety Five Years After *To Err Is Human*, Robert M. Wachter, M.D., *Health Affairs* Web Exclusive, November 30, 2004 W4-534–W4-545.

[73] Berwick, D.M. 2003. Errors Today and Errors Tomorrow. *New England Journal of Medicine*. 348: 25.

[74] Millenson, M.L. 2003. The Silence. *Health Affairs*. 22 (2): 103–104.

[75] Gurwitz J.H. et al. 2000. Incidence and Preventability of Adverse Drug Events in Nursing Homes. *American Journal of Medicine*. 109 (2): 87–94.

[76] Gurwitz J.H. et al. 2003. Incidence and Preventability of Adverse Drug Events Among Older Persons in the Ambulatory Setting. *JAMA*. 289 (9): 1107–1116.

[77] Institute of Medicine. 2000. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academies Press.

[78] McGlynn et al. 2003. The Quality of Health Care Delivered to Adults in the United States. *New England Journal of Medicine*. 348 (26): 2635–2645.

[79] Davis, K. et al. 2002. *Room for Improvement: Patients Report on the Quality of Their Health Care*. The Commonwealth Fund.

[80] Blendon, R.J. et al. 2002. Views of Practicing Physicians and the Public on Medical Errors. *New England Journal of Medicine*. 347 (24): 1933–1940.

[81] *National Survey on Consumer's Experiences with Patient Safety and Quality Information: News Release*. November 2004. Kaiser Family Foundation, Agency for Healthcare Quality and Research, and the Harvard School of Public Health.

[82] Newhouse, J.P. 2002. Why Is There a Quality Chasm? *Health Affairs*. 21 (4): 13–26.

[83] Galvin, R.S. 2001. The Business Case for Quality. *Health Affairs*. 20 (6): 57–59.

[84] Wennberg, J.E., et al. 2002. Geography and the Debate Over Medicare Reform. *Health Affairs*. Web Exclusive. W96–W114.

[85] Midwest Business Group Health (MBGH). 2002. *Reducing the Costs of Poor-Quality Health Care Through Responsible Purchasing Leadership*. Chicago: MGBH.

[86] See for example: Meyer, J.A. 2004. *Hospital Quality: Ingredients for Success—Overview and Lessons Learned*. The Commonwealth Fund; Maio, V. et al. 2003. *Value-Based Purchasing: A Review of the Literature*. The Commonwealth Fund; Smits H. et al. 2003. *The Business Case for Pharmaceutical Management: A Case Study of Henry Ford Heath System*. The Commonwealth Fund; McGlynn, E.A. et al. 2003. *The Business Case for a Corporate Wellness Program: A Case Study of General Motors and the United Auto Workers Union*. The Commonwealth Fund; March, A. 2003. *The Business for Tobacco Cessation Programs: A Case Study of Group Health Cooperative in Seattle*. The Commonwealth Fund; Beaulieu, N.D. 2003. *The Business Case for Diabetes Disease Management at Two Managed Care Organizations: A Case Study of HealthPartners and Independent Health Association*. The Commonwealth Fund.

[87] Maio, V. et al. 2003. *Value-Based Purchasing: A Review of the Literature*. The Commonwealth Fund.

[88] Becher, E.C. et al. 2003. Improving Quality, Minimizing Error: Making It Happen. *Health Affairs*. 20(3): 68–82.

[89] Hibbard J. et al. 1996. What Type of Information Do Consumers Want in a Health Care Report Card? *Medical Care Research and Review*. 53(1): 28–47.

[90] Institute of Medicine. 2003. *Patient Safety: Achieving New Standards for Care*. Washington, DC: National Academies Press.

THE
COMMONWEALTH
FUND