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## **Medical Malpractice: The Role of Patient Safety Initiatives**

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# Medical Malpractice: The Role of Patient Safety Initiatives

## Summary

Medical malpractice and malpractice insurance continue to be issues of great concern to physicians, consumers, legislators, and others. Most of the discussion about rising malpractice insurance premiums has centered on limiting the damage awards in malpractice suits, though some attention also has been given to insurance reforms. A third, related area that has received less consideration in malpractice discussions is patient safety. Patient safety refers to the panoply of rules, practices, and systems related to the prevention of medical injury. Intrinsic to patient safety efforts are strategies to prevent medical errors.

While patient safety and medical errors have generated a great deal of discussion in legislatures in the past several years, such discussion typically has taken place separately from the debates concerning malpractice. For example, S. 544, the Patient Safety and Quality Improvement Act of 2005, encouraged the voluntary reporting and analysis of medical error data. S. 544 became P.L. 109-41 on July 29, 2005. However, medical liability issues were addressed in other legislation — specifically, H.R. 5/S. 354, the Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2005, S. 22, the Medical Care Access Protection Act of 2006, and S. 23, the Healthy Mothers and Healthy Babies Access to Care Act.

The separation of patient safety concerns from medical malpractice issues has not always been the case. Several states have passed legislation that included provisions which addressed both malpractice and patient safety issues. Research studies have explored the links between the two issues, and a few bills introduced during the 109<sup>th</sup> Congress, such as S. 1337 and S. 1784, address those links. Therefore, it is appropriate and timely to reconsider these issues collectively, and revisit the role patient safety initiatives could play in the prevention of both medical errors and medical malpractice.

Strategies to enhance patient safety differ according to the specific provider type targeted. For instance, physician education includes providing clinical guidelines about appropriate treatments for specific medical conditions, while hospital education involves performance feedback from an external organization. At the same time, general approaches may apply to both physicians and hospitals. For example, medical error reporting is a key component for patient safety enhancement, regardless of the provider focus.

The impact of patient safety initiatives on the quality of care provided continues to be an open question. Individual initiatives have resulted in promising outcomes, but the overall impact of these efforts has been mixed. To some degree, this is the case because implementation has not been as pervasive as initial intentions suggested, and also because not enough research has been done to identify, enumerate, and assess patient safety efforts.

This report will be updated periodically.

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# Medical Malpractice: The Role of Patient Safety Initiatives

## Background

Medical malpractice and malpractice insurance continue to be issues of great concern to physicians, consumers, legislators, and others.<sup>1</sup> Most of the discussion about the rising cost of malpractice insurance has centered on limiting the damage awards in malpractice suits. Some attention has been given to insurance market reforms. A third, related area that has received less consideration in malpractice discussions is patient safety.

Patient safety refers to the panoply of rules, practices, and systems related to the prevention of patient injury, also known as “adverse events.” Intrinsic to patient safety efforts are strategies to prevent medical errors; i.e., the use of an incorrect medical treatment or the failure of a specific treatment to achieve the intended result.<sup>2</sup> While patient safety and medical errors have generated a great deal of discussion in the media and in legislatures in the past several years, such discussion typically has taken place separately from the vigorous debates concerning malpractice litigation. Legislation considered during the 109th Congress has been no exception. S. 544, the Patient Safety and Quality Improvement Act of 2005, established a system for the voluntary submission and analysis of medical error data. Similar to other medical error reporting bills in recent years, it prohibited use of error data in administrative, civil, and criminal proceedings. S. 544 became P.L. 109-41 on July 29, 2005. However, medical liability issues were addressed in other legislation — specifically, H.R. 5/S. 354, the Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2005; S. 22, the Medical Care Access Protection Act of 2006; and S. 23, the Healthy Mothers and Healthy Babies Access to Care Act.<sup>3</sup> All of these bills focused on tort reform as the solution to increasing malpractice premiums.<sup>4</sup>

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<sup>1</sup> Medical malpractice generally is defined as any deviation from the accepted medical standard of care that causes injury to a patient. Malpractice insurance is a contractual arrangement whereby an insurance company accepts the financial responsibility for payment of malpractice claims against a health care provider, in return for a premium.

<sup>2</sup> Medical errors do not necessarily result in injury to a patient.

<sup>3</sup> For more details about legislative proposals to address malpractice insurance concerns, see CRS Report RL33358, *Medical Malpractice: An Overview*, by Bernadette Fernandez and Baird Webel.

<sup>4</sup> A tort is a civil (as distinct from a criminal) wrong, other than a breach of contract, that causes injury for which the victim may sue to recover damages.

The separation of patient safety concerns from medical malpractice issues has not always been the case. During the first malpractice insurance “crisis” in the mid-late 1970s, California passed a pioneering bill, the Medical Injury Compensation Reform Act (MICRA), which included provisions not only limiting damage awards and other legal reforms, but also strengthening patient safety and physician disciplinary activities. But the controversy over damage awards eclipsed those other topics, and subsequent state and federal legislative activity centered on reforming malpractice tort law.

This dynamic was repeated during the second malpractice insurance “crisis” during the mid-late 1980s. Another spate of malpractice tort reforms were proposed and debated, separate from the proposals related to health care quality and the mostly academic discussions concerning patient safety. Through most of the 1990s, patient safety issues did not command widespread legislative attention, despite research that found that medical errors caused significant health and financial problems for the individuals injured, their families, and the nation as a whole.

It wasn’t until a 1999 Institute of Medicine study on medical errors, which avoided including discussion about the malpractice insurance controversy, that the issue of patient safety finally reached national prominence. Since publication of that report, the intense media attention helped propel patient safety issues to the forefront of health care debates and legislative proposals. Given the interest in patient safety and observations by some that the nation is in the midst of its third malpractice insurance “crisis,” federal and state legislators have developed proposals to address these issues. Therefore, it may be appropriate to consider these issues collectively, and re-visit the role patient safety initiatives could play in the prevention of both medical errors and medical malpractice.

The link between malpractice and medical error has its detractors. Some health care observers refer to studies that found that the majority of malpractice claims filed do *not* involve negligent medical care.<sup>5</sup> In other words, the majority of patients who file malpractice claims have suffered medical injuries, but not of the type that would be “legally compensable” on the grounds of provider negligence.<sup>6</sup> Moreover, a seminal medical errors study showed that many lawsuits are won by patients even though expert reviewers cannot establish any evidence of negligence. At the same time, only a small proportion of patients whose injuries are caused by negligence actually end up filing a malpractice claim. Some observers cite the gap between malpractice claims and provider negligence as evidence of a faulty litigation system in need of reform. Thus, they support solutions which target the legal system, such as malpractice tort reforms.<sup>7</sup>

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<sup>5</sup> P.C. Weiler, et al., *A Measure of Malpractice*, 1993.

<sup>6</sup> G.B. Hickson, et al., “Development of an Early Identification and Response Model of Malpractice Prevention,” *Law and Contemporary Problems*, winter 1997, p. 9. (Hereafter cited as Hickson.)

<sup>7</sup> For information on state laws concerning punitive damage awards in malpractice cases, see the CRS Report RL31721, *Punitive Damages in Medical Malpractice Actions: Burden of Proof and Standards For Awards in the Fifty States*, by Henry Cohen.

Other observers argue that the emphasis on liability and damage awards negatively impacts the patient-provider relationship which, in turn, affects malpractice claims. A number of studies have shown that communication breakdowns lead to patient frustration and anger which increases the likelihood of litigation.<sup>8</sup> Some health care observers assert that the collapse in communication and trust, in addition to a health care delivery system in which time spent providing services has been compressed, adds an unhealthy, antagonistic component to modern medicine. They conclude that this adversarial element acts as a significant barrier to quality improvement and patient safety efforts.

Such an assessment was reflected in an editorial by several well-respected patient safety researchers who observed that the threat of malpractice liability to deter bad medical care has “had limited impact on reducing patient injuries.”<sup>9</sup> Indeed, the variety of disciplines involved in this debate (i.e., medicine, insurance, law, government) speaks to the complexity of the issues. It follows that any meaningful discussion about them necessitates a thorough analysis, including an analysis of patient safety.

## Patient Safety and Medical Errors

While concern about patient injuries is not new, data about adverse events was sparse and limited until fairly recently. A small, pioneering study looked at a sample of 23 California hospitals in 1974.<sup>10</sup> That analysis found that nearly 5% of hospitalizations involved injuries to patients. Extrapolating from the number of hospitals in the sample to all CA hospitals, the study investigators estimated that there were 140,000 patient injuries in that state alone in 1974. A more comprehensive study was undertaken in 1991, largely in response to the lack of robust patient injury data, by members of the Harvard Medical Practice Study (HMPS) Group. The group analyzed 1984 data from over 30,000 discharges at 51 New York hospitals and more than 67,000 litigation records, and the study is considered to be the most influential patient injury study. The HMPS found that the proportion of hospitalizations involving medical injuries was around 4%. Lucian L. Leape, one of the HMPS investigators, later extrapolated from the NY data and estimated that 180,000 individuals died annually in the U.S. as a result of medical injury. He noted that this was equivalent to “three jumbo-jet crashes every 2 days.”<sup>11</sup> In 1992, a subset of the HMPS investigators conducted a validation study by reviewing 15,000 discharges from a sample of 28 hospitals in Colorado and Utah. The findings of the CO-UT study largely corroborated those of the NY study.

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<sup>8</sup> L. Landro, “The Informed Patient: Some Hospitals Offer New Service: Helping Patients Complain,” *Wall Street Journal*, June 19, 2003.

<sup>9</sup> L.L. Leape, et al., “Promoting Patient Safety by Preventing Medical Error,” *Journal of the American Medical Association*, vol. 280, no. 16, p. 1445.

<sup>10</sup> For more detailed historical information, see P.M. Danzon, *Medical Malpractice: Theory, Evidence, and Public Policy*, 1985.

<sup>11</sup> L. Sprague, “Reducing Medical Error: Can You Be As Safe in a Hospital As You Are in a Jet?,” *National Health Policy Forum Issue Brief*, May 14, 1999, p. 2.

## The Institute of Medicine Report

The analyses from the NY and CO-UT studies formed the bulk of the evidence on which the Institute of Medicine (IOM) based its patient safety recommendations, outlined in the 1999 report, *To Err is Human: Building a Safer Health System*.<sup>12</sup> The report's findings immediately seized the attention of mainstream news media. Along with dramatic stories about individuals seriously harmed by errors, the IOM Report placed medical errors in the forefront of health care discussions. Most of the attention focused on the IOM's estimate of the number of deaths that could be attributed to errors, between 44,000 and 98,000 annually. In addition, the report estimated that the cost to the nation of all *preventable* adverse events was \$17 billion a year.

But beyond those dramatic statistics, the IOM Report emphasized a need to move away from blaming individual providers and focus instead on preventing errors via safer health care systems. The IOM concluded that medical errors generally are the result of many variables. Since blaming a single person does nothing to change those contributing variables, the same error could occur over and over again. Thus, enhancing patient safety requires a systemic approach in order to make changes to system conditions that lead to errors in the first place. In effect, this conclusion broadened the medical errors discussion to include the characteristics of health care delivery systems which contribute to the prevalence of adverse events. Also, this groundbreaking approach to addressing errors was seen as an opportunity for lessening the adversarial quality in patient-provider relationships engendered by the malpractice liability debate.

## Patient Safety Initiatives

Soon after publication of the IOM's findings, strategies to reduce medical errors were put forth from both public and private sector entities. For example, 34 medical error-related bills were introduced in state legislatures in the year following the release of the IOM Report. The proposals addressed a broad spectrum of related issues, such as adverse event reporting, reduction of medication errors, system-wide analysis, and public disclosure of information.<sup>13</sup> At the federal level, then-President Clinton charged an interagency task force to inventory current federal efforts to reduce errors and outline action items for future implementation. Three months later, the task force's report endorsed many of the IOM's recommendations and enumerated a diverse set of strategies for addressing them.<sup>14</sup> Some of those strategies included allocating funds to establish a patient safety center within the Agency for Healthcare Research and Quality (AHRQ), implementing reporting systems at a

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<sup>12</sup> Institute of Medicine, *To Err is Human: Building a Safer Health System*, 1999, can be found at [<http://www.nap.edu/books/0309068371/html/>]. (Hereafter cited as IOM, "To Err is Human.")

<sup>13</sup> L. Flowers, "State Responses to the Problem of Medical Errors: An Analysis of Recent State Legislative Proposals," National Academy for State Health Policy, Feb. 2002.

<sup>14</sup> *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact* can be found at [<http://www.quic.gov/report/>].

number of federal agencies, and developing new labeling standards to prevent medication errors.

In the private sector, one of the more visible responses was establishment of the voluntary Leapfrog Group (Leapfrog). Founded by the Business Roundtable, an association of CEOs from leading corporations, Leapfrog's mission is to mobilize purchasers of health insurance to alert health care providers that progress in patient safety would be rewarded with preferential use. As a first step, Leapfrog recommended three specific standards for comparing hospital performance: computer physician order entry, evidence-based hospital referral, and intensive care unit physician staffing.<sup>15</sup> It also developed and conducted the Leapfrog Hospital Quality and Safety Survey. The survey queries hospitals about their adherence to specific quality standards, including the three original measures recommended by Leapfrog.<sup>16</sup>

## Physician-Focused Initiatives

Some patient safety advocates point out that medical malpractice claims and awards are not a reliable gauge of an individual physician's competence. As discussed earlier, only a small percentage of patients who experience medical injuries end up filing malpractice claims, and of those who do file claims a majority did not experience injuries that meet the legal definition for negligence. Therefore, even the most conscientious physicians face uncertainty as to whether they will be sued, and negligent physicians may not be held accountable through the legal system.<sup>17</sup>

In addition, questions remain as to whether the prior experience of being sued or the threat of possible litigation make physicians practice medicine more safely. Some studies point out that a "large body of research has accumulated showing that medical malpractice liability causes doctors to practice defensive medicine."<sup>18</sup> The premise underpinning defensive medicine is that the fear of liability and the potential negative outcomes associated with malpractice claims lead physicians to administer additional health care treatments or avoid high-risk services primarily to reduce their liability risk. The implication is that defensive medicine results in either an increase in overall spending for health care that may not be medically necessary, or a decrease in access to certain services or for certain patients. Detractors suggest that the growth of cost-conscious managed care has limited physicians' ability to provide care that

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<sup>15</sup> Computer physician order entry refers to electronic prescribing systems that catch errors at the time medications are ordered. Evidence-based hospital referral pertains to a process by which patients with certain conditions are referred to hospitals known for better health outcomes in treating such conditions. Intensive care unit physician staffing refers to management and staffing of ICUs by "intensivists"; i.e., physicians with training in critical care medicine.

<sup>16</sup> The latest survey results can be found at [<http://www.leapfroggroup.org/home>].

<sup>17</sup> M.M. Mello, "Malpractice Liability and Medical Error Prevention: Strange Bedfellows?," 2003. (Hereafter cited as Mello, "Malpractice Liability.")

<sup>18</sup> U.S. Joint Economic Committee, "Liability for Medical Malpractice: Issues and Evidence," May 2003. Available online at [<http://www.house.gov/jec/>].



provides marginal medical benefit. They argue that empirical studies on defensive medicine have produced mixed findings, with “most failing to demonstrate any real impacts on medical practice arising from higher malpractice premiums or prior experience of being sued.”<sup>19</sup> Another issue for consideration is that many physicians may not face the full financial consequences of their professional conduct. Most physicians are insured against medical malpractice, and premiums for professional liability insurance are not adjusted to reflect provider experiences with malpractice claims or other disciplinary actions, (i.e., malpractice premiums are not “experience rated”).

How then can patient safety be improved with the individual provider in mind? Some have suggested that serious deviations from quality care can be addressed by strengthening licensure and accreditation requirements, and modifying physician disciplinary procedures. Others recommend a less-punitive, less-adversarial approach of assessment, feedback, and ongoing professional education.

## Licensing and Disciplining of Physicians

The regulation of physician licensure and standards for appropriate physician conduct has traditionally been the responsibility of the states. Through the licensure process states ensure that all licensed physicians have appropriate education and training, and hold providers accountable to the recognized standards of professional conduct. Under each state’s Medical Practice Act, the responsibility for physician licensure and discipline rests with the state medical boards.<sup>20</sup>

**State Medical Boards.** Any disciplinary sanctions imposed by state medical boards are reported to the Federation of State Medical Boards, medical credentialing societies, and appropriate government agencies, including the National Practitioner Data Bank (see below for more details). State medical boards also can assist the public by disclosing the current status of a physician’s license, any disciplinary actions, or, in some instances, any pending charges. Many state boards have increased consumer accessibility to this information by making it available online. For example, Massachusetts passed a pioneering law in 1996 making information about physicians’ disciplinary activities, malpractice payments, and criminal convictions available to the general public. Other states, including California, Georgia, New York, Virginia, and Washington, now offer similar online physician profiles.

Some consumer groups believe, however, that the state medical boards are not doing an adequate job of protecting the public from negligent physicians, and that the number of doctors disciplined is low compared with the number believed to be providing substandard care. They have voiced concern regarding the boards’ reliance on consumers to bring unprofessional conduct to their attention. Moreover, some observers question the effectiveness of state medical boards in the disciplining of physicians because doctors themselves make up the majority of those boards. Other

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<sup>19</sup> Mello, “Malpractice Liability.”

<sup>20</sup> Physicians who serve in the military, Veterans Administration, Public Health Service, the National Institutes of Health, and other agencies are regulated by the federal government.

observers counter that medical boards are not given adequate resources to respond to the large number of complaints that they receive. They assert that boards lack sufficient funding, authority, and information to be able to act in an appropriate and timely manner. Boards also may not be able to respond quickly because formal actions against physicians must follow a strict process of complaint, investigation, and hearing.

The Federation of State Medical Boards (FSMB), a private, non-profit association of state medical boards, has worked to improve state medical practice acts and the effectiveness of the boards. The FSMB has also developed the Federation Physician Data Center; a repository for formal actions taken and reported against physicians by regulatory and licensing entities throughout the United States and some other countries. Information on medical malpractice settlements or claims is not collected. Reporting to the FSMB is voluntary and only actions that can be legally released or are a matter of public record are included in the Data Center. Beginning in 2001, FSMB reports on disciplinary actions against physicians became available to the public.<sup>21</sup>

**National Practitioner Data Bank.** Established under the Health Care Quality Improvement Act of 1986 and made operational in September 1990, the National Practitioner Data Bank (NPDB) is a central repository for information about physicians, dentists, and, in some cases, other health care professionals. It contains reports on: medical malpractice payments; actions taken by a state Board of Medical Examiners to suspend or revoke a practitioner's license; and actions taken by a hospital or other health care entity to limit or revoke clinical privileges. The intent of the data bank is to improve the quality of health care by encouraging hospitals, state licensing boards, and other health care entities to identify and discipline those who engage in unprofessional conduct, and to restrict the ability of incompetent providers to move from state to state without disclosure or discovery of prior adverse actions taken against them. While hospitals are the only health care entities with mandatory requirements for querying the data bank, NPDB information is available to state licensing boards, professional societies, certain federal agencies, and others as specified in the statute. NPDB information is not available to the general public.

Some legislators and consumer groups have advocated for the public release of NPDB information. They argue that the public has the right to know about adverse actions against health care providers in their communities. Others, however, question the quality of the NPDB data. According to a comprehensive Government Accountability Office (GAO) report,<sup>22</sup> under-reporting may be a severe problem, and so the completeness and accuracy of the NPDB information are an open question. Health care practitioners also oppose the public disclosure of NPDB information for liability and professional reasons. They assert that the NPDB data can be easily misunderstood by laypersons. For example, a simple comparison of malpractice payments made by physicians in different specialties would be misleading, since some medical specialties typically have higher rates of malpractice suits than other

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<sup>21</sup> The information is available for a fee and can be found at [<http://www.docinfo.org>].

<sup>22</sup> U.S. General Accounting Office, "National Practitioner Data Bank — Major Improvements Needed to Enhance Data Bank's Reliability," Nov. 2000.

specialities. The same can be said about certain doctors who take on riskier cases than their colleagues. Also, a data bank entry showing a payment for a malpractice claim does not necessarily indicate negligent care. It is possible this was a case in which the physician was not negligent, but settled out of court in order to avoid the costs and publicity associated with a lengthy trial.

**Public Disclosure of Reported Information.** The concern that many providers voice against making NPDB data public is the same one they express about participating in reporting systems in general. Their concern is rooted in the assumption that such information, whether it be about medical errors, adverse events, or disciplinary actions, will be used against them professionally. At a time when malpractice insurance is becoming increasingly expensive and difficult to find in some regions and for certain specialities, providers may believe they are being asked to disclose sensitive information with no guarantee of legal, administrative, or professional protection. In addition, opponents of public disclosure argue that it creates strong disincentives for openness and candor in the reporting system, thereby reducing the value of the information gathered. Disclosure proponents argue that placing medical practitioners on public notice creates strong incentives for quality improvement and assures consumers that, at a minimum, a mechanism is in place to identify serious errors and negligent providers. Moreover, they characterize physicians' fear about liability as unwarranted. For example, proponents of public reporting say that physicians in states which have posted disciplinary actions on the Internet are reporting that they have seen no negative impact from making this information public.<sup>23</sup>

## **Provider Education, Feedback, and Practice Guidelines**

The Institute of Medicine's report *Health Professions Education: A Bridge to Quality* emphasizes that oversight and reporting must be part of an integrated approach to improving patient safety which includes ongoing professional development. They recommend enabling health care providers to maintain up-to-date skills and competence through an approach that includes evaluation and feedback by peers, medical boards, certification bodies, and employers.<sup>24</sup>

Some reporting systems, particularly those conducted by managed care organizations (MCOs), are designed to furnish performance information to the participating providers on how their practice compares with their peers or with accepted practice guidelines. Practice guidelines provide recommendations about appropriate medical care, and are designed to outline the range of treatments for a given clinical situation. Such guidelines are developed from research findings about the effectiveness of certain medical therapies and practices, and expertise from practicing physicians. The Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) provided funding for the development of clinical practice guidelines and authorized the establishment of the Federal Agency for Health Care Policy and

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<sup>23</sup> "Doctors Resigned to Public Web Profiles," *American Medical News*, May 5, 2003, p. 10.

<sup>24</sup> Institute of Medicine, *Health Professions Education: A Bridge to Quality* (Washington, D.C. National Academy Press, 2003). The report can be found at [<http://www.nap.edu>].

Research (AHCPR).<sup>25</sup> AHCPR ceased internal development of clinical practice guidelines in 1996, and now — as the reauthorized Agency for Healthcare Quality and Research — supports external researchers in the creation and dissemination of evidence-based medical care.

Medical professional societies, research groups, and private-sector firms also have developed practice guidelines. In addition, MCOs and other health care entities have increasingly used practice guidelines and outcomes assessment (i.e., analysis of the impact of certain treatments or procedures on patient health) to monitor and direct the way physicians deliver health care. There is some concern, however, about the effect of practice guidelines on changing physician behavior. One study found that U.S. physicians follow recommended “best practices” for diagnosis and treatment of adults only about 55% of the time.<sup>26</sup> Some have urged that increased compliance with guidelines should be combined with other efforts to improve health care quality, such as better reporting of the quality of care, greater use of Internet technology and decision-support tools, increased patient involvement, and providing financial incentives for investment in quality-improvement infrastructure.<sup>27</sup>

Studies have shown that clinical guidelines are most effective when delivered by a “respected peer or ‘opinion leader.’”<sup>28</sup> Many physicians believe that other physicians are the most appropriate individuals to assess the quality of care delivered, and provide counseling or additional education. Peer review may be conducted at different levels: peer-to-peer, at individual hospitals, or through outside organizations such as the Quality Improvement Organizations (QIOs), which contract with the Medicare program to monitor beneficiaries’ quality of care.<sup>29</sup>

The success of feedback to medical practitioners also depends on the confidentiality, timeliness, and quality of the feedback, as well as provider immunity from administrative and legal reprisals. Similar to the public disclosure debates, supporters of confidentiality and immunity in provider feedback initiatives say that such assurances are necessary to move away from the “blame game” and encourage reporting. Detractors say that such features support a solely internal system of monitoring which is inadequate for proper intervention and enforcement.

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<sup>25</sup> AHCPR succeeded the National Center for Health Services Research and Health Care Technology Assessment. AHCPR was reauthorized in 1999 as the Agency for Healthcare Research and Quality (AHRQ).

<sup>26</sup> E. McGlynn, et al., “The Quality of Health Care Delivered to Adults in the United States,” *New England Journal of Medicine*, June 26, 2003.

<sup>27</sup> E.P. Steinberg, “Improving the Quality of Care — Can We Practice What We Preach?,” *New England Journal of Medicine*, June 26, 2003.

<sup>28</sup> Hickson, p. 26.

<sup>29</sup> QIOs are successors to the Peer Review Organization (PRO) program established by Congress under the Omnibus Budget Reconciliation Act of 1986. Additional information may be found at [[http://www.ahqa.org/pub/media/159\\_766\\_2687.cfm](http://www.ahqa.org/pub/media/159_766_2687.cfm)].

## Hospital-Focused Initiatives

With the majority of medical error studies based on inpatient data and the IOM Report's emphasis on addressing system failures, most patient safety initiatives thus far have focused on hospitals. An abundance of solutions have been proposed, such as reporting hospital performance, disseminating clinical protocols, and adopting innovative technology to aid hospitals in the creation of a "culture of safety." This endeavor was further energized by the implementation of patient safety standards by the nation's largest hospital accrediting body, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The JCAHO standards stressed not only a hospital's role in the prevention of medical errors, but also its responsibility for disclosing to patients when they have been harmed by such errors.

### Reporting of Medical Errors

Patient safety studies and initiatives emphasize the importance of "transparency" in health care delivery. Communication is the principal medium through which transparency concerns are addressed, and one of the key features of a patient safety-based communication strategy is a system for reporting adverse events.<sup>30</sup>

**Lessons from the Airline Industry.** Some of the early thinking on this issue borrowed ideas from other industries, particularly aviation. In the airline industry, pilots, controllers, and others can submit information to the Aviation Safety Reporting System (ASRS), which is administered by the National Aeronautics and Space Administration (NASA).<sup>31</sup> The ASRS is a system for reporting "near misses;" that is, incidents that do not result in accidents but nonetheless violate standard practices or rules. The system also analyzes the root causes of near misses, and communicates the findings to those involved as well as others working under similar conditions. Such a design is considered useful for identifying possible hazards and developing solutions to prevent accidents. Key characteristics of the ASRS are that it operates independently of any regulatory body, is completely confidential, and reporters are given immunity from retribution. In almost 30 years of existence, ASRS has received and processed more than 600,000 reports, and many aviation experts credit ASRS with helping to greatly increase commercial aviation safety. However, it is important to note that the ASRS does not deal with incidents which result in passenger injury or aircraft damage. Serious aviation accidents are investigated by the National Transportation Safety Board under a different system. Moreover, pilots have extra incentive to perform flawlessly since a major mistake puts them in as much immediate danger as their passengers.

The dual-system arrangement for addressing near misses and serious errors in aviation parallels the IOM's recommendation for two-tier medical error reporting. The IOM recommended establishing a mandatory reporting system to hold hospitals

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<sup>30</sup> For additional information about communication between patients and providers see "Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury," 2005.

<sup>31</sup> Additional information on ASRS can be found at [[http://asrs.arc.nasa.gov/main\\_nf.htm](http://asrs.arc.nasa.gov/main_nf.htm)].

and other health care facilities accountable for errors that lead to serious injury or death. It also encouraged the development of voluntary, confidential systems for reporting no harm events (a medical error that has been carried out but does not result in injury), minimal harm events, and near misses. Analysis of such information could then be used to identify system vulnerabilities and develop preventive strategies.

**Mandatory vs. Voluntary Reporting.** There are many ideas among stakeholders regarding the design of a health care reporting system, including who should report and what they should report. A key area of discussion is whether a reporting system should mandate participation or be voluntary.<sup>32</sup>

The primary purpose of a mandatory reporting system is to hold providers accountable by ensuring that serious mistakes are reported and investigated, and that appropriate follow-up action is taken. Medical practitioners that continue unsafe practices risk citations, penalties, sanctions, suspension or revocation of licenses, and possible public exposure and loss of business. However, the focus on collecting adverse event data and disciplining individual providers bypasses the majority of errors; errors which are caused or exacerbated by poorly-designed health care delivery systems.

According to the IOM, voluntary reporting systems play a “valuable role in encouraging improvements in patient safety.”<sup>33</sup> Experience from ongoing voluntary reporting efforts have shown that such systems are helpful in identifying: errors that occur on such an infrequent basis that they would be difficult to detect by any one single health organization, and error trends or patterns which allude to system problems that may impact all health care organizations. Identification of such events could facilitate the development of strategies to prevent more serious errors from occurring. Nevertheless, key criticisms against voluntary systems are that due to their very design, under-reporting is a constant concern, and such systems are inadequate for addressing egregious medical errors.

**Examples of Health Care Reporting Programs.** Both private and public entities have implemented patient safety reporting programs. For example, in 1996 JCAHO implemented its Sentinel Event Policy (SEP).<sup>34</sup> This policy outlines JCAHO’s expectations for how health care organizations should address sentinel events; i.e., medical events involving death or severe physical and/or psychological injury. The SEP instructs organizations to identify sentinel events, complete a thorough analysis of the root causes of those events, implement strategies to reduce their prevalence, and track the effectiveness of those strategies. The policy also encourages health care organizations to share their findings with JCAHO, in order for it to pass on those “lessons learned” to others. As of April 2006, JCAHO has released 36 alerts that describe different types of serious medical events and suggest

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<sup>32</sup> “Medical Mistakes,” *CQ Researcher*, vol. 10, no. 7.

<sup>33</sup> IOM, “To Err is Human,” p. 104.

<sup>34</sup> Additional information about JCAHO’s Sentinel Event Policy can be found at [<http://www.jcaho.org/accredited+organizations/sentinel+event/sefacts.htm>].

ways to prevent them. The alerts also include statistics on the prevalence of these medical events, but do not name specific hospitals.

With respect to the states, 28 have passed legislation or issued regulations mandating the reporting of adverse events or medical errors in hospitals.<sup>35</sup> The reporting requirements vary widely. For instance, state mandates differ in what health facilities are required to do with reported information: review reports about medical violations, share information with patients, disseminate evidence-based, error-prevention protocols, etc. In general, the quality and quantity of information collected are major concerns. Only a few states get enough information to conduct proper analyses, and some of the information reported is not useful. But a few states are able to conduct analyses and use the findings in their role as regulator.<sup>36</sup>

**“Honesty Policies”.** While most of the attention paid to better communication has centered on reporting systems, a few health care entities have implemented programs which directly engage individuals injured by medical errors. “Honesty policies” have been instituted in a small minority of hospital and health care systems to encourage providers and staff to admit that they have committed errors. In addition, these institutions offer compensation to injured patients to pay for medical treatment or cover lost income. Such practices, however, are uncommon. Providers typically resist disclosure of adverse medical events.<sup>37</sup> Supporters of honesty policies assert that such policies help maintain openness and trust in patient-provider relationships, which may diffuse potentially volatile situations. Others argue that these policies elicit declared admissions of guilt, thereby exposing medical practitioners to even greater liability.

## Clinical Standards in Hospital Settings

Medical guidelines generally are developed with a particular health condition in mind and individual providers as the target audience. However, given the increased awareness about medical errors caused by weaknesses in health care systems, there is more attention being paid to the application of clinical standards to hospitals. For instance, AHRQ developed a set of Quality Indicators (QIs) to measure the level of quality associated with the medical care being delivered in hospitals. One of the components which make up the QIs is a set of Patient Safety Indicators (PSIs). The PSIs provide information on potential inpatient adverse events, such as accidental puncture, obstetric trauma, transfusion reaction, etc. AHRQ encourages hospitals to use the PSIs to assess patient safety at their facilities.

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<sup>35</sup> States with mandatory reporting requirements: CA, CO, CT, FL, KS, IL, IN, ME, MD, MA, MN, MO, NE, NV, NH, NJ, NY, NC, OH, PA, RI, SC, SD, TN, TX, VA, WA, and WY. A. McKinley, “Medical Errors and Patient Safety,” *HPTS Issue Brief*, Dec. 31, 2005. (Hereafter cited as McKinley, “Medical Errors and Patient Safety”)

<sup>36</sup> According to National Academy for State Health Policy staff.

<sup>37</sup> C. Liebman and C. Hyman, “A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients,” *Health Affairs*, July/Aug. 2004.

## Information Technology

Another area on which a great deal of attention is focused is information technology (IT). Many observers believe that the health care system lags behind other industries in utilizing such technology and should incorporate these innovations at multiple levels in order to enhance patient safety. The IOM's report, *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century*, concluded that IT's role in the future of health care delivery is key, and the automation of health care transactions is fundamental to the prevention of medical errors.<sup>38</sup>

**Proposed IT Initiatives.** The applicability and potential benefits of IT to health care are immense. Supporters recite a litany of uses: patient-physician communication via e-mail, bar-coding of pharmaceuticals, instantaneous retrieval and sharing of patient records, etc. Some e-health care pioneers tout the savings in time and resources, in addition to a reduction in medical errors, resulting from IT investments.

A number of public and private-sector organizations, to varying degrees, have incorporated IT into their policies, programs, and operations. For example, President Bush in his 2006 State of the Union address expressed his desire to reduce medical errors through wider adoption of information technologies. Moreover, included in the President's FY2007 budget request is \$169 million for health IT initiatives to improve quality and reduce errors, among other objectives.<sup>39</sup>

The Food and Drug Administration (FDA) issued a final rule on February 26, 2004 that required bar codes on labels for pharmaceuticals and biological products, in order to reduce the probability of errors which cause adverse medical events. The FDA estimated that the rule would prevent nearly a half-million drug and transfusion errors over the next two decades.<sup>40</sup>

A related strategy to reduce adverse drug events comes from the private-sector Leapfrog Group. One of the three measures which form the core of its hospital performance monitoring efforts is implementation of computer physician order entry (CPOE) systems. Such systems allow physicians to order medications electronically and alerts them to possible prescribing errors.

In addition to government officials and health care practitioners, corporate managers recognize the benefit of adopting technology for patient safety enhancement. For example, the Health Information and Management Systems Society, a health care IT member organization, conducts an annual survey of chief

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<sup>38</sup> Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century*, 2001, can be found at [<http://www.nap.edu/books/0309072808/html/>].

<sup>39</sup> "Health," Office of Management and Budget (OMB) website, at [<http://www.whitehouse.gov/omb/pdf/Health-07.pdf>].

<sup>40</sup> FDA, press release, "HHS Announces New Requirements for Bar Codes on Drugs and Blood to Reduce Risks of Medication Errors," Feb. 25, 2004, can be found at [[http://www.fda.gov/bbs/topics/news/2004/hhs\\_022504.html](http://www.fda.gov/bbs/topics/news/2004/hhs_022504.html)].



information officers (CIOs) at integrated delivery systems, multi-hospital systems, and stand-alone healthcare facilities from around the country. The latest survey results revealed that half of CIOs cited reduction of medical errors and promotion of patient safety as one of their top priorities for 2006.<sup>41</sup>

**Technology Implementation Considerations.** While the potential benefits from IT are great, so are the implementation challenges. One of the chief challenges relates to the up-front investment. For instance, the FDA's drug bar code policy requires hospitals to spend an estimated \$7-plus billion on necessary equipment.<sup>42</sup> In addition, there are costs associated with training staff, maintaining a technical assistance capacity, and updating systems and applications. There also are other less tangible but nonetheless considerable barriers to IT adoption, including data privacy, system security, and overall reliability. Perceptions of value depend heavily on how those concerns are addressed. And, lastly, culture also plays a substantial role. Familiarity and comfort with electronic systems affect how well consumers, providers, insurers, and payors will respond to e-health care efforts.

## Impact of Patient Safety Programs

The specific challenges associated with IT adoption reflect the larger concerns regarding adoption of patient safety programs in general. Individual initiatives have resulted in promising outcomes, but the overall impact of these efforts has been mixed. To some degree, this is the case because implementation has not been as pervasive as initial intentions suggested, and also because not enough research has been done to identify, enumerate, and assess patient safety efforts.

### Selected Results from the Field

While it would be very difficult to provide a comprehensive, quantitative assessment of the impact of patient safety programs, some insight can be gleaned from individual, private-sector initiatives, as well as public efforts. It is important to note that the results of specific programs are highly dependent on the environment in which they operate, the target audience, and the level of resources provided.

**Tracking and Reducing Medical Errors.** The Agency for Healthcare Research and Quality (AHRQ) submitted an interim report to the Senate Appropriations Committee which included how health care facilities track and record medical errors, and discussed how such information may be used to increase patient safety.<sup>43</sup> Hospitals and other health care facilities used a variety of approaches in their efforts to reduce errors. These approaches include not only investments in

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<sup>41</sup> "17<sup>th</sup> Annual HIMSS Leadership Survey, CIO Results" Feb. 13, 2006, at [[http://www.himss.org/2006survey/docs/Healthcare\\_CIO\\_finalreport.pdf](http://www.himss.org/2006survey/docs/Healthcare_CIO_finalreport.pdf)].

<sup>42</sup> "FDA: Proposes Bar Codes for Medications, New Error Reporting System," American Health Line, Mar. 14, 2003.

<sup>43</sup> AHRQ, Interim Report to the Senate Committee on Appropriations, AHRQ Publication No. 04-RG005, Dec. 2003, can be found at [<http://www.ahrq.gov/qual/pscongrpt/>].

technology and development of patient safety procedures, but also less well-known but equally important strategies, such as changes in organizational culture, involvement of key leaders, and education of providers. Such a breadth of activities underscored the necessity of implementing a comprehensive approach to reduce medical errors, instead of relying on a single strategy (e.g., information technology). For instance, to assist hospital efforts to enhance patient safety, AHRQ developed a survey, with both private and public partners, to measure “organizational conditions that can lead to adverse events and patient harm.”<sup>44</sup>

**Publicizing Hospital Performance Data.** Overall, the research on the impact of publicizing hospital performance measures shows mixed results. Some findings show that patient mortality decreased after hospital performance data was released, whereas other findings showed no effect. While these studies were not necessarily focused on the prevention of medical errors, they still provide some indication of how similar programs may affect patient safety efforts in general.

One study of a hospital reporting system in Wisconsin highlighted some of the common concerns involved in such efforts.<sup>45</sup> The study assessed the impact of disclosing the findings from the “QualityCounts” report, which compared the performance of 24 hospitals. In this study, some hospitals’ performance data was made public; other hospitals’ data was not publicized. The end results provided some evidence of the value of publicizing performance data to encourage quality improvement activities. For example, hospitals with low scores for obstetric and cardiac care, whose results were made public, were later involved in the most quality improvement efforts. In contrast, the hospitals whose performance was not made public had the lowest level of quality improvement activity. Not surprisingly, the analysis also found that making performance data public generated feelings of distrust and anger among the participating hospitals. All of the hospitals had a slightly negative view of public reporting in general, although they differed with respect to how they thought such reporting would affect their public image. As to be expected, hospitals with higher scores were more likely to assert that their public image would be helped, while those with lower scores were more likely to assert that their image would be hurt.

**Disclosing Medical Errors to Injured Patients.** Anecdotal evidence suggests a positive impact of “honesty policies” on the reduction of malpractice claims. The Veterans Affairs medical center in Lexington, Kentucky regularly is held up as a model for such policies. The Lexington center chose to adopt the practice after dealing with two costly malpractice cases. Since then center administrators claim that their policy has led to savings, partly due to decreased legal expenses. Also, the center did not experience a deluge of malpractice litigation as initially feared. Copic Cos., a malpractice insurer in Denver, had similar experiences. Copic’s policy directs providers to report medical complications and adverse events. Copic responds within 72 hours with offers to compensate the patient for medical

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<sup>44</sup> C. Clancy, Testimony before the Subcommittee on Health Committee on Energy and Commerce, June 9, 2005, at [<http://www.ahrq.gov/news/test60905.htm>].

<sup>45</sup> J.H. Hibbard, J. Stockard, and M. Tusler, “Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts?,” *Health Affairs*, vol. 22, no. 2.

expenses related to injuries caused by errors and lost wages. According to Copic, this policy has led to a reduction in the number of claims and smaller claim payments.

Despite these promising outcomes, some observers urge caution. They assert that patients may not receive adequate compensation without the assistance of legal counsel. Furthermore, these policies are not adequate mechanisms for addressing very serious medical errors (e.g., patient deaths). Others point out that it would be inaccurate to generalize the experience of the Lexington center to the general population. They note that VA patients generally are older men with finite resources; individuals who may have limited expectations and a lower-than-average inclination to sue.<sup>46</sup>

**Using Information Technology in Health Care Delivery.** Individual efforts to utilize information technology in health care generally have increased the quality of health care. For example, in order to overcome the lack of specialists in a rural area in California, some providers use e-mail to consult with specialists elsewhere. A Spokane, Washington medical center built an IT system to provide 24-hour pharmacist coverage for review of all medication orders. A heart institute in Kansas City, Missouri is electronically linked to a larger medical system which allows institute staff to remotely monitor cardiac patients at each of the system's care locations.

Specific IT initiatives also have enhanced patient safety. For instance, one study found that the rate of serious medication errors fell more than 50% when computerized prescribing systems were used.<sup>47</sup> Yet, despite the enthusiasm expressed by some experts for the use of IT in health care, the adoption of such technology has progressed slowly, especially in smaller medical settings. For example, "more than 90 percent of medical practices with fewer than 50 doctors do not make significant use of IT."<sup>48</sup>

## **Barriers to the Adoption of Patient Safety Programs**

**Cultural Issues.** Just as there are numerous solutions proposed to enhance patient safety, so to are there numerous barriers to implementing those solutions. Part of the reason why more has not been done is cultural. Medicine is a conservative discipline which does not change easily. Providers, especially physicians, place great value on their professional autonomy and expertise. In an environment such as this, efforts to change day-to-day practice patterns by outsiders are met with resistance. Cultural barriers apply not only to providers, but to other

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<sup>46</sup> A.W. Wu, "Handling Hospital Errors: Is Disclosure the Best Defense?," *Annals of Internal Medicine*, vol. 131, no. 12.

<sup>47</sup> D.W. Bates, et al., "Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors," *Journal of the American Medical Association*, Oct. 21, 1998.

<sup>48</sup> G. Gross, "Lack of Standards Hinders Electronic Health Records," IDG News Service, Jan. 10, 2005, at [<http://www.itworld.com/Tech/2987/050110healthstandards/pfindex.html>].

players in the health care system. For instance, proponents of publicizing patient safety information note the central role of the consumer. But study after study has shown that the vast majority of consumers generally do not seek out, use, or understand the information being made available to the public.<sup>49</sup>

**Limited Resources.** There are also resource issues contributing to the lack of progress in conducting patient safety efforts. The cost of investing in equipment, staff, and supplies are of paramount concern.<sup>50</sup> For example, state mandatory reporting systems are hampered by insufficient funding. The budgets for many state programs are small relative to their responsibilities, and some recently-enacted programs have not been implemented because of lack of funds. Some observers also point out that federal reimbursement does not take into account medical error rates or implementation of error reduction measures, so there is little incentive for providers to enhance patient safety. Unless a “business case” can be made for the potential savings resulting from patient safety initiatives, cost will continue to be a substantial barrier to such efforts. Some organizations have launched individual initiatives to address the financial feasibility concerns expressed by health care providers. For example, in April 2003, a coalition of providers, plans, purchasers, and others launched “Bridges to Excellence,” whose mission is to reward high-quality health care.<sup>51</sup> In the public sector, HHS announced on July 10 of that same year the launch of a demonstration that would provide bonuses to hospitals that perform well on selected quality-of-care standards.<sup>52</sup> More recently, S. 1932, the Deficit Reduction Act of 2005, includes provisions for the Secretary of HHS to develop a plan for value-based purchasing under the Medicare program beginning in FY2009.<sup>53</sup> These initiatives are indicative of the growing interest in pay for performance in health care.<sup>54</sup>

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<sup>49</sup> M.N. Marshall, P.G. Shekelle, S. Leatherman, R.H. Brook, “The Public Release of Performance Data: What Do We Expect to Gain?,” *Journal of the American Medical Association*, vol. 283, no. 14.

<sup>50</sup> J. Rosenthal, M. Booth, and A. Barry, “Cost Implications of State Medical Error Reporting Programs: A Briefing Paper,” *National Academy for State Health Policy*, May 2001.

<sup>51</sup> Additional information may be found at [<http://www.bridgestoexcellence.org/bte/>].

<sup>52</sup> Additional information may be found at the Centers for Medicare and Medicaid Services website, Premier Hospital Quality Incentive Demonstration, at [[http://www.cms.hhs.gov/HospitalQualityInits/35\\_HospitalPremier.asp#TopOfPage](http://www.cms.hhs.gov/HospitalQualityInits/35_HospitalPremier.asp#TopOfPage)].

<sup>53</sup> On Feb. 8, 2006, S. 1932 became Public Law 109-171. For more information, see CRS Report RL33251, *Side-by-Side Comparison of Medicare, Medicaid, and SCHIP Provisions in the Deficit Reduction Act of 2005*, by Karen Tritz, Sibyl Tilson, Julie Stone, Chris L. Peterson, Jennifer O’Sullivan, Paulette C. Morgan, Elicia J. Herz, Jean Hearne, Jim Hahn, April Grady, Hinda Chaikind, and Evelyne P. Baumrucker.

<sup>54</sup> A pay-for-performance (P4P) or value-based purchasing payment system is one where at least some portion of the payments is based on performance assessed against a defined measure. While most of the current discussions about P4P in health care address quality-based measures, performance metrics can target any of a number of variables including profitability, volume, or customer or patient satisfaction. The terms “merit” and “bonus pay (continued...)”

Additional resource concerns focus on the time and effort needed to design, implement, and maintain patient safety programs, including training staff. Some argue that this detracts from time that could be spent on direct health care. However, others counter that these efforts are a more efficient use of time and money in the long run.

**Liability and Professional Concerns.** A third set of barriers are prompted by concerns about professional and legal liability. As was mentioned earlier, some of the resistance to error reporting and public disclosure is born from the fear that such activities would make providers more vulnerable to claims of malpractice. Therefore, individual practitioners and hospitals remain cautious about implementing programs which potentially could be used against them in the courtroom, on the career ladder, and in the marketplace. For instance, the Massachusetts Group Insurance Commission (GIC), the entity that provides health insurance coverage and other benefits to the state's employees, dependents, and annuitants, ordered its health plans to collect health care quality information based on Leapfrog's safety standards. GIC's intention was to use this data for hospital comparisons. Most of the GIC hospitals refused to provide the information. Hospital administrators declared that their respective institutions were working at improving patient safety, but were concerned about the specific questions being asked. A Massachusetts hospital association spokesman noted that hospitals thought that the Leapfrog standards were too narrowly defined, and that they preferred an approach which took into account the progress that had already been made at individual institutions.<sup>55</sup>

## Lack of Patient Safety Research

In addition to implementation barriers, the difficulty in assessing the impact of error prevention efforts also relates to the lack of research in this area. Three of the most highly-regarded experts on patient safety concluded that health care studies have focused on biomedical research for decades. In contrast, "error prevention — especially the systems issues that underlie a great proportion of patient injury — is a young field, which has commanded the attention of only a small number of researchers and, until recently, has received little funding."<sup>56</sup> To illustrate, the \$84 million requested in the President's FY2007 budget to support AHRQ's patient safety efforts is equivalent to the single largest investment in this area by the federal government. However, that appropriation amounted to less than one-half of 1% of the comparable budget request for the National Institutes of Health.

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<sup>54</sup> (...continued)  
systems" also describe similar arrangements.

<sup>55</sup> J.H. Powell, "Hospitals Thwart Ratings Plan," Boston Herald, Oct. 29, 2001.

<sup>56</sup> L.L. Leape, D.M. Berwick, D.W. Bates, "What Practices Will Most Improve Safety? Evidence-Based Medicine Meets Patient Safety," *Journal of the American Medical Association*, vol. 288, no. 4, pp. 503-504.

## Federal and State Patient Safety Activities

Congressional interest in activities at the federal and state levels has evolved from generic quality issues to concerns related specifically to medical errors and patient safety. As part of this evolution, the development and implementation of legislative proposals has varied in scope, focus, and purpose.

### Federal Legislation

Since the states traditionally play the role of regulator of provider behavior, the federal government's presence historically has been small. But there was growing realization in the latter 1970s and throughout the 1980s that the need for quality improvement in health care was so pervasive and severe that efforts of individual states could benefit from federal initiatives. In the 1980s, the U.S. Congress passed a number of legislative proposals designed to address health care quality through a variety of mechanisms. Those mechanisms included state reporting systems, a national data bank, Medicare peer review, and practice guidelines. In general, the proposals focused on the performance of individual providers and generic quality issues.<sup>57</sup> Legislation to address system problems specifically relating to patient safety issues did not come to fruition until the release of the IOM's *To Err is Human* report.

Several patient safety bills were introduced in the 106<sup>th</sup> Congress to address the issues raised in the IOM Report. Members from both chambers and parties expressed support for patient safety legislation, and introduced bills to develop guidelines for error reporting, establish a federal quality improvement center, and fund demonstration projects, among other initiatives. However, patient safety was overshadowed by other legislative priorities and all six stand-alone bills failed to win passage. The only federal action taken on this issue was a \$50 million appropriation to the Agency for Health Care Research and Policy (later reauthorized as AHRQ) to support medical errors research.<sup>58</sup> Most of the patient safety legislation first introduced in the 106<sup>th</sup> Congress was reintroduced in the 107<sup>th</sup>. Once again, not much legislative action took place.

During the 108<sup>th</sup> Congress, a number of patient safety bills were introduced. H.R. 663, the Patient Safety and Quality Improvement Act, was the bill that received the most legislative attention and enjoyed broad bipartisan support. H.R. 663 proposed the establishment of a voluntary reporting system and provided civil and administrative protections for certain types of documents and communications termed "patient safety work products." On March 12, 2004, the House passed H.R. 663 by a vote of 418-6. On the Senate side, the HELP Committee took up S. 720. The Senate bill was broadly similar to the House-passed legislation. S. 720 also established a voluntary system for the reporting of medical errors to patient safety organizations. But there were a few differences between S. 720 and H.R. 663. The

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<sup>57</sup> For additional information, see U.S. Congress, House Committee on Ways and Means, *Medical Malpractice*, committee print, 101<sup>st</sup> Cong., 2<sup>nd</sup> sess., Apr. 26, 1990, WMCP 101-26.

<sup>58</sup> "Congress Clears Bill to Help Women With Cancer; No Progress on Medical Errors," *2000 CQ Almanac*, pp. 12-43.

key difference was that the Senate bill provided greater protection for providers who submitted medical error information. Under S. 720, the submitted information was shielded from use not only in civil and administrative proceedings, but in criminal actions as well (with exception). On July 22, 2004, the Senate incorporated S. 720 in H.R. 663 as an amendment, and passed H.R. 663 by unanimous consent.

During the first session of the 109<sup>th</sup> Congress, Senator Jeffords introduced S. 544, the Patient Safety and Quality Improvement Act of 2005. S. 544 was identical to the Senate-passed patient safety bill, S. 720. It established a system for the voluntary submission and analysis of medical error data, and prohibited the use of patient safety data in administrative, civil, and criminal proceedings. The Senate amended and passed S. 544 unanimously on July 21, 2005. Six days later, the House voted overwhelmingly to pass the bill. S. 544 became **P.L. 109-41** on July 29, 2005.

While the majority of patient safety and medical malpractice bills address problems related to only one of these issues, a few bills have included provisions that address both issues. For example, S. 1337 would authorize the HHS Secretary to award grants to states to develop, implement, and evaluate alternatives to tort litigation for the purposes of resolving malpractice claims and utilizing patient safety data. Each state must demonstrate how the alternative approach encourages prompt and fair resolution of malpractice claims, promotes disclosure of medical errors, increases patient safety, and preserves access to medical malpractice insurance. Another bill, S. 1784, would establish the Office of Patient Safety and Health Care Quality to administer the National Medical Error Disclosure and Compensation (MEDIC) Program. This new federal program would analyze information submitted by program participants about medical errors and patient safety events, provide grants for the development and implementation of programs to disclose medical errors to patients, and require program participants to offer to negotiate with individuals injured by medical errors for some level of compensation. The bill also includes provisions for a number of separate studies to analyze provider accountability within the health care system, factors related to medical liability premiums, and cases that were not negotiated through the program. A couple of other bills also introduced during the 109<sup>th</sup> Congress (H.R. 3359 and H.R. 3378) use a comprehensive approach that addresses multiple issue areas, such as tort reform, mediation, insurance reform, medical errors reporting, and physician supply.

## **Federal Agency Activities**

The Secretary of Health and Human Services (HHS) was charged with promulgating rules pursuant to the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41). This task was given to the Agency for Healthcare Research and Quality (AHRQ) within HHS, and specifically to the Center for Quality Improvement and Patient Safety within AHRQ. In March 2006, AHRQ held a series of public meetings to inform its rulemaking process. These meetings solicited feedback from the public on specific topical areas, including provider-patient safety organization (PSO) relationships, contracts and disclosures (March 8, 2006); the operation of a

component PSO<sup>59</sup> (March 13, 2006); and security and confidentiality issues (March 16, 2006). Although the meetings specifically asked for comments relating to these topics, participants were generally encouraged to provide comments on any issue they believed was relevant to the rulemaking process. A broad range of stakeholders was represented at the meetings, with an average of 200 participants at each meeting.<sup>60</sup>

The first meeting invited comments on provider-PSO relationships, disclosures, and contracts.<sup>61</sup> The Patient Safety and Quality Improvement Act provides for extensive privilege and confidentiality protections for certain patient safety information, deemed patient safety work products. Specifically, information is afforded these protections if it is considered to be existing within a Patient Safety Evaluation System (PSES).<sup>62</sup> In other words, this information is considered to be a patient safety work product if it is created within the boundaries of a PSES. For this reason, AHRQ needs to provide clear guidance as to the boundaries and scope of a PSES to make clear what information falls under its aegis and therefore is protected. In addition, the statute requires entities pursuing certification as a PSO to provide the Secretary with relevant information regarding their existing relationships with health care providers that might constitute a conflict of interest, and AHRQ was interested in gathering information from the public regarding what type of relationships

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<sup>59</sup> A component PSO is a Patient Safety Organization that is a component of another organization, for example, a hospital.

<sup>60</sup> Transcripts of these meetings are available by contacting Eileen Hogan at AHRQ (ehogan@ahrq.gov).

<sup>61</sup> A patient safety organization is defined by law to mean “a private or public entity or component thereof that is listed by the Secretary ...” The criteria for certification of an entity as a PSO are listed below:

(A) The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.

(B) The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.

(C) The entity, within each 24-month period that begins after the date of the initial listing under subsection (d), has bona fide contracts, each of a reasonable period of time, with more than one provider for the purpose of receiving and reviewing patient safety work product.

(D) The entity is not, and is not a component of, a health insurance issuer (as defined in Section 2791(b)(2)).

(E) The entity shall fully disclose:

(i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and

(ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.

(F) To the extent practical and appropriate, the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

(G) The utilization of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

<sup>62</sup> A patient safety evaluation system is defined as “the collection, management, or analysis of information for reporting to or by a patient safety organization.”



specifically would trigger concerns about an entity's ability to perform independently as a PSO.

The second meeting focused on the issues arising during the operation of a component PSO (meaning an entity that is a component of another organization). Specifically, the statute has additional security related requirements for component PSOs to ensure that privacy of the patient safety work products which it collects is not compromised. In particular, these requirements help to make certain that protected information is not shared with the parent organization.

Finally, the third meeting solicited comment on broader issues relating to security and confidentiality. Specifically, the statute allows for certain exceptions to the protection of information, and AHRQ was interested in learning more about how this would affect existing clinical operations. In addition, since it is possible that a PSO might receive information about events that are outside of any contractual relationship it has with a provider, AHRQ wanted feedback on how PSOs should handle such information. The agency also was interested in receiving comments relating to standards for de-identifying data and securing identifiable health information.

The information generated through these meetings has been analyzed by the agency but is not publicly available. The comments received highlighted several important issues, which will be helpful to the agency as it moves forward. AHRQ has made significant progress in formulating a draft rule, and expects to release it in the immediate future. As this will be AHRQ's first operational program, and since the legislation raises a plethora of policy issues, a substantial amount of energy is being directed toward this effort. More information about these meetings can be found on AHRQ's website at [<http://www.ahrq.gov/about/pso06.htm>].

## State Activities

State activity in health care quality preceded the release of *To Err is Human*. A JCAHO survey found that at least a third of the states had implemented reporting systems by the late 1990s. The purpose of those reporting systems was mainly to collect information on patient injuries or issues related to health care facilities (e.g., structural problems). Most of the reports came from hospitals and nursing homes, but some states also collected data from other facilities, such as ambulatory care centers. These systems reportedly protected data confidentiality, though privacy policies varied from state to state. Only a few states aggregated the information or conducted trend analysis. The overall effectiveness of these programs was hampered by resource and data limitations.<sup>63</sup>

On the issue of patient safety specifically, state legislatures did not wait for their federal counterpart to act. The number of patient safety-related bills introduced in the states tripled in the year following the release of the IOM Report, then nearly doubled in the year after that. Out of the 22 states that introduced bills in 2001 — two years after the release of the IOM Report — half of them were introducing

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<sup>63</sup> According to National Academy for State Health Policy staff.

medical error legislation for the first time. However, during the 2005 legislative sessions, states made limited progress. Only three states (KY, VA, and WY) “enacted legislation to address medical errors and to improve patient safety in the first quarter of 2005.”<sup>64</sup>

As previously noted, 28 states have some type of medical error reporting mandate in place. The requirements cover a spectrum of issues, such as the type of information to be reported, to whom the information is submitted, and for what purpose. For example, Washington requires the reporting of medication-related errors, but New Jersey requires the reporting of “serious preventable adverse events.” Connecticut requires medical facilities to contract with patient safety organizations for data collection and recommendations on improving patient safety. In contrast, New York requires hospitals to report infection rates, which are included in an annual report published by the state Health Department.

While federal medical malpractice legislation usually did not include patient safety provisions, there was some evidence that the link between the two issues has been made at the state level. For example, Pennsylvania passed a bill in 2002 which contained provisions concerning malpractice tort reform, insurance reform, and patient safety enhancement. According to Governor Rendell, the comprehensive approach was an attempt to address concerns about malpractice insurance and medical safety. A couple of other states passed or debated similar bills which also linked those issues.

**State Patient Safety Centers.** A budding movement in the states is the creation of state patient safety centers. The common purpose of these entities is to promote patient safety efforts within the state. Approaches, which vary by state, include educating consumers and providers about safety issues, developing systems for error reporting and analysis, recommending patient safety goals to the state, and supporting collaboration among public and private sector organizations. While it is too early to assess the impact of these centers, the state commitment of authority and resources towards these centers lends legitimacy and expectation to efforts that primarily had been conducted on a voluntary basis (e.g., patient safety coalitions). State patient safety centers may yet play an active role in generating the systemic changes cited as key to enhancing patient safety.<sup>65</sup>

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<sup>64</sup> McKinley, “Medical Errors and Patient Safety,” p. 5.

<sup>65</sup> J. Rosenthal and M. Booth, “State Patient Safety Centers: A New Approach to Promote Patient Safety,” *National Academy for State Health Policy*, Oct. 2004.