



# ISSUE BRIEF

The Massachusetts Health Policy Forum

## **MEDICAL ERROR REPORTING: PROFESSIONAL TENSIONS BETWEEN CONFIDENTIALITY & LIABILITY**

A discussion moderated by Judge Herbert P. Wilkins  
Huber Distinguished Visiting Professor  
Boston College Law School  
Newton, MA

Tuesday, November 6, 2001  
2:30 to 3:00 - Registration and Refreshments  
3:00 to 5:00 - Discussion

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*This Issue Brief was prepared by Wendy K. Mariner, Professor of Health Law at Boston University School of Public Health, Professor of Socio-Medical Sciences at Boston University School of Medicine, and Professor of Law at Boston University School of Law; and by Frances H. Miller, Professor of Law at Boston University School of Law, Professor of Public Health at Boston University School of Public Health, and Professor of Health Care Management at Boston University School of Management.*

## **EXECUTIVE SUMMARY**

Improving patient safety depends on a sophisticated understanding of what can jeopardize it. Reports of adverse patient events and “near misses” constitute valuable information that can foster that understanding. Knowing what has gone wrong in the past facilitates the search for systems improvements, which can prevent recurrence. Unfortunately, providers have been generally unenthusiastic about reporting medical error, whether from a sense of shame, from a fear of liability and institutional sanctions, or from anxiety about reputation and relationships with peers. This Issue Brief lays out the factors that may affect reporting, and explores the limited evidence about whether providers’ confidentiality and liability concerns do in fact negatively affect their willingness to report, and if so, what might be done to improve the situation.

This Issue Brief describes the two current mandatory mechanisms for reporting medical error in Massachusetts hospitals, one public and one confidential, along with the limited available evidence about their effectiveness. This imperfect information points toward the conclusion that confidentiality guarantees make little difference concerning what actually gets reported. This Issue Brief also describes three voluntary reporting mechanisms, all with at least initial confidentiality guarantees, and the even more incomplete evidence concerning their effectiveness.

This Issue Brief then examines the relationship between reporting and liability exposure, noting that whether liability fears in fact deter reporting and whether confidentiality guarantees actually encourage it are far from clear. Here again, the limited information available makes it difficult to conclude that increased confidentiality protection or immunity from malpractice liability will be sufficient to improve either reporting behavior or patient safety programs. No-fault medical error compensation mechanisms are explored, and this report concludes that although such systems may be valuable for providing more efficient and equitable compensation to more injured patients, their positive impact on physician reporting behavior is at best questionable. Evaluating the empirical effect of any law on provider propensity to report is very difficult, and most of the discussion in the literature thus far has been based on assumption. Moreover, the societal objective of accountability and notice to the profession must be achieved through some other means when a no-fault system is enacted, and those alternative means (such as increased Board of Registration oversight) may have their own chilling effect on reporting.

This Issue Brief’s key recommendation is to pursue this opportunity to conduct more research on ways to encourage provider participation in reporting adverse patient events, in order to effect further improvements in patient safety. To that end, a research agenda is recommended to explore:

- Financial Incentives for Implementing Reporting and Patient Safety Programs
- Licensure Rewards for Reporting
- Expanding the Range of Sanctions for Failure to Report
- Identifying Standards for Patient Safety, including Technologies to Reduce Errors and Performance Standards for Professionals
- Investigating Options for a No-Fault Compensation System When Providers Actually Report and Implement Effective Patient Safety Programs
- Studying Public/Patient Attitudes Toward Quality of Care and Medical Error and Investigating Public Education about Quality
- Publicizing Success
- Evaluating the Effect of Any New Laws

## INTRODUCTION

Last year, the Massachusetts Health Policy Forum published an Issue Brief, entitled, “Medical Errors and Patient Safety in Massachusetts: What is the Role of the Commonwealth?”<sup>1</sup> It provided for policymakers a context within which to consider current and proposed reporting methodologies, and to examine the systems of medical error reporting and patient safety in Massachusetts. That Issue Brief and the accompanying Forum followed after the Institute of Medicine’s (IOM) 1999 landmark report on patient safety, *To Err is Human*.<sup>2</sup> *To Err is Human* estimated two years ago that anywhere from 44,000 to 98,000 persons die every year in American hospitals as a result of medical error, exceeding the mortality attributed to breast cancer or AIDS.<sup>3</sup> While medical errors persist as a challenge to the health care system, a sense of urgency to prevent their recurrence has been lacking. This Issue Brief focuses its analysis on the professional tensions between liability and confidentiality that pervade any efforts to improve the current situation.

Many reasons for the relative lack of momentum toward patient safety reform were identified in last year’s Issue Brief analysis.<sup>4</sup> These include providers’ generalized reluctance to report errors, which obscures the persistence and prevalence of adverse patient events and thus retards systematic efforts to prevent them.<sup>5</sup> Tensions between the medical and legal professions regarding litigation fears were identified as a major factor in this reluctance.<sup>6</sup> The Forum’s Issue Brief of 2000 advocated open debate on patient safety initiatives in order to “create a culture of safety.” Since all too often a culture of silence has prevailed instead, this Issue Brief focuses on two recommendations for reducing barriers to error reporting from last year’s report:

- **RECOMMENDATION 5: Provide and ensure appropriate confidentiality protection for reporting**<sup>7</sup>
- **RECOMMENDATION 6: Study alternatives to the current medical liability and accountability systems**<sup>8</sup>

This Issue Brief takes as non-controversial the point that in order to devise meaningful and effective efforts to improve patient safety, an accurate picture of conditions that jeopardize that safety is essential. Reports of medical accidents and “near misses” provide information of inestimable value about what can go wrong in the delivery of health care.<sup>9</sup> The above recommendations from last year’s Issue Brief were intended as measures to increase reporting and thus theoretically to enhance patient safety. They were premised on the idea that fear of liability prevents basic information about medical error from reaching those in a position to think strategically about preventing it and implementing systematic changes to preclude repetition. The recommendations were premised also on the idea that an alternative accountability system like no-fault compensation, coupled with confidential reporting systems, could allay that fear. This report explores the relationship between liability and reporting, outlines key questions that should be answered before adopting specific policy changes, and concludes that while confidential reporting and alternative accountability each has merit for some purposes, they may not be sufficient, by themselves or together, to guarantee significant improvements in patient safety.

### Reporting as an Essential Element of Patient Safety Programs

When institutions (or individuals) recognize their own safety lapses and tailor their own efforts to prevent future adverse events, but keep the information “in house” to shield themselves from perceived liability, the lessons that others could learn from them are lost. Moreover, those institutions are less likely to benefit from the similar experiences and ameliorative efforts of others. Information about the constellation of events leading to mistakes - and effective measures for preventing their recurrence -

need to be shared. When individual providers recognize their own complicity in the circumstances contributing to adverse patient events and attempt to remedy shortcomings in isolation, they tend to focus primarily on factors in the local environment that facilitated error. A broader analytic lens, however, can reveal root causes predisposing similar providers to make the same kinds of mistakes.<sup>10</sup> More extensive reporting and analysis of adverse events permits safety experts to devise more efficient and effective ways for reducing them, thus benefiting all patients.<sup>11</sup>

## Factors Influencing Reporting Behavior

The central question is what kind of reporting system can and will be effective in identifying medical errors or problems that can be remedied or prevented in the future. Answering this question entails answering several subsidiary empirical questions, such as what types of problems are capable of being identified or, in other words, what counts as a reportable medical error. Which errors result from system problems that are susceptible to correction and prevention by introducing systemic change? Which errors result from unpredictable or inevitable human error, the risk of which cannot be further

reduced? The patient safety purpose of identifying adverse events is to prevent their recurrence. If errors that are identified cannot be prevented by systematic procedures or protocols, then reporting them may not be necessary to an error prevention *system*. Other reasons for reporting them, such as identifying practitioners who are not capable of practicing within acceptable bounds of competence may, however, be important.<sup>12</sup>

A second subsidiary question – when and why people are sufficiently likely to report errors – may be more difficult to answer. Do confidentiality protections increase reporting? Is it necessary to institute a mandatory reporting system? One commentator has remarked that “all reporting is voluntary.”<sup>13</sup> This argues that even mandatory reporting systems cannot force anyone to report an error that can be hidden. Therefore, identifying the factors that discourage reporting and finding ways to eliminate or counteract them are essential if we are to increase reporting.

There are many plausible reasons for under-reporting medical errors. Last year’s Massachusetts Health Policy Forum Issue Brief drew upon several sources and suggested the following factors:<sup>14</sup>

- Legal:
  - fear of reprisals
  - lack of trust
  - bad publicity
- Organizational Culture:
  - profession-dependent individuals
  - bureaucratic organizations
  - code of silence
  - fear of colleagues in trouble
  - skepticism
  - extra work
  - lack of effectiveness of present reporting systems
- Regulatory:
  - exposure to malpractice liability
  - increased premiums
  - investigation and potential censure
  - license suspension and subsequent loss of income
  - attitude that regulations are unnecessary or irrelevant
- Financial:
  - loss of reputation, job
  - extra work, waste of resources
  - potential loss of revenues, contracts
  - not cost-effective

The following factors were suggested by the Institute of Medicine in its report *To Err Is Human*:<sup>15</sup>

- Concern for keeping the identities of organizations and providers confidential
- Concern that reported information may not be used so that time spent reporting is considered worthwhile
- Lack of training and education in recognizing relevant events
- Lack of clear standards, definitions and tool for reporting
- Lack of payment for reporting

The British Department of Health, in its own study of medical error similar to that of the Institute of Medicine, *An Organization with a Memory*, recommended a mandatory reporting scheme for adverse health events and specified near misses and changing the organizational culture to encourage reporting in the National Health Service (NHS).<sup>16</sup> In its follow-up report of plans to implement a new patient safety system in the NHS, *Building a Safer NHS for Patients*, the British Department of Health noted the following barriers in the NHS that need to be overcome in order to encourage reporting adverse events and near misses:<sup>17</sup>

- Lack of awareness of the need to report, what to report, and why
- Lack of understanding of how to report
- Staff feel they are too busy to make a report
- Too much paperwork involved in reporting
- The patient recovers from the adverse event and the urgency goes out of the situation
- Fear of ‘point-scoring’ by colleagues, retribution by line management, disciplinary action or litigation
- An assumption that someone else will make the report
- No evidence of timely feedback and/or corrective action being taken resulting from making a report

The Bristol Royal Infirmary Inquiry identified the following “barriers to openness” in England:<sup>18</sup>

- The myth of professional infallibility makes it hard to admit error
- Healthcare professionals find it difficult to speak up about others’ errors
- Fear of exposure and blame, whether in the press or through litigation, with the consequent loss of standing, career prospects, or even livelihood

These and other groups have identified several factors in common, although what weight, if any, each of these factors carries has not been adequately studied.

Provider liability fears stemming from disclosure are usually identified as a primary reason why adverse events are under-reported.<sup>19</sup> Despite statistical data demonstrating that these fears are over-stated,<sup>20</sup> many believe they nonetheless have a powerful impact on provider behavior.<sup>21</sup> More complex factors, however—including shame, fear of institutional sanctions, and anxiety about maintaining good relationships with peers—also fuel provider reluctance to identify and report their own patient safety errors (and those of others), and may be equally important motivators for silence. As one doctor put it, “We physicians are afraid to turn up the heat on others, lest we fry in our own fire.”<sup>22</sup> Simply put, reporting medical error—to patients, to peers, to institutions or to the government—has been insufficiently reinforced in the culture of medicine to date, although the ethical obligation to admit mistakes to patients has long been acknowledged.<sup>23</sup> Professional reluctance to report adverse events persists, notwithstanding mounting evidence demonstrating that reporting errors improves patient safety, and disclosing mistakes to patients does not increase the incidence of malpractice lawsuits, and keeps any payouts relatively low.<sup>24</sup>

Providers’ fears that they will be in some way blamed for their medical errors are deeply ingrained and difficult to dislodge, regardless of whether their concerns are supported by the evidence. Regardless of whatever external reform efforts legislatures and others take to allay those fears, many analysts conclude that so long as providers *believe* they are at risk, their reporting activities will be less than ideal. The more the provider establishment takes a leadership role in advocating adverse event disclosure, however, the more medical culture will internalize it, and the less likely those fears will continue to chip away at reporting.<sup>25</sup>

### **Are Incentives to Report Different for Institutions and Individuals?**

The literature discussing the tension between liability and reporting tends to focus on individual health professionals, primarily physicians, rather than the liability of the institution in which errors occur. However, the incentives of both individuals and institutions are of concern because both can be reporters. Individuals may be the first line of

reporting to the institution. But, it is the institution that is responsible for reporting data to government agencies. Therefore, to the extent that reporting to external agencies remains a goal of patient safety systems, it is important to examine what factors might affect the willingness of institutions to report errors.

If liability is a disincentive to reporting by individuals, is it also a disincentive to reporting by institutions? Most, if not all, of the reasons why liability might deter physicians from reporting appear to apply to institutions. Although institutions may not take lawsuits as personally as do individuals who are sued, institutions value their reputations, probably prefer to avoid adverse publicity from disclosures of internal problems, fear loss of patients, revenues and market share, and may suffer from the time and expense of litigation. Any apparent underreporting by health care facilities might be interpreted in the same way that underreporting by physicians has been interpreted—to mean that institutions are deterred from reporting internal errors for fear of liability or at least some form of public accountability.

### **Accountability and Non-Punitive Reporting Systems**

If liability is a disincentive to reporting, are people more likely to report if protected from liability? The answer depends upon on whether there are other disincentives to reporting that persist even in the absence of liability. Many reporting systems are

described as “non-punitive,” but do not specify what is meant by that term. It may simply mean that people who report errors are not punished for the *act of reporting*. But that seems non-controversial. Why should anyone be punished for reporting helpful information?

Alternatively, “non-punitive” may refer to an institution’s commitment not to expose a person who commits a medical error to legal liability for negligence. This might be possible if the institution can withhold that person’s identity. However, if the institution is obligated to report the person’s identity to a public agency, such a board of registration, is that “punitive?” The institution does not impose any punishment, but the board may. But the same holds true for legal liability: the institution does not impose liability; a court may if a patient brings a successful lawsuit.

More literally, “non-punitive” could mean that the institution that receives the report will not impose *any* punishment or sanction on people who are responsible for errors. This does not appear to be what is commonly meant by the term, however. Even those who advocate replacing liability with no-fault compensation systems to remove the “blame” factor argue that an optimal system for preventing medical errors requires some mechanism to deal with incompetent, dangerous or malevolent physicians.<sup>26</sup> The IOM report mentions—albeit only in a few sentences—that institutions should find effective ways to deal with practitioners who harm patients:

*“The committee recognizes, however, that some individuals may be incompetent, impaired, uncaring, or may even have criminal intent. The public needs dependable assurance that such individuals will be dealt with effectively and prevented from harming patients. Although these represent a small proportion of health care workers, they are unlikely to be amenable to the kinds of approaches described in detail in this chapter. Registration boards and licensure discipline is appropriately reserved for those rare individuals identified by organizations as a threat to patient safety, whom organizations are already required by state law to report. . . . [T]he committee believes that health care organizations should use and rely on proficiency-based credentialing and privileging to identify, retrain, remove, or redirect physicians, nurses, pharmacists, or others who cannot competently perform their responsibilities.”<sup>27</sup>*

No matter how carefully phrased, this sounds like punishment. As a practical matter, institutions committed to changing their systems to prevent errors are likely to reserve the right to fire incompetent or dangerous practitioners or at least report them to state disciplinary bodies.<sup>28</sup> Therefore, it is unlikely that any system can be non-punitive in the strictest sense of that term. It may be necessary to examine the possible conceptions of “non-punitive” systems in order to determine whether they preserve forms of punishment —such as job loss—that discourage practitioners from reporting, with or without the possibility of legal liability. Is losing one’s job or being reported to the Board of Registration less threatening than the possibility of being sued? Will physicians, nurses, pharmacists, and other health professionals feel more comfortable losing their jobs than being sued or possibly having their liability insurance premiums increased? Will health care facilities be willing to report errors that might jeopardize their licensure status or cost them patients?

It should be noted that liability is only one method of accountability. Other methods include state licensure systems for individual professionals and health care facilities, as well as institutional policies for employees and affiliated physicians, such as conditions of employment, credentialing and privileges. The question is whether the critical disincentive to reporting is liability for negligence alone or whether it is *any* form of accountability for error. If it is *accountability* in general that makes people reluctant to report, then the disincentive can be removed only by eliminating all forms of accountability entirely. That could mean repealing the power of state boards of licensure and the state Department of Public Health to impose sanctions on individuals or facilities that violate conditions of licensure. In the absence of such authority, the need for licensure itself could be questioned. It may also mean that health care facilities should give up the power to discipline, sanction or terminate individual professionals or employees who are not providing adequate patient care. So far, no one has gone so far as to advocate that there should be no accountability for patient harm. If any form of accountability is to remain, however, it is especially important to identify which specific form (or forms) of accountability actually deters people from reporting medical errors, and whether reporting will increase if any single form of accountability is removed.

## **Current Mechanisms Requiring Medical Error to be Reported in Massachusetts<sup>29</sup>**

Massachusetts has two regulatory mandates for reporting adverse patient events, one at the Board of Registration in Medicine<sup>30</sup> (which provides confidentiality protections<sup>31</sup>), and the other at the Department of Public Health<sup>32</sup> (which is open to scrutiny as a public record).

### *The Board of Registration in Medicine’s Patient Care Assessment Program*

The Board of Registration in Medicine’s Patient Care Assessment (PCA) Program, requires hospitals, clinics, HMOs, nursing homes and other facilities to report, but only quarterly, on all unexpected deaths and serious injuries involving hospital and other healthcare facility patients.<sup>33</sup> These institutions must investigate their adverse events internally, then provide the results of their investigations and report what they have done to prevent recurrence to the Board. Confidentiality protections for these reports are provided by regulation,<sup>34</sup> and the doctors involved in the incidents need not be named in the reports. Moreover, information relating to physician conduct contained in the reports is deemed unavailable to the Board’s enforcement arm for disciplinary proceedings against physicians. The program does not initiate investigations *de novo*, and relies primarily on reports submitted by the institutions it regulates, and follow-up inquiries to ascertain that appropriate ameliorative steps have been taken, for its information.<sup>35</sup>

From 1997 through 1999 the number of major incident reports filed with the Board rose from 150 to 414, indicating increased institutional attention to the issue of patient safety.<sup>36</sup> The PCA program focuses on analyzing these major incident reports and issuing “PCA Updates,” alerting providers to potential patients risks stemming from common medical practices. Since its inception in the 1980’s, the PCA program appears to have issued eight such alerts. These address quality problems identified with medical practices ranging from oncology drug administration to radiology coverage in emergency rooms.<sup>37</sup>

*Massachusetts Department of Public Health,  
Division of Health Care Quality – Hospital  
Reporting of Serious Incidents*<sup>38</sup>

The Department of Public Health has issued regulations pursuant to its statutory licensing authority, requiring hospitals to report “serious physical injury” and “other serious incidents” affecting patient health and safety to its Division of Health Care Quality within 24 hours to seven days.<sup>39</sup> Serious physical injury is defined as injury that is life threatening, results in death, or requires a patient to undergo significant additional diagnostic or treatment measures.” The Department takes an immediate and active role with the affected hospital in responding to many of these incidents.

Reporting has been trending generally upwards over the past four years, and for the year 2000 hospitals made 574 reports to the Department under the regulation. This compares with 415 hospital reports in 1996. In addition, the Department received 309 hospital consumer complaints about quality of care in 2000, whereas four years previously it received only 221.<sup>40</sup> Although these statistics are available to the public, they are more difficult for the public to acquire because they do not appear on the Departmental website (as do comparable reporting statistics for the Board of Registration in Medicine).

The Department issues Best Practices Reports based on what it has learned about error reduction through this reporting and its subsequent investigations. Four of these Best Practices, issued in 1998 and 1999 and dealing with administration of morphine sulfate, assessment of medication knowledge at long-term care facilities, ambulance diversions, and “previously noted recommendations to prevent medical errors,” currently appear on the Departmental website.<sup>41</sup> The Department also issues “circular letters” more regularly, which touch on issues ranging from hospital badges for employees to the disposal of fetal remains.

The Agency for Health Care Research and Quality has recently announced a new round of patient safety research grants. The Massachusetts Department of Public Health is among ten grantees in the Commonwealth. The Department, along with several academic and research partners, will evaluate the effects of its reporting system and work toward the continued development and implementation of

best practices. (The U.S. Department of Health and Human Services press release is available at <http://www.ahrq.gov/news/press/pr2001/patsafpr.htm>.)

## **Voluntary Mechanisms for Reporting Patient Safety Information in Massachusetts**

*The Joint Commission on the Accreditation of Healthcare Organizations*

The Joint Commission on the Accreditation of Healthcare Organizations’ (JCAHO) Sentinel Events Policy also addresses the issue of analyzing and reporting “unexpected occurrence[s] involving death or serious physical or psychological injury, or the risk thereof” occurring in its accredited institutions.<sup>42</sup> Since JCAHO’s policy was instituted in 1995, the number of sentinel events reported to it has risen from 23 in that year to 357 in 2000, and 332 more such events had already been reported to JCAHO by August of 2001.<sup>43</sup> Three-quarters of these reported event outcomes involved patient deaths.<sup>44</sup> Because JCAHO accredits almost 19,000 healthcare organizations nationally (including nursing homes, hospice facilities, etc.), the statistics for the year 2000 reflect a reporting rate of only one adverse incident report for every 53 accredited institutions - hardly an impressive figure.<sup>45</sup>

The reporting standard is technically voluntary because JCAHO accreditation is itself “voluntary,” but hospitals seek accreditation not only for reputational purposes but because many payors (often prodded by employer-purchasers of health insurance) will only contract to reimburse care delivered by an accredited institution.<sup>46</sup> The Commission’s policy statement avers that it “will not disclose legally protected sentinel event-related information to any other party and will vigorously defend the legal confidentiality of this information, if necessary, in the courts.”<sup>47</sup> JCAHO has disseminated 18 Sentinel Event Alerts related to patient safety based on the information gleaned from these reports since the program was initiated.<sup>48</sup>

JCAHO also endorsed disclosing unexpected outcomes (although not specifically errors) to patients in its Patient Safety and Medical/Health Care Error Reduction Standards, which became effective in

July 2001.<sup>49</sup> No information is thus available concerning institutional response to this criterion. Standard RI.2.2 provides: “Patients and, when appropriate, their families . . . [should be] informed about the outcomes of care, *including unanticipated outcomes*.”<sup>50</sup> The standard applies to *any* unanticipated results, not just to adverse events culminating in death or serious patient injury, so theoretically information relevant to many patient safety improvements could come to wider attention through this alternative route.

#### *Massachusetts Medical Society Physician Health Services*

Physician Health Services (PHS) is a nonprofit corporation established by the Massachusetts Medical Society to aid physicians who are at risk for or have substance abuse disorders, and behavioral and mental health problems.<sup>51</sup> PHS has a working relationship with the Board of Registration in Medicine designed to intervene with the affected physician, thereby protecting patient safety. In appropriate cases involving the use of drugs or alcohol information identifying an impaired doctor who could pose a potential risk to patients can be “diverted” to the PHS for assistance, rather than being reported directly to the Board for investigation and disciplinary action.<sup>52</sup> In these cases, information related to the doctor’s impairment acquires confidentiality protection pursuant to Massachusetts’ peer review statute so long as the affected physician complies with PHS recommendations.<sup>53</sup> These may include entering into a chemical dependency monitoring contract, including participating in behavioral therapy sessions and random drug screenings.<sup>54</sup> Most impaired physicians are “diverted” to PHS programs by colleagues, friends and family who are sufficiently concerned about the doctors’ behavior to report them directly to the Board of Registration if they refuse to participate voluntarily. If doctors diverted to PHS refuse to comply with PHS conditions, that information is relayed back to those who were concerned with their behavior in the first place. Those parties may then be obligated to report the impaired doctors directly to the Board for disciplinary action.<sup>55</sup>

PHS has assisted approximately 900 physicians since it was established in 1993, and provided support through monitoring contracts to 137 physicians during the past year.<sup>56</sup> These are substantial numbers, but they represent only the tip of the iceberg as far as the projected number of impaired

licensed physicians in the Commonwealth who may have psychoactive substance use disorders or mental health problems is concerned. For example, if the percentage of the state’s 22,000 - 26,000 licensed doctors facing substance abuse disorders mirrors the approximately ten percent rate observed in the general population, then approximately 3,300 doctors are potentially affected by illnesses that could ultimately result in impairment. The number seen by PHS is only a small fraction of that, despite the fact that impaired physicians who fail to enter the program are at risk of losing their licenses to practice medicine. In the words of the program’s Operations Manager, “Outreach with an eye toward early identification is our number one priority.”<sup>57</sup>

#### *Federal False Claims Act*

The federal False Claims Act (FCA)<sup>58</sup> could provide another incentive for medical personnel to encourage reporting medical errors, although this possibility is more theoretical than widely used at the present time. The FCA applies when a hospital knowingly bills the government for care that was not provided as claimed, or where the medical provider violated an underlying legal requirement. If a hospital fails to meet the required standard of patient care, for example, the hospital could be subject to FCA liability for any bills it submits to Medicare or Medicaid. For example, Medicaid provisions require providers to develop policies and procedures, including reporting, to minimize drug errors.<sup>59</sup> If the required reporting does not occur, the government could claim the bills submitted for services rendered while the hospital was in violation of this requirement were fraudulent.<sup>60</sup> Furthermore, if a provider bills the government for treatment that actually harms a patient, the government is being denied the value of the service for which it is being asked to pay.<sup>61</sup> These specific instances of medical error could theoretically give rise to FCA violations.

The FCA creates statutory remedies of up to \$11,000 per claim, plus treble damages.<sup>62</sup> Perhaps more importantly, the statute also includes a *qui tam* provision allowing whistleblowers to retain fifteen percent to thirty percent of any money recovered for reporting a false claim.<sup>63</sup> This reward gives patients, families, and provider personnel a powerful incentive to utilize the FCA if they find a provider exhibits quality of care deficiencies and nonetheless bills the government for the care.<sup>64</sup> Tufts Health Plan and its Medical Director recently blew the whistle under the FCA on TAPS Pharmaceutical Products’ scheme to

inflate the price of Lupron used for government reimbursement purposes, while selling it to health plan and doctors at a price that ensured them a profit of at least \$100/dose.<sup>65</sup> Tufts and its Medical Director shared \$17 million (which they donated to charity) of the FCA settlement amount for reporting the scam, which induced excess sales of the drug and thus had the capacity to harm patients.

Should FCA claims in this area become more prevalent, providers will have incentives to further strengthen their own adverse event reporting systems. Providers with effective programs for identifying medical errors could in theory avoid being accused of submitting false claims based on deficient care, but several factors make the FCA difficult to apply in this context. Because no accepted standards for reporting systems currently exist, proving that a particular provider's system is ineffective is difficult.<sup>66</sup> The FCA may be a more effective tool for improving reporting adverse patient events once the universe of error reporting systems becomes better established.

### **What Factors Contribute Toward a More Supportive Environment Wherein Reporting Medical Errors is Encouraged?**

As has already been observed, all error reporting is at core voluntary, even though it may be couched in mandatory terms. Carrots can be used to encourage reporting, as with the FCA whistleblower provisions, and sticks can be used to threaten non-reporting, as with the Physicians Health Services-Board of Registration arrangement for dealing with physicians exhibiting substance abuse disorders.<sup>67</sup> An institutional culture that does not have a supportive approach toward reporting, whether rooted in fear or in self-interest, can also effectively undermine it. Changing that culture can be extraordinarily difficult, but occasionally a strong leader can make a real difference to reporting and safety behavior. For example, Julie Morath, Chief Operating Officer of Children's Hospital & Clinics in Minneapolis-St. Paul, has publicly taken a leadership stand with respect to reducing medical error. She claims "patient safety is 'my purpose in life.'" While the program has not existed long enough for the hospital to assess monetary results, the hospital Chief Financial Officer is anticipating long-term cost savings, saying that "it's intuitive that efficient systems will eliminate waste." Morath has won over nurses and many of the younger doctors, as well, who

welcome the opportunity to focus on systemic problems, rather than finger pointing.<sup>68</sup>

### **What Confidentiality Protections Should Accompany Medical Error Reporting?**

The Massachusetts Health Policy Forum Issue Brief No. 10 recommended that state law be changed to provide additional protection of the confidentiality of medical error reports and restrictions on the use of patient safety data, presumably to preclude access by patients and the public and possibly other health professionals not involved with a patient safety program.<sup>69</sup> That Issue Brief and others have advocated "appropriate" confidentiality protection in order to diminish potential liability disincentives for providers to report errors that have harmed patients.<sup>70</sup> The Institute of Medicine, however, recommends that information in state-based mandatory reporting systems be open to public scrutiny once the reporting system determines that error has in fact occurred.<sup>71</sup> Some balance between absolute confidentiality and total transparency of reporting is undoubtedly desirable in order to accommodate the twin goals of safety improvement and accountability. Striking that balance is a delicate legislative task. As Randall Bovbjerg puts it, "We need a third way that blends the strengths of both [the legal process and the patient safety movement] and emphasizes the interests of patients, not those of doctors or lawyers."<sup>72</sup>

#### *Do Confidentiality Protections Increase the Incidence of Reporting Medical Error?*

Only limited data to answer to that question can be found, but a recent study of state mandatory reporting programs concluded that "although most reporting system officials and other informants agreed that without statutory confidentiality protections under-reporting would be a significant problem, states that have such protections nevertheless reported significant under-reporting."<sup>73</sup> Similarly, Congress declared information about physicians collected in National Practitioner Data Bank<sup>74</sup> files to be confidential as far as the public is concerned, yet according to a recent report from the Office of Inspector General, relatively few managed care plans report sanctions against physicians as required by federal legislation.<sup>75</sup> Eighty-four percent of plans have never reported a single adverse action, which may mean that they rely on hospitals and licensing boards to police patient safety concerns.<sup>76</sup>

### *Whose Confidentiality Should Be Protected?*

There are several candidates for confidentiality protection and several points in any system at which confidentiality could be preserved or omitted. The least controversial candidates for confidentiality protection are the patients whose personal medical information is reviewed for purposes of identifying medical errors that can be corrected or prevented. There is rarely any reason to disclose the identity of patient to reviewers, including members of peer review committees or quality assurance groups, or to the public at large.

Protecting the identity of reporters — the health professionals and other staff in a health care facility who report medical errors to the relevant institutional unit or governmental agency — is also typically non-controversial. Not disclosing a reporter's identity is intended to protect the reporter from retaliation by supervisors or colleagues. However, in small organizations or specific circumstances, it may be relatively easy to identify who could have made the report. In addition, it may be important to ensure that confidentiality does not encourage false or malicious reports that damage reputations.

The people most concerned with identification are those who were directly involved in a medical error, who may or may not report the error themselves. Confidentiality is typically recommended in order to encourage them to report their own errors or errors that occurred in circumstances for which they were responsible or in which they participated. However, their identity could also be protected when their involvement is reported by others—at least until the problem is investigated. Again, the degree to which confidentiality can be maintained in practice depends upon how easy it is to associate individuals with specific problems or remedies, by people inside or outside the institution.

### *Combining Confidentiality and Disclosure*

Protecting a person's identity does not preclude disseminating useful information for purposes of patient safety systems. The IOM recommended using de-identified information in developing patient safety strategies and disseminating proposals and protocols for error prevention. Anonymous data aggregated from specific reports is a useful tool, both for analyzing root causes of error and educating health professionals about best practices. Research based on patient medical records is often published

with anonymous, aggregate data that does not violate the patients' confidentiality. Research and analyses of medical errors use the same techniques, as do public agencies like the Massachusetts Department of Public Health. Such information can be distributed to institutional staff as part of the patient safety program. It can also be disseminated to the public.

The controversial question is whether the identity of individuals involved in a medical error should be disclosed to the institution, the public or any patient involved or affected. Here there are competing issues of principle and empirical fact. Physicians have a legal and ethical obligation to disclose information to their patients and this can include information about errors that have occurred in their treatment, whether or not the error has harmed the patient. However, it is precisely when an error has harmed a patient that physicians may be most reluctant to tell (or allow their identity to be reported), for fear of inviting a legal claim. Therefore, deciding whether to protect the identity of individuals involved in a medical error depends importantly upon whether the confidentiality produces benefits that outweigh the general principle of disclosure.

### *Relationships Between Confidentiality and Legal Claims*

A confidential system for reporting error does not necessarily prevent patients from learning that an injury resulted from medical error. Physicians, nurse, and hospitals sometimes tell patients about errors that would not otherwise be reported. Some commentators use these examples to illustrate that good relationships can survive such disclosures. The story of Ben, a child who died after receiving the wrong drug during surgery, has been used as an example of how open discussions with the family can lead to improved systems for patient safety—tracking and administering drugs, in this case.<sup>77</sup> The hospital conducted its own investigation that discovered the error, told the family, and worked with them to develop new systems. The family did not sue, although they negotiated a confidential settlement with the hospital, and reportedly continued to use the hospital. However, individual cases like these may not always enter the data base of errors and so may not be used to develop preventive measures for the future.<sup>78</sup>

The reporting of medical errors does not necessarily give patients a lawsuit that they otherwise would not have filed. Not all medical errors are actionable; that is, not all medical errors are committed

in circumstances that are grounds for any lawsuit. The scope of reportable errors is much broader than the definition of a legal cause of action. A cause of action for malpractice—professional negligence—requires that the patient be injured as a result of someone’s failure to provide care according to the standard of care for that type of medical condition. Medical errors can occur without any negligence and they do not always cause injury. Conversely, negligent medical errors may not cause injury and therefore not be actionable. In addition, where injury occurs, it is not always possible to prove that a negligent error caused injury. Thus, patients are not entitled to bring lawsuits for a significant proportion of cases in which medical error occurred. The Harvard Medical Practice Study found that almost 4% of New York hospital discharges suffered adverse events, and that about 28% of those were attributable to negligence.<sup>79</sup> Fewer than 0.2% of those patients injured by negligence actually filed a malpractice claim.<sup>80</sup> More recent studies in Utah and Colorado found similar results.<sup>81</sup>

At the same time, the failure to tell patients about an error does not necessarily mean that the patient (or his family) will not bring a lawsuit. We do know that people bring lawsuits under our current system in which most medical errors are not reported publicly. Does this mean that reporting is not necessary or that reporting might increase the number of lawsuits or claims? Undoubtedly, many errors would not give rise to a legal claim. Others may not generate sufficient financial losses to justify the expense of legal action. There is also evidence that claims are filed in cases where there is no negligence or where negligence cannot be proved.<sup>82</sup> Possible reasons for such claims include an injury severe enough that a lawsuit for compensation was almost inevitable. It is also possible that some patients file lawsuits in order to obtain information about the cause of the injury because it is not publicly available. In these cases, paradoxically, the filing of lawsuits serves as the method of obtaining information that might have been provided by reporting the error to the patient.

There have been several studies of reasons why patients sue physicians or hospitals. Most have found that many patients sue because they are angry about how they have been treated (or ignored), because they had not been told what really happened in their case or had been misled, to obtain information about what happened, or to do something that will prevent a similar problem from hurting other patients in the future.<sup>83</sup> Some commentators conclude that

physicians are more likely to forestall a lawsuit by telling patients about their errors and apologizing as soon as possible.<sup>84</sup> Unfortunately, these reports do not address whether patients would be more or less likely to sue if they learned of a medical error from a reporting system. However, a study of a Kentucky Veterans Administration (VA) medical center’s 1987 policy of telling patients about errors sheds some light on the subject.<sup>85</sup> Although the incidence of claims increased, the total amount of compensation paid decreased, and the program appears to have been considered a reasonable success by the VA and its patients.

In summary, it remains unclear whether reporting medical errors to patients or to the public would increase or decrease the incidence of lawsuits in Massachusetts. Some patients might find reason to sue; others might learn that they have no legal claim. In some cases, the responsible party might offer to settle. In others, patients may feel respected by being told what happened and eschew legal action.

#### *Relationships Between Confidentiality and Reporting*

In order to determine whether the Commonwealth of Massachusetts should adopt additional confidentiality protections, it will be important to answer the following questions for Massachusetts patients and health professionals:

- (i)** Are health professionals more fearful of being sued when their medical errors are reported to patients or the public than when such errors are kept confidential?
- (ii)** Are patients more likely to sue health professionals if their errors are reported, either to the patient or publicly, than when such errors are not reported?
- (iii)** If medical errors are protected from disclosure, are medical professionals more likely to report errors?

It seems intuitively correct that people would be reluctant to report their own errors if they would be sued for significant damages by a person who suffered as a result.<sup>86</sup> Nonetheless, there is little empirical evidence concerning how much of a deterrent to reporting this fear may produce or whether it can be overcome. There is some evidence that physicians, like all human beings, exaggerate risks to themselves.<sup>87</sup> The Harvard Medical Practice Study found that physicians generally overestimated

the risk of malpractice suits.<sup>88</sup> Similarly, in its study of defensive medicine, the Office of Technology Assessment found that “physicians are very conscious of being sued and tend to overestimate that risk.”<sup>89</sup>

Physicians are not alone in predicting that any law that expands opportunities for lawsuits will encourage an increase in claims. When Texas passed a statute in 1997 allowing patients to sue their health plans for malpractice, the insurance industry predicted that health plans would be hit with thousands of lawsuits. Since the law became effective, between 15 and 25 lawsuits have been filed, among about 4 million Texas HMO members.<sup>90</sup> In July 2001, the first verdict in a case brought under the law found the HMO not liable for failing to treat lung cancer properly.<sup>91</sup>

It is unclear whether perceptions would change significantly if they were shown to be based on mistaken assumptions. On one hand, physicians frequently change their practice methods in light of new information about the effectiveness of medical technologies and interventions.<sup>92</sup> On the other hand, perceptions about the risk of lawsuits may be especially resistant to change, even if proved incorrect. It may be difficult to disentangle fear about lawsuits from fears of other negative repercussions, such as disciplinary action by hospitals, insurers, and professional boards, loss of reputation and standing among colleagues and patients, and loss of one’s job.

As Bovbjerg and colleagues have noted, the liability/discipline system reflects a different approach to medical error than the patient safety movement.<sup>93</sup> The liability system operates after an injury occurs, identifying those who have caused injury as a result of breaching legal or professional duties. It does not address the broader range of errors that are not the result of negligence or do not result in injury. It is not designed to prevent errors (except to the limited extent that it deters future errors). Its major clash with the patient safety movement lies in the fact that it assigns blame (legal responsibility for injury).

## **Evidence of the Relationship Between Reporting and Liability Exposure**

There is little empirical evidence on whether health care professionals will cooperate with patient safety systems by reporting medical errors when they

remain subject to either disciplinary action or legal liability. More to the point, it is not clear whether elimination of liability or protection against disclosure would lead to full or increased reporting. The lack of definitive evidence is probably attributable to the difficulty of measuring the independent effect of a law on human behavior. The following types of information are suggestive, but none offers a completely satisfactory basis for predicting the effects of a medical error reporting system because they do not specifically address the law’s effect on reporting behavior.

### *Massachusetts Reporting Systems*

The most relevant evidence of underreporting comes from the Massachusetts Board of Registration in Medicine, which receives mandatory reports concerning physicians that are not available to the public, and the Massachusetts Department of Public Health, which receives reports from health care facilities and does report certain data publicly, described above. Their data, however, do not include reasons for the apparent underreporting. Board of Registration’s experience is difficult to interpret because, although physicians remain subject to liability in Massachusetts, the reported information remains confidential. It is possible that physicians are not confident that their confidentiality will remain protected, especially if an investigation reveals substantial grounds for discipline.

### *Institutional Experience Reports*

A second category of evidence includes reports of the experience of individual institutions that implemented a reporting system. Most are institution-specific and their conclusions may be premature. Although these reports did not study the effect of any law, they do describe institutional policy changes that were implemented without any change in the law.<sup>94</sup>

The experience of the Dana-Farber Cancer Institute in Boston is encouraging. After the death of Betsy Lehman and near death of Maureen Bateman from a chemotherapy overdose, Dana-Farber launched a system to encourage the reporting of errors and said that error reporting increased dramatically.<sup>95</sup> This was achieved without any change in the law governing legal liability in Massachusetts. Although the reporting system is characterized as “non-punitive,” the institution appears to have reserved the right to fire anyone whose behavior intentionally or negligently puts a

patient at risk or harms a patient. Those are large exceptions—broader than the scope of malpractice liability.<sup>96</sup>

After discovery of the error in Betsy Lehman's case, the pharmacy director resigned. The resident physician who mistakenly ordered the incorrect chemotherapy dose also resigned and later entered into a consent agreement with the Massachusetts Board of Registration in Medicine for a 3-year license suspension, which was applied retroactively to the preceding three years.<sup>97</sup> Dana-Farber moved the head of the clinical trial to another program, which it later terminated. The Massachusetts Board of Registration in Nursing independently initiated complaints against 18 nurses, 16 of whom agreed to sanctions requiring continuing education or specialty certification while they continued to practice. Dana-Farber settled privately with Ms. Lehman's family.\*

What is heartening is the apparent willingness of health professionals to report errors even when they remain exposed to disciplinary action or liability. Ian Kennedy, who argued that fear of disciplinary action inhibits reporting in England, notes that the fact that "some hospitals in the USA have been able [to successfully implement open reporting systems] while clinical negligence flourishes may suggest that such litigation is not a barrier to openness, despite our previously expressed views."<sup>98</sup> On the other hand, the errors in the Lehman case probably could not have been hidden, and the reforms may have been initiated not in spite of liability but because of it.

The Veterans Administration's experience is also encouraging in that health professionals have apparently cooperated in reporting medical errors and liability costs have been reduced.<sup>99</sup> Here, too, progress was achieved without protecting the Veterans Administration from legal liability for malpractice. Its legal position differs from a private hospital or group practice because health professionals who are government employees are not sued for negligence in the performance of their duties. However, patients can and do sue the federal government under the Federal Tort Claims Act as the party vicariously responsible for negligent acts by its employees.<sup>100</sup> In particular, the federal government can be sued for malpractice committed by the Veterans Administration and its employees, including health care professionals.<sup>101</sup> The law governing such malpractice actions is the law of the state in which the

claimed malpractice was committed.<sup>102</sup> Therefore, patients have a legal cause of action against the United States under the same state law rules that apply to patients in private health care facilities.<sup>103</sup> Perhaps more important, Veterans Administration employees are not protected from losing their employment or institutional discipline if they are found to have allowed too many medical errors. The Veterans Administration may have a direct incentive to take action against employees who cause too many errors because the federal government pays all awards of damages against it directly from its own funds, whereas private health care facilities typically have liability insurance that cushions them from the full financial loss.

#### *Limited Immunity from Liability*

A third category of suggestive information might be found in the effects of laws granting physicians immunity from liability in order to encourage them to participate in publicly desired activities, such as peer review and providing aid at the scene of an accident. Although neither type of law requires physicians to report their own errors, both were enacted to encourage physicians to take action deemed to be in the public interest.

In the 1970's, states enacted Good Samaritan Laws in the hope of encouraging physicians to render aid to others in an emergency (outside the hospital).<sup>104</sup> There was concern that physicians would be deterred by the threat of liability for injuries, although there had never been a reported case holding a physician liable for substandard care in such circumstances. Typical Good Samaritan Laws do not require physicians to provide help, but do prohibit legal claims against physicians who injure an individual while providing first aid or emergency assistance.<sup>105</sup> Most laws limited this legal immunity to circumstances in which the physicians acted in good faith or without gross negligence (and outside the scope of their employment). A few commentators reported that, in the 1970's, such laws did little or nothing to encourage physicians to come to the aid of their fellow citizens.<sup>106</sup> The American Medical Association surveyed physicians and found that about half would be willing to offer emergency aid, but they were just as likely to reside in states that had no Good Samaritan liability protection as in states that did.<sup>107</sup> Among the reasons for refusing aid were not having relevant medical expertise and not wanting to

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\* Emended January 24, 2002."

take the time to respond. In the absence of more recent data, it is not known how physicians would respond today.

Similarly, all fifty states have laws to protect peer review records from disclosure in order to encourage physicians to participate in confidential review of the quality of care. States have also enacted laws protecting physicians who participate in peer review committees from lawsuits by the physicians who are the subject of review.<sup>108</sup> Again, most such laws grant qualified immunity for actions taken in good faith, in order to retain accountability for malicious or anticompetitive attacks on other physicians. Unfortunately, physician participation in peer review has not been studied systematically since passage of these laws.<sup>109</sup> There is some evidence that reporting to the National Practitioners Data Bank, like reporting to the Board of Registration and the Department of Public Health, is not complete.<sup>110</sup> Physicians who could be sanctioned may agree to lesser penalties in order to avoid having a privileges sanction reported to the NPDB, even though the information is not publicly available. Some commentators attribute this underreporting to fear of litigation.<sup>111</sup> However, information on individual physicians is not made available to patients.<sup>112</sup> Similarly, the IOM noted that physicians appear to underreport adverse reactions to medications to the FDA, even though the FDA has no jurisdiction over physicians and the information is not made directly available to the public.<sup>113</sup>

Perhaps the most reliable conclusion that can be drawn from these examples is that legislation that is intended to change people's behavior by removing or reducing the risk of liability is rarely evaluated to determine whether it achieved its goal. This contrasts with the beneficial trend toward studying the effects of legislation intended to achieve more traditional public safety and health goals, such as reducing injuries from consumer products, drunk driving and cigarette smoking. Researchers have produced empirical studies of the rates of smoking, sales of cigarettes to minors, and driving with specific blood alcohol level, to name only a few. These studies are valuable aids to policy making, especially when they are able to isolate the effect of the legislation from other factors that influence personal behavior. Comparable studies would help to provide the kind of information needed to determine what, if any, specific laws are likely to alter the behavior of health professionals in reporting medical error.

### *No-Fault Compensation Systems*

A fourth category of suggestive information includes the experience of no-fault compensation systems, which are sometimes recommended in response to concerns that liability is deterring some public good. Four examples may be worth mentioning: Workers Compensation, the newborn injury compensation programs in Virginia and Florida, the National Vaccine Compensation Program, and the New Zealand No-Fault Accident Compensation.

The Worker Compensation system created a mechanism for compensating workers with occupational injuries or diseases in return for eliminating employer tort liability for such harms. At the time, tort law made it difficult for workers to sue their employers successfully, especially when other employees were involved, because negligence on the part of another employee negated the employers' liability.<sup>114</sup> The system attempts to align employers' economic incentives with the goal of worker safety by basing an employer's insurance premiums on the cost of injuries to their employees. This linkage is imperfect because most small employers are part of a large multi-employer insurance pool. There is more controversy over whether the system has in fact reduced occupational injuries.<sup>115</sup> More studies find little or no reduction in rates of injury.<sup>116</sup> Although a few studies have found that claims for compensation have been reduced in some states or industries, these may be explained by reduced rates of claiming where employers discourage or vigorously contest claims. It should also be remembered that most employers are subject to both state and federal occupational safety and health standards that are intended to protect workers, although how well these standards are enforced is also a matter of some dispute. There is more consensus on the system's differential impact on worker injuries resulting from accidents in the workplace and those resulting from occupational diseases. Injuries constitute the vast majority of worker compensation claims. Because accidents are easier to identify and link to the workplace, injuries resulting from occupational accidents are more easily identified and compensated than harm from occupational diseases. The cause of disease is difficult to determine in many cases and linking it with an occupational source exacerbates the difficulty. This, together with the limits on the amounts of compensation available under worker compensation programs, may explain workers' attempts to escape the compensation system in cases of disease, such as asbestosis, and to bring products liability actions

against product suppliers whose liability is not limited by the workers compensation system.

Malpractice cases also raise difficult questions about the “cause” of a disease, medical reaction, or injury.<sup>117</sup> Proof of causation has sometimes posed a problem in the development of no-fault compensation programs for medical injuries. A few commentators have recommended no-fault compensation programs for injuries in which negligence is the most likely explanation.<sup>118</sup> Proposals for a no-fault compensation system for medical malpractice in general, however, have not yet gained widespread support.<sup>119</sup> There may be some support in Utah and Colorado for developing a form of no-fault compensation for at least a subset of medical injuries.<sup>120</sup> It will be useful to monitor the progress of such proposals to see what lessons can be learned.

In the mid-1980’s, when malpractice liability insurance premiums were rising, Virginia and Florida each adopted a no-fault compensation program limited to for newborns with severe disabilities at birth.<sup>121</sup> The laws’ purpose was to reduce the cost of malpractice insurance by protecting obstetricians from malpractice claims and offering compensation to patients.<sup>122</sup> Compensation in Virginia was limited to cases of severe neurological injuries at birth that rendered the newborn “permanently in need of assistance in all activities of daily living.” The number of claims was much lower than predicted by the Virginia State Medical Society, undoubtedly because the definition of a compensable injury applied to so few newborns. The Florida law defined compensable injuries slightly more broadly and received more claims. Both programs have received praised for providing compensation more efficiently, but some parents still try to avoid the program by bringing lawsuits in tort.<sup>123</sup>

The National Vaccine Injury Compensation Program was enacted in 1986 as part of the National Childhood Vaccine Injury Act.<sup>124</sup> The vaccine industry argued that the risk of product liability for adverse reactions to vaccines was a substantial disincentive to developing and producing pediatric vaccines, although it did not produce any data to support its claim. The Program provides compensation on a no-fault basis to children who have medical conditions specified in the legislation that were deemed adverse reactions to the pediatric vaccines that are required for children by state law.<sup>125</sup> The fact that the states required children to be vaccinated with the original covered vaccines was the

primary justification for the creation of a compensation system. Petitioners are not permitted to file lawsuits against a vaccine manufacturer unless they have pursued a claim with the Program and rejected its decision. The Act also limits the remaining causes of action that petitioners can bring. These provisions reduced tort claims after the law took effect. The Program is funded by excise taxes on sales of the covered vaccines. The tax amounts were initially established on the basis of predictions that there would be large numbers of claims, but only a fraction of the predicted claims have materialized.<sup>126</sup> The Compensation Program was part of a larger package of legislation intended to encourage the development of better and safer vaccines. The Compensation Program has been generally well received because it provides compensation in far more cases than tort litigation and with less time and expense; it has been considered as a model for other no-fault compensation proposals in the United States, although not yet used.<sup>127</sup> However, the vaccine development part of the package suffered political neglect and it is not clear whether the Program has encouraged vaccine development.

New Zealand may offer a better model for studying the possible impact of eliminating malpractice liability on physician reporting behavior. The New Zealand no-fault compensation system for injuries resulting from “medical misadventure” is part of its general insurance system for accidental injuries, including workplace and motor vehicle injuries.<sup>128</sup> Patients are entitled to compensation from the Accident Compensation Corporation (ACC) if they are injured as a result of medical misadventure—either a health professional’s negligence (called “medical error”), or an adverse consequence of proper treatment that is both severe and rare (called “medical mishap”). Funds for medical misadventure injuries are derived primarily from insurance premiums paid by health professionals. The compensation system is generally believed to operate reasonably well, although efforts have been needed to control costs.<sup>129</sup> The law also prohibits medical malpractice (and other personal injury) tort claims. Therefore, physicians and other health professionals are entirely immune from any legal liability for malpractice. Claims to the ACC and investigative reports are considered private to the parties involved and are not disclosed to the public, although aggregate data is publicly available.<sup>130</sup>

New Zealand has also begun to encourage patient safety programs as recommended by the

Institute of Medicine and the British National Health Service. The Health and Disability Commissioner notes that “the quality of health care in New Zealand should be enviable. We have a system that is rehabilitative, rather than punitive; one that seeks to protect patients yet support doctors. It includes a number of features consistent with modern approaches to reducing error and improving safety.” And yet, he notes, “a pilot study of Auckland hospitals showed that 10% of admissions were associated with adverse events. Complaints about medical practitioners are a record high.... The public sees a medical profession that is shielded from damages claims for negligence, reluctant to blow the whistle on errant colleagues, and slow to discipline substandard doctors....”<sup>131</sup> Of particular concern is the sense that health professionals are not reporting problems with the quality of care so that they can be remedied. This is particularly troubling in light of the absence of liability exposure. In his words, that it may be “not blame, but shame” that inhibits physicians from reporting medical errors in New Zealand.<sup>132</sup> In response, the Ministry of Health plans to institute mandatory reporting of sentinel events by providers and of medical misadventures by the ACC, encourage all agencies that handle medical complaints to share information in order to improve care, and require that patients be told about medical errors that affect their care or condition.<sup>133</sup>

New Zealand has other ways to identify health care practitioners in ways they might prefer to avoid. The Health and Disability Commissioner, who enforces the Code of Consumers’ Rights, receives and investigates complaints, not limited to injuries, from patients.<sup>134</sup> In the year ended June 30, 2001, 1,397 complaints about health and disability providers were received. If the Commissioner finds that a breach of the Code has been committed, he can impose a range of sanctions on the institution or practitioner, including a written apology to the patient, requirements for retraining, and referral to a licensing board for disciplinary proceedings or the Ministry of Health. The Commissioner also has the power to name responsible parties publicly, although that is not the current practice. The number of practitioners facing disciplinary charges has declined since the Commissioner’s Office was created in 1994. In 2000, 293 complaints were made about GPs; of these, “46 were found to have breached the Code and 8 were subject to professional disciplinary proceedings.”<sup>135</sup>

## Arguments For and Against Liability

The primary argument in favor of retaining liability in the United States is that the existence of liability does not increase medical error but may decrease it. The primary arguments against liability are that it fails to deter medical injury and also fails to provide equitable compensation to injured patients. Tort law has been said to serve several goals: justice (or retribution), deterrence, and compensation.<sup>136</sup> Retribution is more controversial and has lost favor as a goal of modern tort law. Tort law’s goal of deterrence, by which is meant the prevention of unreasonable conduct that causes injury, is compatible with the goals of patient safety. There is little consensus on whether tort law has a deterrent effect.<sup>137</sup> Recognition of the prevalence of medical injuries and the rise of the patient safety movement are perhaps the clearest evidence that, by itself, tort law does not prevent all injuries to patients.<sup>138</sup>

Tort law’s goal of compensation can also be criticized as imperfectly realized. Only a small proportion of people who are negligently injured bring legal claims and not all of those who do obtain compensation, while some who are not negligently injured receive compensation as though they were. While compensation theoretically supports the goal of deterrence by imposing a cost on those who cause injuries, the relationship between compensation and preventing injury is weak, if it exists at all. However, compensation is also an independent goal unrelated to deterrence or injury prevention. It can serve that goal without having any role in the development of patient safety measures. In a perfect system that prevented all harm to patients, there would be no need for compensating injuries.

Tort liability tends to play a larger social function in countries that have few sources of social assistance, little governmental regulation of the quality of products or services, and high public expectations of quality. All these factors exist in the United States system of medical care. In countries with national health insurance programs, national disability insurance or pension programs, government regulation of medical standards, and less public awareness of quality concerns, tort liability plays a more limited role—that of assigning responsibility for injury and offering compensation for the extra services not covered by government programs.<sup>139</sup>

Tort law itself has different goals than patient safety systems do. Patient safety can be achieved in many ways, with and without liability for personal injury. Tinkering only with the liability system may create unwarranted or unexpected consequences—in tort law and in other social institutions.<sup>140</sup> Tort law deals with responsibility for injury. It sets standards of reasonable conduct, both to deter injury and to determine responsibility for injuries that occur nonetheless. Deciding who should be responsible for injuries that have already occurred is conceptually distinct from deciding how injuries should be prevented in the first place. There will be a need for some social mechanism for determining responsibility for injury, regardless of whatever system is put in place to prevent injuries. This is because no system will prevent all injuries and there will always be a need to determine whether anyone should assume responsibility for those injuries.

The patient safety movement has taken inspiration from the safety measures adopted in the airline industry and engineering. It should be remembered, therefore, that those industries remain subject to liability for injuries caused to customers—those are not prevented. Although those industries have adopted reasonably effective measures to prevent injuries, they have not been protected from liability for the injuries that were not prevented. Soon after the September 11, 2001, attacks, however, the airline industry did ask Congress to assume financial responsibility for liability awards in excess of its liability insurance coverage to save itself from bankruptcy.<sup>141</sup> Congress passed legislation 10 days after the attacks creating a compensation fund for families of those who died or were injured as a result of one of the four hijacked plane crashes.<sup>142</sup> The compensation provisions have sparked controversy, including resentment among families of the victims of other terrorist attacks in Oklahoma City, Nairobi, and Tanzania, who received nothing from government, as well as workers who lost their jobs in the wake of the attacks.<sup>143</sup>

Proposals to change tort laws should be considered in light of how they would improve the functioning of the tort system for all cases in personal injury. It can be difficult to justify imposing tort reforms that limit liability only for personal injury that is caused by medical error—unless there is a reasonable basis for expecting a compensating benefit. Compensation for personal injury is too far removed from patient safety measures to affect injury prevention. The reasons most commonly given for

tort reform are the inefficiency, cost, inconsistency, and unpredictability of the tort system in assigning liability and awarding compensation. Those problems are real, but they apply not only to malpractice cases, but also to tort litigation for personal injury from all causes. They are not an argument for treating injuries caused by medical error differently. Instead, they argue for reforming the tort system in order to make it more effective and efficient—or replacing it entirely with something more effective and efficient. The best arguments for treating medical error cases differently would be that liability is, empirically, an obstacle to achieving patient safety and that replacing liability with something else, such as a compensation system, would achieve better medical care for patients or more equitable compensation. There is evidence that more equitable compensation could be achieved with a different compensation system, but as yet little evidence that patient safety would be improved.

Several commentators have recommended that physicians' malpractice liability be eliminated in favor of a form of no-fault compensation system for injured patients, coupled with institutional liability (sometimes called "enterprise liability") for all patient injuries within the institution, including those caused by affiliated physicians and employees.<sup>144</sup> Recommendations for institutional liability raise several questions.<sup>145</sup> For example, who should be liable for injuries caused by physicians in their private practices outside an institution? If institutions are deterred from reporting for fear of institutional liability under current law, will they be willing to accept broader liability for their affiliated physicians under a new enterprise liability?

Should managed care organizations or health insurers accept enterprise liability for the outpatient care provided by their participating physicians? Managed care organizations generally oppose accepting legal responsibility for patient care decisions made by physicians, arguing that, as insurers, they do not make medical judgments. Moreover, the federal Employee Retirement Income Security Act (ERISA) generally preempts the application of state negligence law to ERISA plans, so that states could not require such plans to accept legal liability for patient injuries caused by their participating physicians.<sup>146</sup> Separate bills adopted by the House of Representatives and the Senate this past summer would amend ERISA and subject ERISA plans to liability.<sup>147</sup> It is not clear whether Congress will consider either bill or any compromise version in the foreseeable future. The Senate bill would repeal

ERISA preemption of state laws governing liability for negligence and could permit the state to impose enterprise liability on ERISA plans. The House bill, however, would limit ERISA plans' new liability to injuries resulting from insurance benefit coverage decisions only and would preclude ERISA plan liability for any patient injury caused by medical judgments. Thus, the state would be barred from shifting the liability of participating physicians onto ERISA plans. If Congress does enact federal legislation defining new rules for ERISA plan liability, it seems highly unlikely that Congress would be eager to revisit the issue any time soon, even to help states improve patient safety.

### **Investigating a No-Fault Compensation System**

The Massachusetts Health Policy Forum Issue Brief No. 10 recommended that the Commonwealth investigate the feasibility of developing a pilot no-fault system for compensating victims of medical injuries. This recommendation may be intended to achieve the goal of more equitable compensation for people who are injured or to reduce or to eliminate the threat that liability may pose to reporting medical errors. Before investigating any such program, it will be important to determine the goal of a no-fault system, so that it can be designed to achieve that goal and evaluated in light of whether it achieves that goal.

Compensation systems serve the goal of compensating people with injuries. Since only a small percentage of medical injuries are compensated, a system that compensated all or even most such injuries should be considered more equitable than the tort system. Depending on how they are designed,

compensation systems can also achieve the goals of efficient and expeditious administration, costing less to administer than litigation and often requiring less time. In both respects, they offer significant advantages over the current tort system. By itself, however, a compensation system cannot guarantee that patient safety programs are implemented or that patients are protected from injury. Other systems—including laws, regulations, and financial incentives—are necessary to achieve that very different goal.

Compensation systems have numerous variables that significantly affect their ability to achieve their goals.<sup>148</sup> The major questions for designing a compensation system are summarized in Table I below. The most critical question is whether a compensation system should cover all medical injuries or only those that result from provider negligence or something in-between. True no-fault compensation systems eliminate the need to prove negligence or legal responsibility for injury. This is consistent with efforts to reduce the “blame” element of the tort system.

Some advocates of compensation systems for medical injury recommend fault-based programs that provide compensation only in cases where providers are actually negligent or at fault.<sup>149</sup> This restriction is often intended to limit the pool of injuries and therefore the total cost of awards.<sup>150</sup> However, because it requires claimants to produce evidence of fault, it introduces the requirements—and disadvantages—of tort law into a system inspired to avoid tort law problems. Claimants may have to search for evidence of negligence for purposes of blaming providers. Thus, if the blame element of tort litigation is in fact a deterrent to provider reporting of medical error, then a fault-based compensation system is not likely to remove that deterrent.

***Table 1. Elements of a Compensation Program***

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| <p><b>Eligibility</b></p> <ul style="list-style-type: none"> <li>• Who should be eligible for compensation?</li> <li>• U.S. citizens, Massachusetts residents, patients of Massachusetts providers?</li> <li>• What, if any, time period should be the limit for bringing claims?</li> </ul> <p><b>Covered Injuries</b></p> <ul style="list-style-type: none"> <li>• Should the program cover all injuries, only those caused by medical error or by negligence?</li> <li>• Should covered injuries be limited by severity, permanence, financial cost, effect on earning capacity?</li> </ul> |
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*Table 1. Elements of a Compensation Program (cont.)*

**Causation**

- How is causation to be determined?
- What evidence should be required?
- Is causation understood well enough to permit a list of compensable injuries?
- Who has the burden of proving causation?

**Compensation Benefits**

- Is compensation to be calculated on the basis of actual losses, injury severity, a fixed amount per person or injury, or payments for expenses as incurred?
- Should collateral sources of medical or disability benefits reduce compensation?
- Should attorneys' fees for claimants be covered? Fully or in a limited amount?

**Payment Mechanisms**

- Should payment of compensation be made in a lump sum, periodic payments, by annuity, or a health insurance policy providing coverage for medical expenses?

**Decisionmaking Authority and Procedures**

- What entity is authorized to make decisions about eligibility and compensation?
- State administrative agency, administrative law judge, court, expert panel?
- Should any third party be required or permitted to participate in the decisionmaking process?
- What, if any, type of review or appeal should be available?

**Relationship to Tort Law**

- Should the compensation system be an optional alternative to the tort system or the exclusive source of compensation for claimants?
- If the program ceases operation or is repealed, what, if any, rights should the claimants have?

**Financing**

- What should be the source of funding for the compensation and administration?  
State revenues?
- Taxes on providers? Private insurance?

**Period of Operation**

- Should the program's continuance be contingent upon future events, such as a reduction in medical errors, minimum reporting rates, adequate funding, total costs, or some other event?

True no-fault systems avoid the blame element, but may face a comparable problem. No-fault compensation systems that are limited to injuries from a specific cause—like medical error—must either require claimants to prove the cause of their injury or establish a credible list of injuries that are presumed to be caused by medical error. Proving causation can be difficult and expensive and undermine the system's

ability to operate expeditiously. It should be possible to create a schedule of compensable injuries, but not all injuries could be presumed to be caused by medical error. Here again, claimants who need to prove causation may seek evidence—including provider identity—concerning medical errors in a manner similar to tort litigation or fault-based compensation systems.

No-fault compensation systems raise questions of fairness. Any system that limits no-fault compensation to people with injuries arising out of one cause invites the question why people with similar injuries from a different cause should not also be compensated—an issue of horizontal justice. A related question is whether a no-fault compensation system for medical injuries should be adopted at the state or federal level. It is not known whether a state compensation system would make the state more or less attractive to providers and patients or whether it might attract better or worse providers to its medical care system. State-level compensation systems also require deciding whether to cover patients and providers who are not state residents.

A practical concern is whether a no-fault compensation system would cost more than the current tort liability system.<sup>151</sup> The answer depends greatly on how the system is structured, most importantly what injuries are eligible for compensation and whether and how the amount of compensation is limited. A major issue is whether the amounts could be set high enough to meet the needs of injured people, but low enough to be affordable by those who have to pay. Recommendations for a no-fault system for medical injuries often restrict compensation to serious or permanent injuries or those that result in a minimum amount of financial loss. These limits reduce the total cost of compensation by excluding some proportion of people from the system, typically those with less severe injuries. As a practical matter, people with smaller financial losses probably would not be able to pursue a lawsuit to obtain compensation (because no lawyer would take the case), so they would not necessarily lose anything. However, it is unclear how the public would perceive this trade-off. Some people might welcome a system that is at least more equitable than the tort system. Others might perceive a limited compensation system as worse than the (often unrealistic) legal option of tort liability or as taking away a legal right, even if they would not or could not exercise that right.

Targeted (cause-based) compensation programs are more likely to gain public support when there is believed to be some social or government obligation to compensate people who have been injured in the course of a public program or activity that benefits the public at large. They may also be more popular in times of relative affluence. When a state or country experiences economic difficulties or recession, the public may be more interested in gaining access to

medical care itself than compensating those who already have access and are injured.

The administration and financing of a compensation system can also be structured in various ways, with different cost implications. Decisions about compensation could be assigned to an administrative unit of state government, a newly created expert panel, administrative law judges, or the court system. Revenues for administration and compensation could come from government or from levies on providers, for example. The government's assumption of the cost of such a program would relieve providers from the expense of liability insurance, but would subject the program to the vagaries of the legislature's budget process. Having providers finance the system would spare the government additional expense and could be structured to calculate each provider's contribution or premium to the compensation awarded to its patients, thereby retaining a link to medical errors.

If the goal of reform is to minimize costs to government, then no change in the law is needed because providers and their insurers absorb the cost of liability—except to the extent that such costs are passed on to government programs like Medicaid. A no-fault compensation system funded entirely by the state would be the most costly option for state government. A no-fault compensation system funded by providers would probably fall in between if the costs were passed on to government programs. Ideally, a concurrent, effective patient safety system would reduce the incidence of errors and consequently the incidence of compensable injuries. However, a compensation system does not address patient safety.

Injuries could also be compensated through a federal or state disability insurance system by expanding the eligibility criteria to include injuries resulting from medical error. A disability insurance program is, of course, a no-fault compensation system, although it typically provides for scheduled amounts of compensation according to the degree of disability, rather than compensating specific losses. It may have the advantage of being somewhat easier and less costly to administer than a typical no-fault compensation system. Compensation could be folded into a more general disability insurance program like Social Security by adding injuries from medical error as a basis for eligibility. The incidence of disabilities in general is more predictable than the incidence of medical error. A system limited to disabilities from medical error alone may suffer from two of the dis-

advantages of a cause-based compensation system: the need for proof of causation and objections based on horizontal justice.

## Alternatives to Compensation Systems

If the goal of a no-fault compensation system is to replace liability for medical malpractice in order to eliminate the threat that it may pose to reporting medical error, there are alternative ways to achieve that goal. These alternatives include social insurance, tort reform, criminal liability, professional discipline, government-financed excess liability insurance, and voluntary contractual agreements for compensation.

Numerous scholars have recommended changes in the law governing tort litigation. Reformers have proposed changing the procedures or evidence used in litigation, the amounts of compensation payable, and, less often, the grounds for liability itself.<sup>152</sup> Most proposals are intended to reduce the number of claims brought by plaintiffs or the amount of awards to plaintiffs. It is not clear whether such reforms would affect providers' fears of litigation. If providers' fears are based on the actual probability of losing a lawsuit or the amount of money they would have to pay, then the reforms might reduce such fears. If their fears are based on the prospect of the litigation process, regardless of outcome, then tort reforms may not alter those fears. Tort reforms that put severe limits on damage awards may reduce the remaining incentives to pursue patient safety systems.<sup>153</sup> Again, in the absence of reliable data on the effect of providers' fears of liability on their willingness to participate in patient safety programs, it is difficult to predict what effect tort reforms might have.

Reforms designed to address the inconsistencies in tort litigation might be better received. For example, changes in the substantive law governing compensatory damages to make them more consistent across patients with similar injuries reduces the risk of inequitably or unpredictably large or small awards. People with injuries from other causes might welcome a similar change. This could be accomplished with a schedule of injuries, ranked by severity, loss of function, or other criteria, each with an assigned dollar value or range of values, or by through medical or disability insurance policies. The amounts could be established by calculating reasonable medical expenses, costs of continuing care, and adding real or standardized lost income for each injury. The process could be difficult and even controversial, but not

impossible. Its major disadvantage would be being compared with Workers Compensation, which has been criticized for paying inadequate compensation for serious injuries.

It should be noted that tort liability is not confined to medical malpractice. Patients may have a cause of action for fraud or misrepresentation against hospitals and physicians for failing to tell them about an injury they sustained and its cause, especially if it is not readily identifiable by the patient. If the patient would not recognize the injury because he or she did not suffer noticeable physical harm, there may be little likelihood that the patient would file a legal action. Nonetheless, if the information is discovered, a cause of action is possible. Protecting the confidentiality of medical errors and allowing physicians and hospitals to withhold knowledge of information, especially in cases in which patients were harmed, presents a conflict with moral and legal duties to disclose information to patients.<sup>154</sup> It is particularly problematic in cases in which the harm results from negligence. Physicians have a duty to their patients to treat them with the accepted standard of care. Patients may find it difficult to accept the argument that, given this duty, a physician nevertheless has no duty to tell the patient when the physician has caused harm by failing in that duty. If the reason for not telling the patient is to avoid being sued, is this sufficient justification for not telling the patient?

Good medical practice increasingly recognizes the patient's right to know medical errors that occurred during their medical treatment.<sup>155</sup> If patients are routinely advised of medical errors in practice, however, there is little justification for keeping such information secret from patients. It is even possible that recommendations for confidentiality of medical error reporting may be overtaken by actual medical practice.

## CONCLUSIONS

Patient safety and liability for personal injury operate in different spheres, with different goals, benefits, and problems. A single change in policy or law probably cannot achieve goals of both. It is likely that we will need several policy instruments to do so. In addition, changes in laws that were designed to achieve more general goals than patient safety may have unanticipated effects in other arenas. Therefore, before deciding which policy instruments to adopt, the Commonwealth should know more about the

relationship between patient safety—and reporting in particular—and liability for patient injury.

Empirical evidence on the effect of specific laws on reporting behavior is meager at best, partly because it is difficult to disentangle a law's effect from the many other factors that influence human behavior. Therefore, it is important to remain cautious about predicting specific results from the passage of any law. Although it is reasonable to believe that fear of liability may deter health professionals and facilities from reporting their own medical errors, there are other disincentives—both to reporting and to making the changes necessary to reduce medical errors and improve patient safety. Salient among them is the culture of medical practice that discourages drawing attention to errors. However, there is insufficient evidence to be able to predict that eliminating any one or more of these disincentives would actually result in increased reporting of medical errors and increased patient safety.

Patients are the intended beneficiaries of the patient safety movement. Since it is impossible to identify all members of the group “patients” at any given moment, but almost everyone will be a patient at some point in their lives (typically more than once), it seems fair to say that a movement aimed at protecting patients is directed at the public. This raises the question whether a movement that is directed at protecting the public should withhold information from the public about risks to the public's safety. Laws protecting peer review data from public disclosure were adopted to encourage better patient care. The evidence so far does not suggest success. This does not mean that public disclosure would necessarily improve patient care. It merely reminds us that our assumptions about the effects of specific laws need to be tested. Indeed, some would argue that those who advocate keeping medical errors secret from patients should have the burden of proving why patients should not have the information.

In the ideal world, publicly reporting medical errors might help the public appreciate the uncertainty in medicine and the ubiquity of risk, so that they would not be too quick to heap unwarranted blame on the medical profession. However, it is not clear whether this would be the public's reaction. Public concern about the risk of medical error may have been heightened as a result of the IOM Report and the evolving patient safety movement, especially in Massachusetts. If that concern has not waned in the

aftermath of September 11, patients might react badly to what they might perceive as hiding information about errors from the public. In the absence of information about the causes of medical error, patients might be even more inclined to blame medical professionals and facilities for accidents. On the other hand, the patient safety movement may attract little public attention in this era.

It is possible that the public can be protected without knowing about the instances in which patient safety is (or was) at risk. Some public health measures are undertaken to protect the public from risk without publicly disclosing every instance in which a risk materializes or harm is done—although in this day and age, those cases are becoming rarer. Indeed, the trend is toward increased disclosure of even potential risks, such as the risk of West Nile Virus and tularemia. However, when the risk arises out of personal medical care, there are other considerations, including the principle that individuals have a right to decide what medical risks they wish to take.

The relationship between compensation for medical injuries and reporting medical error is also muddy. There are good reasons for adopting a program to provide compensation to injured patients. At the same time, it must be recognized that compensation systems cannot, by themselves, prevent injuries or improve the quality of care. Therefore, a compensation system should be investigated on its own merits or paired with other measures that are adequately structured to achieve the goals that a compensation system cannot address.

## RECOMMENDATIONS - AN AGENDA FOR RESEARCH

The following two recommendations outline key areas that deserve investigation and research in order to provide a basis for developing public policy to improve patient safety:

### 1. Defining Medical Error for Purposes of Patient Safety

Incidents and errors that should be reported have been defined differently for legitimately different purposes, and different institutions sometimes use the same terms differently. This can make it difficult to aggregate or compare information from different sources, precisely what is needed to improve patient safety. Massachusetts should examine ways to collect and present information about medical errors from different sources in ways that permit comparison and analysis for purposes of patient safety, without unnecessarily duplicating reporting requirements.

- What factors actually dissuade health professionals from reporting medical errors?
- What factors actually persuade health professionals to report medical errors?
- Are there different responses to reporting one's own medical errors and the errors of others?
- Which aspect of tort law is the most unnerving to health professionals: the litigation process in tort law, damage to reputation, loss of money?
- Which aspect of professional licensure law is most unnerving: the disciplinary process, damage to reputation, loss of licensure, the loss of income?
- Can reporting systems be accepted as non-punitive when they co-exist with some form of accountability?

### 2. Reporting Incentives and Disincentives

Despite general agreement on the likely factors that discourage medical professionals from reporting medical errors—their own and others—there is insufficient empirical data to determine exactly what people do and don't report and why. More important, it remains unclear whether removing any single factor would result in increased reporting or whether any increase would be sufficient for purposes of patient safety analysis. There is a need for research to identify what specific factors will make a difference. This is particularly important in an era in which health professionals are under increasing financial and institutional pressure to accomplish more in less time for less money. Research questions include:

- Is de-identified information disclosure less threatening to medical professionals and institutions than identifiable information?
- What proportion of medical errors would be actionable in tort?
- What proportion of medical errors are preventable and what proportion are not amenable to prevention by systems approaches?
- What medical errors would actually be reported in the absence of tort liability?
- What medical errors would actually be reported in the absence of professional discipline?
- Are there circumstances in which liability or an alternative form of accountability should be preserved, no matter what?

### *Financial Incentives for Implementing Reporting and Patient Safety Programs*

Removing disincentives to reporting may not be sufficient to implement a successful patient safety system. Therefore, it is worth investigating ways to make such systems—and reporting to them—more attractive to professionals. One approach that should be considered is financial incentives for hospitals and physicians to report. Would it be feasible to structure payment systems to reward quality of care and reductions in medical error? Currently, payers—government and private insurers—may have little

incentive to pay for quality of care. Payers may not pay the cost of medical error. Liability insurers do. Although providers may pass on the cost of liability insurance premiums to payers, managed care has made it increasingly difficult for providers to negotiate rate increases that would cover the cost of substantial patient safety systems.

There should be ways to insert quality—or at least error reduction—into the financial calculus. For example, the Division of Insurance might consider including quality outcomes in its calculation of acceptable premium rates for managed care

organizations and health insurance carriers. In turn, insurers could base their payment rates to physicians and other professionals on the quality of care they provide to patients and in particular on participation in a patient safety reporting system. Physicians changed their practice patterns rapidly in response to managed care financial incentives. There may be some support in the insurance industry for attention to quality, especially among managed care plans in Massachusetts that have difficulty competing successfully on price because of the high cost of providing care in Massachusetts.<sup>156</sup> This is not to suggest that factoring quality into rates is likely to be a simple matter. Instead, it is to suggest that it should be explored.

#### *Licensure*

The possibility of using licensure to reward both health professionals and health care facilities should be explored. It is possible that making patient safety an integral element of professional obligations could remove the taint of legal “blaming” and align professional culture with patient interests. Among the possibilities are creating a graduated licensure system. Physicians and hospitals could be graded “A,” “B,” “C” and “F” (or something more palatable) based on quality and participation in patient safety reporting system. Professionals and facilities might find a good rating an advantage in marketing themselves. Managed care organizations may begin to publicize their own ratings of physicians.<sup>157</sup> Developing such a system would require substantial expertise and effort. Implementing such a system would require additional resources for the Department of Public Health and the boards of registration. They would undoubtedly need to be able to evaluate patient outcomes in light of severity of disease and other factors, and expand their focus beyond the most egregious of problems. This might include the ability to conduct random, unannounced audits of facilities and practices to see how care is actually provided.

#### *Expand the Range of Sanctions for Failure to Report*

If mandatory reporting remains a necessary element of patient safety systems, and other mechanisms are unsuccessful in achieving sufficient levels of reporting, then the agencies responsible for enforcing reporting requirements will need more effective sanctions. If the Department of Public Health and boards of registration find themselves limited to revoking or suspending licensure—and

possibly depriving patients of access to care—they are unlikely to enforce reporting requirements. Lesser, more targeted sanctions, including fines, public disclosure of violations, and restrictions on services, should be explored. Sanctions could be coordinated with a graduated system licensure, in which those who fail to report are downgraded to a lesser license.

#### *Identify Standards for Patient Safety, Including Technologies to Reduce Errors and Performance Standards for Professionals*

The patient safety movement has taken advantage of the systems thinking prevalent in industry. But it has not yet adapted the resulting system of product and performance standards to medical care. Industry must comply with certain regulatory safety standards in manufacturing products and conducting business operations. Developing standards for medicine is far more difficult. However, where technologies can be used to protect patient safety, they could be required as a condition of licensure or be imposed independently by a regulatory agency responsible for patient safety. In order to establish such standards, however, it will be necessary to distinguish errors that can be fixed by technology and systems approaches from those that are based in human judgment and cannot be fixed by technology.

Patient safety systems work best where a systems approach can prevent error, especially where technologies can be used effectively, such as the pulse oximeter to measure oxygenation in anesthesia, computer programs for checking drug prescription doses and contraindications, and bar codes for patient identification. They may be less effective in preventing errors of human judgment, such as the range of diagnoses that should be evaluated to identify the cause of a patient’s problem. The realm of judgment is where tort law has traditionally applied. As technologies are developed that can prevent human error, tort law has often been displaced by regulatory standards, such as product standards for consumer products and drug standards for prescription drugs. It seems likely that the patient safety movement will develop technologies that can be used in place of human judgment in many circumstances. Such technologies might be adopted as voluntary standards by professional organizations, as mandatory standards by accreditation organizations, or even as mandatory standards by regulatory agencies.

*Investigate Options for a No-Fault Compensation System When Providers Actually Report and Implement Effective Patient Safety Programs*

The feasibility of a no-fault compensation system for medical injury might be considered as a more equitable means of compensating patients who are injured. More research is needed in order to determine the costs and benefits of different structures for any such system in Massachusetts and the feasibility of implementing it in one state—as opposed to nationally—when other states retain liability. Whether a compensation system would affect reporting or patient safety remains unclear. One way to approach that relationship would be to defer the implementation of any such compensation system unless and until Massachusetts providers demonstrated progress in reducing medical errors. This might be considered a “sunrise” law—one that does not take effect until specific conditions are satisfied, in contrast with a sunset law that expires at a predetermined time.

*Study Public/Patient Attitudes Toward Quality of Care and Medical Error and Investigate Public Education about Quality*

Some commentators suggest that efforts to improve the quality of care have not been taken as seriously by clinicians and administrators as by academics and researchers because the general public puts little pressure on providers to assure quality and reduce errors.<sup>158</sup> There is some evidence that consumers, as well as employers, do not use publicly available information about quality to select health plans or physicians.<sup>159</sup> If there is a lack of patient demand for high quality, then one might ask why that should be, especially in Massachusetts, which takes considerable pride in the reputation of its medical institutions. It would be worth investigating whether and how the public should be educated about the value of improved quality of care, how quality can be

defined, the degree of uncertainty and risk in patient care, and the prevalence of medical error. This may include better ways to disseminate aggregate information about reported medical errors. It may be possible to encourage a renewed commitment to patient safety programs by encouraging public demand for quality. In addition, it is worth investigating whether telling patients about medical errors when they happen improves patient understanding of medical care, and, if so, how such disclosure can be encouraged. If health professionals begin to provide such information to patients routinely, then the practice of medicine will incorporate elements of disclosure and possibly encourage better reporting for patient safety program purposes.

*Publicize Success*

Institutions that have reduced errors and injuries should publicize their successes. The growing competition among health care facilities and professional groups may make it harder for institutions to attract patients and health plan contracts simply by lowering prices (and most seek to increase prices), so that advertising safety and value may provide successful institutions with a competitive edge, which will be emulated by other institutions.

*Evaluate the Effect of Any New Law*

One reason for controversy over proposed changes in the law is the absence of empirical evidence about either the need for the change or the effect the proposed law will have. Any proposals for changes in the law should include provision for evaluating the law’s effect, specifically whether it achieves its intended goal. The difficulty of designing and carrying out such research should not be underestimated. However, the likely reward will be better policy and better information for future laws.

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- <sup>2</sup> L.T. Kohn, J.M. Corrigan, M.S. Donaldson, eds., *To Err Is Human: Building a Safer Health System*, Report of the Committee on Quality of Health Care in America, Institute of Medicine, National Academy of Science. [hereafter *To Err Is Human*], Washington, DC: National Academy Press, November 1999.
- <sup>3</sup> *To Err Is Human*, at 1.
- <sup>4</sup> *Medical Errors*, Table 1, p. 9, reprinted from Br. Med. J., 320: 759-763 (March 18, 2000).
- <sup>5</sup> *Medical Errors*, p. 1.
- <sup>6</sup> *Medical Errors*, p. 24
- <sup>7</sup> *Medical Errors*, p. 23.
- <sup>8</sup> *Medical Errors*, p. 24.
- <sup>9</sup> There may be other ways, besides reporting by health professionals within an institution, to identify system errors. For example, observational studies by trained supervisors or independent experts might discover problems areas that could be remedied. Researchers have developed many useful recommendations for preventing errors after formally studying specific patient care protocols. See, e.g., P.G. Nightingale, D. Adu, N.T. Richards, M. Peters, Implementation of Rules Based Computerised Bedside prescribing and Administration. *British Medical Journal* 2000; 320: 737-740; D.W. Bates, L.L. Leape, D.J. Cullen, et al., Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors, *Journal of the American Medical Association*.1998; 280: 1311-1316. Like voluntary reporting, observational studies may suffer from bias, such as changes in behavior by those being observed. Still, opportunities for errors that are embedded in the system, such as inadequate computer tracking of prescriptions, might be identified as or more easily by direct study than by voluntary reporting after an error occurred and should not be neglected in any program to improve patient safety.
- <sup>10</sup> L.L. Leape, Error in Medicine, *Journal of the American Medical Association*. 1994; 272: 1851.
- <sup>11</sup> L.L. Leape, Foreword: Preventing Medical Accidents: Is “Systems Analysis” the Answer?, *American Journal of Law & Medicine*. 2001; 27: 145.
- <sup>12</sup> Some kinds of errors, such as a surgeon’s slip of the scalpel in a hard-to-see body cavity, probably cannot be prevented by structural measures. Arguably, sufficient training in manual dexterity in that particular surgical procedure could reduce the risk of slippage, but probably not to zero. When prevention is not possible, the issue becomes whether patients who are injured as a result of such iatrogenic injury should be compensated.
- <sup>13</sup> Nancy Wilson, Finding Errors in Medicine, Presentation at American Public Health Association Annual Meeting, Boston, MA, November 2000.
- <sup>14</sup> *Medical Errors*, pp. 8-9.
- <sup>15</sup> *To Err Is Human*, pp. 98-99.
- <sup>16</sup> Great Britain, Department of Health, *An Organization with a Memory, Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Office*, p. 80. It proposed to begin with confidential reporting (keeping the reporter’s identity confidential) until staff feel they can report all adverse events without fear of retribution. However, it noted that “in some circumstances it may be impossible or inappropriate to preserve anonymity—for example where there is evidence of gross negligence, criminal activity and/or a threat to patient safety and this cannot be addressed without disclosing the identity of the reporter.” *Id.* at 82. It also recommended that the NHS Litigation Authority, which handles complaints against the NHS, “should work with the medical defence organizations to ensure that maximum learning is drawn from analyses of the extensive information available on clinical negligence litigation.” *Id.* at 83. This learning is then to be fed into the new patient safety system to obtain the most comprehensive system possible. Thus, the litigation and clinical patient safety programs are to work together to develop a comprehensive information base. Of course, there is little litigation against the NHS in England and damage awards tend to be lower because medical expenses are already covered by the NHS.
- <sup>17</sup> Great Britain, Department of Health, *Building a Safer NHS for Patients—Implementing An Organization with a Memory*, p. 40.
- <sup>18</sup> Ian Kennedy, *Learning from Bristol: the report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995*, [hereafter *Bristol Inquiry*], July 2001, para. 42, [www.bristol-inquiry.org.uk/final\\_report/report.htm](http://www.bristol-inquiry.org.uk/final_report/report.htm).
- <sup>19</sup> M. Chaing, Promoting Patient Safety: Creating a Workable Reporting System, 18 *Yale J. On Regulation*. 2001; 383: 396-401.

- <sup>20</sup> A.G. Lawthers, A.R. Localio, N.M. Laird et al., Physicians' Perceptions of the Risk of Being Sued, *Journal of Health, Politics, Policy & Law*. 1992; 17:463-482.
- <sup>21</sup> Chaing, note 19 *supra* (advocating "brightline rule" protecting confidentiality of incident reports made for quality management purposes).
- <sup>22</sup> N.S. Calman, No One Needs to Know, *Health Affairs*. March/April 2001: 243, 248.
- <sup>23</sup> A.W. Wu, T.A. Cavanaugh, et al., To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients, *J. Gen. Intern. Med.* 1997; 12: 770-775. See also R. Delgado, To Tell the Truth: Physicians' Duty to Disclose Medical Mistakes, *UCLA L. Rev.* 1980; 28: 52. In some jurisdictions, a doctor who withholds information about a medical error can be found guilty of fraud. Barry R. Furrow, *Doctors' Dirty Little Secrets: The Dark Side of Medical Privacy*, 37 *Washburn Law Journal*. 1998; 37:283-316, 302.
- <sup>24</sup> S.S. Kraman, G. Hamm, Risk Management: Extreme Honesty May Be the Best Policy, *Annals of Internal Medicine*. 1999; 131: 963-967.
- <sup>25</sup> Leape, Foreword: Preventing Medical Accidents, note 11 *supra* (comparing the internalization of safe practices to the adoption of good medical practices).
- <sup>26</sup> D.M. Studdert, T.A. Brennan, No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention, *Journal of the American Medical Association*. 2001; 286:217-223 (listing 5 characteristics of an optimal system, which should: (1) encourage physicians and other health care providers to report medical errors; (2) send quality improvement signals, supplemented by financial incentives to reduce errors; (3) have mechanisms to deal with incompetent, dangerous or malevolent physicians; (4) reinforce honesty and openness in the physician-patient relationship; (5) provide speedy, equitable, affordable and predictable compensation).
- <sup>27</sup> *To Err is Human*, p. 146.
- <sup>28</sup> S.R. Latham, System and Responsibility: Three Readings of the IOM Report on Medical Error, *American Journal of Law & Medicine* 2001; 27: 163-179.
- <sup>29</sup> See generally *Reporting Requirements Across Agencies*, Massachusetts Coalition for the Prevention of Medical Errors, July, 2001, for a comprehensive table setting forth a broader range of agency reporting requirements relating to health care. [http://mhalink.org/mcpme/mcpme\\_welcome.htm](http://mhalink.org/mcpme/mcpme_welcome.htm)
- <sup>30</sup> M.G.L.A, ch. 111, § 203; ch. 112, § 5.
- <sup>31</sup> M.G.L.A. ch. 111, §§ 204-205.
- <sup>32</sup> 105 C.M.R., § 130.331.
- <sup>33</sup> 243 C.M.R. 3.00.
- <sup>34</sup> 243 C.M.R. 3.04.
- <sup>35</sup> Personal conversation with Nancy Achin Sullivan, Executive Director, Massachusetts Board of Registration in Medicine, October 16, 2001. Notes on file with the authors.
- <sup>36</sup> 2000 Annual Report, 30, Board of Registration in Medicine. Available at <http://massmedboard.org/2000ar.pdf>.
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- <sup>38</sup> 105 CMR 130.331.
- <sup>39</sup> Division of Health Care Quality - Hospital Reporting of Serious Incidents, 105 CMR 130.331.
- <sup>40</sup> Telephone call with Jean Pontikas, Assistant Director, Division of Health Care Quality, Department of Public Health, Oct. 11, 2001. Notes on file with the authors.
- <sup>41</sup> [Http://www.state.ma.us/dph/dphprov.htm#HCO](http://www.state.ma.us/dph/dphprov.htm#HCO).
- <sup>42</sup> [Http://www.jcaho.org/sentinel/se\\_fact.html](http://www.jcaho.org/sentinel/se_fact.html).
- <sup>43</sup> All told, the Joint Commission had reviewed 1,398 sentinel event reports by August of 2001, 75% of which stemmed from patient deaths. [Http:// www.jcaho.org/sentinel/se\\_stats.html](http://www.jcaho.org/sentinel/se_stats.html). The Commission had also issued 19 Patient Alerts compiled from information contained in these reports. [http://www.jcaho.org/sentinel/sentevnt\\_frm.html](http://www.jcaho.org/sentinel/sentevnt_frm.html).

- <sup>44</sup> [Http:// www.jcaho.org/sentinel/se\\_stats.html](http://www.jcaho.org/sentinel/se_stats.html).
- <sup>45</sup> [http://www.jcaho.org/whatwedo\\_frm.html](http://www.jcaho.org/whatwedo_frm.html) (visited Oct. 10, 2001)
- <sup>46</sup> Under the Medicare statute, JCAHO-accredited hospitals are deemed to meet requirements for Medicare certification. 42 U.S.C. §§ 1395x(e), 1395bb.
- <sup>47</sup> [Http://www.jcaho.org/sentinel/se\\_fact.html](http://www.jcaho.org/sentinel/se_fact.html), (visited Oct. 9, 2001).
- <sup>48</sup> [http://www.jcaho.org/edu\\_pub/sealert/se\\_alert.html](http://www.jcaho.org/edu_pub/sealert/se_alert.html), (visited Oct. 9, 2001). As of October 28, JCAHO placed a moratorium on scoring health care organization compliance with sentinel event recommendations pending revisions in its scoring policy designed to make it easier for hospitals to implement improvements.
- <sup>49</sup> Revisions to Joint Commission Standards in Support of Patient Safety and Medical/Health Care Error Reduction, Effective: July 1, 2001, [http://www.jcaho.org/standard/fr\\_ptsafety.html](http://www.jcaho.org/standard/fr_ptsafety.html) (visited August 31, 2001).
- <sup>50</sup> *Id.*, [emphasis supplied].
- <sup>51</sup> Massachusetts Medical Society (Waltham, MA), *Physician Health Services Annual Report for 2001*, at 19.
- <sup>52</sup> 243 CMR 2.07 (23).
- <sup>53</sup> *Id.*
- <sup>54</sup> “The standard contract requires individual therapy, group support meetings, regular meetings with a PHS associate director, random urine screens (if indicated), regular interaction with a monitor, and a chief of service who agrees to help document the physician’s progress. *Physician Health Services Annual Report for 2001*, at 1.
- <sup>55</sup> M.G.L. c. 112, § 5F.
- <sup>56</sup> *Physician Health Services Annual Report for 2001*, note 51 *supra*, at 13.
- <sup>57</sup> Conversation with Linda Bresnahan, PHS Director of Program Operations, October 10, 2001. Notes on file with authors.
- <sup>58</sup> 31 U.S.C. §§ 3729-3733 (1994).
- <sup>59</sup> J.H. Krause, Medical Error as False Claim, *American Journal of Law & Medicine*. 2001; 27: 181- \_\_\_\_, at 191 (2001); 42 C.F.R. § 482.25
- <sup>60</sup> Krause, *id.*
- <sup>61</sup> *Id.*
- <sup>62</sup> 31 U.S.C. § 3729(b); 28 C.F.R. § 85.3(a)(9) (1999).
- <sup>63</sup> 31 U.S.C. § 3730(b), (d).
- <sup>64</sup> Krause, note 59 *supra*, at 193.
- <sup>65</sup> A. Dembner, A Cure for Fraud, *Boston Globe*, Oct. 7, 2001, B1.
- <sup>66</sup> *Id.* at 194.
- <sup>67</sup> See also the \$500 fine for failure to report suspicious deaths, including several categories related to health care, to the Office of Chief Medical Examiner; note 29 *supra*.
- <sup>68</sup> J. Shapiro, Taking the Mistakes Out of Medicine, *U.S. News & World Report*, July 17, 2000, p. 50.
- <sup>69</sup> *Medical Errors*, p. 23.
- <sup>70</sup> R.R. Bovbjerg, R.H. Miller, D.W. Shapiro, Paths to Reducing Medical Injury: Professional Liability and Discipline vs. Patient Safety—and the Need for a Third Way, *Journal of Law, Medicine & Ethics*. 2001 (forthcoming); T.A. Brennan, Hospital Peer Review and Clinical Privileges Actions: To Report or Not Report (editorial), *Journal of the American Medical Association*. 1999; 282: 381-382.
- <sup>71</sup> *To Err Is Human*, note 2, pp. 102, 110.
- <sup>72</sup> R.R. Bovbjerg, Medical Safety: From Stories to Policy, *Health Affairs*. 2001; 20(2): 241-242.
- <sup>73</sup> J. Rosenthal, M. Booth, et al., *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives*, National Academy for State Health Policy, 2001, p. 66.
- <sup>74</sup> The National Practitioner Data Bank was established pursuant to the Health Care Quality Improvement Act of 1986, 42 U.S.C. §§11131-11137 (1995). See generally, B.R. Furrow, *Quality Control in Health Care: Developments in the Law of Medical Malpractice*, 173, 185 (1993).

<sup>75</sup> Office of Inspector General, *Managed Care Organizations Nonreporting to the National Practitioner Data Bank: A Signal for Broader Concern*, OEI-01-99-00690, May 2001; Health Plans Rarely Report Bad Doctors to Databank, *Reuters Medical News*, May 18, 2001 (reporting on OIG report).

<sup>76</sup> Office of Inspector General, *id.*

<sup>77</sup> L. Belkin, How Can We Save the Next Victim?, *New York Times Magazine*, June 15, 1997, 6.

<sup>78</sup> Bristol Inquiry, note 18 *supra*.

<sup>79</sup> J.R. Localio, A.G. Lawthers, T.A. Brennan et al., Relation Between Malpractice Claims and Adverse Events Due to Negligence—Results of the Harvard Malpractice Study III, *New England Journal of Medicine*. 1991; 325:245-251.

<sup>80</sup> *Id.*

<sup>81</sup> E.J. Thomas, D.M. Studdert, H.R. Burstin, et al., Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado, *Medical Care*. 2000; 38: 261-271; D.M. Studdert, E.J. Thomas, H.R. Burstin et al., Negligent Care and Malpractice Claiming Behavior in Utah and Colorado, *Medical Care*. 2000; 38: 250-260.

<sup>82</sup> Studdert et al., *id.*; Localio et al., note 79 *supra*.

<sup>83</sup> F.A. Sloan, et al., *Suing for Medical Malpractice*, Chicago: University of Chicago Press, 1993; G.B. Hickson, E.W. Clayton, C.S. Miller et al., Obstetricians' Prior Malpractice Experience and Patients' Satisfaction with Care, *Journal of the American Medical Association* 1994; 272: 583-587; Edward A. Dauer, Leonard J. Marcus, Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement, *Law and Contemporary Problems*, Winter 1997; 60: 185-218; G.B. Hickson, E.W. Clayton, P.B. Githens, Frank A. Sloan, Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries, *Journal of the American Medical Association* 1992; 267: 1359-1373; C. Vincent, M. Young, A. Phillips, Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action, *The Lancet* 1994; 343:1609-1612; A.B. Witman, D.M. Park, S.B. Hardin, How Do Patients Want Physicians to Handle Mistakes, *Archives of Internal Medicine* 1996; 156: 2565-2568 (survey of cases with moderate physician error found 12% of patients would sue if physician disclosed error, but 20% would sue if they learned later without physician disclosure).

<sup>84</sup> J.R. Cohen, Advising a Client to Apologize, *Southern California Law Review*. 1999; 72: 1009-1069.

<sup>85</sup> Kraman & Hamm, note 24 *supra*.

<sup>86</sup> R.R. Bovbjerg, Medical Safety, note 72 *supra*.

<sup>87</sup> J. Reason, *Human Error*, New York: Cambridge University Press, 1990; P. Slovic, Perception of Risk, *Science* 1987; 236: 280-285; B. Fischhoff, *Acceptable Risk*, Cambridge, UK: Cambridge University Press, 1981.

<sup>88</sup> Lawthers, note 21 *supra*. Estimates of the risks of suit included the following:

| <u>Risk Category</u>                       | <u>Physicians' Estimate</u> | <u>Actual Suits</u> |
|--|-----------------------------|---------------------|
| Low (general, family practice)             | 12.1/100                    | 3.8/100             |
| Medium (e.g., general surgery)             | 23.4/100                    | 10.9/100            |
| High (e.g., neurosurgery, OB, orthopedics) | 34.3/100                    | 20.8/100            |

<sup>89</sup> United States Congress, Office of Technology Assessment, *Defensive Medicine and Medical Malpractice*, OTA-H-602, Washington, DC: U.S. Government Printing Office, July 1994, p. 2.

<sup>90</sup> The Texas Insurance Department reported that patients submitted 996 claims for independent review between November 1997 and July 2000, and independent reviewers reversed HMO decisions in half those cases. Most claims for independent review challenge insurance benefit denials, not medical care. The independent review provisions of the law, however, were found to be preempted by ERISA in *Corporate Health Ins. Inc. v. Texas Department of Insurance*, 215 F.3d 526 (5<sup>th</sup> Cir. 2000), pet. cert. filed 10/24/2000.

<sup>91</sup> M.A. Robbins, Jury: HMO Not Liable, *The National Law Journal*, July 30, 2001, A16.

<sup>92</sup> See, e.g., R.H. Miller, R.R. Bovbjerg, Efforts to Improve Patient Safety in Large, Capitated Medical Groups: Description and Conceptual Model, *Journal of Health Politics, Policy and Law* (forthcoming); N.C. Dean, Decreased Mortality after Implementation of a Treatment Guideline for Community-Acquired Pneumonia, *American Journal of Medicine*. 2001; 110: 451-457; R. Gonzales, Decreasing Antibiotic Use in Ambulatory Practice, *Journal of the American Medical Association*. 1999; 281:1512-1519; E. Peterson et al., The Effects of New York's Bypass Surgery Provider Profiling on Access to Care and Patient Outcomes in the Elderly, *Journal of the American College of Cardiology*. 1998; 32(4): 993-999; B.C. James, Quality Improvement in the Hospital: Managing Clinical Processes, *Internist* 1993; 34(3): 11-13, 17; E.C. Pierce, Jr., Anesthesia: Standards of Care and Liability, *Journal of the American Medical Association*. 1989; 261: 1599-1603; John H. Eichhorn, et al., Standards for Patient Monitoring During

Anesthesia at Harvard Medical School, *Journal of the American Medical Association*. 1986; 256: 1017-1020; Anesthesia Patient Safety Foundation, [www.gasnet.org/societies/apsf/foundation/foundation.html](http://www.gasnet.org/societies/apsf/foundation/foundation.html).

<sup>93</sup> Bovbjerg, Miller & Shapiro, note 70 *supra*.

<sup>94</sup> See, e.g., D. Bates et al., Effect of Computerized Order Entry and a Team Intervention on Prevention of Serious Medication Errors, *Journal of the American Medical Association* 1998; 280: 1311-1316; S. Pestotnik et al., Implementing Antibiotic Practice Guidelines through Computer-Assisted Decision Support, *Annals of Internal Medicine* 1996; 124: 884-890.

<sup>95</sup> C. Paul, Back from the Brink, in Steven Findlay, ed., *Reducing Medical Errors and Improving Patient Safety: Success Stories from the Front Lines of Medicine*, National Coalition on Health Care and the Institute for Healthcare Improvement, 2000, pp. 4-8, [www.nchc.org](http://www.nchc.org). A similar example is reported for Luther Midelfort Hospital in Eau Claire, Wisconsin. K. Rebillot, Tackling Medication Errors Head On, in *id.* For contemporary reporting on the Betsy Lehman case, see R.A. Knox, Doctor's Orders Killed Cancer Patient; Dana-Farber Admits Overdose Causes Death of Globe Columnist, *Boston Globe*, Mar. 23, 1995, p. 1; R. Romano, Fatal Error Becomes Catalyst for Reform, *Boston Globe*, Mar. 15, 1999.

<sup>96</sup> Professional negligence is not actionable unless it causes actual harm to a patient; putting a patient at risk is not sufficient.

<sup>97</sup> B. Mohl, Doctor Penalized for Error in Dosage, *Boston Globe*, Nov. 10, 1998, B3.

<sup>98</sup> Bristol Inquiry, note 18 *supra*, at para. 45. He suggests that one reason might be that the NHS must pay claims out of its own budget (of tax revenues), which reduces the funds available for patient care, while claims against US hospitals are paid from insurance funds, with increased insurance premiums passed along to patients in the form of increased health care costs, rather than reducing the amount of care.

<sup>99</sup> Kraman & Hamm, note 24 *supra*.

<sup>100</sup> The FTCA waives the federal government's sovereign immunity to tort claims, with some exceptions. 28 U.S.C. §1346(a) ("The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgment or for punitive damages.").

<sup>101</sup> *Hughes v. United States*, 2001 U.S. App. LEXIS 19243 (3d Cir. 2001); *Winter v. United States*, 244 F.3d 1088 (9th Cir. 2001); *Fang v. United States*, 140 F.3d 1238 (9th Cir. 1998); *Lather v. Beadle County*, 879 F.2d 365 (8th Cir. 1989); *Collazo v. United States*, 850 F.2d 1 (1st Cir. 1988). However it is not liable for the torts of government contractors (who are not employees). 28 U.S.C. §2671 – 2680. See *Knudsen v. United States*, 254 F.3d 747 (8th Cir. 2001).

<sup>102</sup> The Act provides a remedy for personal injury caused by the negligent or wrongful act any government employee acting within the scope of his employment "under circumstances where the United States, if a private person, would be liable to the claimant for the act in accordance with the law of the place" where the act occurred. 28 U.S.C. §2674. See *Midwest Knitting Mills, Inc. v. United States*, 950 F.2d 1295, 1297 (7th Cir. 1991); *Donais v. United States*, 232 F.3d 595 (7th Cir. 2000).

<sup>103</sup> There is an exception for claims based on government employees' discretionary functions. 28 U.S.C. §2680(a) ("Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused."). But this exception may have few applications to cases of medical error. The discretionary function exception is intended to "prevent judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic and political policy through the medium of an action in tort." *United States v. Gaubert*, 499 U.S. 315, 323 (1991). See *Sigman v. United States*, 217 F.3d 785, 795 (9th Cir. 2000) (noting the "now well-established principle that the discretionary function exception is intended to shield the government from liability for the exercise of government discretion, not to shield the government from claims of garden-variety medical malpractice."). However, under the *Feres* doctrine, which provides that "the Government is not liable under the Federal Tort Claims Act for injuries to servicemen where the injuries arise out of or are in the course of activity incident to service," service personnel in active service could be precluded from a malpractice action against the United States. *Feres v. United States*, 340 U.S. 135, 146 (1950) (interpreting 28 U.S.C. §2680(j)).

<sup>104</sup> G.J. Annas, Beyond the Good Samaritan: Should Doctors Be Required to Provide Essential Services?, *Hastings Center Report*. April 1978; 8(2):16-17.

<sup>105</sup> The State of Vermont's law did require bystanders to render aid as long it would not place the Good Samaritan or anyone he or she was responsible for at risk of harm or interfere with his or her duty to others, such as children. See, Duty to Aid the Endangered Act, Vermont Statutes Annotated [V.S.A.], Title 12, § 519. See also, Massachusetts General Laws, ch. 112, § 12B. See generally, D.R. Veilleux, Construction and Application of Good Samaritan Statutes, 68 A.L.R.4th 294.

<sup>106</sup> S. Law, S. Polan, *Pain and Profit: The Politics of Malpractice*, New York: Harper & Row, 1977, p. 247.

<sup>107</sup> *Id.* at 275.

<sup>108</sup> The federal Health Care Quality Improvement Act also provides protection against such suits as long as reasonable procedures are followed. Health Care Quality Improvement Act of 1986, 101 Stat. 3784, codified at 42 U.S.C. §1101(5).

<sup>109</sup> Some physicians may doubt that such laws can fully protect their confidentiality. S.O. Scheutzow, S.L. Gilles, Confidentiality of Peer Review Information: More Imagined Than Real, *Journal of Health Law*. 1992/93; 7: 169-197. Student reports suggest that physician participation on peer review committees has not increased, and that other factors, like time pressure and lack of interest, continue to discourage physician participation.

<sup>110</sup> L-M. Baldwin, L.G. Hart, R.E. Oshel et al., Hospital Peer Review and the National Practitioner Data Bank: Clinical Privileges Action Reports, *Journal of the American Medical Association*. 1999; 282: 349-355.

<sup>111</sup> T.A. Brennan, Hospital Peer Review and Clinical Privileges Actions: To Report or Not to Report (editorial), *Journal of the American Medical Association*. 1999; 28:381-382.

<sup>112</sup> An attorney who has filed a medical malpractice claim against a hospital can request information about a specific physician, but only if s/he submits evidence that the hospital-defendant failed to request information about that physician in its own credentialing process. Disclosure of Information by the National Practitioner Data Bank, 45 C.F.R. §60.11(a)(5). This means that attorneys and patients cannot peruse the NPDB in a fishing expedition to discover unknown errors. However, they can use the hospital's failure to use due diligence as evidence of the hospital's own negligence.

<sup>113</sup> *To Err Is Human*, note 2 *supra*, p. 85.

<sup>114</sup> G. Calabresi, *The Costs of Accidents: A Legal and Economic Analysis*. New Haven: Yale University Press, 1970.

<sup>115</sup> E. Spieler, Perpetuating Risk? Workers Compensation and the Persistence of Occupational Injuries, *Houston Law Review*. 1994; 31: 119-264; L.I. Boden, Workers' Compensation in the United States: High Costs, Low Benefits, *Annual Review of Public Health*. 1995; 16: 189-218; J.R. Chelius, K. Kavanaugh, Workers' Compensation and the Level of Occupational Injuries, *Journal of Risk & Insurance*. 1988; 55: 315.

<sup>116</sup> Boden, *id.*

<sup>117</sup> P. Weiler, et al., *A Measure of Malpractice: Medical Injury, Malpractice Litigation, and Patient Compensation* Cambridge, MA: Harvard University Press, 1993.

<sup>118</sup> L.R. Tancredi, R.R. Bovbjerg, Rethinking Responsibility for Patient Injury: Accelerated-Compensation Events: A Malpractice and Quality Reform Ripe for a Test, *Law and Contemporary Problems*. 1991; 54(2): 147-177.

<sup>119</sup> For arguments in favor of a limited form of no-fault compensation for medical injuries, see Studdert & Brennan, note 26 *supra*; D.M. Studdert, T.M. Brennan, Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States, *American Journal of Law & Medicine*. 2001; 27(2&3): 225-252; D.M. Studdert, E.J. Thomas, B.W. Zbar, et al., Can the United States Afford a "No-Fault" System for Medical Injury?, *Law and Contemporary Problems*. Spring 1997; 60:1-34; Paul C. Weiler, The Case for No-Fault Medical Liability, *Maryland Law Review*. 1993; 52:908-950; Paul C. Weiler, *Medical Malpractice on Trial* 1991. For critiques of such proposals, see M.J. Saks, Medical Malpractice: Facing Real Problems and Finding Real Solutions, *William & Mary Law Review*. 1994; 35: 693-726; T.B. Metzloff, Understanding the Malpractice Wars, *Harvard Law Review*. 1993; 106: 1169-1196; M.J. Mehlman, Saying 'No' to No-Fault: What the Harvard Malpractice Study Means for Medical Malpractice Reform, *New York State Bar Association*. 1991.

<sup>120</sup> Studdert & Brennan, note 26 *supra*.

<sup>121</sup> Virginia Birth-Related Neurological Injury Compensation Act, Va. Code Ann. 38.2-5001 et seq., enacted in 1987; Florida Birth-Related Neurological Injury Compensation Act, Fla. Stat. 766.301 et seq.

<sup>122</sup> R.R. Bovbjerg, F.A. Sloan, No Fault for Medical Injury: Theory and Evidence, *University of Cincinnati Law Review*. 1998; 67: 53-123.

<sup>123</sup> D.M. Studdert, et al., The Jury Is Still In: Florida's Birth-Related Neurological Injury Compensation Association After a Decade, *Journal of Health Politics, Policy & Law*. 2000; 25: 499-526; R.R. Bovbjerg et al., Administrative Performance of No-Fault Compensation for Medical Injury, *Law & Contemporary Problems*. Spring 1997; 60: 71-115; Bovbjerg & Sloan, note 122 *supra*.

<sup>124</sup> 42 U.S.C. §300aa-10 et seq. For background and early operation, see W.K. Mariner, The National Vaccine Injury Compensation Program, *Health Affairs*. 1992; 11:255-265.

<sup>125</sup> The Program has since been amended to cover adverse reactions from vaccines that are recommended for children. Economic compensation under the program is unlimited, but non-economic damages are limited to \$250,000. In cases of death, compensation is limited to \$250,000. Awards for permanent injury typically average about \$1,000,000.

<sup>126</sup> For current data on claims and awards, see [www.bhpr.hrsa.gov/vicp/monthly.htm](http://www.bhpr.hrsa.gov/vicp/monthly.htm) (reporting an average of about 137 claims per year).

- <sup>127</sup> W.K. Mariner, Liability and Compensation for Adverse Reactions to HIV Vaccines, in Congress of the United States, Office of Technology Assessment, *Adverse Reactions to HIV Vaccines: Medical, Ethical, and Legal Issues*, OTA-BP-H-163, Washington, DC: U.S. Government Printing Office, September 1995, pp. 79-159; D. Ridgway, No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Association After a Decade, *Journal of Health Politics, Policy & Law*. 1999; 25: 499.
- <sup>128</sup> Accident Compensation Act 1972, Accident Rehabilitation and Compensation Insurance Act 1992, Accident Insurance Act 1998, Accident Insurance Amendment Act 2000; Accident Insurance (Transitional Provisions) Act 2000; texts available at [www.rangi.knowledge-basket.co.nz/gpacts/](http://www.rangi.knowledge-basket.co.nz/gpacts/).
- <sup>129</sup> Studdert & Brennan, No-Fault Compensation, note 26 *supra*; Studdert & Brennan, Toward a Workable Model of “No-Fault,” note 119 *supra*; I.A. Campbell, *Compensation for Personal Injury in New Zealand: Its Rise and Fall*. Auckland: Auckland University Press, 1996.
- <sup>130</sup> Data on claims for medical misadventure, as well as other injuries, can be found at [www.acc.org.nz/injury-statistics](http://www.acc.org.nz/injury-statistics).
- <sup>131</sup> Ronald Paterson, “Patients’ Rights in New Zealand: Lessons for Ontario?” Unpublished paper presented at the Second Annual Health Law Symposium, University of Toronto Faculty of Law, Toronto, Ontario, Canada, October 12, 2001.
- <sup>132</sup> *Id.*
- <sup>133</sup> Ministry of Health, New Zealand, Reportable Events: Guidelines; available at [www.moh.govt.nz](http://www.moh.govt.nz) (Section 6 requires consumers to be informed if an event affects their care and treatment or if the event must be reported to an external authority).
- <sup>134</sup> The New Zealand Health and Disability Act 1994; Code of Consumers’ Rights, available at the Health and Disability Commissioner’s website: [www.hdc.org.nz](http://www.hdc.org.nz).
- <sup>135</sup> Paterson, note 131 *supra*.
- <sup>136</sup> G. Williams, The Aims of the Law of Tort, *Current Legal Problems*, 1951; 4: 137-176.
- <sup>137</sup> Bovbjerg, Miller & Shapiro, note 70 *supra*; G.T. Schwartz, Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?, *UCLA Law Review*. 1994; 36: 255-264; S.D. Sugarman, Alternative Compensation Schemes and Tort Theory: Doing Away with Tort Law, *California Law Review*. 1985; 73: 558-664.
- <sup>138</sup> Thomas, et al., note 81 *supra*; T.A. Brennan, L.L. Leape, N.A. Laird, et al., Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I,” *New England Journal of Medicine*. 1991; 423: 370-376; D.H. Mills, Medical Insurance Feasibility Study: A Technical Summary, *Western Journal of Medicine*. 1978; 128: 360-365.
- <sup>139</sup> D. Harris, M. Maclean, H. Genn, et al., *Compensation and Support for Illness and Injury*, 1984; The Royal Commission on Civil Liability and Compensation for Personal Injury, *Report [the Pearson Report]*, HMSO, 1978; F.H. Miller, Medical Malpractice Litigation: Do the British Have a Better Remedy?, *American Journal of Law & Medicine*. 1986; 11: 433.
- <sup>140</sup> N.K. Komesar, *Imperfect Alternatives: Choosing Institutions in Law, Economics, and Public Policy* (1994), at 154.
- <sup>141</sup> L. Zuckerman, A Nation Challenged: The Bailout; Critics Raise Concerns on funds Proposed for Troubled Airlines, *New York Times*, September 21, 2001. (Some critics of the bailout argued that the airlines were already in financial trouble before the attacks and were using the attacks as an excuse to get federal funds.)
- <sup>142</sup> Air Transportation Safety and System Stabilization Act, Public Law 107-42 (Sept. 22, 2001), Title IV, *September 11<sup>th</sup> Victim Compensation Fund of 2001*, §§401-408. Eligible families may either seek economic and non-economic damages from the federal fund without proving negligence, or they may sue the responsible party, but not both. The liability of any airline in a separate lawsuit is limited to the amount of liability insurance coverage maintained by that airline. Awards from the federal fund could reach \$15 billion, according to preliminary rough estimates based on average awards of \$1.5 million to victims of the bombing of the Chinese embassy in Serbia. Awards from the federal fund are to be reduced by any “collateral sources of compensation” (e.g., life insurance, pension funds, death benefits, and government payments). There is some confusion over whether awards would also be reduced by any charity the families receive from other sources.
- <sup>143</sup> D.B. Henriques, David Barstow, Fund for Victims’ Families Already Proves Sore Point, *The New York Times*, Oct. 1, 2001, p. 1, B8.
- <sup>144</sup> Studdert & Brennan, No-Fault Compensation for Medical Injuries, note 26 *supra*; K.S. Abraham, P.C. Weiler, Enterprise Liability and the Choice of the Responsible Enterprise, *American Journal of Law & Medicine*. 1994; 10: 29-36; W.M. Sage, K.E. Hastings, R.A. Berenson, Enterprise Liability for Medical Malpractice and Health Care Quality Improvement, *American Journal of Law & Medicine*. 1994; 10: 1-28.
- <sup>145</sup> Studdert & Brennan, Toward a Workable Model of “No-Fault,” note 119 *supra* (describing issues to be considered).
- <sup>146</sup> W.K. Mariner, Slouching Toward Managed Care Liability, *Journal of Law Medicine & Ethics* (forthcoming); W.K. Mariner, Liability for Managed Care Decisions: ERISA and the Uneven Playing Field, *American Journal of Public Health*, 1996; 86: 863-

869. It does permit ERISA plan vicarious liability for its employees' negligence. The problem for patient safety systems, however, lies with physicians who are not employees of the managed care organization or a hospital.

<sup>147</sup> Patient Rights Program White Paper, *Different Systems of Liability to Patients—Comparative Analysis of the Senate and House of Representatives Bills Entitled “Bipartisan Patient Protection Act” (S. 1052 and H.R. 2563) Provisions on Liability to Patients*, Boston University School of Public Health, September 2001, available at [www.patient-rights.org/publications](http://www.patient-rights.org/publications).

<sup>148</sup> Bovberg & Sloan, note 122 *supra*; Studdert & Brennan, Toward a Workable Model of “No-Fault,” note 119 *supra*; Mariner, note 127 *supra*; Sugarman, note 137, *supra*.

<sup>149</sup> See, e.g., American Medical Association. *A Proposed Alternative to the Civil Justice System for Resolving Medical Liability Disputes: A Fault-Based, Administrative System*. Chicago: AMA/Specialty Society Medical Liability Project, 1988.

<sup>150</sup> Since negligent injuries are a small proportion of all medical adverse events, the number of injuries eligible for compensation would be larger if all are covered. However, it may be that negligent injuries produce the most expensive injuries, so that the difference in the cost of compensation might not be as great as the difference in the number of injuries covered.

<sup>151</sup> Studdert et al., Can the United States Afford a “No-Fault” System for Medical Injury?, note 119 *supra* (comparing cost of tort and no-fault systems and finding that a limited compensation system that covered serious injuries would cost more than the current tort system but provide compensation to more people).

<sup>152</sup> E.R. Kinney, Malpractice Reform in the 1990's: Past Disappointments, Future Successes, *Journal of Health Politics, Policy & Law*. 1995; 20: 99; R.R. Bovbjerg, Medical Malpractice: Research and Reform, *Virginia Law Review*. 1993; 79: 2155-2208.

<sup>153</sup> Komesar, note 140 *supra*.

<sup>154</sup> W.M. Sage, Regulating Through Information: Disclosure Laws and American Healthcare, *Columbia Law Review*. 1999; 1701-1829.

<sup>155</sup> J.R. Cohen, Advising a Client to Apologize, *Southern California Law Review*. 1999; 72: 1009-1069.

<sup>156</sup> A. Milstein, et al., Improving the Safety of Health Care: The Leapfrog Group, *Effective Clinical Practice*. 2000; 3(6): 313-316.

<sup>157</sup> L. Kowalczyk, Tufts Health to Issue Doctor ‘Report Cards,’ *Boston Globe*, Oct. 25, 2001, C1, C4 (Tufts Health Plan announces that it will rate its physicians on certain quality standards).

<sup>158</sup> E.C. Becher, M.R. Chassin, Improving Quality, Minimizing Error: Making It Happen, *Health Affairs*. 2001; 20(3): 68-81.

<sup>159</sup> M. Chassin, E. Hannan, B. DeBuono, Benefits and Risks of Reporting Medical Outcomes Publicly, *New England Journal of Medicine*. 1996; 334:394-398.