Note

Promoting Patient Safety: Creating a Workable Reporting System

Melissa Chiang†

Over the last year, medical error has become a prominent issue. As policymakers and health professionals begin to address the issue, they are turning towards reporting systems as a way of determining the magnitude and nature of the problem. This Note provides a framework for creating and evaluating useful reporting systems. Reporting systems are important tools for describing the kinds of situations that result in medical error, but high-quality reporting requires two changes: removing legal and practical disincentives to reporting and fostering reporters' dedication to reporting. This Note concentrates on the legal issues and ultimately proposes a brightline rule protecting confidentiality of incident reports made for the purposes of quality management.

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† M.D./J.D., expected May 2003, Yale School of Medicine & Yale Law School; B.A., 1997, University of Southern California. Special thanks to Barbara Safriet for her suggestions and encouragement.

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Introduction

Medical error is now a public health issue. Medical error is defined as a *preventable* adverse event. An adverse event occurs when a patient suffers injury from her medical care, rather than from her illness.¹ Some adverse events are not preventable, as when a patient allergic to penicillin receives the medication for the first time. The patient will suffer from an unpreventable adverse event—the allergic reaction—because no one knew or could have known that she was allergic. By contrast, any subsequent administration of penicillin to that patient constitutes a medical error because her allergic response is predictable, and thus preventable. Examples of medical error include drug complications, infections that originate in the hospital, and technical mistakes.

Although numerous studies documenting the high rate of medical error have been published,² the issue reached the public consciousness when the Institute of Medicine (IOM) released its long-awaited report, *To Err Is Human.*³ The piece, which contained no new information about how often medical error occurs, quoted statistics from publications using pre-1993 data: though most injuries are minor and temporary, 44,000 to 98,000 of the deaths that occur in hospitals every year are preventable.⁴ The report received much press coverage.⁵ Medical professionals, policymakers, and the general public began to discuss seriously medical error and avenues of adequately addressing this profound problem.⁶

Policymakers and health professionals generally agree that medical error is a problem, that the first step in addressing the challenge is to gain a sense of its contours, and that reporting systems offer a useful way to gather information. So far, their discussion has focused narrowly on the

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¹ COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., TO ERR IS HUMAN 22 (1999) [hereinafter TO ERR IS HUMAN].
³ TO ERR IS HUMAN, supra note 1.
⁴ The report cited two major studies that took place in New York and Colorado/Utah respectively. The New York study, which used 1984 data, was published a decade ago. The Colorado/Utah study used 1992 data and corroborated the findings in New York. These studies defined adverse events as those that resulted in longer hospital stays, disability at discharge, or both. The studies found that adverse events occur in about 3-4% of hospitalizations. Both studies found that greater than 50% of adverse events were preventable. *Id.* at 22; Brennan, supra note 2; Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients,* 324 NEW ENG. J. MED. 377 (1991).
⁵ A search of Lexis, News library, Major Newspaper file produced 80 hits. The search included records from Nov. 30, 1999 to May 18, 2000 containing “To Err Is Human.”
issues of underreporting and mandatory reporting. This debate misses the point because all reporting systems are voluntary at their core. The cost of monitoring reporting to ensure compliance is prohibitive in a fragmented health care system, such as ours, where errors are diffuse. Moreover, in terms of improving patient safety, the actual number of reports is not as important as their representativeness and quality. A strict tabulation of the frequency of each type of error is probably not as useful as an accurate sense of the kinds and proportionate occurrence of errors. If an error has serious repercussions or occurs regularly, then it should be addressed.

High-quality reporting requires two changes. First, reporters' legal and practical disincentives to reporting must be addressed. Second, reporters need to be dedicated to the reporting system. Being committed means that they acknowledge the important role of reporting systems in addressing medical error.

Part I of this Note briefly lays out general strategies for addressing medical error. Part II summarizes IOM's multi-faceted approach to increasing patient safety. Part III focuses on IOM's second recommendation and critiques its call for a mandatory reporting system for serious errors. It identifies the kind of information that is useful to error analysts and describes why a mandatory system cannot access that information because mandatory systems do not address the legal and non-legal contexts that help explain why providers hesitate to report. Part IV makes suggestions about how to ease legal barriers.

I. General Strategies for Addressing Medical Error

Major strategies for enhancing patient safety generally and reducing medical error specifically include regulation, competition, and continuous quality improvement. All of these strategies may contribute to improving patient safety and decreasing error. The important question is what mixture of legal and non-legal institutions and mechanisms will achieve an optimal level of patient safety. Many have commented on the strengths and

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7 This is a question of comparative institutional analysis:

Safety is a goal choice; tort liability is a law or public policy choice. No goal choice standing on its own dictates law or public policy choices. The goal of safety is consistent with a wide variety of law and public policy choices. . . . Put in institutional terms, depending on the setting, optimal safety might be achieved by tort liability through the adjudicative process, by regulation through the political process, or by transactions through the market process. The link between goals and law and public policy results is institutional choice.

weaknesses of each strategy, which I review briefly below before recapping IOM's multi-faceted approach.  

First, traditional regulation, such as accreditation and licensure, exhibits several shortcomings with regard to quality improvement. These shortcomings include inadequate flexibility and protracted modification procedures, which inhibit timely responses to rapidly changing health care delivery systems and markets. Moreover, regulation has traditionally focused on processes—inspecting documentation, credentialing procedures, and the work of oversight committees in hospitals—rather than outcomes. Regulation assures a minimum level of quality by delineating and enforcing a floor on acceptable performance, even if it does not improve directly the health outcomes of patients.

Second, the health care market has not traditionally placed pressure on providers to improve quality. The market focuses on price because quality is difficult to measure and health care consumers often do not have sufficient information to make informed buying decisions. Theoretically, if the public had good data about quality and could discriminate among health care providers based on that information, providers would compete by enhancing quality. Currently, practical obstacles stand in the way of

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9 Chassin, supra note 8, at 154. See generally Brennan & Berwick, supra note 8 (examining the relationship between health care regulation and quality).
10 Brennan & Berwick, supra note 8, at 1-2. The authors consider traditional regulatory measures, such as hospital accreditation, to be a "meaningless waste of resources." Id. at 3. The Joint Commission for Accreditation of Health Care Organizations (JCAHO) accredits hospitals. JCAHO has traditionally focused on structural measures of quality assurance. With respect to nosocomial infections (that is, infections originating in the hospital), for example, JCAHO honed in on the minutes from hospital epidemiologists' meetings. It ignored how often nosocomial infections actually occur or how a hospital's infection rate compares with its competitors. Id. at 2-3. The authors quote a hospital administrator: "What good . . . was regulation if the regulators ignored our quality improvement efforts?" Id. at 2.
12 Mark R. Chassin, Quality of Health Care. Part 3: Improving the Quality of Care, 335 NEW ENG. J. MED. 1060 (1996).
13 But see Duncan Moore Jr., Protocols Reduce Errors in Washington Heart Program, MOD. HEALTHCARE, Feb. 14, 2000, at 69. Moore describes Sacred Heart Medical Center's heart transplant program, a small program that ranks among the best. The program works because it is committed to patient safety: it builds in redundancy (for example, two people must confirm a blood type before transfusion), the transplant team regularly discusses whether processes should be modified to improve safety, and the two program directors review every physician decision. Even with the redundancy, transplants at Sacred Heart cost only half the national average. The program director attributes the savings to Sacred Heart's emphasis on safety, which helps to avoid unnecessary mistakes and complications. Despite Sacred Heart's track record, the program is shrinking. The director, John Iacono, sighs, "Nobody really looks at quality data." Id.
testing this theory. These obstacles include getting health care providers to create accurate data about quality, getting access to that data, and distributing the data to the public before it is obsolete.\textsuperscript{14}

Even if such obstacles could be overcome, Mark Chassin, former New York State Health Commissioner and a member of the panel that wrote the IOM report, asks how the process of making a market for quality would work. Assuming 100 excellent measures of quality, the chance of any institution scoring at the top for each measure is small. How then would a consumer with more than one health issue choose among hospitals? Chassin doubts that patient-consumers would select providers using quality measures, especially given the fact that rankings would most likely change from year to year.\textsuperscript{15} Substantial barriers prohibit health plans, like individuals, from responding to quality information effectively. Even supposing that they could tailor their networks to include the best hospitals, changing networks in response to shifting quality data disrupts health care systems\textsuperscript{16} and may interfere with doctor-patient relationships, which may by itself adversely affect quality.

However, health care providers have an incentive to improve quality even if doing so will not affect their market share. Increased quality means lower costs. Organizations that enhance the quality of production processes can save money by reducing delays, duplicative or unnecessary services, and the costs associated with correcting or ameliorating errors.\textsuperscript{17} For example, anesthesiologists' greater than 95\% reduction of mortal error over the last three decades shows how powerfully markets can affect the drive toward patient safety.\textsuperscript{18}

\begin{footnotesize}
\footnote{14}{Chassin, \textit{supra} note 8, at 156. For example, current programs in New York and Pennsylvania collect quality data on Coronary Artery Bypass Graft and publish when the data is two years old. \textit{Id.} at 157.}
\footnote{15}{\textit{Id.} (noting that quality data will change even if it is only because of the random variation inherent in any measurement). Anyone who follows the \textit{U.S. News & World Report} rankings of colleges and graduate schools has witnessed this phenomenon. \textit{But see} Barry R. Furrow, \textit{The Problem of Medical Error: The Institution as Taxin}, \textit{Health L. News}, Mar. 2000, at 5, 13 (noting that as patients become more sophisticated, they are able to process outcomes data about medical treatments and choose their providers and institutions accordingly).}
\footnote{16}{Chassin, \textit{supra} note 8, at 157.}
\footnote{18}{Larry I. Palmer, \textit{Patient Safety, Risk Reduction and the Law}, 36 \textit{Hous. L. Rev.} 1609, 1624-25 (1999). Anesthesiology's record of progress in patient safety is an example of the market at work. In the 1970s and 1980s, insurance premiums for high-risk specialties, including anesthesiology, skyrocketed. David M. Gaba, \textit{Anaesthesiology as a Model for Patient Safety in Health Care}, 320 \textit{Brit. Med. J.} 785, 785 (2000). Faced with increasingly exorbitant insurance costs, anesthesiologists confronted issues of patient safety head on and achieved dramatic results. In the 1950s, one in 3000 to 4000 patients died from anesthesia. In the 1970s, the number shrank to one death per 10,000 patients receiving anesthesia. By the 1990s, the number further decreased to one death in 200,000 to 300,000 anesthetic administrations. Anesthesiology is now widely acknowledged as the leading medical specialty in terms of addressing patient safety. \textit{See, e.g., id.}; Jan Ziegler, \textit{A Medical Specialty Blazes a Trail}, in \textit{Reducing Medical Errors and Improving Patient Safety} 26 (Nat'l Coalition on Health}
Third, Continuous Quality Improvement (CQI) is a relatively recent addition to the repertoire of tools for improving patient safety. Imported from the industrial setting, CQI focuses on the cause of adverse events from a "systems" perspective and asks about the context or conditions that led to the error. Instead of blaming the easiest to identify and the last link in the error chain (the practitioner who made the mistake), CQI asks why the practitioner made the mistake. CQI assumes that error is not the result of negligence or lack of skill. It focuses on modifying the health care context in order to make errors less likely.

CQI's use of systems analysis demonstrates the complexity of the chain of events that may lead to an adverse event. James Reason, a social psychologist and CQI expert, distinguishes between active and latent failures in order to make plain that an error results when a series of events coalesce in an unfortunate way. He calls those errors committed by frontline practitioners (physicians, nurses, pharmacists, etc) active failures. These are mistakes that can result from, for example, a lapse in attention when the practitioner is particularly fatigued or busy. Latent failures are the "delayed action consequences" of decisions that are removed from, but nevertheless mold the context where active failures will take place. These include choices about protocols, the structure of the organization, allocation of resources, the number of employees, training and organization, the length of shift, and so forth. Latent failures are summed up by the phrase "disaster waiting to happen." Sometimes, frontline practitioners know about latent failures before accidents happen. Other times, latent failures become apparent only when they combine with active failures. Reason believes that to deal with error efficiently, the health care system should focus on latent errors, which, once recognized, can be tackled systematically. In contrast, active failures, by their very nature, are difficult to predict in advance.

Care ed., 2000). In their drive towards increased safety and away from high malpractice premiums, anesthesiologists orchestrated their safety revolution with the help of engineers knowledgeable in industrial safety techniques, equipment manufacturers, and nurses. Ziegler, supra, at 27.

Cf. Chassin, supra note 8, at 157-58 (discussing CQI as a "third major strategy" for improving quality of care).


Vincent et al., supra note 2, at 1154.

James T. Reason, Foreword to HUMAN ERROR IN MEDICINE, at vii, xi (Marilyn Sue Bogner ed., 1994).

Id.

Id.

Id.

E.g., Carol Ukens, Deadly Dispensing: An Exclusive Survey of Rx Errors by Pharmacists 141 DRUG TOPICS 100 (1997) (stating that pharmacists know they commit drug dispensing errors because they need "more time, more techs, and more tranquility behind the counter").

Reason, supra note 22, at xii.

Anesthesiology’s innovations provide some concrete examples of CQI at work. Oxygen
As we have seen, regulation, the market, and CQI are all potentially viable approaches to improving patient safety by reducing medical error. The question is what blend of these approaches will improve patient safety. In hypothesizing about the correct mix, IOM made a series of recommendations that touched all three, but particularly embraced CQI.  

II. IOM’s Recommendations for Improving Quality

In its report, IOM recommended a “comprehensive approach” which balances regulation with market incentives. Through monitoring, regulation ensures a minimum level of safety by identifying problems and taking corrective action. Market incentives can direct the priorities of a health care organization by rewarding institutions that perform beyond the standards set by regulatory agencies. Marketplace inducements include not only economic motivation such as group and individual purchasing activities, but professional norms and values, as well as social demands.

The IOM committee believed that “[c]areful alignment of regulatory, deprivation of anesthetized patients used to be one of the most common problems in anesthesia. This occurred when anesthesiologists accidentally put the oxygen tube into the esophagus (which leads to the stomach) instead of the trachea (which leads to the lungs). This blunder can lead quickly to suffocation, brain damage, and death. The anesthesiologist’s technical gaffe is an example of an active error. The nonexistence of equipment designed to warn an anesthesiologist when her patient was about to suffer permanent injury from oxygen deficiency can be characterized as a latent error. Ultimately, the introduction of the pulse-oxymeter, a device that reads the amount of oxygen in the patient’s bloodstream, eliminated the occurrence of oxygen deprivation due to misplaced tubes. Although anesthesiologists still sometimes insert oxygen tubes into the esophagus, the pulse-oxymeter allows them to catch their mistake before harm occurs.

For another example, the anesthesiologist’s job has been described as long intervals of boredom punctuated with moments of heart-rending terror. Anesthesiologists watching a typical and, from their point of view, boring surgery commonly find that their attention drifts. The result is that they are not prepared for the moments when the patient spirals into crisis. Once anesthesiologists began to acknowledge and accept that humans typically do not keep up their vigilance for hours at a time, they corroborated with equipment manufacturers to design inattentiveness into the system. They adjusted medical equipment so that when the patient’s vital signs wander from the acceptable range, a beep calls the anesthesiologist back to attention so that he can appropriately address the situation. Ziegler, supra note 18, at 27-28.

29 To ERR IS HUMAN, supra note 1, at 42. Chapter 3, entitled “Why Do Errors Happen,” explicitly embraces the systems approach put forth in CQI:

The common initial reaction when an error occurs is to find and blame someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients requires a systems approach in order to modify the conditions that contribute to errors. People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer.

Id. at 15, 18.
31 Id. at 17.
economic, professional and other incentives in the external environment is 
critical if significant improvements in safety is to occur." Though IOM 
sought to carefully balance the incentive structure, it acknowledged that 
the proper equilibrium is unknown.

IOM made four proposals. The first was the creation of a “Center for 
Patient Safety,” which would articulate nationwide safety targets, verify 
advancement towards those targets, and issue annually a report about 
patient safety to Congress and the President. The idea behind the Center 
is to focus attention on the important social goal of increasing patient 
safety and to evaluate whether the health care system is moving towards 
that goal. The second proposal was the establishment of nationwide 
reporting system for injuries that lead to serious adverse events. Although 
many states already have collecting systems in place, they vary widely as 
to what constitutes a reportable event and the information collected; a 
number of these states do not analyze their databases to identify trends. A 
nationwide system would homogenize information-gathering which would 
allow for data aggregation and analysis. The reason behind limiting 
obligatory reports to serious errors is that such errors are difficult to 
hide. The third proposal suggested that public and private entities can encourage 
health care organizations to improve their safety records. Regulators would 
require that health care organizations create programs that advance patient 
safety within their organizations. Purchasers of group plans (i.e. 
employers) could make safety concerns an issue when contracting with 
health care organizations and by disseminating safety information to their 
employees. Finally, the fourth proposal was the development of a 
“culture of safety” in health care organizations, which would include 
“respect[ing] human limits in process design.”

III. Mandatory Reporting Systems and The Surrounding Debate

Part III focuses on IOM’s second recommendation concerning 
reporting systems. Such systems and the data they generate are at the core 
of any workable CQI program. The most important question is how to 
design a system that encourages reporting. While general agreement exists 
that voluntary systems are a good idea, people are deeply divided about 
whether mandatory systems will encourage better and more reporting.

32 Id. at 18.
33 Id. at 59.
34 Id. at 76.
35 Id. at 115-16.
36 Id. at 135.
37 Id. at 136.
38 E.g., Robert Pear, Clinton To Order Steps To Reduce Medical Mistakes, N.Y. Times, 
Feb. 22, 2000, at A1 [hereinafter Clinton to Order Steps] (stating that the “[m]ost controversial
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Advocates of mandatory reporting believe that practitioners won’t report unless forced. They say that health care professionals have ignored egregious errors for years and ask why the public should now trust these professionals to start combating error. They demand mandatory systems to ensure accountability. They believe that once mandatory systems collect and disperse information, a market for quality will force health care providers to devote resources to patient safety.

In contrast, representatives of individual and institutional providers speak out against mandatory reporting systems. They typically say that mandatory reporting systems will not improve, and may even harm, the patient safety movement. For example, Nancy W. Dickey, former president of the American Medical Association, said, “We are opposed to mandatory reporting. It may well drive underground the very information you need to improve safety. A number of states have mandatory reporting, and there’s no evidence that they have greater or fewer errors.” Richard Davidson, president of the American Hospital Association echoed, “The idea that a mandatory reporting system is going to change behavior is naive at best. You need to focus on making a cultural change in hospitals, to promote open discussion of errors, and that’s not possible if some plaintiff’s attorney is climbing on your back.” Similarly, Stanton Smullens, a spokesman for the AHA, said, “We have to create an environment in which we learn from failure. This cannot be achieved in an environment of punishment or fear of legal prosecution for doctors, nurses and other caregivers who step forward after an unfortunate mistake is made.”

These statements underscore some common themes in the debate about reporting systems. Health officials, research experts, and professional associations generally agree that the first step in reducing error is to collect information so that we understand the problem, and further, they concur that reporting systems can adequately gather the necessary data. At the same time, they concede that underreporting is a

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40 Clinton To Order Steps, supra note 38.
41 Id.
problem. Patient advocates have looked to mandatory reporting as the solution to underreporting. Health care providers do not believe that obligatory reports are the answer, and they suggest that the best way to encourage reporting is to remove legal disincentives.

The rationale behind mandatory systems is misguided for two reasons. First, empirical evidence shows that providers do not report, even when they are obligated to do so. Second, even when they do report, mandatory systems are unlikely to create a reporting context that would elicit information likely to reduce future errors. In fact, the current system disincentives providers from providing the very information that is most helpful in reducing patient risk.

A. Mandatory Reporting Systems

The primary purpose of mandatory reporting systems is to "hold providers accountable" for errors. Typically, state regulatory programs run mandatory reporting systems and have the authority to investigate, penalize, and fine individuals for wrongdoing. Mandatory systems guarantee some level of patient safety because they respond to the most serious errors and provide an incentive to health care organizations to avoid errors in order to evade censure and potential public exposure.

Mandatory reporting systems can be public or confidential. In its proposal for a mandatory reporting system, IOM gave two reasons why the public should be able to access the results of analysis for individual cases. First, patients should know the risks they will encounter when receiving medical care. Second, once consumers understand the risks they face, they will demand improvement and health care organizations will be forced to invest in patient safety.

In essence, the purpose of making the information available is to create a floor for quality. I use the term "floor" because mandatory systems only collect data about events that result in serious disability or death. As such, mandatory systems will force health care organizations fearful of a reputation for extremely poor quality to make some investments in patient safety. The theory that a non-confidential mandatory system will improve quality by making providers accountable depends on

\[\text{E.g., TO ERR IS HUMAN, supra note 1, at 79; Clinton To Order Steps, supra note 38; Robert Pear, U.S. Health Officials Reject Plan to Report Medical Mistakes, N.Y. TIMES, Jan. 23, 2000, at A14 (hereinafter Health Officials Reject Plan).} \]

\[\text{Id. at 88.} \]
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a number of assumptions: (1) providers will report; (2) the mandatory nature of the system can be enforced; (3) that information will be timely and in a form that consumers can use; (4) consumers will use it; and (5) health care organizations will respond by improving quality.

The first and most fundamental factor is whether providers will report to the mandatory system. Professional organizations have protested vehemently against such systems. Presumably, the reason why reporting systems focused on accountability have to be mandatory is that practitioners will protect themselves unless they are forced to report. But, empirically, providers don’t report to mandatory systems. At least a third of states had mandatory systems in place at the time of the IOM report. Despite their “mandatory” nature, “underreporting . . . plague[d] all programs.”

For example, in Pennsylvania, which requires reports for gross events such as deaths due to injuries, suicide or malnutrition, the Department of Health received only one report for the one-year period that ended in June 1999. Philadelphia’s hospitals alone probably encountered thousands of reportable errors. The story in Pennsylvania is not unique. North Carolina’s mandatory reporting system received 15 reports in its first year and Colorado received 17 reports in two years.

How do hospitals get away with failing to report? In Pennsylvania, the Department of Health does not enforce the regulation. According to the Department’s spokeswoman, the law “doesn’t provide for us to go out and see what’s taking place.” Even if the Department had the authority and the desire to investigate, how would it? The costs of monitoring providers to make sure they report would be prohibitively expensive. Medical errors

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48 Id. at 79.
49 Pennsylvania defines a reportable event as:
   
   an event that seriously compromises quality assurance or patient safety, including: deaths due to injuries, suicide, or unusual circumstances; deaths due to medication error; deaths due to malnutrition, dehydration, or sepsis; elopements; patient abuse; rape; surgery on the wrong patient or modality; hemolytic transfusion reaction; infant abduction or discharge to wrong family; fire or structural damage; unlicensed practice of a regulated profession.

Id. app. E, at 214.
51 Id.
53 Gerlin, supra note 38, at A1 (quoting Amy Riegelman).
are dispersed throughout a fragmented system that consists of thousands of practitioners scattered among hundreds of institutions. The costs of monitoring such a diffuse system would be too costly.

Given that state health departments cannot enforce reporting directives, adequately addressing the problem of underreporting requires making sure that potential reporters are devoted to the reporting system. Providers understandably hesitate to report adverse events to a system that will hold them accountable, and as a result, their compliance efforts are minimal. For example, the Philadelphia hospitals claim their failure to report is a result of their being perplexed about the regulations. This somewhat feeble excuse underscores Charles Billings’ contention that ultimately, all reporting systems are voluntary.

In some form, in one way or another, all incident reporting becomes voluntary. It either becomes voluntary because of inertia on the part of reporters, or it becomes voluntary because of constraints within the establishment and the environment, or it becomes voluntary because hospitals decide that they are not required to report this particular event because of the fine print in that particular incident reporting regulation or statute.

Thus, I suggest that increased reporting will not be achieved through a mandatory reporting system because whether practitioners report does not turn on the mandatory or voluntary nature of the system, but rather on whether the reporters feel comfortable reporting.

Arguably, the ultimate goal of any system should be to increase patient safety by reducing medical error. In a sense, mandatory systems attempt to ensure accountability in order to improve safety. Holding providers accountable for lapses in patient safety will encourage them to invest resources in avoiding error. However, empirical evidence shows that providers simply do not report to punitive systems. Thus, mandatory systems are at odds with the goal of increasing patient safety. If the primary goal is safety, the first step is to establish a mechanism to find out the extent of the medical error problem. One answer to this information conundrum is well-planned, thoughtfully-designed reporting systems that encourage reporting. The key to a good design is (1) to determine what

54 Id.
55 Billings, supra note 52, at 55.
56 E.g., Neil M. Davis, Nonpunitive Medication Error Reporting Systems: Tough to Accept but Safest for Patients, 31 HOSP. PHARMACY 1036 (1996). Davis writes:

In the long run, what is in the best interest of patient safety, to punish and inhibit the reporting of errors, or to encourage error reporting in a nonpunitive system and let individuals go unpunished for making errors? Although I say “going unpunished,” this is actually a misnomer, because there is always self-punishment. In my opinion, the benefits of increased error reporting far outweigh the benefits achieved by punishment. ... [I]n the long run, ... it is
kind of information you need and (2) to identify and remove disincentives to reporting that information. The next parts discuss each of these factors in turn.

B. The Information a Reporting System Should Collect

If reducing medical error is "fundamentally an information problem," what kind of information is required to reduce medical error? An ideal report contains a recounting of the facts, the provider's mental impressions, her opinion about why the error happened, and any recommendations for reform. The last two components are crucial. Practitioners offer the best information about why a mistake happened. For example, if a pharmacist mixes up two drugs, the pharmacist knows if she made the mistake because she was fatigued, she failed to check the technician's output, she couldn't read the physician's handwriting, or she confused the prescribed medication with a similarly-named drug. The reporters' perceptions seem crucial to any analysis about why an error occurred. As such, the reporting format of any successful system should reserve a central space for their insights.

Error analysts emphasize the importance of capturing a vivid and textured narrative of what happened in a particular case. The story is the key piece of data. Researchers can then search and research the database of descriptions using many schemes of classification. In other words, they can group and regroup the narratives in an attempt to find new connections, patterns, trends, and contrasts. Rich detail is especially important in complex situations where there may be many reasons for

safer to know what is going on, so that you can attempt to fix it, than to punish employees for making errors.

Id. Taking a systems perspective, as IOM does, requires the recognition that from a frontline provider's vantage point, the difference between active failures that result in a serious injury and those that result in a "near miss" is quite small. As such, IOM was quite torn about whether to hold on to accountability. The following quotation displays that tension:

[Events that are reported inside health care organizations or to voluntary systems should be protected because they often focus on lesser injuries or non-injurious events that have the potential to cause serious harm to patients, but have not produced a serious adverse event that requires reporting to the mandatory system.]

TO ERR IS HUMAN, supra note 1, at 95 (emphasis added).


This honest and probing recollection of how an error occurred cannot be coerced by a standardized and obligatory form. The potentially damning detail that error analysts require is important to consider when trying to identify and remove disincentives to reporting.

C. Identifying Disincentives to Reporting

The number of studies investigating the problem of underreporting is small and their sample sizes are smaller. Nevertheless, they provide a starting point for thinking about impediments to reporting: (1) fear of litigation and (2) extra-legal barriers, such as lack of education about quality improvement and deficient awareness or access to the incident reporting system.

1. Fear Of Litigation And The Current Legal Landscape

Fear of liability is often cited as an explanation for practitioners’ failure to report. Adequately addressing providers’ fears requires not only protecting the confidentiality of incident reports, but attending to providers’ often erroneous perceptions about the law. Physicians do not know much about the law, but what little they do know scares and angers them. They believe that the tort system aggressively punishes medical errors. They almost uniformly agree that the tort system drives them to

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60 E.g., Hearing on Medical Errors, supra note 57 (commenting that the “fear of litigation is a significant impediment [to reporting] for the majority of health care providers”); David J. Cullen et al., The Incident Reporting System Does Not Detect Adverse Drug Events, 21 JT. COMM’N J. QUALITY IMPROVEMENT 541, 547 (1995); Marshall B. Kapp, Medical Error Versus Malpractice, 1 DEPAUL J. HEALTH CARE L. 751, 765 (1997) [hereinafter Kapp, Medical Error] (“[P]hysicians’ legal anxieties serve as a powerful barrier to the implementation of a concerted strategy to identify, prevent, mitigate, and correct those errors.”); Brian A. Liang, The Legal System and Patient Safety: Charting a Divergent Course: The Relationship between Malpractice Litigation and Human Errors, 91 ANESTHESIOLOGY 609, 610 (1999) (arguing that potential discovery of information in tort suits “chill[s]” reporting of medical error); J. Bryan Sexton et al., Error, Stress, and Teamwork in Medicine and Aviation: Cross Sectional Survey, 320 BRIT. MED. J. 745, 747 (2000) (reporting that 71% of 1033 practitioner participants find it difficult to acknowledge mistakes because of the threat of malpractice suits).

61 MARSHALL B. KAPP, OUR HANDS ARE TIED 12-20 (1998) [hereinafter KAPP, OUR HANDS]. Physicians get their legal information from a panoply of sources, including and especially “folklore, anecdotes, and stereotypes.” Id. Physicians tend to “grossly overestimate” their risk of being sued and this is partly because horror stories get repeated again and again. Id. Interestingly, a very non-scientific web-based opinion survey found that 85% of responding healthcare professionals believed that the government could not protect the confidentiality of those making errors. Health Care Professionals Overwhelmingly Fear Mandatory Reporting of Medical Errors, BUS. WIRE, Mar. 22, 2000, LEXIS, News Library, BUS. Wire File.

62 Nathaniel Hupert et al., Processing the Tort Deterrent Signal: A Qualitative Study, 43 SOC. SCI. MED. 1 (1996) (arguing that what matters is not what the tort system does, but how physicians perceive or “process” the lessons of malpractice cases). Their perceptions are not backed by fact. In a study of malpractice claims, researchers found that the severity of the patient’s disability is
hide errors in an effort to avoid suits because they *suffer* when they are sued.³³ Physicians tend not to distinguish professional from personal competency, so they tend to see lawsuits as attacks on their personal being.³⁴

Physicians' exaggerated perceptions of legal liability are due, in part, to the fact that they do not understand the law, and in part to the fact that the current legal landscape is a muddle with respect to knowing ex ante whether an incident report can be discovered. Potential reporters often do not know before they report whether a plaintiff’s attorney will be able to use the report when suing the reporter.

Currently, hospital incident reports are generally discoverable. Hospitals have tried to use three federal rules of evidence or state medical peer review statutes to protect incident reports from plaintiffs’ attorneys with varying, but mostly limited, success. I will discuss the remedial action rule, the attorney-client privilege, the work product doctrine, and state medical peer review statutes in turn.

a. **Remedial Action Rule**

Federal Rule of Evidence 407 codifies the remedial action privilege: “When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence [or] culpable conduct . . .”.³⁵ The public policy behind the rule is to encourage—or at least greatly diminish disincentives for—subsequent repairs. In the rule’s absence, defendants might hesitate to make corrections for fear that such actions would be viewed by a jury as an admission of guilt. As stated, the privilege does not extend to hospital incident reports because the reports themselves are not remedial

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³³ KAPP, OUR HANDS, supra note 61, at 9 (“A lawsuit is particularly and uniquely offensive to physicians, and the vehemence of their negative reaction to the experience far exceeds that of any other kind of professional defendant.”); Hupert, supra note 62, at 1 (finding that respondents to a questionnaire largely define medical negligence in terms of the moral qualities of the practitioner); Kapp, Medical Error, supra note 60, at 755-56 (quoting a physician as saying, “[U]pon being served with a summons, the initial reaction is one of benumbed disbelief followed by self-deprecating analysis, schooled as the physician is in the pursuit of excellence, then feelings of inadequacy, and, finally, anger, frustration, and a tremendous sense of isolation”).

³⁴ Many commentators have noted that not talking to patients about errors is not good risk reduction. Patients are less likely to sue when their doctors admit their errors. E.g., John D. Lantos, *Should Doctors Tell the Truth?*, CHI. TRIB., May 4, 1997, at C12.

³⁵ KAPP, OUR HANDS, supra note 61, at 9.

FED. R. EVID. 407.
However, a cogent argument exists for extending the privilege to incident reports produced for quality improvement purposes. Incident reports are an essential first step to making reparations. The policy rationale for the extension is that the public's interest in improving quality in health care will be compromised if incident reports are available to plaintiffs' attorneys. Reporters may hesitate to disclose all material facts if the evidence implicates them or their superiors. Some states have extended the remedial action privilege to incident reports, but many have not.

b. Attorney-Client Privilege

The attorney-client privilege is absolute and protects the communications between a client and her attorney. The privilege extends to an incident report only if three conditions are met. First, the attorney and the reporter must contemplate the existence of an attorney-client privilege. Second, the reporter must seek advice from the attorney in his capacity as a legal advisor. Finally, the communication between the attorney and the reporter must remain confidential. The privilege extends to reports where the primary purpose is to inform the hospital's attorney or liability insurer about an event that could lead to litigation. Although hospitals frequently invoke this argument when they do not want to turn over their incident reports, the privilege does not extend comfortably to routine incident reports made for quality improvement measures. In West Virginia ex rel. United Hospital Center, Inc. v. Bedell, for example, the court held that a nurse's incident report was not protected by attorney-client privilege. In making its determination, the court noted that the hospital failed to show that the nurse had contemplated an attorney-client relationship or had sought advice from the hospital attorney when she

66 Dollar, supra note 58, at 284-85.
67 Id. at 284.
68 Id. at 285.
69 To ERR IS HUMAN, supra note 1, at 101.
70 Of note is that the privilege extends only to communications, not to facts. "A fact is one thing and a communication concerning that fact is an entirely different thing. The client cannot be compelled to answer the question, "What did you say or write to the attorney?" but may not refuse to disclose any relevant fact within his knowledge merely because he incorporated a statement of such fact into his communication to his attorney." Upjohn Co. v. United States, 449 U.S. 383, 395-96 (1981) (quoting Philadelphia v. Westinghouse Elec. Corp., 205 F. Supp. 830, 831 (E.D. Pa. 1962)). Currently, most incident reports contain only statements of fact. Although, as I have suggested earlier in this Note, incident reports need to contain much more if they are to be effective. See supra Section III.B.
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prepared the incident report. Rather the nurse filled out the report in the ordinary course of her work. The nurse testified that she filed a report "any time there's any kind of incident, not necessarily an injury, but anything that's out of the ordinary." She was simply following the hospital's guidelines for filling out incident reports for the express purpose of enhancing care and providing a safe environment. In terms of reporting for quality improvement purposes, the nurse was doing exactly what we want her to do. However, the narrow attorney-client privilege does not cover this situation.

c. Work Product Doctrine

The third federal rule that hospitals invoke to protect incident reports is the attorney work product doctrine. The work product doctrine is a qualified privilege, which protects any material that an attorney produces in preparation for possible litigation. The doctrine does not grant an absolute privilege, so the party requesting discovery may gain access to factual work product materials if he shows substantial need. Where the work product is opinion, the court will not allow discovery. Whether a particular report falls within the scope of the work product doctrine depends on a factual determination of whether the hospital produced the report in anticipation of litigation or in the ordinary course of business. The work product does not readily apply to CQI incident reports, which are generated in the ordinary course of business and handed over to the reporting system or the hospital's internal quality improvement team.

For example, in United Hospital Center, Inc., the hospital's guidelines promulgated reporting for the purposes of patient safety and implored all people associated with the hospital to report any unusual incidents. The court held that the work product privilege applied where the primary purpose behind a report's production was to prepare for litigation. In this case, the court determined that the incident report

72 Id.
73 Id. at 205.
74 Id. at 204-05.
76 Hickman, 329 U.S. at 495.
77 United Hosp. Ctr., Inc., 484 S.E.2d at 213. The court notes that although the majority of courts take a similar approach, at least one jurisdiction has construed the privilege more narrowly. Id. at 212. The court reproduces the following quotation from Stout v. Illinois Farmers Ins. Co., 150 F.R.D. 594 (S.D. Ind. 1993), aff'd, 852 F. Supp. 704 (S.D. Ind. 1994):

If a document or thing would have been created for non-litigation uses regardless of its intended use in litigation preparation, it should not be accorded work product protection. Because the document would have been created for non-litigation reasons anyway, disclosure of the information therein would not
addressed quality as well as claims management. This court is not unusual in its determination that reports produced for the purposes of risk management and quality improvement are not protected under the work product privilege.  

d. Medical Peer Review Statutes

Most states have a statute granting a peer review privilege. Peer review is a retrospective process whereby standard procedures and the care provided by particular health care providers are subject to scrutiny by other health care professionals. The purpose is to elevate the standard of care by learning from mistakes, thereby reducing error. If the system works optimally, participants will produce documents and critical analyses of the care rendered. These statutes generally give immunity to good-faith participants in the peer-review process and protect the “proceedings” and “records” of the review committee from discovery or admission to trial. Legislatures grant these protections in order to encourage health care providers to speak candidly and thereby improve health care quality. If these safeguards were not available, participants might hesitate to speak openly if they thought that their comments and conjectures would become the basis for a case against one of their colleagues.

In trying to balance the anxieties of peer reviewers and the discovery needs of plaintiffs, many courts construe “proceedings” and “records” narrowly and limit the privilege to the committee’s formal proceedings and internal records. In other words, unless a formal committee created or directed the creation of the document, the privilege does not apply. Incident reports, which are generally filled out by staff members as part of their employment, do not fall within the narrow reading of the privilege. These courts allow discovery of incident reports because they do not want to give hospitals a way to hide incriminating information by funneling it through peer review committees. Other courts grant peer review privilege to incident reports because they recognize that these reports, like peer

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United Hosp. Ctr., Inc., 484 S.E.2d at n.18.


80 See Columbia/HCA Healthcare Corp., 936 P.2d at 848-49 (reviewing several state courts’—Arizona, Nevada, North Dakota, Texas, and Illinois—narrow constructions of the privilege).

review committees, play a crucial role in improving health care quality. Courts that extend the privilege to incident reports assume that the participants in the process are committed to patient safety. However, problems may occur if the reviewers are not devoted foremost to patient well-being. The confidentiality of the documents means that in practice, the committee may ignore egregious infractions precisely because it knows that the data is confidential. In other words, the peer review privilege may protect peer review boards that do not do their jobs. For example, in *Glickman v. South Park Medical Center Inc.*, the defendant anesthesiologist had a serious history of drug abuse and administering anesthesia while high. The anesthesiologist mistakenly administered potent drugs into the patient’s vena cava, the major vessel that leads directly to the heart. The patient died, and her father sued the hospital. The plaintiff had no access to the hospitals’ peer review documents, and he was unable to prove the hospital’s negligence in allowing the anesthesiologist to continue to practice within its operating rooms. Fortuitously for the plaintiff, the anesthesiologist documented his drug problem in correspondence. Evidence showed that the hospital peer review committee knew about the anesthesiologist’s drug problem and did nothing. If peer reviewers are not committed to quality, extending protections to them is harmful, not desirable.

2. Extra-Legal Reasons for Not Reporting

Most of the controversy surrounding the reporting systems has been about institutional and individual health care providers’ fears of liability. Even supposing that such fears can be adequately addressed by expansive protections, other impediments to reporting must be considered before implementation of a successful reporting system is possible. I group these barriers into three categories: barriers caused by lack of awareness, barriers due to lack of access, and cultural barriers.

a. Awareness Barriers

In order for a reporting system to work towards total quality management, reporters must (1) know what kinds of incidents to report and (2) know what to include in their reports. Frontline employees—those at what James Reason calls the sharp end—are the best source of

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82 Dollar, * supra* note 58, at 282.
85 Frontline practitioners are at the “sharp end” and they commit “active failures.”
information on weaknesses and areas for improvement. Through their reports about accidents and near misses, they can create a useful database for expert analysis. In order for reporters to know when and what to report, they must understand the general goals of quality improvement. Although medical personnel are highly trained, their understanding of quality improvement cannot be assumed since most medical schools and residency programs do not offer training in quality assurance or quality improvement. 86 Most house officers are unfamiliar with the philosophy of continuous quality improvement. During residency training, they rarely, if ever, discuss organizational processes as a target for reducing error. 87 If the house staff does not understand the potential benefits of incident reporting, they may regard it as a nuisance and “yet more paperwork.” 88 For example, staff may feel no need to report a “near miss” because they have dealt effectively with the incident and dodged a bad outcome. 89 According to the continuous quality improvement philosophy, however, near misses are as important a source of information as actual accidents because the same latent processes can lead to either outcome. If staff understood and believed in CQI, they might be more likely to invest the time to report near misses and thereby help to avoid accidents that are “waiting to happen.”

The following example of why nurses fail to report the most common type of error, drug medication errors, 90 shows how reporters that are unaware of the reporting system’s rationale can devastate the system’s usefulness. A medication error occurs unless the right drug is given to the right patient at the right dose through the right route at the right time. 91 Nevertheless, nurses often do not report specific drug errors because they

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86 Saul Weingart, *House Officer Education and Organizational Obstacles to Quality Improvement*, 22 J. COMM’N J. QUALITY IMPROVEMENT 640, 642 (1996). Weingart includes a brief discussion about the deficits in medical education with respect to quality assurance and improvement. A 1990 survey of 98 medical school deans found that less than a third of respondents’ medical schools and residency programs offered any training on quality assurance. Id. Surveys of medical residents have found that fewer than one-fifth expressed comfort with the basic principles of quality assurance and only one-half agreed that quality assurance activities benefit physicians and are applicable to health care. Id.

87 Id. at 643.


89 Id. at 14.

90 See Kris Rebillot, *Tackling Medication Errors Head On*, in REDUCING MEDICAL ERRORS AND IMPROVING PATIENT SAFETY, supra note 18, at 18. In Luther-Midelfort Hospital, Roger Resar conducted a year-long study of charts and procedures to assess drug errors. He found 200-230 actual or potential errors for every 100 patient charts.

91 This “five rights” definition is traditional. Patti Ludwig-Beymer, *The Effect of Testing on the Reported Incidence of Medication Errors in a Medical Center*, 21 J. CONTINUING EDUC. IN NURSING 11, 12 (1990). Recently, some have advocated expanding the definition to include administrations of medications to patients with known allergies to said medication (for example, penicillin). Id.
view them as “non-errors” in their clinical judgment. In Osborne’s study about nurses’ reporting habits with regard to medication error, respondents split on the question of whether a patient’s missing a nebulizer treatment constituted a drug error. This is surprising because a patient’s missing a treatment is an objective drug error. In addition, most respondents reported that they would not consider it an error to administer an additional Percocet pill upon a patient’s request. Though the nurses believed that a patient’s continuing pain warranted administration of a second pill, the nurse’s second administration constitutes an objective drug error.

In addition to having a general understanding of quality improvement, individual reporters should know about the particular reporting system. First, they need to know that the reporting system exists. Second, they need to know the types of incidents the reporting system collects. Third, they need to know how to report an incident. This seems intuitive, but their understanding of these matters cannot be taken for granted. A study of physicians and nurse midwives of two obstetric units showed that while most of the staff knew about the reporting system and 90% knew how to report an incident, only 70% knew where to find a list of reportable incidents.

b. Access and Ease-of-Use Barriers

Any incident reporting system must be easy for the reporter to access and to use. Health care providers are wary of demands on their time and may be easily dissuaded from reporting if the reporting system is too cumbersome. About one-third of the previously-mentioned study’s participants failed to report because the system increased work load. Similarly, nearly one-third agreed that they did not report because they were too busy and forgot.

Technology can increase access and ease of the system. The reporting system can use technologies that are already available and heavily used by providers. For example, a 1993 study made use of the fact that house officers actively used e-mail and the hospital had over 2000 e-mail terminals dispersed throughout the hospital. The investigator encouraged the officers to send incident reports via e-mail, which worked well.

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92 Id.
93 Joan Osborne, Nurses’ Perceptions, When Is It a Medication Error? 29 J. NURSING ADMIN. 33, 36 (1999). The study was a comparative survey of full- and part-time RNs employed at a 700-bed community hospital. The investigator distributed surveys to all RNs involved in dispensing medicine. Participation was voluntary and anonymous, and 62% of ninety-two nurses responded for a total of fifty-seven responses. Id. at 35. Although the study’s small size warns against generalization, it gives qualitative information about what nurses may be thinking when they do not report errors.
94 Vincent et al., supra note 88, at 15.
95 Id. at 17. Note that this third of the staff is not necessarily the same third mentioned in the text accompanying note 94.
c. Cultural Barriers

Even supposing that legal disincentives to reporting have been adequately addressed, medicine's traditionally hierarchical, perfectionist, and less-than-candid culture does not lend itself to vigorous reporting. Physicians do not acknowledge or discuss mistakes because of concerns about personal reputation. Junior physicians hesitate to report blunders of senior physicians who the juniors will ultimately ask to write recommendations. Non-physicians are reluctant to convey physician errors. Nurses do not acknowledge mistakes because they fear their nurse manager's and coworkers' reactions. Nurses pause before recounting even minor mistakes of their colleagues, especially if the colleagues will be disciplined.

A good reporting system requires that reporters be willing to report detailed and potentially embarrassing information about errors. The IOM report focuses on medical error and ushers in a cultural change about how medicine perceives error. Policymakers, institutions, and health care practitioners have begun to acknowledge that medical error is rampant and that patient safety is an indispensable goal. As importantly, a movement from blaming individuals towards blaming systems is occurring. The venerable IOM made an innovative leap when it embraced a systems approach in its report. The centrality of this shift is manifest in the report's carefully chosen title: To Err Is Human.

As we have seen, providers hesitate to report for legal and extra-legal reasons. Legal barriers include providers' fears that any information they furnish with the goal of improving quality may be used against them in the tort system. Such fears are overblown, yet understandable, given the current environment where the discoverability of quality improvement reports is determined ex post. As importantly, providers fail to report for extra-legal reasons, which include their ignorance about how to improve safety and medicine's traditional culture of blame. This Note focuses on how the legal system can encourage providers to take patient safety seriously, and the next section outlines methods of diminishing legal

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96 Andrea Gerlin, Hospital Mistakes Kill 1 of Every 200 Patients, TIMES-PICAYUNE, Sept. 19, 1999, at A20. "Beginning in medical school, the culture of medicine discourages acknowledging mistakes, asking for assistance, exhibiting any weakness, or challenging a supervisor. In medicine's carefully ordered hierarchy, admitting or pointing out a mistake is frowned upon." Id.
97 Sexton et al., supra note 60, at 747.
99 Cullen, supra note 60, at 547.
100 Jill Gladstone, Drug Administration Errors: A Study Into the Factors Underlying the Occurrence and Reporting of Drug Errors in a District General Hospital, 22 J. ADVANCED NURSING 628 (1995); Osborne, supra note 93.
101 Rebillot, supra note 90, at 19.
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barriers.

IV. Recommendations and Current Proposals For Legal Barriers

Legislators should pass a bright-line rule protecting confidentiality of incident reports made for the purposes of quality management. As has been shown, practitioners are overly concerned about legal risks.\textsuperscript{102} Legally, much will have to be done to assure them that incident reports are and will remain confidential. This is especially true given the fact that the most useful incident reports are those that contain details and conjectures about causation.\textsuperscript{103}

Before delving into how a bright-line rule might look, this section briefly addresses physicians' fears about the National Practitioner Data Bank (NPDB).\textsuperscript{104} In 1986, Congress authorized the creation of the NPDB, a national database containing information about physicians' malpractice payments and any professional sanctions including adverse licensure and hospital privileging actions.\textsuperscript{105} Hospitals must query the data bank about new appointments and existing staff every two years, thereby addressing the problem of interstate movement by physicians who have been disciplined in their previous state.\textsuperscript{106} The data bank was never intended for the public. Nevertheless, periodically, legislators and many public advocacy groups discuss opening the data bank to the public.\textsuperscript{107} Such an action would seriously undermine whatever faith physicians might have in legal guarantees of confidentiality concerning incident reports.

A uniform, bright-line statute will allay practitioners' confusion about what they can expect from the courts in terms of discoverability of incident reports. As discussed earlier, courts currently make an ex post determination about whether to allow discovery of a particular incident report, based on the individual characteristics of that report's production. Practitioners do not appreciate the nuances, and they respond by assuming that reports are discoverable. This, in turn, reduces candor.

The Department of Defense Authorization Act for Fiscal Year 1987 (DOD Act) contains the kind of broad provision that should allay providers' fears about litigation. The DOD Act, which applies to the

\textsuperscript{102} Kapp characterizes physicians' attitudes towards lawyers and the medical malpractice system like this: "We are swimming in a pool of sharks." KAPP, OUR HANDS, supra note 61, at 6.

\textsuperscript{103} See supra pp. 12-13.

\textsuperscript{104} See Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11,101-11,152 (2000), and regulations passed pursuant to the act. The regulations, which became effective on October 17, 1989, established the NPDB. 45 C.F.R. 60 (1994).

\textsuperscript{105} Fitzhugh Mullan et al., The National Practitioner Data Bank: Report from the First Year, 268 JAMA 73, 73-74 (1992).

\textsuperscript{106} Prepared Testimony of the Honorable Fred Upton Before the House Commerce Committee Subcommittee of Oversight on Oversight & Investigations, FED. NEWS SERV., Mar. 1, 2000.

\textsuperscript{107} Id.
Army’s Quality Assurance program, explicitly ensures the confidentiality of all quality assurance (QA) records and precludes QA participants from testifying about the records or about any aspect of the QA proceedings or conclusions. The statute’s definition of QA records is expansive: QA records are “the proceedings, records, minutes, and reports that emanate from quality assurance program activities.” A QA program is “any activity carried out . . . to assess the quality of medical care.” The statute’s definition of a QA program includes activities conducted by individuals, committees, and other review bodies. It is important to recognize that Congress extended confidentiality to QA activities, but not QA committees. The statute explicitly covers individuals as well as committees. As such, the statute covers incident reports filled out by individuals. In protecting quality assurance activities, Congress did not quash plaintiffs’ access to information entirely. The statute specifically says that information maintained outside the QA program—for example, information in the medical record—will remain available for discovery, even if that information is presented during QA activities.

As with the DOD Act, IOM recommended that Congress extend peer review protections to all quality improvement data that are collected by health care organizations, whether the data is used internally or shared with others for the purpose of enhancing patient safety. IOM’s recommendation is reflected in the Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000 (SAFE bill). The SAFE bill states among its purposes the extension of “existing confidentiality and peer review protections to the additional required reports of error under such [reporting] systems that are developed for safety and quality improvement purposes under the Medicare and Medicaid programs.” The bill mandates that institutional providers provide incident reports (with health care workers’ and patients’ names deleted) to designated state regulatory agencies or national accreditation agencies. The state agencies are prohibited from using the information against the provider in its survey or

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110 Id. § 1102(j)(1).
111 Id. The statute reads: “activities conducted by individuals, military medical or dental treatment facility committees, or other review bodies responsible for quality assurance, credentials, infection control, patient care assessment (including treatment procedures, blood, drugs, and therapeutics), medical records, health resources management review and identification and prevention of medical or dental incidents and risks. Id. (emphasis added).
112 Id.; see also Woodruff, supra note 108, at 7 (emphasizing the breadth of the federal statute’s protection as compared to state statutes).
114 To Err Is Human, supra note 1, at 96.
116 Id. § 2.
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certification processes. Rather than trust institutions to control quality from within closed doors, this mandatory reporting helps to ensure that institutions are putting some resources into patient safety. Under the bill, institutional providers are punished for not reporting; if the institutional provider does not report adequately for more than two years, the institution’s failure to comply with the law will become public information.

The bill attempts to minimize individual reporters’ fears about liability by stipulating that institutions submit reports without individuals’ names. This approach puts the pressure on the institution to encourage its practitioners to report. Whether this is the correct pressure point is currently unknown. In order to quell any residual fears that the incident may be distinctive enough to reveal the identity of the health care provider, the Act explicitly extends confidentiality to quality improvement documents. The Act supersedes any conflicting laws (for example, state laws) and defines the protected documents expansively to include data, reports, records, memoranda, analyses, statements, and other communications developed by or on behalf of a provider of services with respect to quality improvement.

Conclusion

Safer medical care is an imperative social goal that can be achieved through a variety of institutional mechanisms. Establishing a workable reporting system is the first step in discovering the contours of the medical error crisis. Whether the system is mandatory or voluntary is not as important as (1) assuring reporters that incident reports will not be used against them in litigation and (2) removing non-legal disincentives, such as access and cultural barriers to reporting. The legal system can alleviate the first factor by protecting consistently the information contained in incident reports. Currently, hospital incident reports for the purposes of quality control are discoverable in most states. Protecting such reports should encourage candid reporting and result in improved quality. If regulatory agencies reviewed the incident reports and the institution’s response, the risk of inadequate institutional responses would be minimized. The legal system’s treatment of incident reports in conjunction with a well developed reporting system and the current paradigm shift towards

117 Id. § 3(g)(1).
118 Id. § 3(e)(3)(B).
119 This portion of the Act is crucial because some states’ peer review protections do not extend to incident reports. By contrast, Senators Specter, Harkin, and Inouye introduced a bill that provides for confidentiality, but the bill’s section on confidentiality is not to supersede any state law. Medical Error Reduction Act of 2000, S. 2038, 106th Cong. § 922(c)(2) (2000).
120 Id. §§ 923-924.
systems analysis should reduce non-legal disincentives to reporting.