Proponent for SB 96

Senate Judiciary Committee

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Attached supporting materials for oral testimony by Nancy Clarkson:

- Statement by Nancy Clarkson
- "A New, Evidence-based Estimate of Patient Harms Associated With Hospital Care" by John T. James, PhD
- "Full Disclosure and Apology–An Idea Whose Time has Come" by Lucian L. Leape, MD
- "Shining A Light, Safer Health Care Through Transparency", The National Patient Safety Foundation's Lucian Leape Institute Report of the Roundtable on Transparency
- "The Flaws in State 'Apology' and 'Disclosure' Laws Dilute Their Intended Impact On Malpractice Suits" by Anna C. Mastroianni, Michelle M. Mello, Shannon Sommer, Mary Hardy, and Thomas H. Gallagher

Proponent for HB2081 / SB96
The Kansas Disclosure of Unanticipated Medical Outcomes and Medical Errors Act

About the bill

This bill requires that if a patient experiences an unanticipated medical outcome or is harmed by a medical error, this information is shared with the patient (and family, when appropriate). This bill also requires medical institutions to develop policies for disclosure and to provide training to administrators and providers on how to have disclosure conversations. In addition, the information that medical institutions now provide to licensing agencies about "reportable incidents" will be expanded to indicate whether or not a disclosure conversation has taken place. Fines will be imposed for failure to disclose.

Why this bill is needed

When hospital and physicians are given a choice whether or not to tell a patient about harm that has occurred, too often the choice is to not tell. For example, one published study (L. Iezzoni *et al*. 2012. *Health Affairs*. 31(2):383-391) found that only 65.9% of physicians completely agreed with the statement "Physicians should disclose all significant medical errors to affected patients."

Patients have both a right and a responsibility to be active participants in their own healthcare. This requires transparency within the healthcare system.

My family's experience

This bill is being proposed because of the experiences my children and I went through with my late husband, Glenn Clarkson. Glenn was severely burned on March 30, 2012 while taking part in a controlled grass burn. I took him to an emergency room where he was admitted to the ICU, even though the hospital was not equipped to treat severe burns. His condition deteriorated rapidly during the night as he became severely dehydrated. Not until fifteen hours later, when he was near death, was he transferred to the burn center at Via Christi in Wichita. While at the burn center Glenn underwent extensive skin graft surgery, but died on April 11.

After his death my daughter and I investigated guidelines for transfer of burn victims and learned that he should have been transferred immediately. We met with the CEO of my local hospital in search of answers as to why Glenn was not transferred sooner and what changes the hospital has made to prevent this from happening to another patient. But instead of a having a meaningful conversation, we were met with the "wall of silence."

The way our family was treated prompted us to study the issue of medical errors and their disclosure. We learned that medical errors occur with alarming frequency and that the "wall of silence" is the norm, not the exception. This set us on a journey to lift the veil of secrecy and silence about medical errors in Kansas. We believe that patients (and their families) have the right to know when they have been harmed by a medical error. It is time for hospitals and physicians to act with honesty, transparency, and integrity when errors occur. We ask for your help.

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How frequently are patients harmed in hospitals?

One early study of New York hospitals found that 3.7% of hospitalized patients experienced injuries, and 0.5% of patients experienced an injury leading to death.[1] A more recent study of Medicare patients found that 13.5% experienced a serious adverse event while hospitalized, and 1.5% experienced an event that contributed to their death.[2]

Estimates for the number of Americans who die each year due to medical harm range from 44,000–98,000 to 210,000–440,000.[3, 4] This means that medical harm is at least the sixth, if not the third, most common cause of death in this country.

What are other states doing to mandate disclosure of harmful medical errors?

A number of other states have statutes that require patients to be informed about medical harm, including Nevada, Florida, New Jersey, and Pennsylvania.[5] Unfortunately, these laws do not specify the types of information to be included in disclosure conversations. "Thus, an institution could adhere to the letter of the law simply by telling a patient, 'The outcome of your surgery was unanticipated.'"[6] Therefore, our bill specifies the minimal information for disclosure.

What are "apology laws"?

Physicians have given many reasons for failure to disclose harmful medical errors to patients. One is the fear that what they say will become evidence during a malpractice lawsuit. In an effort to address this fear, many states have passed laws that disallow the use of apologies and expressions of sympathy as evidence of malpractice. Unfortunately, the moral promise implied by these laws has not been fulfilled. By leaving disclosure optional, patients remain uninformed.

Aren't there already too many medical malpractice lawsuits? Wouldn't disclosing errors make this worse?

First, the amount of *medical malpractice* far exceeds the number of *medical malpractice lawsuits* that are filed. Second, the majority of lawsuits have merit. One study from the Harvard School of Public Health found that 97% of claims involved injury. 63% of those injuries were due to medical error.[7] Third, one of the major reasons patients and their families file lawsuits is because that is their only way to get information.

Some states, such as Washington state, are embracing disclosure-and-resolution programs. These can be an excellent alternative to the current "deny-and-defend" approach common in Kansas. However, there is a danger that without proper regulatory oversight many patients and families will be pressured to accept a settlement that is much too low—placing the economic burden of the medical harm on the patient and family. In order to protect the rights of patients, they need to be represented by their own lawyer. Therefore our bill requires that if a financial settlement is proposed, patients must be advised of their right to consult an attorney.

What will it take to make healthcare in Kansas safer?

The first step must be to acknowledge when patients are harmed and to disclose that information to patients. Our bill is the catalyst for this first step. Only then, once it is established that patients have a right to know when they have been harmed—and healthcare providers have been trained in disclosure—will institutions and providers have a mindset to truly focus on preventing patient harm.

Kansas has an organization, the Kansas Healthcare Collaborative (KHC), that could take a leadership role in honest conversations about medical harm and patient safety. The question is whether the parent organizations of KHC—The Kansas Medical Society and The Kansas Hospital Association—are willing to support this.

1 T. A. Brennan *et al.* 1991. *New England Journal of Medicine* 324(6): 370–376.

2 Office of the Inspector General. November 2010.

3 *To Err is Human.* 1999. The Institute of Medicine.

4 J. T. James. 2013. *Journal of Patient Safety* 9(3): 122-128.

5 Nevada (Nev. Rev. Stat. 439.855), Florida (Fla. Stat. Ann. 395.1051, 456.0575), New Jersey (N. J. Stat. Ann. 26:2H-12.25(d)) and Pennsylvania (40 Pa. Stat. Ann. 1303.308).

6 A. Mastroianni *et al.* 2010. *Health Affairs* 29(9): 1611–119.

7 D. M. Studdert *et al*. 2006. *New England Journal of Medicine* 354:2024–33.

A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

John T. James, PhD

Objectives: Based on 1984 data developed from reviews of medical records of patients treated in New York hospitals, the Institute of Medicine estimated that up to 98,000 Americans die each year from medical errors. The basis of this estimate is nearly 3 decades old; herein, an updated estimate is developed from modern studies published from 2008 to 2011.

Methods: A literature review identified 4 limited studies that used primarily the Global Trigger Tool to flag specific evidence in medical records, such as medication stop orders or abnormal laboratory results, which point to an adverse event that may have harmed a patient. Ultimately, a physician must concur on the findings of an adverse event and then classify the severity of patient harm.

Results: Using a weighted average of the 4 studies, a lower limit of 210,000 deaths per year was associated with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm.

Conclusions: The epidemic of patient harm in hospitals must be taken more seriously if it is to be curtailed. Fully engaging patients and their advocates during hospital care, systematically seeking the patients' voice in identifying harms, transparent accountability for harm, and intentional correction of root causes of harm will be necessary to accomplish this goal.

Key Words: patient harm, preventable adverse events, transparency, patient-centered care, Global Trigger Tool, medical errors

(*J Patient Saf* 2013;9: 122–128)

''All men make mistakes, but a good man yields when he knows his course is wrong, and repairs the evil. The only crime is pride.''— Sophocles, Antigone''

Medical care in the United States is technically complex at the individual provider level, at the system level, and at the national level. The amount of new knowledge generated each year by clinical research that applies directly to patient care can easily overwhelm the individual physician trying to optimize the care of his patients.[1] Furthermore, the lack of a well-integrated and comprehensive continuing education system in the health professions is a major contributing factor to knowledge and performance deficiencies at the individual and system level.[2] Guidelines for physicians to optimize patient care are quickly out of date and can be biased by those who write the guidelines.[3–5] At the system level, hospitals struggle with staffing issues, making suitable technology available for patient care, and executing effective handoffs between shifts and also between inpatient and outpatient care.[6] Increased production demands in cost-driven institutions may increase the risk of preventable adverse events (PAEs). The United States trails behind other developed nations in implementing electronic medical records for its citizens.[7] Hence, the information a physician needs to optimize care of a patient is often unavailable.

At the national level, our country is distinguished for its patchwork of medical care subsystems that can require patients to bounce around in a complex maze of providers as they seek effective and affordable care. Because of increased production demands, providers may be expected to give care in suboptimal working conditions, with decreased staff, and a shortage of physicians, which leads to fatigue and burnout. It should be no surprise that PAEs that harm patients are frighteningly common in this highly technical, rapidly changing, and poorly integrated industry. The picture is further complicated by a lack of transparency and limited accountability for errors that harm patients.[8,9]

There are at least 3 time-based categories of PAEs recognized in patients that are or have been hospitalized. The broadest definition encompasses all unexpected and harmful experience that a patient encounters as a result of being in the care of a medical professional or system because high quality, evidence-based medical care was not delivered during hospitalization. The harmful outcomes may be realized immediately, delayed for days or months, or even delayed many years. An example of immediate harm is excess bleeding because of an overdose of an anticoagulant drug such as that which occurred to the twins born to Dennis Quaid and his wife.[10] An example of harm that is not apparent for weeks or months is infection with Hepatitis C virus as a result of contaminated chemotherapy equipment.[11] Harm that occurs years later is exemplified by a nearly lethal pneumococcal infection in a patient that had had a splenectomy many years ago, yet was never vaccinated against this infection risk as guidelines and prompts require.[12]

METHODS

The approach to the problem of identifying and enumerating PAEs was 4-fold: (1) distinguish types of PAEs that may occur in hospitals, (2) characterize preventability in the context of the Global Trigger Tool (GTT), (3) search contemporary medical literature for the prevalence and severity of PAEs that have been enumerated by credible investigators based on medical

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records assessed by the GTT, and (4) compare the studies found by the literature search.

Types of PAEs

The cause of PAEs in hospitals may be separated into these categories:

- Errors of commission,
- Errors of omission,
- Errors of communication,
- Errors of context, and
- Diagnostic errors

These distinctions are important because investigators searching for preventable harm must be aware of what they can find and what they cannot find. The easiest error to detect in medical records is an error of commission. This occurs when a mistaken action harms a patient either because it was the wrong action or it was the right action but performed improperly. For example, the patient may need his gall bladder removed, but during the surgery, the intestine is nicked, and the patient develops a serious infection, such as was alleged to be the cause leading to the death of Representative John Murtha. Errors of omission can be detected in medical records when an obvious action was necessary to heal the patient, yet it was not performed at all. For example, a patient may need a β-blocker, but because it was not prescribed, the patient died prematurely.[13] Errors of omission because of failure to follow evidence-based guidelines are much more difficult to detect, partly because there are many complex guidelines and also because adverse consequences of failure to follow guidelines may be delayed until after discharge.[14,15]

Errors of communication can occur between 2 or more providers or between providers and patient. One example of a lethal error of communication between provider and patient occurred when cardiologists failed to warn their 19-year-old patient not to run. The patient had experienced syncope while running, and 5 days of inpatient, diagnostic testing were inconclusive; however, his cardiologists knew he was not ready to return to running but failed to warn him against this risk. Having not been warned against running, he resumed running and died 3 weeks later while running.[15]

Contextual errors occur when a physician fails to take into account unique constraints in a patient's life that could bear on successful, postdischarge treatment. For example, the patient may lack the cognitive ability to comply with a medical treatment plan or may not have reasonable access to follow-up care.[16] Diagnostic errors resulting in delayed treatment, the wrong treatment, or no effective treatment may also be considered separately, although a small subset of these might be included as errors of commission or omission. For example, a diagnostic error may lead to harm from errors of commission by overtreatment or mistreatment of the patient until the mistake is discovered. The apparent eagerness of the U.S. health-care industry to over diagnose patients often leads to harmful consequences for patients.[17]

Preventability and the Global Trigger Tool

The prevailing view is that "preventability" of an adverse event links to the commission of an identifiable error that caused an adverse event. Adverse events that cannot be traced to a likely error should not be called "preventable." The portion of adverse events that are deemed preventable tends to be about 50% to 60%; however, recently, experts have postulated that virtually all adverse events they identified with the "GTT are preventable."[18] The GTT depends on systematic review of medical records by persons trained to find specific clues or triggers suggesting that an adverse event has taken place. For example, triggers might include orders to stop a medication, an abnormal lab result, or prescription of an antidote medication such as naloxone. As a final step, the examination of the record must be validated by 1 or more physicians. As will be shown shortly, the methods used to find adverse events in hospital medical records target primarily errors of commission and are much less likely to find harm from errors of omission, communication, context, or missed diagnosis.[19] There are some overlaps in these categories and cascades of harmful events can ensue from a single root cause. A "perfect storm" of unrecognized but correctable medical errors can result in serious harm or death.[15,20]

Literature Search

Our literature search included the following three terms: medical error, global trigger tool, and hospital. We searched Pub Med and "reports and publications" from the government Web site *http://oig.hhs.gov.* Those searches turned up 20 articles published between 2006 and 2012, of which, 4 were found to be suitable for the present analysis. The unsuitable studies included studies of populations outside the United States, studies confined to narrow hospital populations (e.g., intensive care unit), studies of ambulatory patients, studies involving only methodological comparisons, adverse-event issue papers, failures of incident reporting systems, and studies that did not classify the severity of the harm associated with adverse events.

Characterization of the Core Studies

The 4 key studies were reviewed for similarity and difference in methods used to find adverse events. It was found that each one employed similar methods to flag, confirm, and then classify adverse events according to level of harm. All studies used a 2-tier approach that consisted of screening of medical records by nonphysicians, usually nurses or pharmacists, to flag suspect events. In the second tier, physicians examined the suspect events to determine if a genuine adverse event had occurred and, if so, the level of seriousness of the event. In all studies, the GTT from the Institute for Healthcare Improvement was the primary screening tool;[21] however, there were variations in the supplementary tools used to detect potential adverse events.

A 2008 pilot study by the Office of Inspector General (OIG) of the Department of Health and Human Services used 5 methods in its search for adverse events—nurse reviews using the GTT, conditions that were not present on admission (POA), beneficiary interviews, hospital incidence reports, and patient safety indicators.[22] The pilot study revealed that the GTT captured the highest percentage (78%) of the events ultimately deemed to be adverse events in the second tier review by physicians. The use of POA indicator codes was second best at 61%. Together, these methods were found to identify 94% of the flags that led physicians to declare that an adverse event had taken place. A more comprehensive OIG study in 2010 employed these 2 screening methods and a third based on whether the patient had been readmitted to the hospital with 30 days of discharge from the last discharge during the October 2008 index period.[23]

A study by Classen and colleagues also employed the GTT along with Agency for Healthcare Research and Quality Patient Safety Indicators (PSIs) and hospital reports of adverse events. Of the 167 flagged events that ultimately were deemed true adverse events by physician review, the GTT detected 90% in the severity levels F through I (Table 1).[18] The longitudinal

TABLE 1. Adverse Events Classified as Serious

Level of Harm	Description
F	Required prolonged hospital stay
G	Permanent harm
H	Life sustaining intervention required
I	Contributing to death of patient

Adapted from the National Coordinating Council for Medication Errors Reporting and Prevention.

study by Landrigan and colleagues relied on the GTT and POA indicators to flag possible adverse events. Like the other studies, the ultimate determination of a genuine adverse event and the severity of the event were judged by physicians during the second-tier analysis.[24] Although there are slight variations in the approach used to discover flags in the records examined by the 4 studies, the GTT was the core method placed in the hands of trained and experienced nurses. All studies used a second tier requiring physicians to determine whether a flag signaled a genuine adverse event and, if so, then assign a severity level to that event. All studies used the National Coordinating Council for Medication Reporting and Prevention scale (Table 1).

RESULTS

Recent data from the 4 key studies provide a more comprehensive, evidence-based estimate of the number of lethal and serious medical errors than the one provided by the Institute of Medicine (IOM).[25] These data are compiled in Table 2, and the studies are described below.

A pilot study by the OIG was published in 2008 in an effort to explore the effectiveness of search methods for adverse events.[21] As noted in the methods section, this study relied on 5 search methods for flagging potential adverse events in medical records but did not specify whether such events were preventable. The 278 medical records reviewed by screeners and physicians were not randomly selected to be representative of Medicare hospitalizations; instead, they originated from hospitals in 2 unspecified counties. Of the 51 serious adverse events identified, only 3 were on the National Quality Forum's list of serious reportable events and only 11 were on Medicare's Hospital Acquired Condition (HAC) list. In 2010, the OIG estimated adverse events in hospitalized Medicare patients.[23]

Investigators looked at the medical records of 780 randomly selected patients chosen to represent the 1 million Medicare patients "discharged" from hospitals in the month of October 2008. The total number of hospital stays for the 780 patients during this period was 838 because some of the beneficiaries were hospitalized and discharged more than once during the 1-month index period. Using primarily the GTT developed by the Institute for Healthcare Improvement to find adverse events, investigators found 128 serious adverse events (level of harm F, G, H, or I) that caused harm to patients, and an adverse event contributed to the deaths of 12 of those patients. Seven of these deaths were medication related, 2 were from blood stream infections, 2 were from aspiration, and the 12th one was linked to ventilator-associated pneumonia. Only 2 of these events were on the National Quality Forum list, and none were on the Medicare HAC list. The authors of this report estimated that "events" contributed to the deaths of 1.5 % (12/780) of the 1 million Medicare patients hospitalized in October 2008. That amounts to 15,000 per month or 180,000 per year.

TABLE 2. Recent Studies of Preventable Adverse Events

Reference	Source of Medical Record Data	Time Covered by Records	No. records Reviewed	Search Tool or Method	Serious Adverse Events (Class F to I) Found (%)	% Deemed Preventable	Lethal Adverse Events (%)	Major Causes of Lethal Events
OIG (2008)	Medicare beneficiaries in 2 counties	1 wk in August 2008	278	Global trigger tool	43 (15%)	n/s	3 (1.1%)	n/s
OIG (2010)	Representative Medicare patients	October 2008	838	Global trigger tool	128 (15%)	44%	12 (1.4%)	7-medication, 2-sepsis, 2-aspiration, 1-other*
Classen et al. (2011)	3 tertiary-care hospitals	October 2004	795	Global trigger tool	167 (21%)	~100%	9 (1.1%)	4-procedure, 2-pulmonary, 1-infection, 2-not specified
Landrigan, et al. (2010)	10 hospitals in North Carolina	Jan 2002 through Dec 2007	2341	Global trigger tool	332 (14%)	63%	14 (0.6%)	7- HAI, 3-Renal/endocr. 4-other systems†

* Ventilator-associated pneumonia.
† Cardiac arrest, pulmonary embolism, hematologic event, neurological event.

Note that the percentage of deaths per hospitalization was slightly lower at 1.4% (12/838). The authors did not explicitly state the percentage of the lethal adverse events that were preventable, but given their description of the events, it seems that most were preventable. Overall, physician reviewers estimated that 44% of serious medical events were preventable.

In a somewhat similar study published in March 2011 in the journal *Health Affairs*, investigators examined the medical records of 795 patients treated in 1 of 3 tertiary hospitals in the month of October 2004.[18] These hospitals had been recognized for their efforts to improve patient safety. The investigators also used the GTT to discover adverse events. They found 167 adverse events in the categories F through I, and 9 of the adverse events contributed to the deaths of patients (category I). Thus, an adverse event contributed to death in 1.1% of these patients. The causes were as follows: procedure related (not infection)—4, nosocomial infection—1, pulmonary/venous thromboembolism—2, and unspecified other—2. Interestingly, none of the deaths were explicitly associated with medication errors, which were the primary causes of death in the Medicare patients studied by the OIG.[23] Medication-related errors caused 35% of the category-F harms in the *Health Affairs* study.[18] The average age of the patients whose records were examined was 59 years. The 10 authors of the original study did not formally assess the preventability of errors, declaring instead that it is their belief that all adverse events are preventable.

In a fourth recent study targeting changes in patient safety in 10 hospitals in North Carolina, there was a lower incidence of deaths associated with adverse events.[24] Hospitals in North Carolina were chosen because hospitals in that state had shown a "high level of engagement in efforts to improve patient safety." In that state, 96% of the hospitals had enrolled in a national campaign to improve patient safety, whereas the average in other states was only 78%. A priori, a lower rate of preventable adverse events than the national average could be expected. The investigators studied the change in incidence of adverse events using the GTT on 10 randomly selected medical records per quarter from the first quarter of 2002 to the last quarter of 2007. The tool was applied by internal and external reviewers; however, the internal reviewers had better kappa scores (a measure of agreement) when compared with experienced external reviewers, so the results of internal reviews, which were the only ones given in detail in the original paper, will be used here. Based on 2341 admissions and the finding of 14 cases where adverse events contributed to death, the percentage of lethal adverse events was 0.60%. The primary causes of death were hospital-acquired infections (HAIs) (7) and acute renal failure (2). Other causes are shown in Table 2. This study involved many more medical records than the OIG or *Health Affairs* study, but the hospitals and patients were not selected to be representative of hospitals around the country. The hospitals were selected because the investigators felt that North Carolina had made a concerted effort to improve patient safety over the study period. It is not surprising that the percentage of serious or lethal adverse events was lower than in the other studies summarized in Table 2.

All 4 studies (Table 2) have similar, 2-tier search methods to identify serious adverse events. The GTT, supplemented by other less comprehensive methods, was applied to medical records by experienced nonphysicians to identify possible adverse events, and then, physician reviewers determined which flags were associated with an adverse event. However, the study populations were quite different. One would expect the OIG studies of Medicare patients, who tend to have more comorbidity than the average hospitalized patient, to show the highest incidence of lethal PAEs. One would expect the incidence of lethal adverse events in tertiary hospitals to be above the national average for all hospitalizations because more complex illnesses are treated there with longer hospital stays. One would expect, as the original authors did, that the incidence data from North Carolina would be below the national average for lethal adverse events because of concerted efforts in that state to improve patient safety in hospitals compared with the average of other states in the United States.

It is our opinion that none of the 4 studies alone can provide a defensible estimate for hospitals across the United States; however, by combining the studies, an evidence-based estimate of the number of lethal PAEs across the country can be developed. The most favorable way to combine the 4 studies to find the lowest reasonable estimate is to weigh the studies according to how many medical records from a single hospital stay were reviewed by each team of investigators. This means that the study of patients hospitalized in North Carolina was heavily weighted compared with the other studies. Thus, there were a total of 4252 records reviewed (compiled from Table 2). Among the records reviewed, there were 38 total deaths associated with adverse events. The ratio projects to a death rate from adverse events of 0.89%. This is well below the percentages from Medicare and tertiary-care studies (1.1%–1.4%) and well above the data from the North Carolina study (0.60%). There were an estimated 34.4 million hospital discharges in 2007,[26] and the average percentage of preventable adverse events among all adverse events in the 3 studies where this was reported or postulated was 69% (averaged from Table 2). Thus, the best estimate from combining these 4 studies is $34{,}400{,}000 \times 0.69 \times 0.0089 = 210{,}000$ preventable adverse events per year that contribute to the death of hospitalized patients—based primarily on evidence in hospital medical records found by the GTT method.

DISCUSSION

There has been no lack of contention about the prevalence of PAEs, which herein will be considered synonymous with medical errors that cause harm to patients; this does not include near misses that do not harm patients.[27,28] The first estimate of medical errors that received widespread attention was declared by the IOM in its now- famous book called "To Err is Human."[25] The IOM provided 2 estimates of the number of deaths from medical errors, but careful inspection of the origin of these estimates show that they were based on data that are now quite old. The earliest estimate originated from the Harvard Medical Practice Study in which 30,000 randomly selected discharge records from 1984 in 51 New York hospitals were examined.[29] The investigators found that serious adverse events occurred in 3.7% of the hospitalizations. Of the adverse events, 58% were attributable to error (i.e., they were preventable). Of this fraction, 13.6% resulted in death. Extrapolated to 33.6 million hospitalizations nationwide in 1997, simple arithmetic yielded the following: $33{,}600{,}000 \times 0.037 \times 0.136 \times 0.58 = 98{,}000$ deaths per year. Another study of 15,000 medical records from Colorado and Utah in 1992 found lower rates of adverse events and death, from which the IOM estimated 44,000 deaths nationwide per year.[25] Although physician reviews reveal adverse events due to "negligence," which was about 28% to 29% in both studies, a later publication from the IOM suggested that the 44,000 to 98,000 deaths did not include errors of omission.[30] Because the New York study included a larger sample, the deaths-per-year figure of 98,000 attributed to the IOM is the estimate most often quoted. In fact, the IOM declared that the "number of deaths [per year] due to medical error may be as high as 98,000."

Why is the present estimate of the number of lethal PAEs so much higher than the highest estimate (98,000) from the IOM? It is likely that the bar for identification of a PAE in the New York/IOM study was much higher than in the 4 modern studies and that the GTT is better able to identify adverse events than general reviews by physicians, which was the method used in the older studies cited by the IOM.[19] It is also possible that the frequency of preventable and lethal patient harms has increased from 1984 to 2002–2008 because of the increased complexity of medical practice and technology, the increased incidence of antibiotic-resistant bacteria, overuse/misuse of medications, an aging population, and the movement of the medical industry toward higher productivity and expensive technology, which encourages rapid patient flow and overuse of risky, invasive, revenue-generating procedures.[31–33]

Several observations about the 4 varied studies described in the "Results" section are in order. Although they used varied selection criteria for the patient populations and hospitals, the results in terms of the portion of adverse events found and the portion of death-associated events are not remarkably varied. The percentage of serious adverse events (class F to I) ranged from 14% to 21%, and the percentage of death-associated adverse events (class I) varied from 0.60% to 1.4%. The result found in records from North Carolina hospitals (0.60%) is likely to be below the national average because patient safety efforts in that state have been more intense when compared with other states. The results from the other studies would be expected to be above the national average because of the age of the patients and seriousness of the illnesses. This dispersion of percentages makes sense and gives one confidence that the estimate of the average number of preventable, lethal adverse events based on hospital medical records screened by the GTT approach is representative of the nation as a whole. The portion of serious adverse events that were not lethal (class F, G, and H) were roughly 10- to 20-fold larger than the portion of lethal PAEs. This leads to a rough estimate of 2 to 4 million serious, PAEs per year that would be discoverable in medical records using the GTT approach.

There are important limitations to the 4 modern studies that must be considered. Premature deaths as a result of medical errors may occur many years after the hospital stay because the patient's care was not optimal or did not follow guidelines.[12] Furthermore, lethal PAEs can been missed by the GTT and by physician reviews. The GTT does not detect diagnostic errors or errors of omission, especially those involving failure to follow guidelines.[19] Lethal diagnostic errors have been estimated to affect 40,000 to 80,000 people per year including outpatients.[34] Physicians have been indefensibly slow to adopt guidelines that would potentially prevent premature deaths or harm.[35] One egregious example is the estimated 100,000 heart failure patients that died prematurely each year in the late 1990s because they did not receive beta-blockers.[13] The efficacy of beta-blockers was established by a study published in the *JAMA* in 1982.[36]

The 4 modern studies also rely heavily on information in medical records. One study of medical records showed that quality scores of 607 randomly selected medical records on cardiac patients treated in 219 hospitals from January 2004 to June 2005 averaged 12.5/20 points, which suggests rather poor medical record keeping.[37] The quality scores were determined based on the medical records including cardiac history, performance and cognition levels, current medications and medication allergies, differential diagnosis, and planned use of evidence-based medicine. Hospitals with low-scoring records (0–10 points) had a 40% higher in-hospital death rate than those that scored high (15–20 points). Furthermore, the larger OIG study noted that "To the extent that the study did not identify an event, it was likely because the three screening methods failed to flag the case for physicians review or because documentation in the medical records was incomplete."[23]

A few years after the seminal publication by the IOM, another IOM panel recognized the limitations of using medical records provided by medical institutions as the basis for identifying medical errors. When an adverse event is alleged and an evaluation is undertaken, the "sentinel effect can significantly alter the data that are recorded."[30] There are anecdotal accounts of data altering or omission of critical data when mistakes are alleged; however, to our knowledge, scientific studies of this phenomenon have been lacking until recently.

In a study that broke past the wall of silence about discovery of medical errors that were missing from medical records, Weissman and colleagues found that 6 to 12 months after their discharge, patients could recall 3 times as many serious, preventable adverse events as were reflected in their medical records.[14] This study involved review of 998 medical records of patients hospitalized in Massachusetts for medical or surgical treatment from April to October 2003. Record reviews by specially trained nurses and doctors identified 11 serious PAEs from the records. The method was one adapted from the Harvard Medical Practice Study, which is the method used by the core result in the report from the IOM asserting up to 98,000 deaths per year occur from medical errors.[25] However, interviews with patients identified 21 additional serious PAEs that were not documented in the medical records. Of the 21 undiscovered, serious PAEs, 12 occurred predischarge and 9 occurred postdischarge. The predischarge serious PAEs included the following: adverse drug events (3), nerve or vessel injury or wrong operation (4), deep venous thrombosis (2), hospital acquired infection (2), and postoperative respiratory distress (1). The serious PAEs postdischarge included the following: wound infection (6), deep venous thrombosis (1), operative wound dehiscence (1), and operative organ injury (1). Even in this study, the investigators found only those errors that patients were aware had happened. There certainly may be more serious errors that went undocumented and were unknown to patients. Weismann's finding that evidence of many serious adverse events is not apparent in medical records is reinforced by some older studies. For example, it has been pointed out that some medical errors are not known by clinicians and only come to light during autopsies, which have found misdiagnoses in 20% to 40% of cases.[38] "Aggressive" searches for adverse drug events and prompted self-reports from clinicians have shown a much higher rate of adverse drug events than are evident in the medical records.[39] A comparison of direct observation for medication errors with review of documentation in medical records in 36 hospitals and skilled-nursing facilities found that far more errors were found by direct observation than by inspection of medical records.[40]

A recent national survey showed that physicians often refuse to report a serious adverse event to anyone in authority.[41] In the case of cardiologists, the highest nonreporting group of the specialties studied, nearly two-thirds of the respondents admitted that they had recently refused to report at least one serious medical error, of which they had first-hand knowledge, to anyone in authority. It is reasonable to suspect that clear evidence of such unreported medical errors often did not find their way into the medical records of the patients who were harmed.

The bottom line on total, lethal PAEs as a result of care in hospitals cannot be estimated in a statistically rigorous way.

Based on our extrapolation from the 4 modern studies, there are at least 210,000 lethal PAEs detectable by the GTT approach to record reviews. To deal with other factors that should be applied to this estimate, the "weight of evidence" approach must be engaged. In addition to the core estimate of 210,000, one must consider evidence of the following:

- life-shortening errors of omission due to failure to follow medical guidelines that the GTT approach misses,[19]
- a factor for evidence of errors of commission that are not documented in medical records,[37,39]
- failure to make life-saving diagnoses.[38]

In light of the evidence above, and especially that of the Weisman study,[14] and although it is probably an underestimate, a minimum estimate of a 2-fold increase in the medical record–based estimate is reasonable to compensate for the known absence of evidence in medical records of errors of commission and the inability of the GTT to detect errors of omission even when the evidence that guidelines were not followed may be present in the medical record. Note that the Weisman study suggests a factor of 3 (32/11) for undocumented evidence of serious PAEs caused during hospitalization, but here, we settle for a factor of 2.[14] To this, one should add the undetected diagnostic errors. If we begin with the minimum estimate of 40,000 and assume that only half of these occur in hospitals, then the math looks like this: $(210{,}000 \times 2) + 20{,}000 \sim 440{,}000$ PAEs that contribute to the death of patients each year from care in hospitals. This is roughly one-sixth of all deaths that occur in the United States each year. The problem of PAEs must emerge from behind the "Wall of Silence" and be addressed for the sake of prolonging the lives of Americans.

Needed changes involve not only doctors and hospitals but increased participation by patients in their health-care decisions. Perhaps it is time for a national patient bill of rights for hospitalized patients that would empower them to be thoroughly integrated into their care so that they can take the lead in reducing their risk of serious harm and death.[15] All evidence points to the need for much more patient involvement in identifying harmful events and participating in rigorous follow-up investigations to identify root causes.[42] Even for those harms identified in the medical records of Medicare patients, only 14% become part of the hospital's incident reporting system.[9] Physician observers of our hospitals have made Congress painfully aware that the hospital peer-review system has widespread failures that permit negligent care by physicians.[43] Hospitals are simply not going to heal without attentive, systematic listening to those harmed patients or their survivors.

CONCLUSIONS

There was much debate after the IOM report about the accuracy of its estimates. In a sense, it does not matter whether the deaths of 100,000, 200,000 or 400,000 Americans each year are associated with PAEs in hospitals. Any of the estimates demands assertive action on the part of providers, legislators, and people who will one day become patients. Yet, the action and progress on patient safety is frustratingly slow; however, one must hope that the present, evidence-based estimate of 400,000+ deaths per year will foster an outcry for overdue changes and increased vigilance in medical care to address the problem of harm to patients who come to a hospital seeking only to be healed.

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Full Disclosure and Apology—An Idea Whose Time has Come

By Lucian L. Leape, MD

IN THIS ARTICLE...

Examine some persuasive arguments that support full disclosure and apologies for medical errors and learn the key steps hospitals need to take.

One of the groundbreaking trends set in motion by the famous Institute of Medicine reports of 2000 and 2001[1,2] and promoted by a growing number of patient advocacy groups is increasing transparency in all aspects of health care.

Perhaps the most important manifestation is the call for full disclosure following an adverse event. While both the Joint Commission on Accreditation of Healthcare Organizations and the American Medical Association call for informing the patient when complications occur, what takes place in practice is often less than "full" disclosure. Why is this, and what do hospitals need to do?

What hospitals need to do is develop and implement policies that ensure that all patients who are harmed by their treatment receive timely, open, complete information on the causes and circumstances that led to their injury, delivered in a compassionate manner by the responsible caregiver. When the injury results from an error or system breakdown, the response should include an apology and restitution.

The arguments for such an approach are both theoretical and practical. The theoretical argument has two pillars: ethical and therapeutic.

The ethical case is straightforward and rarely challenged: the patient has a right to know what happened. Conversely, hospitals and physicians or nurses have no right, morally or legally, to withhold information from patients.

Just as patients are entitled to know all the results of laboratory tests, opinions from consultants, risks of treatment and alternative therapeutic options, they are entitled to know what the causes of the breakdown are when things go wrong. It is also what each of us would want for ourselves. We want to know what went wrong, why, and what will be done to prevent it from happening again.

Full disclosure is the right thing to do. It is not an option; it is an ethical imperative.

The therapeutic argument is also simple and straightforward: full disclosure is essential for healing.

Curiously, for the healing professions, this aspect of disclosure is frequently overlooked in the obsession with liability. But the evidence is clear that a serious preventable injury causes severe emotional trauma. The patient was wounded by those he or she trusted for care.

Unfortunately, on the surface, in the absence of other information, for the patient the accident may appear to have resulted from lack of caring, from not being careful.

The incident damages the patient's trust—in the physician and in the institution. If it is not openly and honestly dealt with, trust is irrevocably destroyed and the patient will be psychologically scarred for life.

The doctor-patient relationship also suffers, for it is based on trust. Trust is based on truth. If there is silence, or dissembling, or incomplete information (partial "truths"), trust crumbles, both in the physician and in the institution.

The only treatment, the only way trust can be restored and the patient begin to heal, is for the caregiver to acknowledge the error, take responsibility—and apologize.

Apology vs disclosure

The case for apology is very different from that for disclosure. Apology is not an ethical right, but a therapeutic necessity. Apology makes it possible for the patient to recognize our humanity, our fallibility, our remorse at having caused harm. It "levels the playing field." It makes it possible for the patient to forgive us.

Apology is necessary for healing, for "getting over it." It doesn't always work. Sometimes the patient's anger is too great for forgiveness. But healing cannot occur without it. To be effective, it must be a true apology, in which the caregiver takes responsibility for the event and shows remorse and a desire to make amends.

"I'm sorry this happened to you," is no substitute, for it lacks responsibility and remorse. Making amends should include reimbursement for expenses as well compensation for long-term disability.

Apologizing is also necessary for healing of the doctor or nurse who made the error. They, too, are emotionally traumatized. They are the "second victims," devastated by having been the unwitting instrument that seriously harmed another. They feel shame and guilt that sometimes can be overwhelming.

Apologizing, expressing their remorse and desire to make amends, can lead to forgiveness and healing for them as well. So apology is a balm for both the patient and the caregiver. It heals their psychological wounds.

Can we afford it?

The practical arguments for open and complete communication, with apology and restitution, are that it is effective treatment for patient and doctor and that it is less costly for all parties.

For decades, lawyers and risk managers have claimed that admitting responsibility and apologizing will increase the likelihood of the patient filing a malpractice suit and be used against the doctor in court if they do sue.

However, this assertion, which on the surface seems reasonable, has no basis in fact. There is to my knowledge not a shred of evidence to support it. It is a myth.

The reality, in fact, appears to be just the reverse. Patients are much more likely to sue when they feel you have not been honest with them. There now are several experiments under way—the Veterans Administration, University of Michigan, COPIC in Colorado—where full disclosure and small early settlements have resulted in dramatic reductions in suits and in payouts. These need to be expanded and replicated in other locations.

Apology makes it possible for the patient to recognize our humanity, our fallibility, our remorse at having caused harm.

Again, the ethical argument is clear: patients should not have to bear expenses caused by our mistakes. From a practical standpoint, the figures are encouraging.

In the 1990 Harvard Medical Practice Study in New York state, it was found that compensating all patients with disabling injuries for their out-of-pocket expenses would cost less than liability insurance premiums paid by doctors and hospitals.[3]

A no-fault compensation system was recommended. While this has yet to happen, the experience at the VA, Michigan, and COPIC provides further evidence of its feasibility.

Barriers to disclosure

Why does full disclosure so often not occur? Why do so many patients fail to receive a full and truthful explanation of what went wrong and hear their caregiver accept responsibility and apologize? The reasons are many and complex, but several stand out.

First, apologizing is hard to do—for anyone. As we all know, it is difficult in non-medical situations, even when the "injury" is merely a slight or an insult. But a medical apology is much more difficult.

The harm we have caused is physical and may even be disabling or fatal. The more serious the injury, the more difficult it is to apologize. Showing sympathy ("I'm sorry you were hurt.") is much easier, but lacks the essence of true apology, which is to take responsibility for the harm and express true remorse.

In fact, because it seems to specifically communicate no responsibility or remorse, some believe it can be, paradoxically, more harmful than no expression of concern.

Second, the injury was not intentional. The doctor or nurse didn't harm the patient on purpose. It was an accident, due to an error, not a deliberate act. Even though the caregiver may feel bad for the patient, and chagrined, it was an "honest mistake."

Third, many physicians lack the skills, which are considerable, to present bad news well. We haven't been trained to control our own emotions while we try to handle patients' anger, frustration and disappointment.

But probably the most important reason caregivers don't readily admit errors and apologize is shame and fear. Shame at failing to live up to our own and the patient's expectations of perfection. Fear of the consequences: loss of the patient's trust, loss of respect of colleagues, the risk of being sued.

These rational fears have been fed and amplified by bad legal advice that ignores the emotional consequences of injury for both patient and caregiver. Indeed, hospital lawyers and insurance companies sometimes demand that doctors and nurses not admit responsibility or apologize following a preventable adverse event. Fortunately, that is changing.

Moving ahead

What should hospitals do? It is time to take our focus off self-protection and put it on our mission, which is patient care.

Leaders have an obligation to their patients and to their staff to help heal the emotional trauma that follows a serious adverse event. The core is to establish effective methods for disclosure, apology and support. To do this, leaders have to set expectations, provide training, and provide support systems for patients and personnel.

First, set expectations. Hospital policy should be clear and unequivocal (and in writing): patients are entitled to a full and compassionate explanation when things go wrong. Usually, this will be the responsibility of the patient's physician, although nurses, pharmacists and others should be involved when appropriate. The policy also should include providing apology when indicated.

Second, doctors and nurses, as well as risk managers and other support personnel, need training in communicating with patients after adverse events. They also need training on how to support colleagues when they are "second victims."

Third, support systems need to be developed for all parties. Patients need help after an event, including after discharge from the hospital. We also need to provide support and "just-in-time training" to help the physician communicate with the patient following the event. And we need to help these second victims deal with their emotional trauma. Professional and peer support systems must be developed.

Finally—and this is the tough part—after enlisting full support of the boards of trustees, hospital leaders need to insist that liability carriers provide early settlements for injured patients.

Making amends, financial or otherwise, is intrinsic to a meaningful apology. No patient should have to sue to receive a just settlement. The amounts required are often surprisingly small. But they should be sufficient to meet the actual expenses, and should be given freely, not grudgingly, as true reparations.

The new world of transparency can be daunting, requiring substantial changes in many of our practices and ways of thinking. The benefits for our patients, and for ourselves, can be tremendous.

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THE NATIONAL PATIENT SAFETY FOUNDATION'S LUCIAN LEAPE INSTITUTE

NPSF

SHINING A LIGHT

Safer Health Care Through Transparency

The National Patient Safety Foundation's Lucian Leape Institute

Report of the Roundtable on Transparency

EXECUTIVE SUMMARY

During the course of health care's patient safety and quality movements, the impact of transparency—the free, uninhibited flow of information that is open to the scrutiny of others—has been far more positive than many had anticipated, and the harms of transparency have been far fewer than many had feared. Yet important obstacles to transparency remain, ranging from concerns that individuals and organizations will be treated unfairly after being transparent, to more practical matters related to identifying appropriate measures on which to be transparent and creating an infrastructure for reporting and disseminating the lessons learned from others' data.

To address the issue of transparency in the context of patient safety, the National Patient Safety Foundation's Lucian Leape Institute held two roundtable discussions involving a wide variety of stakeholders representing myriad perspectives. In the discussions and in this report, the choice was made to focus on four domains of transparency:

- Transparency between clinicians and patients (illustrated by disclosure after medical errors)
- Transparency among clinicians themselves (illustrated by peer review and other mechanisms to share information within health care delivery organizations)
- Transparency of health care organizations with one another (illustrated by regional or national collaboratives)
- Transparency of both clinicians and organizations with the public (illustrated by public reporting of quality and safety data)

One key insight was the degree to which these four domains are interrelated. For example, creating environments in which clinicians are open and honest with each other about their errors within organizations (which can lead to important system changes to prevent future errors) can be thwarted if these clinicians believe they will be treated unfairly should the same errors be publicly disclosed. These tensions cannot be wished away; instead, they must be forthrightly addressed by institutional and policy leaders.

In this report, the NPSF Lucian Leape Institute comes down strongly on the side of transparency in all four domains. The consensus of the roundtable discussants and the Institute is that the evidence supports the premise that greater transparency throughout the system is not only ethically correct but will lead to improved outcomes, fewer errors, more satisfied patients, and lower costs. The mechanisms for these improvements are several and include the ability of transparency to support accountability, stimulate improvements in quality and safety, promote trust and ethical behavior, and facilitate patient choice.

In the report, more than three dozen specific recommendations are offered to individual clinicians, leaders of health care delivery organizations (e.g., CEOs, board members), and policymakers.

If transparency were a medication, it would be a blockbuster, with billions of dollars in sales and accolades the world over. While it is crucial to be mindful of the obstacles to transparency and the tensions—and the fact that many stakeholders benefit from our current largely nontransparent system—our review convinces us that a health care system that embraces transparency across the four domains will be one that produces safer care, better outcomes, and more trust among all of the involved parties. Notwithstanding the potential rewards, making this happen will depend on powerful, courageous leadership and an underlying culture of safety.

SUMMARY OF RECOMMENDATIONS

Actions for *All Stakeholders*

1. Ensure disclosure of all financial and nonfinancial conflicts of interest.
2. Provide patients with reliable information in a form that is useful to them.
3. Present data from the perspective and needs of patients and families.
4. Create organizational cultures that support transparency at all levels.
5. Share lessons learned and adopt best practices from peer organizations.
6. Expect all parties to have core competencies regarding accurate communication with patients, families, other clinicians and organizations, and the public.

Actions for Organizational Leadership: *Leaders and Boards of Health Organizations*

7. Prioritize transparency, safety, and continuous learning and improvement.
8. Frequently and actively review comprehensive safety performance data.
9. Be transparent about the membership of the board.
10. Link hiring, firing, promotion, and compensation of leaders to results in cultural transformation and transparency.

Actions Related to Measurement

Agency for Healthcare Research and Quality (AHRQ) and National Quality Forum (NQF)

11. Develop and improve data sources and mechanisms for collection of safety data.
12. Develop standards and training materials for core competencies for organizations on how best to present measures to patients and the public.
13. Develop an all-payer database and robust medical device registries.

Accreditation Bodies

14. Work with the Centers for Medicare and Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ), and the Health Resources and Services Administration (HRSA) to develop measures of care that matter to patients and clinicians across all settings.

Centers for Medicare and Medicaid Services (CMS)

15. Require as a condition of participation in Medicare or Medicaid that all performance data be made public.

All Parties

16. Ensure that data sources are accessible to patients and the public, including claims data, patient registry data, clinical data, and patient-reported outcomes.

Actions to Improve Transparency Between Clinicians and Patients: *CEOs, Other Leaders, Clinicians*

Before Care

17. Provide every patient with a full description of all of the alternatives for tests and treatments, as well as the pros and cons for each.
18. Inform patients of each clinician's experience, outcomes, and disciplinary history.
19. Inform patients of the role that trainees play in their care.
20. Disclose all conflicts of interest.
21. Provide patients with relevant, neutral, third-party information (e.g., patient videos, checklists) and expand the availability of such resources.

During Care

22. Provide patients with full information about all planned tests and treatments in a form they can understand.
23. Include patients in interprofessional and change-of-shift bedside rounds.
24. Provide patients and family members with access to their medical records.

After Care

25. Promptly provide patients and families with full information about any harm resulting from treatment, followed by apology and fair resolution.
26. Provide organized support for patients involved in an incident.
27. Provide organized support for clinicians involved in an incident.
28. Involve patients in any root cause analysis, to the degree they wish to be involved.
29. Include patients and families in the event reporting process.
30. Involve patients in organizational operations and governance.

Actions to Improve Transparency Among Clinicians: *CEOs and Other Leaders*

31. Create a safe, supportive culture for caregivers to be transparent and accountable to each other.
32. Create multidisciplinary processes and forums for reporting, analyzing, sharing, and using safety data for improvement.
33. Create processes to address threats to accountability: disruptive behavior, substandard performance, violation of safe practices, and inadequate oversight of colleagues' performance.

Actions to Improve Transparency Among Organizations

CEOs, Other Leaders, Boards

34. Establish mechanisms to adopt best safety practices from other organizations.
35. Participate in collaboratives with other organizations to accelerate improvement.

Federal and state agencies, payers, including the Centers for Medicare and Medicaid Services (CMS), and liability insurers

36. Provide the resources for state and regional collaboratives.

Actions to Improve Transparency to the Public

Regulators and Payers

37. Ensure that all health care entities have core competencies to accurately and understandably communicate to the public about their performance.
38. Ensure that health care organizations publicly display the measures they use for monitoring quality and safety (e.g., dashboards, organizational report cards).

Health System Leaders and Clinicians

39. Make it a high priority to voluntarily report performance to reliable, transparent entities that make the data usable by their patients (e.g., state and regional collaboratives, national initiatives and websites).

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The Flaws In State 'Apology' And 'Disclosure' Laws Dilute Their Intended Impact On Malpractice Suits

ABSTRACT **Apologies are rare in the medical world, where health care providers fear that admissions of guilt or expressions of regret could be used by plaintiffs in malpractice lawsuits. Nevertheless, some states are moving toward giving health care providers legal protection so that they feel free to apologize to patients for a medical mistake. Advocates believe that these laws are beneficial for patients and providers. However, our analysis of "apology" and "disclosure" laws in thirty-four states and the District of Columbia finds that most of the laws have major shortcomings. These may actually discourage comprehensive disclosures and apologies and weaken the laws' impact on malpractice suits. Many could be resolved by improved statutory design and communication of new legal requirements and protections.**

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Patients justifiably expect that they will be told about mistakes or errors—sometimes known in the medical industry as "unanticipated outcomes"—in their care.[1,2] This expectation is increasingly being codified into state laws, accreditation requirements for health care facilities, and medical society consensus statements.[3–5] However, a sizable gap exists between current practice and the expectation that patients will be notified of a medical error.[6–8] The failure of health care providers to communicate information about unanticipated outcomes may impair patients' decision making, increase their distress, and heighten their desire to seek legal redress.[9–12]

A key barrier to more-open communication between health care providers and patients is the concern that such conversations might precipitate lawsuits, especially when an adverse health outcome may have been preventable.[1,13–15] In response, many states have recently passed laws encouraging health care providers to discuss unanticipated outcomes with patients.[16–17]

One approach uses what are called "apology laws" to protect aspects of a provider's conversation with a patient from use as evidence of liability in a lawsuit.[18] A second approach, using "disclosure laws," typically mandates disclosure of certain unanticipated outcomes to patients and may protect the communication from being used in a legal or administrative action. Both types of laws are intended to encourage providers to share more information about unanticipated outcomes with patients by reducing liability exposure and shaping standard practices.

Although these laws are motivated by noble intentions, it is unclear whether they will achieve their goals. It is too early for a rigorous empirical evaluation of these initiatives, and key data on disclosures and malpractice litigation costs are not systematically collected outside of individual institutions. Predicting the effect of these laws is further hampered by the scarcity of research exploring the impact of specific communication strategies on patients' intent to sue.[19]

Notwithstanding this lack of evidence, both state and federal policy makers remain intensely interested in disclosure and apology approaches. For example, the U.S. Department of Health and Human Services (HHS) has committed $23 mil-

lion to funding pilot projects of innovative medical liability reforms, including several institutional programs that provide for disclosure, apology, and rapid offers of compensation.[20]

Because such programs generally do not bar patients from filing suit, the scope of legal protection in existing state laws is important. State disclosure and apology laws may also influence what is communicated to patients through these programs, and in what form.

In this article we contribute preliminary findings to inform these policy deliberations, based on an analysis of existing statutes (Appendix Exhibit 1).[21] We then address three policy questions. First, are the existing laws likely to foster transparency around medical injuries and reduce malpractice litigation? Second, do the strengths and weaknesses of disclosure and apology laws suggest best practices for designing future laws? Finally, on balance, are these laws worth adopting, or can their goals be more effectively achieved through alternative public or private initiatives such as disclosure and settlement offer programs?

Background

DISCLOSURE AND APOLOGY Disclosure and apology are conceptualized differently in the medical literature than they are in state statutes. In the medical literature, the term "disclosure" refers to informing the patient that an unanticipated outcome has occurred and providing some explanation for it.[1] Specifically, studies have shown that the information that patients desire following an unanticipated outcome includes an explanation of what happened, whether the outcome was caused by an error, how it happened, and plans for preventing recurrences.[22,23] The term "apology" refers at a minimum to an expression of sympathy, although some commentators suggest that a "full" apology for an unanticipated outcome caused by an error also includes providing an explanation, accepting responsibility, and making amends.[24–26]

CONVERSATION ABOUT UNANTICIPATED OUTCOMES In contrast, state laws recognize three distinct components of conversations with patients about unanticipated outcomes: "expression of sympathy," "explanation," and "admission of fault." The first two are roughly equivalent to the concepts of apology and disclosure. However, "admission of fault" does not have a close analogue in current disclosure guidelines promulgated by the medical profession, such as those from the National Quality Forum.[27]

The growing interest in communication between health care providers and patients about unanticipated outcomes has been stimulated in part by research suggesting that such communication might improve outcomes, including a reduction in litigation, amounts awarded, and greater patient satisfaction.[28–30] Nonetheless, health care workers and the institutions where they work still identify fear of malpractice suits as a major barrier to disclosure conversations.[31]

LEGAL RAMIFICATIONS Lawyers and insurance carriers have traditionally advised clients to avoid expressions of sympathy, explanations, and admissions of fault to patients out of concern that such statements could be used in litigation.[32–34] Worries about stimulating rather than ameliorating litigation persist. One group of scholars recently described disclosure as "an improbable risk management strategy."[29]

Study Data And Methods

We identified and reviewed statutes, regulations, judicial cases, and legislative histories of the fifty states and the District of Columbia that concerned the use in litigation and other legal proceedings of health care providers' statements of apology and disclosure to patients following unanticipated outcomes. The review is current through June 18, 2010.

We used online legal databases (LexisNexis and Westlaw) and annotated compilations of state laws. We then analyzed the laws for common themes (Appendix Exhibit 1),[21] categorizing them through a rigorous classification scheme. In states that have adopted both an apology law that is specific to the medical context and a more general apology statute that applies to other kinds of accidents, we analyzed only the law that would apply to medical malpractice litigation. (Appendix Exhibit 2 provides legal citations by state.)[21]

Study Results

PREVALENCE OF LAWS Thirty-four states and the District of Columbia have adopted an apology law, and nine states have adopted a disclosure law.[35] Six states have both types of laws, and thirteen have neither.[36] Among the states with apology laws, eleven have laws of general applicability,[37] and twenty-five have laws specific to the medical context. One state, Washington, has both a general apology law and an apology law specific to the medical context.

Sixteen states do not currently have any apology law. In these states, sympathetic statements by a provider could be used by a plaintiff as evidence of provider liability.

VARIATIONS IN FEATURES OF APOLOGY LAWS The vast majority of the apology laws—found

in twenty-five states and the District of Columbia—are sympathy-only laws, which protect only the expression of sympathy made after an unanticipated outcome (Exhibit 1). Although some experts assert that a meaningful apology includes an explanation for the injury and an acceptance of responsibility,[38] the legal protection provided by sympathy-only laws does not inherently extend to statements of explanation or fault. Indeed, more than half of the sympathy-only laws explicitly indicate that expressions of fault made in conjunction with an expression of sympathy are admissible in litigation.[39]

These laws suggest that portions of a statement that explain or acknowledge responsibility—such as, "I'm sorry *I hurt you*," or, "I'm sorry *I made a mistake when I administered the wrong medication*"—could be used in litigation.

In the remaining sympathy-only laws, the statutes are less clear about whether a statement of fault embedded in a statement of sympathy would be admissible in litigation. In states with those laws, any expression of fault or liability would be likely to be admissible, as other evidence rules generally permit plaintiffs to use such statements against defendants.

Three states have sympathy and explanation-apology laws. These laws protect expressions of sympathy as well as the description of the event, such as, "I'm sorry you had an unexpected reaction to the medication." Like the sympathy-only laws, they do not explicitly protect expressions of fault. Therefore, the portions of statements that identify the responsible party—for example, "I'm sorry you were hurt *when I prescribed the wrong dose of medication*"—may be admissible in litigation.

Six states have laws that protect both a provider's expression of sympathy and any admission of responsibility or fault. We assumed in our

EXHIBIT 1

Characteristics Of State Apology Laws

Provision	Number
CONTENT OF COMMUNICATION RECEIVING LEGAL PROTECTION	
Statement of sympathy, explanation, and fault	0
Statement of sympathy and fault	6
Statement of sympathy and explanation	3
Statement of sympathy	26
COVERED PARTIES	
Not restricted to health care providers	9
Institutional and individual health care providers	25
Institutional health care providers only	1
TRIGGERING EVENT	
All accidents[a]	6
Unanticipated outcomes of medical care[a]	25
Serious unanticipated outcomes of medical care	0
Medical errors/alleged negligence	4
TIMING OF COMMUNICATION	
No time frame specified	33
Communication must be made within *X* days of discovery	2[b]
FORM OF COMMUNICATION	
May be oral, written, or by conduct	34
May be oral or written	0
Must be written	0
Must be oral	1
Must be both oral and written	0
RECIPIENT OF COMMUNICATION	
Not limited to certain recipients	7
Recipient must be injured patient, family, representative, or friend	3
Recipient must be injured patient, family, or representative	23
Recipient must be injured patient	1
Recipient must be family (wrongful death cases only)	1

SOURCE Authors' analysis of LexisNexis and Westlaw searches of state statutes, regulations, and case law, last updated June 18, 2010.
NOTES $N = 35$, which includes thirty-four states and the District of Columbia. [a]The category "all accidents" includes statutes that do not specify a triggering event, if the statute is not limited to incidents involving health care providers. The category "unanticipated outcomes of medical care" includes statutes that do not specify a triggering event, if the statute is limited to health care providers. [b]30 days (VT, WA).

classification scheme that the protection for admissions of fault would be construed to cover any accompanying explanation of the event, and therefore that these sympathy-and-fault statutes provide the most expansive legal protection for providers.

In most jurisdictions, the protected communication may be verbal or nonverbal. For example, oral and written "statements," "affirmations," "gestures," "activities," or "conduct" are forms of protected communication. One state, Vermont, protects only oral communications. Two states encourage timely disclosure by protecting statements made within a defined time period. Although nearly all of the laws apply to apologies for unanticipated medical outcomes, four statutes apply more narrowly to medical errors or allegedly negligent care.

VARIATIONS IN FEATURES OF DISCLOSURE LAWS Since 2002, seven states have passed mandatory disclosure laws, and two have passed discretionary disclosure statutes (Exhibit 2). Mandatory disclosure laws require health care facilities to notify patients or their families, or both, of unanticipated outcomes of medical care. The discretionary disclosure law in Washington allows health care facilities to determine when disclosure of unanticipated outcomes to patients is appropriate. Oregon's discretionary law allows hospitals to voluntarily participate in the state's patient safety program, which mandates patient disclosures of serious unanticipated outcomes.

Six of the nine states with mandatory or discretionary disclosure laws provide legal protection for the communication in subsequent litigation. In five of those states, the protected communication is limited to a statement that an unanticipated outcome occurred, such as, "During the operation, your ureter was injured." Only one state, Washington, also protects explanations and expressions of sympathy such as, "I'm sorry your ureter was injured during the surgery." All six of the states whose disclosure laws provide legal protection also have separate apology laws that may be relevant.[40] The remaining three states offer no protection.

Among the nine states with mandatory or discretionary disclosure laws, Washington's approach is unique, offering the most comprehensive protection of disclosure conversations for health care providers. It adopted what reads like a combination disclosure-and-apology law. The statute explicitly provides protection for an explanation of the event and an expression of sympathy offered as part of a voluntary disclosure conversation with the patient, such as, "I'm sorry your ureter was injured when a surgical tool malfunctioned during the operation." Washington also has a separate apology law that could extend protection to an admission of fault.

Except in Florida, state disclosure laws apply to health care facilities only, not to individual providers. Although most apology laws apply to all unanticipated outcomes, disclosure laws typically apply only to events that have caused serious harm. Only two states—Oregon and Pennsylvania—require that the notification be in writing. For these two states, oral communications are permitted but not sufficient. Four states' disclosure laws require that the communication be made within a specified time frame.

All nine state disclosure statutes require institutions to inform patients that an unanticipated outcome occurred, but none requires disclosure of specific information. One state requires disclosure of the patient's legal rights in certain situations. None requires or even suggests that the institution explain what happened, what impact it will have on the patient's health, or how institutions will follow up on the incident. Thus, an institution could adhere to the letter of the law simply by telling a patient, "The outcome of your surgery was unanticipated."

Discussion

Our research revealed that more than two-thirds of states have apology laws. The majority of such laws protect only the provider's voluntary expression of sympathy to the patient from use by a patient in malpractice litigation. A small number of states also protect explanations of the event or expressions of fault, or both. The definitions and scope of coverage vary in other ways, including requirements for timely communication in two state laws.

Nine states have disclosure laws, most of which require health care facilities to notify patients of events that have caused serious harm. States vary on whether the disclosure receives protection from subsequent use by a plaintiff in malpractice litigation. For the most part, states provide limited, if any, procedural guidance; some states require written—versus oral—communication or timely communication.

LIKELY EFFECTIVENESS OF EXISTING LAWS Our analysis reveals that most of these laws have structural weaknesses that may discourage comprehensive disclosures and apologies and weaken the laws' impact on malpractice suits. Disclosure laws do not require, and most apology laws do not protect, the key information that patients want communicated to them following an unanticipated outcome. Patients view the apology and disclosure processes as inextricably intertwined, seeking not only an expression of sympathy but also information about the

EXHIBIT 2

Characteristics Of State Disclosure Laws

Provision	Number
CONTENT OF COMMUNICATION RECEIVING LEGAL PROTECTION	
Statement of sympathy, explanation, and fault	0
Statement of sympathy and fault	0
Statement of sympathy and explanation	1
Statement of sympathy	0
Statement that an unanticipated outcome occurred	5
None	3[a]
COVERED PARTIES	
Not restricted to health care providers	0
Institutional and individual health care providers	1
Institutional health care providers only	8
TRIGGERING EVENT	
Unanticipated outcomes of medical care	1
Serious unanticipated outcomes of medical care	7
Preventable serious adverse outcomes of medical care	1[b]
Medical errors	0
TIMING OF COMMUNICATION	
No time frame specified	5
Communication must be made within *X* days of discovery	4[c]
FORM OF COMMUNICATION	
May be oral, written, or by conduct	0
May be oral or written (not specified)	6
Must be written	2
Must be oral (if patient is available)	1
Must be both oral and written	0
RECIPIENT OF COMMUNICATION	
Not limited to certain recipients	0
Recipient must be injured patient, family, or representative	9
VOLUNTARINESS	
Communication is mandatory	7
Communication is discretionary	2
INFORMATION REQUIRED TO BE CONVEYED	
Statement that unanticipated outcome occurred	9
Explanation of facts, context of unanticipated outcome	0
Acknowledgment of harm	0
Explanation of impact on treatment plans or health status, or both	0
Explanation of investigation or follow-up done or to be done	0
Explanation of cause of unanticipated outcome	0
Offer of support services	0
Statement of accountability or responsibility	0
Statement of patient's legal rights	1

SOURCE Authors' analysis of LexisNexis and Westlaw searches of state statutes, regulations, and case law, last updated June 18, 2010.
NOTE $N = 9$. [a]One state (TN) has no explicit statutory protection for patient notification but does provide explicit liability protection for hospitals reporting the same event to the state. [b]This state (NJ) also requires disclosure of adverse events arising from allergic reactions. [c]Range: 24 hours to 7 days (NJ, CA, NV, PA).

nature of the event and why it happened, and how recurrences will be prevented.[1,2,41]

Yet disclosure laws require only a bare-bones statement that an unanticipated outcome occurred. And most apology statutes protect only an expression of sympathy, failing to appreciate the importance of providing additional information to patients.[16]

A related problem is that some disclosure laws do not appear to extend protection to communications about events that occur outside the narrow context specified in the law. Pennsylvania has no apology law. However, the state does protect certain communications under a mandatory disclosure law that requires a health care facility to provide written notification to patients affected by a "serious event."[42] A reasonable interpretation of this law is that a clinician who

orally apologizes to a patient risks having that communication used by a plaintiff as evidence of fault. Physicians may be unaware of such limitations and may mistakenly assume that an entire disclosure conversation is legally protected.

Where legal protections are unclear or perceived to be inadequate, health care workers and facilities might not provide all of the information that patients want about unanticipated outcomes. Merely expressing sympathy without sharing information about an injury's cause and prevention or accepting responsibility may strike patients as insincere,[43] provoking rather than appeasing a potential plaintiff.

Similarly, laws that protect only expressions of sympathy and explanation may make for awkward communications, as it may be difficult to explain an error without discussing the different but closely related issues of responsibility or fault. For these reasons, narrowly crafted disclosure and apology laws might not achieve their objectives of fostering transparency and deterring lawsuits.

Because apology and disclosure statutes are fairly new, it is unclear how they will be interpreted and implemented in practice. For example, in a sympathy-only state, the legal system will have to determine exactly what language constitutes a protected expression of sympathy and what constitutes an unprotected explanation or admission of fault.

Lastly, the impact of mandatory disclosure laws may be limited by the difficulty of enforcing them.[28] To our knowledge, none of the states with disclosure laws has plans to monitor the occurrence or quality of disclosures.

Many of these problems could be resolved by improved statutory design and communication of new legal requirements and protections. But even well-designed laws might not dampen some patients' propensity to file malpractice claims and indeed could stimulate claims.[29] Although a provider's words to a patient may be legally protected, the communication can still alert the patient to a potential legal claim. The legal discovery process can then be used to obtain independent evidence to prove malpractice.

Even a sincere apology might not dissuade some patients from suing, particularly if the injury entails large economic losses and there is no offer of compensation. These considerations do not mean that providing legal protections for disclosures and apologies is valueless, but they should militate against unqualified optimism about the impact of improvements in transparency on malpractice claims.

Determining the effectiveness of these laws will ultimately hinge on future research. As institutions, insurers, and states begin tracking the disclosure and apology process, research projects can assess the real-world impact of different communication and compensation strategies on patient trust and satisfaction, on provider distress and burnout, and on malpractice claims and malpractice insurance premiums.[44–48]

BEST PRACTICES FOR DISCLOSURE AND APOLOGY LAWS Research into patients' needs surrounding unanticipated outcomes of care, the National Quality Forum's recommendations on disclosure, and analysis of existing disclosure and apology laws suggest some recommendations for future statutory design (Exhibit 3).[27,49] Several principles should inform design choices: Disclosure requirements should acknowledge both patients' needs and providers' anxieties about legal risk; disclosure and apology should be considered as an integrated process; and legal protection should be broad, in order to encourage comprehensive disclosures and willingness to accept responsibility for error.

These principles suggest that apology and disclosure laws should be drafted in more expansive terms than most existing statutes. Legal protections should apply to individual as well as institutional health care providers; to both oral and written communications; and to statements of explanation and fault as well as sympathy.

The principles also point toward greater specificity in disclosure laws. Such laws should require the disclosure of all serious unanticipated outcomes and articulate a minimum set of information to be disclosed, beyond a simple statement that an unexpected event occurred. Legislatures should delegate responsibility for specifying the information set to a state agency, so that modifications can be implemented in response to evolving knowledge about best practices without legislative amendment.

Based on current research about patients' needs, disclosures should include what is known about the event's cause, plans for prevention, and available patient support services. Disclosure laws should also provide mechanisms for monitoring disclosures to ensure compliance with the law, such as reporting and audit provisions.

What accounts for the gap between current laws and best practices in provider-patient communication? The language on the books probably reflects political compromises in the legislative process. Some legislatures have been motivated to pass apology laws because of the potential emotional benefit to providers and patients of more-open communication.

The most common rationale, though, has been that apologies could decrease medical malpractice litigation and related costs. State trial law-

EXHIBIT 3

Best-Practice Recommendations For State Disclosure And Apology Laws

Provision	Recommended practice
Protected content	Disclosure and apology laws should be drafted broadly to protect statements that an unanticipated outcome occurred and statements of sympathy, explanation, and fault
Covered parties	Disclosure and apology laws should cover individual and institutional health care providers
Triggering event	Apology laws should apply to statements made in response to any unanticipated outcome; disclosure laws should require disclosure of all unanticipated outcomes
Timing of communication	Apology laws should not limit protection to a specific time frame; disclosure laws should specify a time frame in which communications must be made The time frame should encourage prompt initial disclosures that an unanticipated outcome occurred but should permit additional investigation time before an explanation of the outcome is required
Form of communication	Apology laws should protect oral statements, written statements, and conduct; disclosure laws should require both oral and written notification for serious unanticipated outcomes, but should permit oral communications to suffice for less serious events The statute should provide a definition of a serious unanticipated outcome
Recipient of communication	Disclosure and apology laws should apply only to communications made to the injured patient, his or her family, representative, or friend
Voluntariness[a]	Disclosure laws should mandate communications following unanticipated outcomes
Required content	Disclosure laws should require that the communication include a statement that an unanticipated outcome occurred, an explanation of the facts or context of the event, an acknowledgment of harm, an explanation of the impact on the patient's treatment plans and health status, an explanation of the investigation or follow-up done or to be done, and an offer of support services, where available

SOURCE Authors' analysis. [a]Applicable to disclosure laws only.

yers' associations do not share that goal and have often opposed apology laws, concerned that evidentiary exclusions make it more difficult to bring successful malpractice claims. The limited scope of protection in the laws eventually passed may have been an attempt to accommodate such concerns.

Disclosure laws, on the other hand, have typically been enacted as part of patient safety reform efforts and are frequently paired with provisions that mandate state reporting. We can only speculate, but the lack of specificity about disclosure content may be a response to health care providers' concerns about liability exposure for explanations of the cause of an injury, particularly in states where apology protection is limited or absent.

ALTERNATIVE MECHANISMS FOR ENCOURAGING DISCLOSURE Are apology and disclosure laws a desirable means of fostering transparency in health care? On balance, the answer is yes.

Some experts have argued that the aims of apology and disclosure laws can be more effectively pursued through private initiatives. In particular, health care institutions can implement their own disclosure policies, accompanied by early settlement programs.[50] Although none of the existing institutional programs has yet been studied by external evaluators, program administrators report success in fostering transparency around medical injuries and reducing malpractice litigation costs.[28,48]

These programs show promise, but they are best viewed as complements, rather than alternatives, to apology and disclosure laws. They now exist at only a handful of institutions, and widespread change beyond these early adopters is unlikely in the current legal environment without substantial legislative encouragement. Further, although some programs appear to be flourishing even in the absence of a law, others have benefited from having such legal structures in place.[28] Colorado's comprehensive apology law, for example, has been credited with contributing to the success of the program implemented by COPIC Insurance, which reimburses patients up to $30,000 for "loss of time" and out-of-pocket expenses associated with adverse events, without regard to whether the standard of care was met.[51]

Particularly in programs like COPIC's that extend beyond the walls of a single institution, the legal environment in a state may greatly influence providers' willingness to participate in disclosure, although insurers could promote disclosure by making it a condition of having

an incident covered by malpractice insurance. In contrast, in closed systems such as self-insured academic medical centers, the institution can exert greater leverage over its physicians, and the legal regime may play a secondary role in shaping practices.

States should recognize that advances in disclosure and apology are likely to continue at individual institutions and support institutions committed to transparency. Legislators can also collaborate with other state agencies to support institutional disclosure and apology programs. COPIC, for example, believes that its program's success is linked not only to the state's apology law and tort reforms, but also to close ties with key stakeholders, including the state board of medicine and the state insurance commissioner's office.[51]

Conclusion

Honest communication with patients is a moral imperative.[52] States are to be commended for confronting the serious deficiencies in how patients are currently informed about unanticipated outcomes. Substantial conceptual and practical problems, however, are likely to diminish the effectiveness of existing apology and disclosure laws.

Legislation can be ineffective or even counterproductive if it is drafted too narrowly, if health care providers overestimate the protection it offers, or if the resulting disclosures or apologies are interpreted by patients as insincere. Policy makers and health care providers need to have realistic expectations about what these laws will accomplish. They should not rely on laws as the primary means of changing the culture of communication with patients following unanticipated outcomes. Such culture change is likely to be most effective when it originates from within institutions that develop systems to support health care workers in conducting these difficult conversations.[5]

Practical policy options do exist for state legislators to increase transparency with patients. By understanding the relationship between disclosure and apology; ensuring that broad legal protections for disclosed information are in place; and collaborating with all key stakeholders, including health care institutions, states can support the development, evaluation, and dissemination of effective disclosure and apology programs. ■

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35 Citations for all statutes are available in the online Appendix, as in Note 21.

36 The states with both types of laws are California, Florida, Oregon, Tennessee, Vermont, and Washington. The states without laws are Alabama, Alaska, Arkansas, Illinois, Kansas, Kentucky, Mississippi, Minnesota, Missouri, New Mexico, New York, Rhode Island, and Wisconsin.

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