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

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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

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''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

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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.

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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."

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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.

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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.

REFERENCES

1. Zilberberg MD. The clinical research enterprise—time to change course? JAMA. 2011;305:604–605.
2. IOM (Institute of Medicine). *Redesigning Continuing Education in the Health Professions*. Washington, DC: The National Academies Press; 2010.
3. Sniderman AD, Furberg CD. Why guideline-making requires reform. *JAMA*. 2009;301:429–431.
4. Ferket BS, Colkesen EB, Visser JJ, et al. Systematic review of guidelines on cardiovascular risk assessment. *Arch Intern Med*. 2010;170:27–40.
5. Mendelson TB, Meltzer M, Campbell EG, et al. Conflicts of interest in cardiovascular clinical practice guidelines. *Arch Intern Med*. 2011;171:577–585.
6. Gittell JH. *High Performance Healthcare—Using the Power of Relationships to Achieve Quality, Efficiency and Resilience*. New York, NY: McGraw Hill; 2009
7. American College of Physicians. Achieving a high performance health care system with universal access: What the United States can learn from other countries. *Ann InternMed*. 2008;148:55–75.
8. Reid, RO, Friedberg MW, Adams JL, et al. Associations between physician characteristics and quality of care. *Arch Intern Med*. 2010;170:1442–1449.
9. Levinson DR. *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm. DHHS, OIG*. 2012, OEI-06-09-00091.
10. California Injury Lawyers Blog. Available at: http://www.californiainjurylawyersblog.com/2009/06/california-medical-malpractice-dennis-quaids-twins-to-receive-500000-for-heparin-overdose.html. Accessed July 12, 2012.
11. McKnight EV, Bennington TT. *A Never Event—Exposing the Largest Outbreak of Hepatitis C in American Healthcare History*. Fremont, NE: History Examined, LLC; 2010
12. Ghandi TK, Zuccotti G, Lee TH. Incomplete care—On the trail of flaws in the system. *N Engl J Med*. 2011:365:486–488.
13. Gheorghaide M, Gattis WA, O'Conner CM. Treatment gaps in the pharmacologic management of heart failure. *Rev Cadiovasc Med*. 2002;3:S11–S19.
14. Weismann JS, Schneider EC, Weingart SN, et al. Comparing patient-reported hospital adverse events with medical records reviews: Do patients know something that hospitals do not? *Ann Intern Med*. 2008;149:100–108.
15. James JT. *A Sea of Broken Hearts—Patient Rights in a Dangerous, Profit-Driven Health Care System*. Bloomington, IN: AuthorHouse; 2007.
16. Weiner SJ, Schwartz A, Weaver F, et al. Contextual errors and failures in individualizing patient care. *Ann Intern Med*. 2010;153:69–75.
17. Welch HG, Schwartz LM, Woloshin S. *Over-diagnosed—Making People Sick in the Pursuit of Health*. Boston, MA: Beacon Press; 2011.
18. Classen, DC, Resar R, Griffin F, et al. "Global trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff*. 2011;30:581–589.
19. Parry G, Cline A, Goldmann D. Deciphering harm measurement. *JAMA*. 2012;307:2155–2156.
20. Walter D. *Collateral Damage—A Patient, a New Procedure, and the Learning Curve*. Charleston, SC: CreateSpace; 2010.
21. Institute for Healthcare Improvement. IHI Global Trigger Tool Guide. Cambridge MA, 2008. Available at: http://www.ihi.org/knowledge/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx. Accessed July 12, 2012.
22. Department of Health and Human Services, Office of the Inspector General. *Adverse Events in Hospitals: Case Study of Incidence among Medicare Beneficiaries in Two Selected Counties*. Washington, DC; 2008, Available at: *http://oig.hhs.gov/oei/reports/OEI-06-08-00220.pdf.*
23. Department of Health and Human Services, Office of the Inspector General. *Adverse Events in Hospitals: National Incidence among*

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Medicare Beneficiaries. Washington, DC; 2010, Available at: http://oig.hhs.gov/oei/reports/OEI-06-09-00090.pdf.

24. Landrigan, CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med*. 2010;363:2124–2134.
25. IOM (Institute of Medicine). *To Err is Human—Building a Safer Health System*. Washington, DC: The National Academies Press; 2000.
26. Hall MJ, DeFrances CJ, Williams SN, et al. *National Health Statistics Report. CDC Report Number 29*; 2010. Available at: http://www.cdc.gov/nchs/data/nhsr/nhsr029.pdf.
27. Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors. *JAMA*. 2001;286:415–420.
28. Goodman JC, Villarreal P, Jones B. The social cost of adverse medical events, and what we can do about it. *Health Aff*. 2011;30:590–595.
29. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospital patients: results of the Harvard Medical Practice Study. *N Engl J Med*. 1991;324:370–376.
30. IOM (Institute of Medicine). *Patient Safety–Achieving a New Standard of Care*. Washington, DC: The National Academies Press; 2004.
31. Moody J, Cosgrove SE, Olmsted R, et al. Antimicrobial stewardship: a collaborative partnership between infection preventionists and healthcare epidemiologists. *Infect Control Hosp Epidemiol*. 2012;33:328–330.
32. Schneider EL, Campese VM. Adverse drug responses, an increasing threat to the well- being of older patients. *Arch Intern Med*. 2010;170:1148–1149.
33. Stergiopoulos K, Brown DL. Initial coronary stent implantation with medical therapy vs medical therapy alone for stable coronary artery disease. *Arch Intern Med*. 2012;172:312–319.
34. Newman-Toker DE, Pronovost PJ. Diagnostic errors—the next frontier for patient safety. *JAMA*. 2009;301:1060–1062.
35. Kotchen TA. Why the slow diffusion of treatment guidelines into clinical practice? *Arch Intern Med*. 2007;167:2394–2395.
36. A randomized trial of propranolol in patients with acute myocardial infarction. I. Mortality results. *JAMA*. 1982;247:1707–14. Available at: http://www.ncbi.nlm.nih.gov/pubmed/7038157.
37. Dunlay SM, Alexander KP, Melloni C, et al. Medical records and quality of care in acute coronary syndromes. *Arch Intern Med*. 2008; 168:1692–1698.
38. Leape L. Institute of Medicine medical error figures are not exaggerated. *JAMA*. 2000;284:95–97.
39. Weingart SN, Wilson RM, Gibberd RW, et al. Epidemiology of medical error. *BMJ*. 2000:320:774–777.
40. Flynn EA, Barker KN, Pepper GA, et al. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health-System Pharm*. 2002;59:436–446.
41. Campbell EG, Regan S, Gruen RL, et al. Professionalism in medicine: results of a national survey of physicians. *Ann Intern Med*. 2007; 147:795–802.
42. Junya Z, Struver S, Epstein A, et al. Can we rely on patients' reports of adverse events? *Med Care*. 2011;49:948–955.
43. Rogan GN, Sebat F, Grady I. How Peer Review Failed at Redding Medical Center, Why It Is Failing Across the Country and What Can be Done About It. Congressional Report, June 1, 2008. Available at: http://www.allianceforpatientsafety.org/redding-failure.pdf. Accessed July 12, 2012.

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