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Revisiting Medical Error: Five Years after the IOM Report, Have Reporting Systems Made a Measurable Difference

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REVISITING MEDICAL ERROR:

FIVE YEARS AFTER THE IOM REPORT, HAVE REPORTING SYSTEMS MADE A MEASURABLE DIFFERENCE?

Maxine M. Harrington[†]

I. INTRODUCTION

It is said that beauty is in the eye of the beholder. So, too, might be said of medical error, an elusive concept brought to national prominence in 1999 by the Institute of Medicine (IOM) with its landmark report, *To Err is Human, Building a Safer Health System.*[1] Relying primarily on two studies conducted in 1984 and 1992, the IOM concluded that between 44,000 and 98,000 patients die every year in hospitals as the result of medical error.[2] Using the lower estimate, the IOM asserted that more people die annually from medical error than from automobile accidents, breast cancer or AIDS.[3]

Even though much of the material was not new, the IOM report galvanized public and political attention on the problem of medical error.[4] A torrent of publicity following the release of the report fo-

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[1] COMM. ON QUALITY OF HEALTH CARE IN AM., INSTITUTE OF MEDICINE, TO ERR IS HUMAN (Linda Kohn et al. eds., 2000), *available at* http://books.nap.edu/books/0309068371/html/index.html [hereinafter IOM REPORT]. The Institute of Medicine is a private, non-profit component of the National Academy of Sciences and serves to advise governmental and private bodies on issues pertaining to health and science. *See* INST. OF MED. NAT'L ACADS., *About, at* http://www.iom.edu/about.asp (last visited Jan. 29, 2005).

[2] IOM REPORT, *supra* note 1, at 26.

[3] *Id.*

[4] Health professionals have long recognized that medical care can cause harm to patients and several studies, dating back to the 1960s, demonstrated high rates of adverse events, many of which were preventable. *See e.g.*, Lucian A. Leape,

cused primarily on the shocking number of deaths due to medical errors. *The New York Times* compared the IOM's estimate of deaths "to having three jumbo jets filled with patients crash every two days."[5] One poll showed that fifty-one percent of the public closely followed news of the IOM's report about the high number of medical errors in hospitals.[6]

The IOM set a clear goal to reduce error: "[g]iven current knowledge about the magnitude of the problem, the committee believes it would be irresponsible to expect anything less than a 50 percent reduction in errors over five years."[7] To accomplish this objective, the IOM suggested a four-part strategy.[8] The most important from a legal perspective was a recommendation that error-reporting systems be established.[9] Reporting is a central element of patient safety because it can identify medical errors, allow providers to learn from their mistakes, and monitor progress in the prevention of error.[10] The IOM called for a nationwide, mandatory system administered by the states for reporting errors that cause serious harm or death, and voluntary, non-regulatory reporting programs for those errors that cause minor or no harm to patients.[11] The recommendation for mandatory reporting systems has been controversial because the IOM felt strongly that reports of serious errors should be made available to the public and that health care providers should be held "accountable" for such errors.[12] On the other hand, it saw a need for protection of data col-

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Error in Medicine, 272 JAMA 1851, 1851 (1994).

[5] Editorial, *Preventing Fatal Medical Errors*, N.Y. TIMES, Dec. 1, 1999, at A22 (quoting Dr. Lucian Leape's assessment of the IOM Report).

[6] *What the Public Understands About Health Stories in the News*, THE KAISER/HARV. HEALTH NEWS INDEX (Nov./Dec. 1999), *available at* http://www.kff.org/kaiserpolls/upload/13350_1.pdf. Despite widespread public attention on the number of deaths, it is interesting that just three years after the IOM report, a survey of physicians and the public found that a majority of both groups believed that fewer than 5,000 deaths occurred in hospitals each year due to error. Robert J. Blendon, et al., *Views of Practicing Physicians and the Public on Medical Error*, 347 NEW ENG. J. MED. 1933, 1935 (2002).

[7] IOM REPORT, *supra* note 1, at 4.

[8] *Id.* at 6 (recommending establishing leadership at the national level to enhance patient safety; identifying and learning from errors through reporting systems; raising standards and expectations in safety through oversight groups; and creating safety systems in health care organizations).

[9] *Id.* at 9.

[10] *Id.* at 8. *See also* Lucian L. Leape, *Reporting of Adverse Events*, 347 NEW ENG. J. MED. 1633, 1633 (2002).

[11] IOM REPORT, *supra* note 1, at 9-10.

[12] *Id.* at 8.

lected by voluntary reporting systems and urged Congress to enact legislation to provide peer review protection for these reports.[13]

Since the IOM report, the patient safety movement has burgeoned. There has been a flurry of activity in Congress and in state legislatures focusing primarily on the IOM's alarming numbers and its recommendation for medical error reporting systems. In February 2000, President Clinton, echoing the IOM's objective, announced a national action plan to reduce preventable medical errors by fifty percent within five years.[14] But has this goal been realized? The public was recently confronted with a report that not only refuted the notion that safety in hospitals has improved in the last five years, but also asserted that the IOM had vastly underestimated the scope of the problem.[15] Citing 195,000 deaths due to medical error each year, the press release announcing the report stated: "[t]he equivalent of 390 jumbo jets full of people are dying each year due to likely preventable, in-hospital medical errors, making this one of the leading killers in the U.S."[16]

The true incidence of medical error may be more uncertain than either the IOM or other studies suggest. Acceptance of the IOM's estimates of error-related deaths has broad implications for federal and state policy, which has largely been driven by the IOM report. States have responded to the alarming numbers by implementing mandatory error reporting systems or revising existing systems. Health care professionals and organizations have balked at state mandates because of fear of increased malpractice litigation or disciplinary actions due to disclosure of errors. Beginning in 2000 and each following year, both Houses of Congress introduced, but did not pass, legislation that would protect reported errors from disclosure in legal proceedings.[17]

Although the goal of patient safety is a laudable one, it is questionable whether state and national policy can be made on so vague a concept as "medical error." There is neither an accurate baseline nor

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[13] *Id.* at 10.

[14] President William J. Clinton, Remarks by the President on Medical Errors at the Dwight D. Eisenhower Executive Office Building (Feb. 22, 2000), *available at* http://www.ahrq.gov/wh22200rem.htm.

[15] HEALTHGRADES QUALITY STUDY: PATIENT SAFETY IN AMERICAN HOSPITALS 1, 8 (July 2004), *available at* http://www.healthgrades.com/media/english/HG_Patient_Safety_Study_Fund.pdf [hereinafter HEALTHGRADES STUDY].

[16] Press Release, In-Hospital Deaths from Medical Errors at 195,000 Per Year, HealthGrades Study Finds (July 27, 2004), *available at* http://www.healthgrades.com/PressRoom/index.cfm?fuseaction=PressReleases (quoting Dr. Samantha Collier).

[17] *See* discussion *infra* Part III. C.

reliable current data that could be used to validate the effectiveness of reporting systems as tools for improving patient safety. This Article examines the difficulty in estimating the incidence of medical error, including the lack of uniform standards of measurement and the legal and cultural disincentives to accurate reporting of error. Part I provides a brief background of the IOM report and addresses the reliability of error statistics derived from clinical studies, including those relied on by the IOM. Clinical empirical data are pertinent to the legal discussion of medical error because they provide a baseline from which to measure a reduction in error and because the IOM used these figures in support of its proposal for comprehensive medical error reporting laws as part of the cure for an ailing health system. Part II examines the inherent problems with using current reporting systems to identify and to measure any reduction in the rate of medical error. Most systems are not effective in capturing medical errors because they lack standardized definitions of reportable events. In particular, there is a patchwork of legislation at the state level that substantially limits the usefulness of the data collected. Efforts to obtain reliable information on medical error have also been hindered by the problem of underreporting, primarily due to fear of malpractice litigation and employer retaliation. Part III explores a framework for state and federal legislation to improve reporting systems and to enhance the ability to gather useful and valid information on medical errors. Part IV presents a brief conclusion.

II. CLINICAL ESTIMATES OF MEDICAL ERROR: THE CORRECT DIAGNOSIS?

The IOM's estimate of 44,000-98,000 error-related hospital deaths has been controversial. The problem with using these statistics as a baseline is deciding if either number or some figure in between is a reliable estimate of annual hospital deaths due to medical error. The upper and lower estimates vary by over 100%, which is an unacceptable range for a scientific study. Using these numbers, one could plausibly argue that between 1984 and 1992, when the studies on which the IOM relied were conducted, the death rate due to medical error fell by over fifty percent.[18] The IOM implicitly rejected this view, however, by concluding that temporal changes in health care and differences in patient populations and systems could explain the

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[18] Richard E. Anderson, Comment, *How Many Deaths are Due to Medical Error?*, 284 JAMA 2188, 2188-89 (2000) (criticizing the IOM Report).

difference.[19]   What the IOM did not explain is how a fifty percent reduction in health care can be measured without a reliable baseline.

A. The IOM Report – The Underlying Studies

The numbers of deaths due to medical error advanced by the IOM were derived from two studies of hospital discharges, the Harvard Medical Practice Study (HMPS), conducted in New York, and a similar study analyzing data in Utah and Colorado hospitals, the Utah-Colorado Medical Practice Study (UCMPS).[20] The HMPS, published in 1991, was based on a retrospective review of 30,121 medical records of patients discharged from acute care hospitals in New York in 1984.[21] The UCMPS looked at hospital discharges in 1992.[22]

In the HMPS, nurses and medical analysts screened the records for evidence of a possible adverse event. An adverse event was defined as "an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both."[23] If records met screening criteria for an adverse event, they were referred to two physicians for separate evaluation. The investigators concluded that adverse events occurred in 3.7% of hospitalizations.[24] Although most of these adverse events gave rise to disability lasting less than six months, 13.6% resulted in death, and 2.6% caused permanent, disabling injuries.[25] A later published article concluded that approximately one-half of the deaths caused by adverse events in the study were preventable.[26]

Using the same methods as the HMPS, the UCMPS looked at 15,000 medical records of hospital patients discharged in 1992 from

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[19] IOM REPORT, supra note 1, at 30.

[20] Id. at 26.

[21] Troyen A. Brennan et al., Incidence of Adverse Events and Negligence in Hospitalized Patients – Results of the Harvard Medical Practice Study I, 324 NEW ENG. J. MED. 370 (1991).

[22] Eric J. Thomas et al., Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado, 38 MED. CARE 261 (2000).

[23] Brennan et al., supra note 21, at 370. The IOM defined an adverse event as "an injury caused by medical management rather than by the underlying condition of the patient." IOM REPORT, supra note 1, at 28.

[24] Brennan et al., supra note 21, at 371.

[25] Id. at 373.

[26] Lucian L. Leape et al., Preventing Medical Injury, 19 QUALITY REV. BULL. 144, 147 (1993). The authors found that seventy-eight percent of the fatal adverse events were preventable, but not that seventy-eight percent of the deaths were preventable. Many patients were severely ill and would have died even if the adverse event had not occurred. Id. This is a distinction not always noted by other studies in determining the incidence of deaths due to preventable medical error.

twenty-eight Utah and Colorado hospitals.[27] The investigators found an adverse event rate of 2.9% in each state.[28] Over one-half of the adverse events were deemed preventable.[29] Death occurred in 6.9% of preventable adverse events.[30]

Extrapolating the data from these two studies to over 33.6 million hospital admissions in the United States in 1997, the IOM calculated that the UCMPS study implied an annual rate of approximately 44,000 deaths due to medical errors, while the HMPS suggested approximately 98,000 deaths.[31] Interestingly, neither the HMPS nor the UCMPS was a study of medical error. The purpose of the studies was to obtain reliable statistics on the incidence of adverse events and negligence in hospitalized patients and their relationship to malpractice claims.[32]

Proper terminology is important in the discussion of medical error. An adverse event is not equivalent to medical error.[33] An adverse event is a complication of treatment and many such events are not preventable. Medical care entails risk and bad outcomes occur in medicine, not all of which are attributable to error or negligence. Adverse drug events provide the best example of this problem. The IOM defined an adverse drug event as "an injury resulting from medical intervention related to a drug."[34] An adverse drug event may arise from an unanticipated reaction to the drug, a medication error committed by a health care professionals or improper use by the patient. For instance, a patient who receives a medication for the first time, such as an antibiotic, may experience an allergic reaction. This would be an adverse drug event because it is caused by the drug, and not by the patient's underlying condition. Because no one could anticipate the patient was allergic to the antibiotic, it is not a preventable adverse event. However, if the patient receives a second dose after a demonstrated allergy, the second dose causing an allergic reaction is a preventable adverse event and, in the opinion of the IOM, an error.[35] The

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[27] Thomas et al., *supra* note 22, at 261.

[28] *Id.* at 265.

[29] Eric J. Thomas, et al., *Costs of Medical Injuries in Utah and Colorado*, 36 INQUIRY 255, 259 (1999).

[30] *Id.* The authors did not distinguish between the preventability of the adverse events and the preventability of the deaths. *See* Leape et al., *supra* note 26, at 147.

[31] IOM REPORT, *supra* note 1, at 31.

[32] *See* Brennan et al., *supra* note 21, at 370.

[33] IOM REPORT, *supra* note 1, at 28 (defining "preventable adverse event" as an adverse event caused by error).

[34] *Id.* at 33.

[35] *See id.*

failure of the patient to take the drug as directed could also constitute an error.[36]

The IOM's estimate of error-related deaths proved controversial. Troyen Brennan, one of the authors of both the HMPS and the UCMPS, has warned that a fifty percent decrease in the rate of error will be difficult to accomplish because there is no baseline information on errors in the general medical population, and because "the reliability of identifying errors is methodologically suspect."[37] According to Brennan, a preventable adverse event and an error are not the same, and the classification of events in the HMPS may not represent the views of other physicians and should not be generalized beyond the investigators' individual judgments.[38] Other critics contend that the numbers cited by the IOM are exaggerated and that the IOM failed to explain its reasoning and used unaccepted scientific methods in calculating the estimates.[39]

Coming to the IOM's defense, Lucian Leape, a well-known safety expert and participant in both the HMPS and IOM report, responded that the estimate of up to 98,000 deaths a year was conservative.[40]

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[36] The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, monitoring and use." NAT'L COORDINATING COUNCIL FOR MEDICATION ERROR REPORTING & PREVENTION, *Consumer Information for Safe Medication Use, at* http://www.nccmerp.org/consumerInfo.html. This definition includes errors that are not attributable to a health care professional such as patient misuse.

[37] Troyen A. Brennan, *The Institute of Medicine Report on Medical Errors — Could It Do Harm?*, 342 NEW ENG. J. MED. 1123, 1124 (2000).

[38] *Id.* at 1123.

[39] *See* Rodney A. Hayward & Timothy P. Hofer, *Estimating Hospital Deaths Due to Medical Errors: Preventability is in the Eye of the Reviewer*, 286 JAMA 415, 419 (2001) (stating that actual deaths due to medical error are much lower than the IOM's estimates); Harold C. Sox, Jr. & Steven Woloshin, *How Many Deaths Are Due to Medical Error? Getting the Number Right*, 3 EFFECTIVE CLINICAL PRACT. 277, 278 (2000) (criticizing the IOM's failure to explain its calculations); Clement J. McDonald et al., *Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report*, 284 JAMA 93, 94 (2000) (contending the IOM failed to use a control group that would provide evidence of the death rate in a similar population that did not experience adverse events).

[40] Lucian L. Leape, *Institute of Medicine Medical Error Figures Are Not Exaggerated*, 284 JAMA 95, 97 (2000) (stating that record-review studies actually produce a conservative result). *See also* Saul N. Weingart et al., *Epidemiology of Medical Error*, 320 BRIT. MED. J. 774, 774 (2000) (concluding the HMPS and UCMPS probably represent the lower boundary of medical error); Lori B. Andrews et al., *An Alternative Strategy for Studying Adverse Events in Medical Care*, 349

Noting that the HMPS and UCMPS included only hospital patients, Leape contended that with more than half of surgeries performed in ambulatory surgery centers and millions of patients in nursing homes, the report, if anything, underestimated the total number of medical errors.[41] Leape further suggested that many errors are not documented in the medical record and are not captured by chart review.[42] Finally, several respected, large-scale studies in other countries using methods similar to the HMPS have reported even greater rates of preventable adverse events in hospitalized patients.[43]

The debate following the IOM report illustrates the difficulty in measuring medical error. This article neither endorses nor rejects the IOM statistics on the rate of medical error, but rather, challenges the assumption that we can achieve a finite reduction in error and questions whether patient safety policies can rest on numbers that are uncertain and elusive. Questioning the precision of the estimates, however, does not detract from the fact the IOM brought much-needed public attention to patient safety. Medical errors are a serious problem and occur far too often in both inpatient and outpatient settings. The shocking numbers of deaths reported by the IOM were likely intended to "to break [the] cycle of inaction"[44] where medical error was not addressed by the media, health care providers or the public.

Although the estimates did indeed capture the public's and politicians' attention, they also overshadowed the primary message of the IOM that broad systemic changes are needed in the health care system. In its most recent report on patient safety, the IOM appeared to recognize the controversy over its estimate of error-related deaths and retreated from providing hard numbers.[45] Yet, the IOM's earlier figures linger, and five years later the figures are still used by state legislatures, Congress, and others in support of their political agendas.[46]

LANCET 309, 312 (1997) (suggesting that the HMPS statistics may underestimate the extent of the problem).

    [41] Leape, *supra* note 40, at 97.
    [42] *Id.*
    [43] G. Ross Baker et al., *The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada*, 170 CAN. MED. ASS'N J. 1678, 1683 (2004) (7.5% adverse event rate; 36.9% were considered preventable); Ross McL Wilson et al., *The Quality in Australian Health Care Study*, 163 MED. J. AUST. 458, 465 (1995) (16.6% adverse event rate; 51% of those were considered preventable).
    [44] IOM REPORT, *supra* note 1, at 3 (discussing the goal of the report).
    [45] COMM. ON DATA STANDARDS FOR PATIENT SAFETY, INST. OF MED., PATIENT SAFETY: ACHIEVING A NEW STANDARD FOR CARE 3 (Philip Aspden et al. eds., 2004) [hereinafter PATIENT SAFETY] ("It is not possible to quantify the full magnitude of the safety challenge with certainty.").
    [46] *See, e.g.,* Patient Safety and Quality Improvement Act of 2005, S. 544,

Further, as discussed in Part II, the number of errors captured annually by reporting systems do not approach even the lower estimate of 44,000 error-related deaths cited by the IOM. The IOM Report's focus on numbers raises questions about its accuracy and leads to an examination of the methods used by the studies on which it relied.

B. The Problem of Hindsight Review

The two studies that serve as the basis for the IOM's numbers have themselves been subject to criticism for their methodology.[47] The HMPS and the UCMPS used one to three physicians to review medical records and to judge whether an adverse event occurred and whether it caused the patient's death or disability. Both involved retrospective analysis of medical records in which the outcomes were already known. It has long been recognized that retrospective or "hindsight" reviews are tainted by outcome bias.[48] Hindsight or outcome bias refers to the tendency of individuals with knowledge of the outcome to assign higher probability estimates to an event than those without such knowledge.[49] A review of the literature led several experts to remark that "hindsight bias is the greatest obstacle to evaluating the performance of humans in complex systems after bad outcomes."[50]

109th Cong. (2005). Findings in the pending legislation include: "[i]n 1999, the Institute of Medicine released a report entitled 'To Err is Human' that described medical errors as the eighth leading cause of death in the United States, with as many as 98,000 people dying as a result of medical errors each year." *Id.*; DEP'T OF HEALTH AND HUMAN SERVICES & OFFICE FOR THE NAT'L COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, THE DECADE OF HEALTH INFO. TECH.: DELIVERING CONSUMER-CENTRIC AND INFORMATION-RICH HEALTH CARE, FRAMEWORK FOR STRATEGIC ACTION 2 (2004), *available at* http://www.hhs.gov/healthit/documents/ hitframework.pdf (citing to the IOM's estimates of 44,000-98,000 annual deaths in support of a new federal initiative on health information technology). *See also infra* notes 95, 96 (using the estimates to oppose legislation affecting medical malpractice actions).

[47] *See, e.g.,* McDonald et al., *supra* note 39, at 94.

[48] *See generally,* Baruch Fischoff, *Hindsight ≠ Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty,* 1 J. EXPERIMENTAL PSYCHOL.: HUM. PERCEPTION & PERFORMANCE 288 (1975) (demonstrating that outcome affected the prediction of events, and that subjects were unaware of the effect outcome bias had on their decision making); Richard I. Cook & David D. Woods, *Operating at the Sharp End: The Complexity of Human Error in* HUMAN ERROR IN MEDICINE 255, 293 (Marilyn Sue Bogner ed., 1994).

[49] Hal R. Arkes et al., *Hindsight Bias Among Physicians Weighing the Likelihood of Diagnoses,* 66 J. APPLIED PSYCHOL. 252, 252 (1981). *See also* Leape, *supra* note 40, at 95 ("Hindsight bias would tend to overestimate the number of deaths due to adverse events.").

[50] Cook & Woods, *supra* note 48, at 295.

Applying these principles to physicians, Hal Arkes, a researcher in medical decision making, demonstrated that despite the fact that physicians were by training and knowledge well-equipped to assess medical decisions, they were still susceptible to hindsight bias and "tried to make sense out of what they knew had happened rather than analyzing the available data independently."[51] Arkes' conclusions were later confirmed in a study dealing with the appropriateness of anesthesia care.[52] One hundred twelve anesthesiologists were provided twenty-one cases with the same descriptive facts, but with outcomes randomly assigned as permanent or temporary. When asked to judge the quality of care, the physicians tended to rate the care in cases where the outcome was permanent as inappropriate, while they viewed the same conduct as appropriate when the injury was only temporary.[53] The authors concluded that knowledge of the severity of the outcome significantly influenced a reviewer's judgment of the appropriateness of care.[54]

Labeling an event as error often depends on after-the-fact knowledge of the outcome.[55] In the HMPS, errors of omission, including failure to use appropriate tests, avoidable delays in treatment and failed diagnoses, were a large percentage of the total.[56] These types of errors may be particularly susceptible to hindsight bias for in many cases those errors involve an assessment of whether the physician, or other health care provider, used appropriate clinical judgment, given the outcome that occurred. Diagnostic errors, in particular, have been recognized as less preventable than those related to other causes.[57] An error does not occur simply because a diagnosis turns out to be incorrect. The boundary between an acceptable practice and a mistake is

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[51] Arkes et al., *supra* note 49, at 254.

[52] Robert A. Caplan et al., *Effect of Outcome on Physician Judgments of Appropriateness of Care*, 265 JAMA 1957 (1991).

[53] *Id.* at 1959 (finding that physicians' opinions as to acceptable treatment decreased by thirty-one percent when the outcome was changed from temporary to permanent and increased by twenty-nine percent when the outcome was changed from permanent to temporary).

[54] *Id.* at 1960.

[55] Outcome is important in cases dealing with an adverse event. An adverse event implies injury or a bad outcome from treatment. Many errors don't cause harm; they are close calls. The HMPS and UCMPS included only adverse events that resulted in patient death or disability. *See supra* note 23 and accompanying text.

[56] Lucian A. Leape et al., *The Nature of Adverse Events in Hospitalized Patients – Results of the Harvard Medical Practice Study II*, 324 NEW ENG. J. MED. 377, 381 (1991).

[57] John Sanders & Aneez Esmail, *The Frequency and Nature of Medical Error in Primary Care: Understanding the Diversity Across Studies*, 20 FAM. PRAC. 231, 233 (2003).

not always clear-cut, and if the physician exercises appropriate clinical judgment, a "wrong" diagnosis is neither preventable nor correctable.

The tendency to impute causation with knowledge of the outcome is also a weakness in retrospective reviews.[58] There can be multiple causes of patient injury. In many complex cases the cause of an event is not observable and requires the exercise of clinical judgment to distinguish between complications from the underlying disease, complications from treatment and complications from medical error.[59]

The IOM itself seems to have succumbed to hindsight bias in its recommendation for the voluntary reporting of errors that cause little or no harm, but mandatory reporting of errors that cause serious disability or death.[60] This is an outcome-dependent analysis. Some errors may be egregious, but cause no harm. Other errors may be minor, but cause serious harm. For example, in the HMPS study, negligent errors were ranked in order of seriousness, but the type of error, not the outcome, determined the classification of seriousness.[61] The authors recognized that "[a] momentary lapse that delays the diagnosis of a skin rash is usually of little consequence, for example, whereas a similar lapse during a brain operation can have disastrous effects." [62]

Although the IOM recognized the limitations inherent in retrospective reviews,[63] it seemed to minimize the problem by failing to address hindsight bias in the studies on which it relied. Its only reference to hindsight bias reflects that the IOM thought this issue was primarily a problem with reviewers simplifying the cause of an event, i.e., blaming the accident on an individual rather than on system failure.[64]

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[58] G. Neale & M. Woloshynowych, *Retrospective Case Record Review: A Blunt Instrument That Needs Sharpening*, 12 QUALITY & SAFETY HEALTH CARE 2, 3 (2003).

[59] *See* Timothy P. Hofer & Rodney A. Hayward, *Are Bad Outcomes from Questionable Clinical Decisions Preventable Medical Errors? A Case of Cascade Iatrogenesis*, 137 ANNALS INTERNAL MED. 327, 328 (2002) (stating that many incidents that are classified as preventable errors are not so obvious and may actually have little impact on the patient's prognosis).

[60] *See supra* notes 11-13 and accompanying text.

[61] Leape et al., *supra* note 56, at 382, table 8.

[62] *Id.* at 383.

[63] *See* IOM REPORT, *supra* note 1, at 53.

[64] *Id.* ("[H]indsight bias makes it easy to arrive at a simple solution or to blame an individual, but difficult to determine what really went wrong.").

C. Reviewer Reliability

In addition to the problem of hindsight bias, studies have also confirmed that the reliability of ratings on retrospective chart reviews among reviewers is not high.[65] Investigators have demonstrated that physicians have a difficult time agreeing on what kind of conduct constitutes an adverse event and whether the event itself, or rather, the patient's underlying condition caused an injury or death.

Five years after the original HMPS was published, a team of investigators reviewed records from the study in order to determine the degree of agreement among physicians on the cause of adverse outcomes.[66] In 12.9% of cases, paired physicians strongly disagreed about the occurrence of an adverse event.[67] The cases of disagreement outnumbered those in which the physicians agreed (ten percent), with the lowest rate of consensus on adverse events caused by failure to diagnose or lack of therapy.[68] The authors noted that chart review might be particularly unreliable when physicians are asked to ascertain which deaths are preventable.[69] Noting the "common tendency"[70] of experts to disagree, this study casts doubt on the accuracy of the data on which the IOM relied to extrapolate deaths due to medical error.

A recent analysis of records from the UCMPS also challenges the lower figure set by the IOM.[71] The investigators randomly selected

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[65] *See, e.g.,* Eric J. Thomas & Laura A. Petersen, *Measuring Errors and Adverse Events in Health Care,* 18 J. GEN. INTERNAL MED. 61, 63 (2003) (noting judgments about adverse events by chart reviewers have low to moderate reliability); A. Russell Localio et al., *Identifying Adverse Events Caused by Medical Care: Degree of Physician Agreement in a Retrospective Chart Review,* 125 ANNALS INTERNAL MED. 457, 461 (1996) (corroborating other studies that found implicit record review produces disagreement among physicians on the quality of care); Ellen J. MacKenzie et al., *Inter-rater Reliability of Preventable Death Judgments,* 33 J. TRAUMA 292, 300 (1992) (finding that inter-rater reliability of preventable death judgments was generally low.)

[66] Localio et al., *supra* note 65, at 457.

[67] *Id.* at 460.

[68] *Id.*

[69] *Id.* at 462-63. *See also* Robert W. Dubois & Robert H. Brook, *Preventable Deaths: Who, How Often, and Why?,* 109 ANNALS INTERNAL MED. 582, 586-588 (1988) (during a chart review of hospital deaths, using a majority rules criterion, twenty-seven percent of hospital deaths were judged definitely or probably preventable. When unanimity was required, the percent of definite or probable deaths dropped by almost half (fourteen percent)).

[70] Localio et al., *supra* note 65, at 457. In the Australian study, there was a fifty-one percent agreement among the reviewers on whether an adverse event was preventable, i.e. a medical error. Wilson et al., *supra* note 43, at 465.

[71] Eric J. Thomas et al., *The Reliability of Medical Record Review for Esti-*

500 records from the original study that had been screened by nurses and referred to a single physician reviewer.[72] Records were submitted to three independent reviewers. The investigators found "moderate to poor inter-rater reliability" among reviewers trying to identify both adverse events and negligent adverse events.[73] The study concluded that the figures for error-related death reported by the IOM are "imprecise" and that the estimate of 44,000 deaths could be approximately fifty percent lower if the study had required agreement by two reviewers rather than the single reviewer, but could be thirty percent higher if the required reviewer confidence about the presence of an adverse event was lower.[74] The authors of the study cautioned researchers in using the data from the UCMPS to estimate the incidence and prevalence of errors.[75]

Adverse events caused by a wrong diagnosis, delay in diagnosis, or inappropriate treatment may be particularly susceptible to disagreement.[76] In these cases, reviewers must not only determine if an adverse event occurred, but also decide if an accurate diagnosis and alternative therapy would have changed the outcome. The more seriously ill the patient, the more difficult it is to assign a cause for a bad outcome.[77] The HMPS researchers warned that determining the cause of death due to adverse events required "a note of caution."[78] Many of the patients in the study were seriously ill and had very shortened life expectancies. Even a terminally ill patient who had a few hours to live was counted as a death resulting from medical injury if the adverse event contributed in part to the patient's death.[79]

The ability of investigators to agree on whether adverse events are preventable or involve negligence varies widely.[80] For instance, in the

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mating Adverse Event Rates, 136 ANNALS INTERNAL MED. 812, 814 (2002) (showing that the lower figure is possibly more sensitive to the reviewer consensus and confidence).

[72] *Id.* at 812. Some experts have noted that using a single physician reviewer to ascertain quality of care deficiencies is unreliable, and have suggested multiple reviewers to increase inter-reviewer reliability. *See, e.g.,* Dubois & Brook, *supra* note 69, at 588 (suggesting that garnering reliable data may require unanimity among three physicians).

[73] Thomas et al., *supra* note 71, at 814.

[74] *Id.*

[75] *Id.*

[76] Localio et al., *supra* note 65, at 462.

[77] *Id. See also* Hayward & Hofer, *supra* note 39, at 419.

[78] Brennan et al., *supra* note 21, at 375.

[79] *Id.* The authors also cautioned against making comparisons based on cost between the number of deaths due to hospital adverse events and deaths due to automobile accidents in which the victims are healthier and younger. *Id.*

[80] *See* Hofer &. Hayward, *supra* note 59, at 328.

HMPS, the authors conceded that the physician reviewers "disagreed frequently about the extent of substandard care."[81] Other studies have similarly shown that professionals cannot agree on what kind of conduct amounts to negligence, let alone medical error.[82] This is not surprising, as our medical malpractice system contemplates the use of dueling experts to testify about acceptable medical standards of care and whether a breach caused the patient's injury or death. In claims of medical error, there are similar complex issues surrounding the quality of care and the cause of events. Often no cause for the error can be found.[83] Studies have shown that patients may experience "adverse events" even with placebo or no treatment.[84] In other cases, although it is evident the health care provider made a mistake (or failed to comply with the standard of care), the complexities of the case reveal multiple or uncertain causes.[85]

The available studies indicate there are substantial problems of bias and unreliability in the retrospective review of medical records. In many cases, the ability to distinguish error from a complication of treatment or the negative outcome of disease is difficult and uncertain. Whether 44,000 or 98,000 is the "right" number is also uncertain.

D. The Taxonomy of Medical Error

No one denies that errors occur in medicine, but "'[y]ou can't measure what you can't define.'"[86] One problem with ascertaining the extent of medical error is the tendency by both laypersons and professionals to confuse or use interchangeable terms, such as adverse event,

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[81] Brennan et al., *supra* note 21, at 374.

[82] *See* Bryan A. Liang, *Assessing Medical Malpractice Jury Verdicts: A Case Study of an Anesthesiology Department*, 7 CORNELL J.L. & PUB. POL'Y 121, 140 (1997) (finding approximately one-half of the physicians involved had a different understanding of appropriate care than the other half). *See also* Brennan et al., *supra* note 21, at 374 (admitting that in the HMPS, judgments regarding negligence had a low degree of reliability).

[83] *See* Sanders & Esmail, *supra* note 57, at 233 (in up to fifty percent of primary care cases, no cause for the error was identified).

[84] *See, e.g.*, U Reuter et al., *Placebo Adverse Events In Headache Trials: Headache as an Adverse Event of Placebo*, 23 CEPHALALGIA 496, 498 (2003) (finding ten to thirty percent of patients experienced headache after placebo and that many of these headaches were mistakenly designated as drug related while the study was still blinded); Frank P. Meyer et al., *Adverse Nondrug Reactions: An Update*, 60 CLINICAL PHARMACOLOGY & THERAPEUTICS 347, 348 (1996) (finding healthy volunteers not administered any drugs often had symptoms similar to reactions associated with drugs).

[85] *See* Hofer & Hayward, *supra* note 59, at 330-31.

[86] Saul N. Weingart & Lisa I. Iezzoni, *Looking for Medical Injuries Where the Light is Bright*, 290 JAMA 1917, 1917 (2003).

medical error, and negligence. There is little consensus as to what constitutes a medical error or even an adverse event.[87]

Error is a loaded term. The IOM defined error as "the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)."[88] As Brennan points out, this is not the generally accepted meaning of error.[89] Merriam-Webster's first definition of error is "an act or condition of ignorant or imprudent deviation from a code of behavior."[90] Common synonyms include mistake, blunder, slip, and lapse.[91] The large number of error-related deaths, combined with the connotation of the word error, led Brennan to conclude that the IOM report left a negative impression that was not warranted by the underlying studies or the progress made in patient safety in recent decades.[92]

Many people, including professionals, equate medical error with negligence.[93] After the IOM report, a national magazine ran the headline, *Doctors' Deadly Mistakes*.[94] Ignoring the lower figure of 44,000, patients and their attorneys often raise the issue of 98,000 dead due to medical error as evidence of "bad doctors" and call for licensing boards to crack down on those who are responsible for such errors.[95] Today, amidst the cries for tort reform, arguments again are surfacing that use the IOM's statistics as evidence that malpractice kills almost 98,000 patients every year and that the solution to the medical malpractice crisis is not fewer suits, but more against the doctors who commit mistakes.[96] Such claims are a misuse of the IOM

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[87] *See, e.g.,* Sanders & Esmail, *supra* note 57, at 233.

[88] IOM REPORT, *supra* note 1, at 28.

[89] Brennan, *supra* note 37, at 1123.

[90] MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 425 (11th ed. 2003).

[91] *Id.* Brennan noted a few other pejorative synonyms: blooper, boner, bungle, goof, miscue, misstep and slip-up. Brennan, *supra* note 37, at 1123.

[92] Brennan, *supra* note 37, at 1123-1124.

[93] Investigators in the HMPS were careful to distinguish error from negligence. *See* Leape et al., *supra* note 56, at 381 ("Negligence occurs not merely when there is error, but when the degree of error exceeds an accepted norm."). Other professionals may not understand the difference. *See* Leape *supra* note 4, at 1851 (stating a common belief by physicians is that an error is the result of negligence).

[94] Michael D. Lemonick, *Doctors' Deadly Mistakes*, TIME, Dec. 13, 1999, at 74.

[95] *E.g.,* Leo V. Boyle, *Keeping Patients and Our Wallets Safer* (Jan. 28, 2002), *available at* http://www.atla.org/public/columns/wallets.aspx:
> We can try to stop malpractice from occurring in the first place. According to the Institute of Medicine's report To Err is Human, up to 98,000 patients die in hospitals per year victims of preventable medical errors. . . . No one wants good doctors to have their rates raised because of a few bad doctors' medical malpractice.

[96] *E.g., Patient Access Crisis: The Role of Medical Litigation, Before the S.*

report as its key finding was that systems, not individual providers, were at fault for the vast majority of medical errors.[97] The IOM stressed that the primary means to prevent error is not to increase individual accountability but to shed the shame and blame system that places responsibility for error on individual health care providers.[98] Recognizing that human error in any system is unavoidable and that today's complex medical system provides the opportunity for errors to occur, the IOM called for nothing less than a redesign of the health care system.[99] Yet, the IOM could not have been naïve as to its choice of the term error, with its pejorative connotation and its potential for misuse by those with a political or economic agenda. Despite the IOM's focus on system failures, the term error suggests blame.

The IOM distinguished adverse events from errors by whether they were preventable. But there often is no fine line to guide a physician in determining whether an undesirable result is preventable. Some errors may increase the risk of a bad outcome, but leave open to debate what caused the outcome. For example, if a physician delays in diagnosing cancer and the patient dies, it may be difficult to decide if the death is due to the delay or the cancer. Absent error, the patient may have died from the burden of disease.

Not all professionals agree that preventable adverse events imply error. Brennan, in particular, took issue with the IOM's equating pre-

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Comm. on the Judiciary and the S. Comm. on the Health, Educ., Labor, and Pensions, 108th Cong. 14 (2003) (statement of Linda McDougal, Woodville, WI) ("Medical malpractice kills as many as 98,000 Americans each year. . . . A good start would be to discipline health care providers who repeatedly commit malpractice."); Michigan Trial Lawyers Association, *Medical Malpractice: Medical Malpractice Insurance–Why the Price Hikes?, at* http://mtla.net/news4.html ("Medical malpractice is now the eighth leading cause of death in America."); Academy of Florida Trial Lawyers, AFTL Position Papers, *Medical Malpractice Update, available at* http://www.aftl.org/legislativeUpdates_positionPapers_detail.asp?ID=11 (last visited Feb. 5, 2005) ("The IOM examined actual medical charts for a wider range of medical errors, resulting in the conclusion that as many as 98,000 Americans are killed every year by medical malpractice in hospitals.").

[97] IOM REPORT, *supra* note 1, at 49 ("The problem is not bad people; the problem is that the system needs to be made safer."). A striking example of a system error occurred in the well-publicized death of Jessica Santillan at Duke University Medical Center. She was treated by some of the best transplant physicians in the world, but died due to a breakdown in the system to ensure she received a heart and lung transplant from a donor with compatible blood type. *See e.g.,* Edward W. Campion, *A Death at Duke,* 348 NEW ENG. J. MED. 1083 (2003).

[98] *See* IOM REPORT, *supra* note 1, at 49.

[99] Since its 1999 report, the IOM has issued two other comprehensive reports designed to spur overhaul of the health care system: COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001); PATIENT SAFETY, *supra* note 45.

ventable adverse events with errors. In the HMPS, certain events were labeled preventable even though there was no evidence that a mistake was made.[100] What is preventable is also constrained by cost. Adverse events that may be averted only at enormous cost may not be truly preventable given the capabilities (and realities) of the modern health care system.[101]

Most experts concede that it is often difficult to distinguish adverse events caused by error from those caused by the patient's medical condition.[102] Although it is fairly straightforward to conclude that giving a patient the wrong drug or operating on the wrong leg is an error, other mistakes, such as a "wrong" diagnosis, are not so easily categorized. Harm can occur from many interrelated factors, including disease burden, age, co-existing conditions, and even bad luck.[103]

In an article aptly titled, *What is an Error?*,[104] the authors posit four scenarios in an attempt to answer their question:

> A patient scheduled for an amputation of the right leg has the left leg removed.
> A patient is discharged from the hospital after myocardial infarction without having a β-blocker prescribed.[105]
> A hospitalized patient with multiple medical problems dies of cardiac arrest. The endotracheal tube inserted during the resuscitation is found to be in the right bronchus.

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[100] Brennan, *supra* note 37, at 1123. In his use of the example of postoperative hemorrhage, Brennan noted that with proper technique most such hemorrhages can be prevented. However, surgeons can expect that a certain number will occur even with the best surgical technique. All postoperative hemorrhages were labeled in the HMPS as preventable even if there was no apparent mistake by the surgeon. These cases were considered errors in the IOM report. *Id.*

[101] *Id.* Brennan used the following illustration: If every patient were tested for drug allergies before being given antibiotics, most drug reactions would be prevented. Thus, allergic reactions to drugs could be considered preventable. But it is not cost-effective to test all patients for allergies. *Id.*

[102] *See* UNITED STATES GEN. ACCT. OFFICE, REPORT TO CONGRESSIONAL REQUESTORS, ADVERSE DRUG EVENTS: THE MAGNITUDE OF HEALTH RISKS IS UNCERTAIN BECAUSE OF LIMITED INCIDENCE DATA 26 (Jan. 2000), *available at* http://www.gao.gov/archive/2000/he00021.pdf [hereinafter GAO REPORT] ("It can often be difficult to distinguish adverse events caused by a drug from those caused by the medical conditions that the drugs are intended to treat.").

[103] Weingart & Iezzoni, *supra* note 86, at 1917.

[104] Timothy P. Hofer et al., *What is an Error?*, 6 EFFECTIVE CLINICAL PRAC. 261, 262 (2000).

[105] A β-blocker, or beta-blocker, is a drug that blocks beta-adrenergic receptors of sympathetic impulses. DORLAND'S ILLUSTRATED MED. DICTIONARY 38 (30th ed. 2003). In this instance it would be used to reduce the heart rate and muscle contraction and to lower blood pressure.

While waiting for correction of coagulopathy, a patient with overwhelming infection, multiorgan failure, and pleural effusion dies before having thoracentesis[106] to check for empyema.[107]

The first two incidents are clearly error. The authors note, however, that the first event, a "wrong-site" surgery, is a more egregious error than the second, although the second is more common and the patient is more likely to die without the beta-blocker.[108] They question whether the third scenario should even be called an error because it did not cause harm, and certainly not the patient's death from cardiac arrest. Even though the endotracheal tube was misplaced, it probably had no affect on the outcome.[109] The fourth incident represents a debate about whether the intervention, thoracentesis, should be used in a patient with bleeding. The authors note that the outcome might affect the answer to whether this was an error: "[i]If the patient died without having the procedure, the omission might be labeled an error: "[i]f the patient died of a bleeding complication after thoracentesis, the decision to do the procedure might be considered an error."[110] As these examples demonstrate, in many cases there is no easy categorization of the event.

E. Reliability of Estimates of Medical Error from Other Studies

Recently, a study performed by an Internet health care quality ratings company, HealthGrades, Inc., received considerable media attention.[111] Using sixteen of twenty AHRQ indicators,[112] HealthGrades reviewed Medicare discharge data from all fifty states and the District of Columbia. Contending that the IOM underestimated the number of

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[106] Thoracentesis is aspiration to remove fluid from the pleural cavity (space between the lining of the outside of the lungs (pleura) and the wall of the chest). *Id.* at 1904.

[107] Empyema is a collection of pus in the pleural space. *Id.* at 607.

[108] Hofer et al., *supra* note 104, at 262.

[109] *Id.*

[110] *Id.*

[111] HEALTHGRADES STUDY, *supra* note 15.

[112] The Agency for Healthcare Research and Quality (AHRQ) was established in 1989 as the Agency for Health Care Policy and Research. Part of the U.S. Department of Health and Human Services, AHRQ is charged with supporting research designed to improve the quality, safety and effectiveness of health care. AHRQ PROFILE ADVANCING EXCELLENCE IN HEALTH CARE, *at* http://www.ahrq.gov/about/profile.htm (last visited Feb. 5, 2005). AHRQ annually publishes patient safety indicators. AHRQ QUALITY INDICATORS: GUIDE TO PATIENT SAFETY INDICATORS, AHRQ PUB. NO. 03-R203 REVISION 2 (Oct. 22, 2004), *available at* http://www.qualityindicators.ahrq.gov/downloads/psi/psi_guide_rev3.pdf.

deaths due to medical error and that safety had not improved in the past five years, HealthGrades concluded that more than 195,000 potentially preventable deaths occur each year as a result of hospital error.[113] The reliability of this study is questionable. First, it was not published in a peer-reviewed medical journal, but on the website that markets HealthGrades' hospital-rating service.[114] The project used administrative abstracts, not patient charts, as a basis for its study.[115] Use of administrative data to identify quality problems is fraught with reliability problems.[116]

The usefulness of the HealthGrades study is also hampered by its extrapolation of Medicare data to the general population. Elderly patients are known to suffer more adverse events than younger patients because they are sicker, have multiple diseases or co-morbid conditions and are subjected to more complex procedures.[117] In addition, the overwhelming majority of deaths of Medicare patients in the HealthGrades report was due to "failure to rescue," defined by the study as failure to diagnose and timely treat a complication.[118] According to the AHRQ, however, the failure to rescue indicator excludes anyone aged seventy-five years and older,[119] which calls into question the use of this instrument in a population of Medicare patients who are generally over sixty-five. In an interview concerning the HealthGrades report, Leape also points out that failure to rescue is not an accepted standard for calculating medical errors.[120]

The study also fails to acknowledge the limitations placed by AHRQ on use of its patient safety indicators, including the difficulty

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[113] Press Release, In-Hospital Deaths from Medical Errors at 195,000 Per Year, HealthGrades Study Finds (July 27, 2004), *available at* http://www.healthgrades.com/PressRoom/index.cfm?fuseaction=PressReleases (quoting Dr. Samantha Collier).

[114] HealthGrades: The Quality Care Experts, *at* http://www.healthgrades.com (last visited Jan. 28, 2005).

[115] HEALTHGRADES STUDY, *supra* note 15, at 9.

[116] *See* Weingart & Iezzoni, *supra* note 86, at 1918; Patrick S. Romano & David H. Mark, *Bias in the Coding of Hospital Discharge Data and Its Implications For Quality Assessment,* 32 MED. CARE 81 (1994).

[117] *See* Eric J. Thomas & Troyen A. Brennan, *Incidence and Types of Preventable Adverse Events in Elderly Patients: Population Based Review of Medical Records,* 320 BRIT. MED. J. 741, 742-43 (2000).

[118] HEALTHGRADES STUDY, *supra* note 15, at 3-4.

[119] The AHRQ defines failure to rescue somewhat differently. The indicator is intended to identify those who die in the hospital following a complication, but excludes patients age seventy-five and older. AHRQ QUALITY INDICATORS: GUIDE TO PATIENT SAFETY INDICATORS, *supra* note 112, at 33.

[120] Amanda Gardner, *U.S. Hospital Medical Errors Kill 195,000 Annually: Report,* HEALTHDAY (July 27, 2004), *at* http://www.forbes.com/lifestyle/health/feeds/hscout/2004/07/27/hscout520330.html (last visited Feb. 14, 2005).

in extricating those adverse events in which error may have occurred from those which occurred through no fault of the health care professional.[121] AHRQ recommends that its safety indicators be utilized only as a *screening* mechanism for potentially preventable adverse events.[122]

In a peer-reviewed study published in 2003 in the Journal of the American Medical Association, researchers – who also used AHRQ patient safety indicators – examined 7.45 million abstracts for inpatient stays in 2000 from 994 hospitals and estimated that "medical injuries" may cause 32,591 deaths annually.[123] This study was much larger than the HMPS or UCMPS and involved records from approximately twenty percent of all nonfederal acute-care hospitals in the United States.[124] However, because they were using administrative abstracts, the authors conceded they were not able to make a distinction between medical injuries that were preventable from those that were treatment related.[125]

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[121] *See* AHRQ QUALITY INDICATORS: GUIDE TO PATIENT SAFETY INDICATORS, *supra* note 112, at 23:
> The information about the ability of these data to distinguish adverse events in which no error occurred from true medical errors is limited. A number of factors—such as the heterogeneity of clinical conditions included in some codes, lack of information about event timing available in these data sets, and limited clinical detail for risk adjustment—contribute to the difficulty in identifying complications that represent medical error or may be at least in some part preventable.

[122] *Id.* (recognizing that the AHRQ PSI's are limited in their scope and only offer information and guidance). The nonspecificity of administrative data and most of the AHRQ patient safety indicators was confirmed by a technical study commissioned by the AHRQ in 2002:
> Few adverse events captured by administrative data are unambiguous enough for a great deal of certainty that every case identified reflects medical error. Most adverse events identified by the PSIs [patient safety indicators] have a variety of causes in addition to potential medical error leading to the adverse event, including underlying patient health and factors that do not vary systematically. Clinician panelists rated only two of the accepted indicators as very likely to reflect medical error: 1.) "Transfusion reaction" and 2.) "Foreign body left in during a procedure". . . . All other accepted indicators identify adverse events which represent a spectrum of likelihood of reflecting either medical error or potentially preventable complications of care, but cannot be expected to identify only cases in these categories.

Agency for Healthcare Research and Quality, *Measures of Patient Safety Based on Hospital Administrative Data – The Patient Safety Indicators*, AHRQ Publication No. 02-0038 8 (Aug. 2002), *available at* http://www.ahrq.gov/clinic/tp/hospdatp.htm.
[123] Chunliu Zhan & Marlene R. Miller, *Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization*, 290 JAMA 1868, 1872 (2003).
[124] *Id.* at 1869.
[125] Chunliu Zhan & Marlene R. Miller, *Definitions of Medical Injuries, Let-*

Other clinical studies have produced wide variation in the number of medical errors. A review of the literature regarding errors in primary care found estimates ranging from five to eighty per 100,000 consultations.[126] An observational study of general surgical units in a Chicago hospital concluded that 45.8% of patients suffered an adverse event.[127] The prevalence of adverse drug events among hospital inpatients ranges from 0.7% to 25%.[128] Estimates vary widely as to how many adverse drug events are preventable.[129] Hospital based studies on adverse drug events may seriously underestimate their incidence because large numbers of people take prescription medications on an outpatient basis. One study found adverse drug events in twenty-five percent of the outpatients surveyed, of which eleven percent were allegedly preventable.[130]

There are many reasons for the wide discrepancy in the empirical data as to the prevalence of medical error. Direct comparison of numbers is problematic because investigators use different research methods. Many studies, including those relied on by the IOM, use chart review to determine if an error occurred. As discussed previously, retrospective analysis of medical records is known to be less than accurate. Using patient safety indicators or other administrative data to identify medical errors is an insensitive way to capture error.[131] Observational studies, which usually capture a higher rate of adverse events and errors, are costly and limited by necessity to a small population.[132]

Studies are conducted at different times and the passage of years may skew the data.[133] Divergent populations are used that do not in-

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ters, In Reply, 291 JAMA 304 (2004). Accordingly, it can be assumed that the number of error-related deaths each year would be less than the 32,000 deaths found by the study.

[126] Sanders & Esmail, *supra* note 57, at 232.

[127] Andrews et al., *supra* note 40, at 311. The numbers in this study cannot be directly compared to other studies because the authors counted events in which the patient suffered no harm, i.e., the event was not "adverse." *Id.* at 310.

[128] B Dean, *Adverse Drug Events: What's the Truth?,* 12 QUALITY & SAFETY IN HEALTH CARE 165 (2003).

[129] David Classen, *Medication Safety: Moving From Illusion to Reality*, 289 JAMA 1154, 1155 (2003) (citing to literature showing thirteen to seventy percent of medication errors are preventable).

[130] Tejal K. Gandhi et al., *Adverse Drugs in Ambulatory Care*, 348 NEW ENG. J. MED. 1556, 1559-60 (2003).

[131] *See supra* note 116 and accompanying text.

[132] An observational study uses observers on hospital units to record adverse events or medical errors as they occur.

[133] For example, the HMPS found an adverse drug event rate of 0.7% in hospital patients, compared to rate of 6.5% documented in 1995. David W. Bates et al., *Relationship between Mediation Errors and Adverse Drug Events*, 10 J. GEN.

vite easy comparison. Some clinical reports involve only inpatients in intensive care units or surgical units, while others focus on the general hospital population or outpatients.[134] Many studies focus on specific populations, such as the elderly or children.[135] While some research-ers count only those errors or events that cause injury, others tabulate errors that are potentially harmful.[136] A drawback to extracting medi-cal error from studies of preventable adverse drug events is that many include patient error or misuse as well as provider error.[137]

Finally, there is no consistent definition of adverse event or error across the studies.[138] Significant variations exist in nomenclature, including the frequent interchangeability of the terms adverse event and error.[139] Add to these factors the difficulty in determining whether an error is causally related to the harm suffered by patient, and it is easy to understand why the clinical estimates of medical error are uncertain.[140]

Whatever the true figure of preventable deaths, the divergent re-sults of the studies sound a note of caution in measuring medical er-ror. Some have called it "shortsighted" to focus solely on the accu-racy of the number of deaths due to error when the IOM served the more important function of focusing much-needed attention on the

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INTERNAL MED. 199 (1995). The difference may be related, in part, to the increase in the number of medications available, heightening the possibility of an adverse drug event.

[134] *E.g.*, Andrews et al., *supra* note 40, at 311 (studying surgical and ICU patients); David J. Cullen et al., *Preventable Adverse Drug Events in Hospitalized Patients: A Comparative Study of Intensive Care and General Care Units*, 25 CRITICAL CARE MED. 1289 (1997) (finding the rate of preventable adverse events in an ICU twice the rate of a non-ICU).

[135] *See generally* Jerry H. Gurwitz et al., *Incidence and Preventability of Adverse Drug Events Among Older Persons in the Ambulatory Setting*, 289 JAMA 1107 (2003) (presenting data from a study focusing on elderly patients).

[136] Andrews et al., *supra* note 40, at 310 (including adverse events even if they did not result in harm). In contrast, in the HMPS, to count as an adverse event, the patient must have suffered an injury or death. *See* Brennan et al., *supra* note 21 and accompanying text.

[137] *See, e.g.*, Gurwitz et al., *supra* note 135, at 1112-13 (lapses in patient adherence constituted twenty-one percent of preventable errors).

[138] *See* Dean, *supra* note 128, at 165 (discussing the term "harm" within the definition of "adverse event" as being a cause of discrepancies).

[139] *See, e.g.*, Andrews et al., *supra* note 40, at 312 (incorrectly stating the HMPS found *errors* (not adverse events) in 3.7% of hospital charts).

[140] Adverse drug events may be less susceptible to judgment calls, particularly when detected by computer software programs. *See* David W. Bates et al., *Policy and the Future of Adverse Event Detection Using Information Technology*, 10 J. AM. INFORMATICS ASS'N 226 (2003).

problem of medical error.[141] However, when health care professionals and analysts argue whether the IOM estimates of deaths due to error are exaggerated or conservative, it is difficult to arrive at a reasonably accurate baseline by which we can determine if providers have achieved or can ever achieve the IOM's goal of a fifty percent reduction in medical error.

III. REPORTING SYSTEMS: PROPER TREATMENT FOR AN AILING SYSTEM?

To achieve the goal of reducing errors, the errors must first be identified. A system that relies on facilities and professionals to report events is one way to identify, track and monitor the incidence of medical error. If the scientific studies raise questions about the accuracy of the number of preventable errors, can we look to spontaneous reporting systems to give us a baseline and to measure a decline in medical errors with some degree of reliability? Looking at current systems, the answer to this question is, unfortunately, "No."

The IOM envisioned two parallel reporting systems: a nationwide, mandatory system at the state level for reporting deaths and serious injuries due to error,[142] and confidential, non-regulatory, voluntary systems for reporting other mistakes, including "near misses."[143] These dual systems have differing purposes. The primary aim of a system where reporting is mandatory is to hold providers accountable for mistakes, including public disclosure and possible penalties in specific cases.[144] On the other hand, the focus of voluntary systems is on identifying systemic errors and vulnerabilities before they occur.[145] For near misses or minimal harm, the IOM felt data should be protected from disclosure, particularly in litigation.[146]

Since the IOM report, there has been continuing debate in the literature as to whether reporting systems should be voluntary or mandatory.[147] This article accepts the IOM's recommendation for state

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[141] Thomas et al., *supra* note 71, at 814.

[142] The IOM contemplated that mandatory reporting would be done initially by hospitals, with the system eventually expanding to other institutions and ambulatory care settings. IOM REPORT, *supra* note 1, at 9.

[143] *Id.* at 9-10. A "near miss" is an error that results in no harm. *Id.* at 87.

[144] *Id.* at 8.

[145] *Id.* at 87.

[146] *Id.* at 110 ("Protecting such information encourages disclosure of problems and a proactive approach to correcting problems before serious harm occurs").

[147] *See* Bryan A. Liang, *The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in the Health-Care and Legal Systems*, 29 J.L. MED. & ETHICS 346, 359, n.167 (2001) (advocating voluntary reporting); Barry R. Furrow, *Medical Mistakes: Tiptoeing Toward Safety*, 3 HOUS. J. HEALTH L. & POL'Y 181, 204-

mandatory systems, but rejects its premise that providers should be penalized for their errors or that data should be provided to the public. A system that requires health care providers to report but ensures the confidentiality of data satisfies both the need for regulatory oversight and providers' concerns about the disclosure of errors.

Ultimately, professionals and organizations will not report under either voluntary or mandatory systems if it is not in their best interests. There are risks for the professional and the facility in making errors visible and the collection of accurate data under both systems suffers when patient safety information is publicly available. To date, the compilation of error data under both mandatory and voluntary systems has been problematic, primarily due to provider underreporting.

A. The Problem of Underreporting

Despite the existence of multiple reporting systems, underreporting of adverse events and medical error is widely recognized in the literature.[148] The reasons for this include professionals' and facilities' concerns about adverse publicity, fear of litigation and professional sanctions, burden of reporting, uncertainty about what is required to be reported and lack of feedback.[149]

The myth of professional infallibility looms large in reporting schemes. Admitting mistakes, let alone reporting them, is not ingrained in the culture of medicine.[150] Professionals feel that admitting error will lead to colleagues censuring them or regarding them as incompetent.[151] These fears are often justified since "[e]ven a minor

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06 (2003) (advocating mandatory reporting).

[148] *See* Melissa Chiang, Note, *Promoting Patient Safety: Creating a Workable Reporting System*, 18 YALE J. ON REG. 383, 393 (2001); Liang, *supra* note 148, at 351-53; Marshall B. Kapp, *Medical Error Versus Malpractice*, 1 DEPAUL J. HEALTH CARE L. 751, 764 (1997).

[149] MIMI MARCHEV ET AL., NATIONAL ACADEMY FOR STATE HEALTH POLICY, HOW STATES REPORT MEDICAL ERRORS TO THE PUBLIC: ISSUES AND BARRIERS 20 (2003). *See also supra* note 147.

[150] *See* Leape, *supra* note 4, at 1851 ("Physicians are expected to function without error."). *See also* J Bryan Sexton et al., *Error, Stress and Teamwork in Medicine and Aviation: Cross Sectional Surveys*, 320 BRIT. MED. J. 745, 747 (2000) (stating seventy-six percent of staff in the intensive care unit studied felt errors were not discussed because of personal reputation).

[151] Leape, *supra* note 4, at 1852. *See also* Joan Osborne et al., *Nurses' Perceptions: When is it a Medication Error?*, 29 J. NURSING ADMIN. 33, 37 (1999) (finding that eighty-six percent of nurses thought medication errors were not reported because nurses were afraid of the reaction from supervisors or coworkers).

error can place the physician's entire career in jeopardy if it results in a serious bad outcome."[152]

Concern over the legal protection of data, including the lack of confidentiality of the reports, is a substantial impediment.[153] Professional associations criticized the IOM's call for a mandatory reporting system because it was perceived as punitive and a continuation of the blaming of individuals for medical errors, and not the systems in which they worked.[154] This may have been an overreaction to the IOM's report as the stated purpose of mandatory reporting is to hold hospitals and other facilities, not health care workers, accountable for serious errors.[155] Nevertheless, the concern by professionals over increased liability exposure is real. Although there is scant data on the relationship between acknowledging errors and malpractice claims, it is generally acknowledged that the mere *fear* of litigation due to disclosure of data is the greatest barrier to reporting.[156]

In addition to providers' concern about fostering lawsuits through disclosure of errors is the apprehension that safety data could be subject to discovery in litigation.[157] Legal protection for reports of adverse incidents and errors varies among states and data provided to internal quality assurance committees or patient safety organizations may be discoverable.[158] In particular, peer review statutes provide

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[152] Leape, *supra* note 4, at 1852.

[153] *See* Chiang, *supra* note 148, at 396; Thomas R. McLean, *The Implications of Patient Safety Research & Risk Managed Care*, 26 S. ILL. U. L.J. 227, 235-36 (2002) (arguing that the IOM call for mandatory reporting will increase medical malpractice litigation and sanctions against providers).

[154] *See, e.g., Medical Mistakes: Joint Hearings Before the Senate Subcomm. On Labor, Health and Human Services, and Education, and Related Agencies*, 106th Cong. 28 (1999) (statement of Nancy Dickey, Immediate Past President, American Medical Association) (expressing "serious concern" with the IOM's recommendation for a mandatory reporting system).

[155] *See* IOM REPORT, *supra* note 1, at 86-87.

[156] Mimi Marchev, *National Academy for State Health Policy, Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears* (Nat'l Acad. for State Health Policy, Portland, ME), Dec. 2003 at 2.

[157] *See* Chiang, *supra* note 148, at 396-401.

[158] *Id.* The tension between discovery of safety reports and physicians' fear of the use of reports in malpractice litigation is starkly illustrated by the state constitutional amendment Floridians approved in November 2004. The amendment, supported by the Academy of Florida Trial Lawyers, allows patients to have access to any record of an adverse medical event (without patient identifiers) kept by a provider or facility. Florida Dep't of State Division of Elections Initiatives/Amendments/Revisions, *Patients' Right to Know About Adverse Medical Incidents*, *available at* http://election.dos.state.fl.us/initiatives/initiativelistBallot.asp (last visited Nov. 15, 2004). Such records were previously protected from disclosure under Florida law. FLA. STAT. ANN. § 395.0197 (West. Supp. 2005) (mandating the establishment of an internal risk management program to address the reporting of

inconsistent protection. For example, in a malpractice claim against Cook County Hospital in which a patient had been accidentally disconnected from a ventilator, the court allowed the discovery of incident reports submitted to a hospital peer review committee as well as recommendations for corrective action of the committee.[159]

Physicians and facility employees, primarily nurses, are also concerned about job security and the use of reports in disciplinary and adverse employment actions.[160] The tension between reporting errors and their possible punitive effect has not gone unnoticed by state lawmakers. For example, when the New Jersey legislature enacted a mandatory reporting statute in 2004, it explicitly recognized the problem of underreporting: "[f]ear of sanctions induces health care professionals and organizations to be silent about adverse events, resulting in serious under-reporting." [161]

Institutions' fear of adverse publicity and its impact on revenue makes them hesitate to report.[162] One study indicates they may have reason to be concerned about loss of patients after negative publicity. Media reports about adverse events at Veteran's Administration (VA) hospitals were associated with lower enrollment rates.[163]

Finally, professionals complain there is seldom any change seen as a result of the reporting of adverse events or errors. In a survey of state reporting systems, only two states used the data to develop quality improvement projects.[164] This gives professionals a "what's the use" excuse to avoid reporting.

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adverse medical events).

[159] Chicago Trust Co. v. Cook County Hosp., 698 N.E.2d 641(Ill. App. Ct. 1998). *See also* Adams v. St. Francis Reg'l Med. Ctr., 955 P.2d 1169 (Kan. 1998) (holding records in possession of the Board of Nursing, a third party, were discoverable); Columbia/HCA Healthcare Corp. v. Eighth Judicial Dist. Court of the State of Nevada, 936 P.2d 844 (Nev. 1997) (finding occurrence reports prepared by hospital after incident were not protected under hospital peer review statute). *But see* Hofflander v. St. Catherine's Hosp., Inc., 664 N.W.2d 545, 580 (Wis. 2003) (holding that JCAHO survey documents were immune from disclosure under peer review statute).

[160] *See* McLean, *supra* note 153, at 235-36.

[161] N.J STAT. ANN. § 26:2H-12.24(e) (2005), *available at* http://lis.njleg.state.nj.us/cgi-bin/om_isapi.dll?clientID=61725695&Depth=4&TD= WRAP&advquery=%22patient%20safety%20act%22&headingswithhits=on&infobas e=statutes.nfo&rank=&record={9DB1}&softpage=Doc_Frame_Pg42&wordsaroundh its=2&zz= (last visited Apr. 14, 2005).

[162] *See* MARCHEV ET AL., *supra* note 149, at 20.

[163] William B. Weeks & Peter D. Mills, *Reduction in Patient Enrollment in the Veterans Health Administration After Media Coverage of Adverse Medical Events*, 29 JOINT COMMISSION J. QUALITY & SAFETY 652 (2003).

[164] JILL ROSENTHAL ET AL., STATE REPORTING OF MEDICAL ERRORS AND ADVERSE EVENTS: RESULTS OF A 50-STATE SURVEY 15 (2000) (stating that only Mas-

The IOM recognized the legal and cultural barriers to reporting, but nevertheless recommended that, to ensure accountability, reports of serious injury or death be made public.[165]   Some commentators have questioned why the IOM would recommend a confidentiality rule for near misses but not for situations in which errors lead to serious harm or death. If fear of litigation is the primary reason for underreporting, providers need more protection when reporting an incident involving death or serious disability. Hospitals and other health care providers have less reason to fear the reporting of incidents where a patient suffers little or no harm because such incidents are unlikely to result in litigation.[166]

With a few exceptions, states with mandatory reporting systems have generally not accepted the IOM's recommendation of public access to reports, viewing the problem of underreporting a greater concern than accountability.[167] The majority of states have statutory exemptions from discovery or other legal protection of reported data.[168] Those that provide public access to information often release only aggregate data,[169] and the trend in recent legislation is toward greater protection of data.[170] There is a lack of uniformity in the protection of reports, however, and federal legislation shielding patient safety data from disclosure is a crucial next step.[171]

B. A Review of Federal and Private Reporting Systems

1. Federal Legislation

The IOM recommended several Congressional initiatives. First, it encouraged Congress to create a Center for Patient Safety within AHRQ that would establish and monitor national goals for patient safety, with annual reports to Congress and the President.[172] As envisioned by the IOM, the Center for Patient Safety would develop and

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sachusetts and Ohio use data to develop quality improvement projects).

[165] IOM REPORT, *supra* note 1, at 10.

[166] Jeffrey O'Connell & Patrick B. Bryan, *More Hippocrates, Less Hypocrisy: "Early Offers" As a Means of Implementing the Institute of Medicine's Recommendations on Malpractice Law*, 15 J.L. & HEALTH 23, 33 (2000-01).

[167] *See* Marchev, *supra* note 156, at 6 (describing state legal protections against disclosure of reported data includes exemptions to open records acts, anonymous reporting, nondiscoverability of data, and peer review protections.).

[168] *See* MARCHEV ET AL., *supra* note 149, at 12.

[169] *Id.* Colorado is the only state that currently makes individual incident reports available on a public website. *Id.* at 17.

[170] *See* Marchev, *supra* note 156, at 7.

[171] See discussion Part III. C.

[172] IOM REPORT, *supra* note 1, at 7.

fund research activities to identify errors and to improve patient safety.[173]

Second, a role was expected for the federal government to assist states in implementing mandatory reporting systems. The IOM recommended that Congress designate the National Forum for Health Care Quality Measurement and Reporting as the entity responsible for developing a core set of reporting standards to be used by the states; require all providers to report standardized information; and provide funds and technical expertise to states that establish mandatory systems.[174] Should a state choose not to have a mandatory system, the IOM suggested the Department of Health and Human Services be designated as the responsible entity.[175]

Third, the IOM recognized that for voluntary reporting of medical error to be effective, health care providers would need to be reassured that information would be kept confidential and not be used against them in malpractice or disciplinary proceedings.[176] The IOM called on Congress to establish a national database and to pass legislation to extend peer review protection for data related to patient safety and quality improvement. [177]

Since 2000, a host of bills have been introduced in Congress to improve patient safety in accordance with the IOM's recommendations.[178] None of the bills have been enacted, although the House and

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[173] *Id.*

[174] *Id.* at 9. The National Forum for Health Care Quality Measurement and Reporting is the umbrella organization of The National Quality Forum. *See infra* note 274.

[175] IOM REPORT, *supra* note 1, at 9.

[176] *See id.* at 10.

[177] *Id.* at 9-10.

[178] *See* Medical Error Reduction Act of 2000, S. 2038, 106th Cong. (2000) (seeking to reduce accidental injury and death resulting from medical mistakes); Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000, S. 2378, 106th Cong. (2000) (amending the Social Security Act to improve the safety of the Medicare and Medicaid programs); Patient Safety and Errors Reduction Act, S. 2738, 106th Cong. (2000) (amending the Public Health Service Act to reduce medical mistakes and medication-related errors); Voluntary Error Reduction and Improvement in Patient Safety Act, S. 2743, 106th Cong. (2000) (developing an infrastructure for creating a national voluntary reporting system); Patient Safety and Quality Improvement Act, S. 2590, 107th Cong. (2002) (providing for the improvement of patient safety and reducing the incidence of events adversely affecting patient safety); Patient Safety Improvement and Medical Injury Reduction Act , S. 3029, 107th Cong. (2002) (seeking to improve patient safety and reduce the incidence of accidental medical injury); Patient Safety Improvement Act of 2002, H.R. 4889, 107th Cong. (2002) (attempting to amend the Social Security Act to improve patient safety); Patient Safety and Quality Improvement Act, H.R. 5478, 107th Cong. (2002) (providing for the improvement of patient safety and reducing the incidence of events adversely

Senate each passed similar patient safety legislation in 2004.[179] The Senate version was reintroduced in March 2005, and provides that private or public patient safety organizations certified by the Secretary of the Department of Health and Human Services may submit nonidentifiable information to a network of national databases established by the Secretary.[180] All information reported to a patient safety center would be privileged and protected from subpoena or discovery in legal proceedings.[181]

2. Federal Agencies

A number of federal agencies have established reporting systems, most of which predate the IOM report. Under the Food and Drug Administration's (FDA) MedWatch program, professionals and patients voluntarily report serious adverse reactions, product problems or medication errors associated with an FDA-regulated drug or device.[182] The FDA and Centers for Disease Control (CDC) jointly administer the Vaccine Adverse Event Report System (VAERS), which collects and analyzes data from reports of adverse events following vaccination.[183] Rather than focusing solely on medication errors, these data-

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affecting patient safety); Better HEALTH Act of 2003, S. 1374, 108th Cong. (2003) (providing health care professionals with immediate relief from increased medical malpractice insurance costs and dealing with the root causes of the current medical malpractice insurance crisis); Health Care Coverage Expansion and Quality Improvement Act of 2003, S. 10, 108th Cong. (2003) (protecting consumers in managed care plans and providing for parity with respect to mental health coverage); Patient Safety Improvement Act of 2003, H.R. 877, 108th Cong. (2003) (seeking to improve patient safety by amending the Social Security Act).

[179] Patient Safety and Quality Improvement Act, S. 720, 108th Cong. (2004) (Engrossed Amendment as Agreed to by Senate); Patient Safety and Quality Improvement Act, H.R. 663, 108th Cong. (2004) [hereinafter referred to as House version]. On July 22, 2004, the Senate incorporated S. 720 in H.R. 663 as an amendment and passed H.R. 663 in lieu of S. 720. Patient Safety and Quality Improvement Act of 2004, H.R. 663, 108th Cong. (2004) (Engrossed Amendment as Agreed to by Senate) [hereinafter referred to as Senate version], *available at* http://thomas.loc.gov.

[180] Patient Safety and Improvement Act of 2005, S. 544, 109th Cong., § 923 (2005).

[181] *Id.* § 922(a)(1)-(2). *See* discussion *infra* Part III.C.

[182] U.S. FOOD AND DRUG ADMINISTRATION, MEDWATCH, THE FDA SAFETY INFORMATION AND ADVERSE REPORTING PROGRAM, *at* http://www.fda.gov/medwatch (last visited Jan. 29, 2005). Although health care professionals and consumers voluntarily report to MedWatch, manufacturers are required to report all adverse events associated with drugs. *See* Postmarketing Reporting of Adverse Drug Experiences, 21 C.F.R. § 314.80 (c) (2004) (establishing the reporting requirements for drug manufacturers).

[183] U.S. FOOD AND DRUG ADMINISTRATION, VACCINE ADVERSE EVENT REPORT SYSTEM (VAERS), FREQUENTLY ASKED QUESTIONS, *at* http://www.fda.gov/cber/vaers/faq.htm (last visited Jan. 29, 2005).

bases are primarily concerned with adverse reactions to drugs and vaccines or product problems.[184] For example, "[s]ince 1990, VAERS has received over 123,000 reports, most of which describe mild side effects such as fever."[185] The FDA monitors medication errors through MedWatch and other reports that are forwarded to the FDA.[186] The FDA receives 300,000 adverse drug reports each year, of which only about 3,000 are cited as medication error.[187] A review of case reports over a six-year period revealed that almost ten percent of medication errors reported to the FDA involved fatalities.[188] However, the investigators concluded that only about one-half of the deaths were related to an error, while the rest were possibly related or unrelated.[189]

The Veteran's Administration (VA), often held up as a model for hospital safety initiatives,[190] has both internal and external systems for reporting adverse events.[191] Each VA facility is required to have a reporting system for adverse events and close calls (also known as "near misses").[192] An analysis must be conducted to determine the

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[184] An adverse drug reaction is often distinguished from an adverse drug event. *See* Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients, A Meta-Analysis of Prospective Studies*, 279 JAMA 1200, 1200 (1998) (stating an adverse drug event includes errors in administration while an adverse drug reaction is an injury due to a properly prescribed and administered drug).

[185] VACCINE ADVERSE EVENT REPORT SYSTEM, *supra* note 183.

[186] U.S. FOOD & DRUG ADMIN. CTR. FOR DRUG EVALUATION & RESEARCH, MEDICATION ERRORS, *at* http://www.fda.gov/cder/drug/MedErrors/ default.htm (last visited Jan. 29, 2005).

[187] Stephen Barlas, *FDA Planning Next Steps on How to Reduce Medication Errors*, 148 DRUG TOPICS 58 (2004), *available at* http://www.drugtopics.com/ drugtopics/ (last visited Jan. 29, 2005) (discussing proposed rules and guidance issued by the FDA, aimed at decreasing medication errors).

[188] Jerry Phillips et al., *Retrospective Analysis of Mortalities Associated With Medication Errors*, 58 AM. J. HEALTH-SYS. PHARMACY 1835 (2001) (providing a review of the causes and factors involved in fatal medication errors as reported from 1993 to 1998).

[189] *Id.* at 1837. It is sometimes difficult to separate deaths that are associated with but not caused by preventable adverse drug events from deaths that would have been prevented had the adverse event not occurred. *See* GAO REPORT, *supra* note 102, at 26.

[190] *See* IOM REPORT, *supra* note 1, at 80 (noting the Veteran's Health Administration's establishment of four Patient Safety Centers of Inquiry, which focus on researching and disseminating information to improve patient safety).

[191] VETERANS HEALTH ADMIN., NATIONAL CENTER FOR PATIENT SAFETY (NCPS), *available at* http://www.patientsafety.gov (last visited Jan. 29, 2005) (providing information pertaining to NCPS's patient safety program); NASA, PATIENT SAFETY REPORTING SYSTEM, *at* http://psrs.arc.nasa.gov (last visited May 5, 2005) (describing a method of reporting adverse events in regard to patients' safety).

[192] DEPT. OF VETERAN'S AFFAIRS, VETERAN'S HEALTH ADMIN., VHA

root cause of each incident.[193] In 2002, the VA, in association with the National Aeronautics and Space Administration (NASA), implemented the Patient Safety Reporting System (PSRS) where professionals are encouraged to report voluntarily any safety-related event, including those that cause no harm, under promises of anonymity and confidentiality.[194]

Since 1970, the CDC has operated the National Nosocomial Infections Surveillance (NNIS) database for nosocomial (hospital-based) infections and antimicrobial use and resistance.[195] Approximately 315 acute care general hospitals participate in the NNIS System.[196] Aggregate data is released, but incidents due to medical error are not separately reported.[197]

3. Private reporting systems

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) accredits more than 15,000 health care facilities in the United States.[198] The JCAHO has implemented a voluntary sys-

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NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK 2 (Jan. 30, 2002), *available at* http://www.patientsafety.gov/NCPShb.pdf (requiring that both adverse events and close calls be reported in the Patient Safety Information System).

[193] *Id.* at 3.

[194] NASA, PATIENT SAFETY REPORTING SYSTEM, *at* http://psrs.arc.nasa.gov (last visited May 5, 2005). NASA administers the Aviation Safety Reporting System that has been widely viewed as a model of safety reporting for the health industry. The IOM's proposal for a two-pronged reporting system of mandatory reporting for serious events and deaths and voluntary reporting of near misses was patterned after the aviation error reporting system. IOM REPORT, *supra* note 1, at 95-96 (describing NASA's aviation safety reporting system).

[195] DEPT. OF HEALTH & HUMAN SERVS.: CTR. FOR DISEASE CONTROL & PREVENTION, ISSUES IN HEALTH CARE SETTINGS: ABOUT NNIS, *at* http://www.cdc.gov/ncidod/hip/NNIS/@nnis.htm (last visited Feb. 2 2005).

[196] *Id.*

[197] The most recent summary of the data reported by hospitals participating in the NNIS is available from US Department of Health and Human Services, Division of Healthcare Quality Promotion, *National Nosocomial Infections Surveillance (NNIS) System Report, Data Summary from January 1992 through June 2004*, 32 AM. J INFECTIOUS CONTROL 470 (Dec. 2004), *available at* http://www.cdc.gov/ncidod/hip/NNIS/2004NNISreport.pdf.

In 1999, the CDC also initiated a system allowing hemodialysis centers to record and track rates of infection in patients receiving dialysis. CENTERS FOR DISEASE CONTROL AND PREVENTION, DIVISION OF HEALTH CARE QUALITY PROMOTION, ISSUES IN HEALTH CARE SETTINGS, DIALYSIS SURVEILLANCE NETWORK, (2002), *available at* http://www.cdc.gov/ncidod/hip/Dialysis/dsn.htm (last visited Jan. 30, 2005).

[198] Joint Comm'n on Accreditation of Health Care Orgs., *What is the Joint Commission on Accreditation of Healthcare Organizations, at* http://www.jcaho.org/general+public/who+jc/what+is+the+joint+commission.htm (last visited May 5, 2005).

tem of reporting sentinel events, defined broadly as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."[199] Although the reporting of a sentinel event is voluntary, once a report is made the facility is required to conduct a root cause analysis of the event.[200] From January 1995 through December 2004, JCAHO reviewed 2966 sentinel events reported by its accredited facilities, 2279 of which involved a patient's death.[201] Because of the broad definition of sentinel event, the JCAHO program does not capture incidents that reflect only medical error. Many experts acknowledge that there has been serious underreporting to JCAHO, which is directly tied to providers' fear of disclosure of the reports in litigation.[202]

Recognizing that adverse drug events may the largest source of iatrogenic error, United States Pharmacopeia (USP) operates two voluntary systems for reporting medication errors, Medication Errors Reporting (MER) and MedMARx.[203] The MER program encourages patients and health professionals to report errors to a national reporting program.[204] From its inception in 1991, through 2003, more than 8,000 reports were submitted to the program.[205] The MedMARx program allows hospitals to anonymously report and track medication errors through an internet-accessible format.[206] In 2002, 192,477 medication errors were voluntarily reported to MedMARx by 482

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[199] Joint Comm'n on Accreditation of Health Care Orgs., *Sentinel Event Policy And Procedures*, (Mar. 2005), *available at* http://www.jcaho.org/accredited+organizations/sentinel+event/se_pp.htm#1.

[200] *Id.*

[201] Joint Comm'n on Accreditation of Health Care Orgs., *Sentinel Event Statistics* (Mar. 2005), *available at* http://www.jcaho.org/accredited+organizations/sentinel+event/sentinel+event+statistics.htm (on file with author).

[202] *See* Bryan A. Liang & Steven D. Small, *Communicating About Care: Addressing Federal-State Issues in Peer Review and Mediation to Promote Patient Safety*, 3 HOUS. J. HEALTH L. & POL'Y 226-28 (2003) (contending underreporting to JCAHO is due to lack of legal protection of the data from discovery or other disclosure).

[203] The MER program is administered by USP in cooperation with the Institute for Safe Medication Practices. THE UNITED STATES PHARMACOPEIAL CONVENTION, PATIENT SAFETY: USP MEDICATION ERRORS REPORTING PROGRAM, *at* http://www.usp.org/patientSafety/reporting/mer.html (last visited Feb. 2, 2005) (on file with the author).

[204] *Id.*

[205] UNITED STATES PHARMACOPEIA PATIENT SAFETY INITIATIVES 1, *available at* http://www.usp.org/pdf/patientSafety/biPatientSafetyOverview.pdf (last visited Nov. 15, 2004).

[206] *Id.*

hospitals and health systems.[207] Only 1.7% resulted in patient injury, down from 2.4% in 2001.[208] Twenty deaths were reported.[209]

As demonstrated by these reporting systems, both federal and private, the incidence of adverse events, let alone the subcategory of medical errors, is a far cry from those estimated by the IOM. For example, the IOM estimated there were 7,000 deaths annually due to medication errors.[210] Neither the FDA's MedWatch nor the USP programs capture such a large number of fatal errors. The gap between the number of errors reported and the purported actual incidence of error is often explained by the serious problem of underreporting of errors. For example, the FDA estimates that it receives reports of only one percent of suspected adverse drug reactions.[211] In addition to understating the problem of medical error, these systems may not be effective in determining the general incidence of medical error because the focus is on specific treatments or populations.

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[207] Press Release, U.S. Pharmacopeia, USP Releases Fourth Annual Report on Medication Errors in U.S. Hospitals (Nov. 18, 2003), *available at* http://www.onlinepressroom.net/uspharm.

[208] *Id.*

[209] *Id.* In 2003, 235,159 medication error reports were submitted to USP. U.S. PHARMACOPEIA 2004 ANNUAL REPORT 8 (2004), *available at* http://www.usp.org/pdf/annualReport/04AnnualReport.pdf (last visited May 5, 2005).

[210] IOM REPORT, *supra,* note 1, at 2. This figure was based on a study that reviewed death certificates that indicated in 1993, there were 7391 deaths due to medication errors in the United States. David P. Phillips et al., *Increase in US Medication-Error Deaths Between 1983 and 1993,* 351 LANCET 643, 643 (1998) (the study compared trends in medication errors with trends in related causes of death). The IOM has also been criticized for relying on this study because the authors' definition of medication error included "accidental poisonings" by patients, including accidental overdose of drugs. *See* McDonald et al., *supra* note 39, at 94; *see also* Henri R. Manasse, *Correspondence: Increase in US Medication-Error Deaths,* 351 LANCET 1655, 1655 (1998); R.E. Ferner & C. Anton, *Correspondence: Increase in US Medication-Error Deaths,* 351 LANCET 1655, 1655-56 (1998); Cleone Rooney, *Correspondence: Increase in US Medication-Error Deaths,* 351 LANCET 1655, 1656-57 (1998). Other studies have concluded that although medication errors are common, they do not generally cause serious harm. *See, e.g.,* David W. Bates et al., *Relationship between Mediation Errors and Adverse Drug Events,* 10 J. GEN. INTERNAL MED. 199, 199 (1995) (0.9% of medication errors caused harm). *See also supra* note 207 and accompanying text (among MedMARx medication errors, 1.7% caused harm).

[211] *Adverse Events: Surveillance Systems for Adverse Events and Medical Errors, J. Hearing Before The House Subcomm. on Health and Environment and Oversight and Investigations of the Comm. On Commerce and the Subcomm. on Health of the Comm. on Veterans' Affairs Representatives,* 106th Cong. 92, 95 (2000) (statement of Janet Heinrich, Associate Director, Health Financing and Public Health Issues, General Accounting Office).

C. State Mandatory Reporting Systems – Counting the Errors

The IOM called for all states to have mandatory reporting systems in place as part of a nationwide effort to collect information on events that result in death or serious harm.[212] There are currently twenty-two states that require the reporting of some type of adverse event or incident. [213] Contrary to the IOM's recommendation, the federal government has not stepped in to provide a mechanism for reporting in states that have failed to implement a mandatory system.[214]

It is difficult to assess the success of state reporting systems. Instead of establishing separate systems for the reporting of serious events and minor incidents, many states have a single system for both. Some states collect not only reports of serious events or deaths, but also incidents that cause no or minimal harm. Further, the IOM envisioned accountability in the form of public access to data collected by the states. In many states, however, the information is protected from disclosure to the public.[215] No study has used the data collected by the states, primarily because the data is not made public in a useable form.[216]

The information compiled to date from those few systems that release patient safety data does not reveal the substantial number of errors suggested by the IOM. In fact, the number of reported adverse events, which may or may not be errors, is considerably less than the IOM report suggests for errors alone. New York, home of the HMPS, collected a total of 28,689 incident reports (1,159 reports per 100,000 discharges) in 2001 through its NYPORTS internet-based system.[217]

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[212] IOM REPORT, *supra* note 1, at 9.

[213] According to the National Academy for State Health Policy, which tracks state reporting systems, the states are California, Colorado, Connecticut, Florida, Georgia, Kansas, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah and Washington. *See* NAT'L ACAD. FOR STATE HEALTH POLICY, QUALITY & PATIENT SAFETY: POLICIES, *at* http://www.nashp.org (last modified Mar. 31, 2004) (on file with author). Some states have established voluntary reporting systems. *E.g.,* OR. REV. STAT. § 442.820(2)(a) (2003).

[214] *See supra* note 175 and accompanying text.

[215] *See* Marchev, *supra* note 156, at 6. The protection afforded by statute may be ephemeral. In a survey of fifteen states that have statutory protection, six were not sure whether the legal protection afforded would withstand requests under their freedom of information acts. ROSENTHAL ET AL., *supra* note 164, at 12.

[216] Zhan & Miller, *supra* note 123, at 1868.

[217] N.Y. STATE DEP'T OF HEALTH, NYPORTS: THE NEW YORK PATIENT OCCURRENCE REPORTING AND TRACKING SYSTEM ANNUAL REPORT 2000/2001: EXECUTIVE SUMMARY, *available at* http://www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2000-2001/annual_report.htm (last modified Sept. 2003).

The number of errors alone is not publicly disclosed, although officials acknowledged that "the volume of medical errors in the system is a small percentage compared to the overall volume of reporting."[218] The number of incidents equates to slightly more than a one percent adverse event rate, compared to the HMPS adverse event rate of 3.7%, with more than half of HMPS events considered preventable.

During 2002, the first year of Utah's new program of reporting sentinel events, there were thirty-four such events, with eighteen deaths reported among nearly 450,000 inpatient hospital and outpatient surgical center discharges.[219] The Utah Department of Health has calculated that using the data from the UCMPS, it would be expected to have 327 deaths a year related to medical error, or nearly eighteen times the sentinel event deaths reported in 2002.[220] To officials, the discrepancy not only meant improving reporting in Utah, but also "taking a closer look at the methodology that informed the IOM's conclusions."[221] In Colorado, the other state involved in the UCMPS, and where facility-specific data is collected and reported online, the number and nature of the reports is either disheartening or encouraging, depending on the accuracy of the information.[222] For example, Presbyterian/St Luke's Medical Center, the largest hospital in Denver,[223] reported thirty-three occurrences to the Department of Public Health in 2003.[224] Of these, twenty-six were missing person reports

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[218] Id.

[219] Utah Dep't of Health, *Utah Rule Provides First Year of Patient Safety Data*, UTAH PATIENT SAFETY UPDATE, JAN. 2003, at 2, *available at* http://health.utah.gov/psi/pubs/psup_v1n2.pdf.

[220] Id.

[221] Id. The rates of sentinel events and deaths have remained consistent from 2002 through 2004. Utah Dep't of Health, *State-Level Sentinel Event Information 2001-2004*, UTAH PATIENT SAFETY UPDATE, Oct. 2004, at 2, *available at* http://health.utah.gov/psi/pubs/PSU6_v2n2.pdf.

[222] Under Colorado law, reportable occurrences include unexplained deaths, brain or spinal cord injuries, life-threatening complications of anesthesia or transfusion errors/reactions, severe burns, missing persons, physical, verbal or sexual abuse, neglect, misappropriation of property, diverted drugs and malfunction/misuse of equipment. Facilities must report these occurrences within one business day. The Department of Public Health must investigate the occurrence and determine if appropriate action has been taken. Summaries of the occurrences are available for public viewing. The summaries do not reflect the names of the patients or health care professionals involved. COL. REV. STAT. § 25-1-124 (2004).

[223] Colo. Dep't of Pub. Health and Env't, COLORADO HEALTH FACILITY DEMOGRAPHIC INFORMATION-GENERAL (2004), *at* http://www.hfd.cdphe.state.co.us/hfd2003/srch.aspx (ranked by number of beds).

[224] Colorado Dep't of Health and Environment, Health Facility Information for: PRESBYTERIAN/ST LUKE'S MEDICAL CENTER, *at* http://www.hfd.cdphe.state.co.us/hfd2003/dtl.aspx?id=010431&ft=hospital (last visited May 5, 2005).

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due to patient elopement.[225] No deaths were reported from any cause.[226]

Connecticut, where reporting of adverse events began in October 2002, fielded 1359 reports as of March 8, 2004.[227] Follow-up was performed in about fifty percent of the reports in an effort to distinguish adverse events from medical error.[228] There was a steep decline in reporting after the first twelve months, which stabilized at less than half of the original monthly reports.[229] The decline was attributed not only to underreporting, but also to confusion over what was a reportable event.[230]

A comparison of reportable events between Florida and New York demonstrates the difficulty in trying to assess the scope of reporting and its relationship to patient safety. In 1999, the last year for which comparable annual data are available,[231] Florida received 3,808 reports of adverse events.[232] In that year, Florida had more hospitals and almost as many hospital beds as New York,[233] which saw 16,939 reportable incidents.[234] One cannot conclude from this data that in 1999, hospitals in Florida were safer than those in New York. Differences in the definition of events, ease of reporting, or underreporting

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[225] *Id.*

[226] *Id.* At University of Colorado Hospital, also in Denver, twenty-two occurrences, including one death, were reported and investigated in 2003. The majority of incidents reported were also due to patient elopement. COLO. DEP'T OF HEALTH & ENV'T, OCCURRENCE SUMMARY REPORTS FOR: HEALTH FACILITY INFORMATION FOR: UNIVERSITY OF COLORADO HOSPITAL AUTHORITY *at* http://www.hfd.cdphe.state.co.us/hfd2003/dtl.aspx?id=010432&ft=hospital (last visited Feb. 17, 2005).

[227] CONN. DEP'T OF PUB. HEALTH, ANNUAL LEGISLATIVE REPORT TO THE GENERAL ASSEMBLY: ADVERSE EVENT REPORTING 5 (March 2004), *available at* http://www.dph.state.ct.us/Agency_News/2004ADVERSE%20EVENTREPORT.pdf.

[228] *Id.* at 5. There is no breakdown for medical errors alone.

[229] *Id.* at 11.

[230] *Id.* at 12. Connecticut has recently amended its legislation with a new definition of adverse event. *See infra* note 280 and accompanying text.

[231] Florida maintains a public website where statewide summaries of reports are posted. The state has not yet publicly released total reports for the years 2000 and later. AGENCY FOR HEALTH CARE ADMIN.: DIV. OF MANAGED CARE & HEALTH QUALITY, MANDATORY SERIOUS PATIENT INJURY REPORTING: SUMMARY REPORT, HOSPITALS AND AMBULATORY SURGICAL CENTERS, *available at* http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Risk/annual_report.shtml (last visited Feb. 5, 2005).

[232] *Id.*

[233] JILL ROSENTHAL ET AL., COST IMPLICATIONS OF STATE MEDICAL ERROR REPORTING PROGRAMS: A BRIEFING PAPER 8 (2001) (stating Florida had 273 hospitals and 52,000 hospital beds; New York had 260 hospitals and 66,757 beds).

[234] N.Y. STATE DEP'T OF HEALTH, *supra* note 217.

offer reasonable, but not conclusive, explanations for the gap in numbers recounted by these two states.

Although it is widely thought that mandatory reporting systems are unreliable, these systems may capture more patient-related injuries than voluntary systems. A recent study compared the number of incidents reported voluntarily by JCAHO-accredited hospitals to JCAHO with those reported to fifteen mandatory-reporting states.[235] Noting that there was "considerable state-to-state variation in reporting requirements,"[236] the researchers attempted to limit the data to nine states that defined events similar to the sentinel event used by JCAHO.[237] In each of the nine states, the number of events reported to the state agencies was equal to or greater than the number reported to JCAHO.[238] In New York, the number of care-related deaths reported to the New York State Health Department in 1999 exceeded the total number of sentinel events reported to JCAHO by all nationally accredited hospitals in that year.[239]

Other than the mandatory nature of the state reporting systems, there are several reasons why providers may prefer to report to state agencies rather than JCAHO. State law often offers protection from lawsuit-related discovery that JCAHO, a private organization, cannot.[240] JCAHO's system is voluntary, but if JCAHO discovers a sentinel event that was not reported, it can require an investigation of the event or an on-site visit at the hospital's expense.[241] Loss of accreditation by JCAHO can have grave financial consequences for a hospital because Medicare reimbursements depend on JCAHO accreditation.[242]

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[235] L. Keoki Williams et al., *Differences in the Reporting of Care-Related Patient Injuries to Existing Reporting Systems*, JOINT COMMISSION J. QUALITY & SAFETY 460, 460 (2003).

[236] *Id.* at 461.

[237] *Id.*

[238] *Id.* at 462-63.

[239] *Id.* at 463.

[240] *Id.*

[241] *Id.*

[242] *Id.* A hospital is "deemed" to have met the requirements for Medicare certification if it is accredited by JCAHO. 42 U.S.C. §§ 1395x(e), 1395bb (2000). This may change. A recent report by the General Accountability Office criticized JCAHO for missing many serious safety deficiencies. U.S. GOV. GEN. ACCOUNTABILITY OFFICE, MEDICARE: CMS NEEDS ADDITIONAL AUTHORITY TO ADEQUATELY OVERSEE PATIENT SAFETY IN HOSPITALS (2004), *available at* http://www.gao.gov/new.items/d04850.pdf. Congressional legislation to increase CMS oversight has been proposed. Medicare Hospital Accreditation Act of 2004, H.R. 4877, 108th Cong. (2004).

Most experts believe that the low incidence of reporting is due not to a tremendous decrease in adverse incidents or medical errors, but to widespread underreporting.[243] The difficulty with this explanation is that, at this point, no one knows how many events should be reported by health care providers.[244] Care must also be taken in interpreting the data from those states that show an increase in number of events reported. A surge in the number of reports does not mean that hospitals are becoming less safe. In this instance, more may be better. Contrary to the IOM's expectations, in the years after its report, one should expect the numbers to increase, rather than decrease, due to renewed commitment to reporting such events.[245]

D. The Lack of Standardized Data in State Systems

State systems not only suffer from underreporting, they are also plagued by inconsistent, vague and cumbersome reporting formats. The task for any reporting system is to define and measure reportable error. However, programs are not in place to capture error. Although twenty-two states have mandatory reporting systems, none addresses medical error alone. There is also no uniform definition across reporting systems of an "error" or "adverse event." The lack of standard nomenclature limits the usefulness of information collected by the states and makes it difficult, if not impossible, to compare results across the reporting systems.[246]

The IOM called on Congress to require all health care organizations to use a common language for reporting serious events.[247] However, with the exception of a few states, health care workers are instead being required to report under the general rubric of adverse

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[243] *See supra* notes 148, 149 and accompanying text.

[244] New York may come closest to having a reasonable estimate because it compares variations in reporting among hospitals and is able to target those hospitals that have low reporting rates. *See* N.Y. DEP'T OF HEALTH, NYPORTS: THE NEW YORK PATIENT OCCURRENCE REPORTING AND TRACKING SYSTEM ANNUAL REPORT 2000/2001: COMPLETENESS OF REPORTING, *available at* http://www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2000-2001/annual_report.htm (last modified Sept. 2003). Even so, New York acknowledges that it is difficult to assess the completeness of reporting because "a gold standard database that includes cases that should be reported, does not exist." *Id.*

[245] "[W]ith better awareness, recognition, documentation, and tracking, the rates of adverse events will initially increase for the first few years as data continues to be collected." Utah Dep't of Health, *supra* note 219, at 2.

[246] *See* IOM REPORT, *supra* note 1, at 89.

[247] IOM REPORT, *supra* note 1, at 9 (recommending that Congress require organizations "to report standardized information on a defined list of adverse events").

events or incidents, only a portion of which are caused by medical error. The type and definition of reportable events in state legislation vary considerably.[248] Some systems mandate the reporting of general events, such as unanticipated deaths, while others include a list of specific incidents that must be reported.[249] Some states count only serious adverse events, whereas others have no severity threshold.[250]

For example, Florida broadly defines a reportable adverse incident as an event that is associated with medical intervention, rather than the condition for which the intervention occurred.[251] Kansas considers a reportable incident as one falling below the standard of care or a disciplinary violation.[252] Several states require the reporting of sentinel events, using the same definition found in JCAHO standards.[253] Other systems have incorporated a list of events for providers to report.[254]

New Jersey's recent legislation requires health care providers to distinguish between adverse events, preventable adverse events, serious preventable adverse events, and near misses.[255] The law mandates the reporting of serious preventable adverse events and encourages the voluntary reporting of other adverse events and near misses.[256] Penn-

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[248] *See* JILL ROSENTHAL & MAUREEN BOOTH, DEFINING REPORTABLE ADVERSE EVENTS: A GUIDE FOR STATES TRACKING MEDICAL ERRORS 9-18 (2003), *available at* http://www.nashp.org/Files/GNL50.pdf (displaying results of survey of the states).

[249] *Id.*

[250] *Id.*

[251] FLA. STAT. ANN. § 395.0197(5) (West. Supp. 2005).

[252] KAN. STAT. ANN. § 65-4921(f) (Supp. 2003) ("'Reportable incident' means an act by a health care provider which: (1) Is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency.").

[253] *E.g.*, NEV. REV. STAT. ANN. 439.830 (Michie Supp. 2003) (defining a sentinel event).

[254] *E.g.*, R.I. GEN. LAWS § 23-17-40 (Supp. 2004).

[255] These terms are defined as follows:
"Adverse event" means an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable. . . . "Near-miss" means an occurrence that could have resulted in an adverse event but the adverse event was prevented. "Preventable event" means an event that could have been anticipated and prepared against, but occurs because of an error or other system failure. "Serious preventable adverse event" means an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.
N.J. STAT. ANN. § 26:2H-12.25a (2004), *available at* http://lis.njleg.state.nj.us/cgi-bin/om_isapi.dll?clientID=61727294&Depth=4&TD=WRAP&advquery=%2226%3a2H-12.25%22&headingswithhits=on&infobase=statutes.nfo&rank=&record={9DB4}&softpage=Doc_Frame_Pg42&wordsaroundhits=2&zz=.

[256] *Id.*

sylvania also distinguishes between events based on the extent of harm to the patient.[257] Under Pennsylvania law, health care workers are required to report serious events to their medical facility within twenty-four hours, with the facility making a report to state agencies.[258] There are penalties for failing to report a serious event, but not for failing to report an incident.[259]

New York requires all hospitals to report certain incidents to the public health department, including "patients' deaths or impairments of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards."[260] On the other hand, Kansas requires the reporting of incidents even if no harm results.[261]

A recent study demonstrates the problem providers may have with a discrepant reporting taxonomy. Investigators, seeking to assist clinicians in the requirements for reporting adverse drug events, attempted to classify five different untoward drug events: adverse events, adverse drug reaction, adverse drug event, medication error, and side effect.[262] They noted that the FDA's MedWatch program is

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[257] The Pennsylvania statute defines reportable occurrences as follows: "Incident." An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event. . . . "Serious event." An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident.
PA. STAT. ANN. tit. 40, § 1303.302 (West Supp. 2004).
[258] *Id.* §§ 1303.308(a),1303.313(a).
[259] If a medical facility discovers that a professional did not report a serious event, that facility must report the professional to his or her licensing board. § 1303.313(e). Facilities may also be subjected to an administrative penalty of $1,000 per day for failing to report a serious event. § 1303.313(f).
[260] N.Y. PUBLIC HEALTH LAW § 2805-l(2)(a) (McKinney 2002). New York also provides a list of events by code that must be reported. N.Y. DEP'T OF HEALTH, NYPORTS: THE NEW YORK PATIENT OCCURRENCE REPORTING AND TRACKING SYSTEM ANNUAL REPORT 2000/2001: ANALYSIS OF PROCEDURES ASSOCIATED WITH NYPORTS CODES, *available at* http://www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2000-2001/annual_report.htm (last modified Sept. 2003).
[261] *See supra* note 252.
[262] Jonathan R. Nebeker et al., *Clarifying Adverse Drug Events: A Clinician's Guide to Terminology, Documentation, and Reporting*, 140 ANN. INTERNAL MED. 795, 796 (2004). Adverse event is defined as "[h]arm in a patient administered a drug but not necessarily caused by a drug." Adverse drug reaction is "[h]arm directly caused by a drug at normal doses." Adverse drug event is "[h]arm caused by the use of a drug." Medication error is "[i]nappropriate use of a drug that may or may not

interested in unexpected serious adverse drug reactions, not adverse drug events,[263] while adverse drug events (but not side effects) "are the targets of broader efforts to improve patient safety."[264] Such parsing of terms, however well intentioned, may further lead to providers' difficulty in knowing what to report.

The cost associated with collecting ambiguous reports is also a significant burden on states.[265] The IOM contemplated that data collected under state systems would be released to the public only when the state agency completes an investigation and determines that an error has occurred.[266] Questionable reports require follow-up and analysis to separate the preventable from non-preventable. Collecting data and analyzing each report is an expensive process, however, and states have often not allocated sufficient resources to this task.[267] In a survey of states that had considered but rejected reporting systems, a primary impediment to implementation was inadequate funding.[268] Even with sufficient funding, the methods currently in place to capture medical error often produce imprecise data. Interviews with caretakers or retrospective review of records containing adverse events or adverse drug reactions may be unreliable in attempting to sort the preventable from the unpredictable.[269]

The IOM recognized that mandatory reporting systems existing in 1999 had wide variations in definitions and processes.[270] This problem has not improved much in five years. In its 2004 report, *Patient Safety: Achieving a New Standard for Care,* the IOM found that state systems still had different definitions for patient safety terms such as adverse event, had many different classifications of adverse events and had diverse approaches to collecting data.[271]

The lack of a uniform taxonomy hampers the ability to measure error and to determine if reporting has any positive impact on patient safety. In addition, numbers from one state cannot be compared to another because there is no national classification of errors. Without

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result in harm." Side effect is "[a] usually predictable or dose-dependent effect of a drug that is not the principal effect for which the drug was chosen; the side effect may be desirable, undesirable, or inconsequential." *Id.* at 796.

[263] *Id.* at 799.

[264] *Id.* at 800.

[265] ROSENTHAL ET AL., *supra* note 233, at 6.

[266] IOM REPORT, *supra* note 1, at 91-93, 110, 254-265.

[267] MARCHEV ET AL., *supra* note 149, at 29.

[268] ROSENTHAL ET AL., *supra* note 164, at 17.

[269] *See* discussion *supra* Part I. B., C.

[270] IOM REPORT, *supra* note 1, at 91-93 (discussing the various state adverse event tracking programs).

[271] PATIENT SAFETY, *supra* note 45, at 248.

standardized data, we cannot accurately assess the magnitude of the problem or measure the results.

IV. PROGNOSIS FOR REPORTING

A. A Framework For Capturing Medical Error Through Mandatory Reporting Systems

The preceding discussion demonstrates there are significant impediments to the collection of dependable and consistent data on medical error. To address this problem, states must begin to shift the focus from gathering reports on ambiguous adverse incidents to capturing a smaller set of objectively quantifiable data. Considerable evidence suggests that states should not use terms such as adverse event or sentinel event in legislation because they are vague and do not accurately reflect the true incidence of error.[272] If states are to adopt and implement mandatory reporting systems, there is a need to concentrate on a narrow, unambiguous list of errors that do not involve individual judgment as to whether a reportable event occurred.

In response to the IOM's call for the development of standardized data definitions to be used by states,[273] The National Quality Forum (NQF) has published a list of serious, largely preventable adverse medical events that should be reported under any mandatory or voluntary system.[274] This list provides one of the first frameworks for reporting systems and includes twenty-seven "never" events that should always be reported:

1. SURGICAL EVENTS

    A. Surgery performed on the wrong body part
    B. Surgery performed on the wrong patient
    C. Wrong surgical procedure performed on a patient
    D. Retention of a foreign object in a patient after surgery or other procedure

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[272] *See* discussion *supra* Part I. D.

[273] IOM REPORT, *supra* note 1, at 9.

[274] THE NATIONAL QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE: A CONSENSUS REPORT 6-7 (2002). The NQF is a non-profit organization whose twenty-three member board includes health care consumers, purchasers, providers, health plans, and experts, with representatives from two federal agencies, CMS and AHRQ. THE NATIONAL QUALITY FORUM, ABOUT THE NATIONAL QUALITY FORUM, *at* http://www.qualityforum.org/about/home.htm#councils (last visited Feb. 15, 2005).

    E. Intraoperative or immediately post-operative death in an ASA Grade 1[275]

2. PRODUCT OR DEVICE EVENTS

    A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility

    B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended

    C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

3. PATIENT PROTECTION EVENTS

    A. Infant discharged to the wrong person

    B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours

    C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

4. CARE MANAGEMENT EVENTS

    A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)

    B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products

    C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility

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[275] ASA refers to assessment of fitness for anesthesia and surgery. ASA Grade 1 is a healthy individual who has a predicted 0.06-0.08% mortality risk from surgery. CLINICAL ANESTHESIOLOGY 8-9 (G. Edward Morgan et al., eds., 3d ed. 2002).

D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility

E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates

F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility

G. Patient death or serious disability due to spinal manipulative therapy

5. ENVIRONMENTAL EVENTS

A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility

B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances

C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility

D. Patient death associated with a fall while being cared for in a healthcare facility

E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

6. CRIMINAL EVENTS

A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider

B. Abduction of a patient of any age

C. Sexual assault on a patient within or on the grounds of a healthcare facility

D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility

The NQF designed its list to be used by all health care facilities in states that adopt it as part of a reporting system.[276] The list is not intended to be exhaustive and states may expand the type of events to be included.[277] Minnesota was the first state to adopt the entire NQF list as part of its patient safety legislation.[278] In January 2005, the Minnesota Department of Health reported that between July 2003 and October 2004, ninety-nine events on the NQF list had been reported statewide, with twenty deaths.[279]

Connecticut, which had only begun collecting data from its reporting system in 2002, quickly recognized the problem with vague definitions. Less than two years after enacting patient safety legislation, the statute was amended to define an adverse event as any event on the NQF list or a list adopted by the Commissioner of Public Health.[280] The legislature was prompted by the Department of Public Health's 2004 annual report, which had addressed the difficulty in distinguishing adverse events from medical errors.[281] The report also questioned whether Connecticut's reporting scheme was so unnecessarily complicated as to reduce the reliability and comparability of adverse event reporting.[282] The adoption of the NFQ list ostensibly alleviates these concerns.[283]

Although most events on the NFQ list are clear-cut indications of a serious mistake, such as operating on the wrong patient, it is debatable whether all of the events on the NQF list can truly be categorized as medical error. If error is defined as inadvertent or unintended conduct, criminal acts may not belong in a medical error reporting system. Intentional harm to a patient should be reported to law enforcement officials or licensing boards, who have the authority to impose

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[276] *Serious Reportable Events in Healthcare, supra* note 274, at 9.

[277] *Id.* at 5, 8.

[278] MINN. STAT. ANN. §§ 144.706-144.7069 (West Supp. 2004), *amended by* 2004 Minn. Sess. Law Serv. 186 (West 2004). In 2003, Texas adopted a medical error reporting statute that incorporates some, but not all, of the events on the NQF list. TEX. HEALTH & SAFETY CODE ANN. § 241.202 (Vernon Supp. 2004-2005).

[279] ADVERSE HEALTH EVENTS IN MINNESOTA, FIRST ANNUAL PUBLIC REPORT 9 (Jan. 2005), *available at* http://www.health.state.mn.us/patientsafety/aereport0105.pdf (last visited May 15, 2005).

[280] CONN. GEN. STAT. ANN. § 19a-127n(a)(1) (West, WESTLAW through Feb. Reg. Session and May 11 Sp. Session).

[281] CONN. DEP'T OF HEALTH, *supra* note 227, at 9.

[282] *Id.* at 10.

[283] Reporting began under Connecticut's new program in July 2004. The Department of Public Health estimates that it will receive 50-100 reports each year. CONN. DEP'T OF HEALTH, ANNUAL LEGISLATIVE REPORT TO THE GENERAL ASSEMBLY: ADVERSE EVENT REPORTING 7 (Oct. 2004), *available at* http://www.dph.state.ct.us/oppe/quality/Adverse%20Event%20Report_Oct%202004.pdf (last visited May 15, 2005).

criminal or disciplinary sanctions.[284]   Further, although intentional
acts, such as sexual or physical assaults on staff, are egregious and
highly undesirable, it is questionable whether health care facilities
have sufficient control over third parties to prevent such acts. Finally,
a truly confidential, non-punitive reporting system may not be politi-
cally feasible if the system shields criminal acts or other intentional
harm from disclosure.

Several categories advanced by the NQF also appear to require
further investigation before determining whether an error occurred.
For example, not every intraoperative or post-operative death of an
otherwise healthy patient is due to error. Suicide of a patient in a
mental health facility on suicide watch is different than suicide of a
patient admitted to a general medical facility with no known suicidal
tendencies. The latter may be unpredictable, or as tort law would de-
scribe, unforeseeable. Similarly, patients leaving a medical facility
against the advice of their physicians are in a different category than
patients confined in a mental health facility or residing in a nursing
home who manage to elope.[285]

A final "drawback"[286] to the NQF list is that widespread adoption
of the list may not move states significantly closer to the IOM's goal
of quantifying and reducing the incidence of all serious medical er-
rors. The NQF chose to target the most egregious system errors. By
doing so, the list captures only a subset of errors and does not identify
many judgment or skill related events such as wrong diagnoses, fail-
ure to use appropriate tests, avoidable delays in treatment, and surgi-
cal mishaps or other technical lapses. These events, as discussed pre-
viously, make up a large percentage of preventable errors identified in
the HMPS, UCMPS and other studies.[287]   Labeling these events as
errors also provokes the most controversy because the reviewer's as-

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[284] The VA's mandatory reporting system excludes intentionally unsafe acts
from events to be reported. *See* DEP'T OF VETERAN'S AFFAIRS, VETERAN'S HEALTH
ADMIN., VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK 6 (Jan. 30,
2002), *available at* http://www.patientsafety.gov/NCPShb.pdf
[285] The NQF additionally specifies that the category of patient elopement
excludes "competent adults." SERIOUS REPORTABLE EVENTS IN HEALTH CARE, *supra*
note 274, at 6. But mental illness and incompetency do not necessarily coexist and
determining who is competent and for what purpose is not always easy. There are
many different legal and medical definitions of competency. *See* Samantha Wey-
rauch, *Decision Making for Incompetent Patients: Who Decides and By What Stan-
dards?*, 35 TULSA L.J. 765 (2002).
[286] Focusing on a finite list of events is a drawback only if one wants to con-
tinue the current system of trying to measure all adverse events, many of which do not
involve error.
[287] *See supra*, note 56.

sessment usually involves complex variables on which it is difficult to obtain reliable data.[288] Understanding these difficulties, the NFQ wisely chose to formulate a limited number of objective, clearly defined events for legislatures to use, at least as a starting point, in setting policy for reporting adverse events.[289] Not only will providers have guidance in knowing what to report, but also by having a finite number of events to investigate to determine if error occurred, the financial burden on states will be significantly reduced. Although the numbers reported under the NQF list will not mirror (or even approach) the IOM's estimates of error, they will reflect its goal of focusing on system, not individual, errors.

Ultimately, as the IOM recognized, better reporting will not improve safety if nothing is done with the data.[290] The value of reporting systems may not be in the number of reports, but rather in dissemination of the lessons learned from interpretation of the information collected. Analysis of the cause of errors and feedback to health care providers are crucial to any reporting system, whether mandatory or voluntary. However, adequate funding and technical expertise are needed to accomplish this task. Five years ago, President Clinton stated that the federal government wanted to give states with mandatory reporting systems "the tools to do it right."[291] To date, the federal government has not responded to the IOM's recommendation that it assist states financially with establishing and implementing their reporting systems.[292] Without federal assistance, it is unlikely most states will find the resources either to create or improve their programs.

B. Voluntary Reporting Systems

The data collected by Minnesota and Connecticut demonstrate that states using the NQF list or similar criteria will capture a much lower number of medical errors than projected by the IOM. Undoubtedly, many events labeled as errors by the IOM will not be counted, but it is neither cost-effective nor practical to expect states to assume the primary reponsibility in a national reporting scheme. Private agencies and the federal government also have a role in assessing and monitoring medical error.

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[288] *See* discussion *supra* Part I.B., C.

[289] The NQF concedes that the list is a starting point for discussion. SERIOUS REPORTABLE EVENTS IN HEALTHCARE, *supra* note 274, at v.

[290] *See* IOM REPORT, *supra* note 1, at 8.

[291] President William J. Clinton, Remarks by the President on Medical Errors, *supra* note 14.

[292] *See* ROSENTHAL & BOOTH, *supra* note 248, at 1.

Although some analysts have suggested a national reporting system,[293] the IOM recognized that a unitary, federal program was probably not feasible from either a political or financial standpoint.[294] Instead, the IOM encouraged the development of voluntary reporting programs that collect evidence of near misses and less serious harms. Analysis of these incidents can provide valuable insight into identifying systemic problems and recommending safer practices.[295] However, there are far more near misses and events that cause minimal harm than serious adverse events,[296] and a national system would be cost-prohibitive due to the large numbers of errors that would require analysis and feedback to health care providers.[297]

Congress also appears poised to reject a program run by the federal government in which health care providers report events directly to a national system. Instead, proposed legislation requires the Secretary of Health and Human Services to establish a national database that would be a repository of information reported to patient safety organizations certified by the Secretary.[298] Data would be submitted in a common format to be determined by the Secretary.[299]

Current programs or those under development that cover specific health care sectors or specialties provide a reasonable alternative to a national system.[300] For example, the USP MedMARx program has been successful in capturing medication errors and in providing feedback to providers.[301] There are several initiatives that are being undertaken in the area of intensive care, which involve easy to use, web-based reporting.[302] Under these focused systems, data can be stan-

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[293] *E.g.*, Nat'l Patient Safety Found., *Reporting as a Means To Improve Patient Safety: Roundtable Discussion* (Mar. 2000), *available at* http://www.npsf.org/download/patientsafetyroundtable.pdf. In early 2004, England established the first national reporting system to tackle errors in the National Health System. It is expected to cost $1.9 million for the first eight years. Vittal Katikireddi, *National Reporting System for Medical Errors is Launched*, 328 BRIT. MED. J. 481 (2004).

[294] IOM REPORT, *supra* note 1, at 105-06.

[295] *Id.* at 8.

[296] Leape, *supra* note 10, at 1636 (noting the annual numbers of errors could be as many as 5,000,000).

[297] *Id.* at 1636-37. In 1994, the aviation reporting system cost $70 per case to investigate. Even if only ten percent of the possible five million errors were reported each year, at $70 per case, the cost would approach $35 million. *Id.* That figure is probably higher today. *See* Lucian L. Leape, *Reporting of Medical Errors, Time for a Reality Check*, 9 QUAL. HEALTH CARE 144, 145 (2000) (estimate of $100 per case).

[298] Patient Safety and Quality Improvement Act of 2005, S. 544, 109th Cong., § 923(a).

[299] *Id.* at § 923(b).

[300] *See* Leape, *supra* note 10, at 1637.

[301] *Id.* at 1635.

[302] *See, e.g.*, ICUSRS Intensive Care Unit Safety Reporting System, *at*

dardized and accessible to analysts who can provide health care providers with specific advice on safer practices.[303]

There is considerable overlap in reporting systems and, to avoid duplication of effort, consideration should be given to a reduction in the number of programs now in operation. If a patient in a VA hospital experiences harm as a result of a medication error, there are at least seven possible systems to which that error can be reported.[304] To reduce the burden on providers, the Department of Health and Human Services is currently spearheading an effort to coordinate federal reporting systems. In April 2001, Secretary Thompson announced the formation of the Patient Safety Task Force composed of representatives of AHRQ, CDC, FDA and CMS (Centers for Medicare and Medicaid Services) to coordinate data collection and research activities among federal agencies.[305] Goals of the coordinated network include establishing a reporting system that avoids cumbersome and inconsistent formats by utilizing uniform data standards, disseminating best safety practices, and protecting confidentiality of patients and providers.[306]

The effectiveness of any reporting system depends in large part on the commitment of professionals to implement safe practices. Any system should be designed to be "safe, simple and worthwhile."[307] A federally protected voluntary network for reporting that leads to the examination of the causes of errors, rather than merely counting numbers or pointing blame, should ease health care provider's concerns and burdens and encourage them to discuss errors openly, providing an atmosphere for change.

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http://www.icusrs.org (last visited Feb. 25, 2005) (implementing anonymous reporting for ICUs); Gautham Suresh, et al., *Voluntary Anonymous Reporting of Medical Errors for Neonatal Intensive Care*, 113 PEDIATRICS 1609 (2004) (finding anonymous reporting in neonatal units captured significant number of errors).

[303] For example, the USP's MER program regularly issues alerts and recommendations for preventing medication errors. United States Pharmacopeia, Patient Safety, *USP Medication Tools*, *at* http://www.usp.org/patientSafety (last visited May 5, 2005).

[304] These include FDA, MER, MedMARx, JCAHO, the VA internal and external reporting systems and any applicable state system.

[305] Agency for Healthcare Research and Quality, *Patient Safety Task Force Fact Sheet* (July 2003), *available at* http://www.ahrq.gov/qual/taskforce/psfactst.htm (last visited Apr. 15, 2005).

[306] *Id.*

[307] Leape, *supra* note 10, at 1635.

C. Legislative Protection of Patient Safety Data

Although using common terms and easing the burden of reporting will improve the quality of reports, the number of reports will not increase until steps are taken to protect the confidentiality of reporters and their communications. Some experts claim "all reporting is fundamentally voluntary."[308] This statement is in recognition of the fact that no system can force providers to report when it is inimical to their own interests. To increase reporting, the focus should be on patient safety and away from the "shame and blame" of the current health care and legal systems.[309]

First, whistleblower protection for reporters from adverse employment actions is an important part of any legislation. Confidential data acquired through the reporting system should be not used for punishment. Removing names of involved professionals in the reports would be the most protective of health care professionals, although anonymous reporting may hinder follow-up investigation. [310]

Non-punitive does not mean that the person who committed the error will be free from any responsibility for harm to a patient. It simply means that no action may be taken by an employer or reporting agency against a person who reports an error, and that safety reports will be kept confidential and not used for retribution. Mechanisms exist outside reporting systems for holding professionals and facilities accountable when they are negligent, incompetent, or dangerous. Disciplinary actions, license revocations, individual lawsuits and criminal penalties currently exist to deter and punish such acts.

Further, if some form of public accountability is a priority, it should be directed not at the reporter, but at facilities or health care systems that fail to institute safe practices based on the lessons learned from reporting events.[311] To fulfill their duty to the public, state regu-

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[308] IOM REPORT, *supra* note 1, at 98 (citing Charles Billings).

[309] By 2004, the IOM appeared to question its previous recommendation for public disclosure of serious errors. PATIENT SAFETY, *supra* note 45, at 308 ("The Committee also believes that further study is needed to define the appropriate conditions for disclosure and protection of data from patient safety reports in all systems.").

[310] *See* MARCHEV, *supra* note 156, at 4, n.8.

[311] If part of the reasoning for the disclosure of information is so the public can make informed decisions as to the choice of a health care facility, a different type of reporting, which involves performance measures of the quality of care actually provided, may hold more promise than the collection of errors. The National Voluntary Hospital Reporting Initiative is an effort of the American Hospital Association, the Federation of American Hospitals and the Association of American Medical Colleges to provide information about hospital quality to the public. *See* NATIONAL VOLUNTARY HOSPITAL REPORTING INITIATIVE CENTERS FOR MEDICARE & MEDICAID SERVICES FACT SHEET (Feb. 18, 2004), *available at*

latory agencies must be able to follow up on reports to ensure that action has been taken to prevent, or at least minimize, the possibility of reoccurrence of a similar event. With a short, definable list, these agencies are in a better position to ensure the public that remedial efforts will be made by the reporting facility. Connecticut, for example, requires hospitals and outpatient surgical facilities to file a corrective action plan within thirty days after the adverse event occurred.[312] Failure to implement a corrective plan may result in disciplinary action by the Department of Public Health.[313] All reports are confidential, however, and the organization is not punished for making or reporting an error.[314] Minnesota has also embraced a non-punitive approach to mandatory reporting. Its statute emphasizes that the purpose of reporting is not to punish errors by professionals or facility employees but to ensure that hospitals develop plans to improve the health care system.[315]

Although various measures can and have been taken by states to address professionals' concerns about exposure to liability and retaliation for reporting errors, what is needed is guaranteed federal protection of the data gathered by state, federal and private health care safety systems. Federal legislation to safeguard the confidentially of data is a critical part of improving patient safety, but as yet is unrealized. Action by Congress is needed to assure professionals in all

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http://www.cms.hhs.gov/quality/hospital/NVHRIFactSheet.pdf.   CMS and other agencies have joined these organizations to collect reports from hospitals that voluntarily agree to provide data concerning their compliance with selected safety measures. Initially, ten measures representing generally agreed upon standards of care were chosen for three serious medical conditions in the Medicare population. Hospitals that agree to participate in the project report performance information demonstrating compliance with the quality measures. For example, one of the illnesses is Acute Myocardial Infarction (heart attack). The measures include (1) aspirin prescribed at arrival; (2) aspirin prescribed at discharge; (3) beta-blocker prescribed at arrival; (4) beta-blocker prescribed at discharge; and (5) ace-inhibitor prescribed for left ventricular systolic dysfunction. THE CENTER FOR MEDICARE AND MEDICAID SERVICES, NATIONAL VOLUNTARY HOSPITAL REPORTING INITIATIVE, TEN MEASURE STARTER SET, QUALITY HOSPITAL INITIATIVE, *available at* http://www.cms.hhs.gov/quality/hospital/ Listof10Measures.pdf. The public can access online the reports for those hospitals that volunteer to participate in the program. Only compliance rates are reported; patients and individual practioners are not identified. *See* United States Dep't of Health & Human Servs., Hospital Compare, *at* http://www.hospitalcompare.hhs.gov/ (last visited May 5, 2005).

    [312] CONN. STAT. ANN. § 19A-127n (b) (West, WESTLAW through Feb. Reg. Session and May 11 Sp. Session).

    [313] *Id.*

    [314] *Id.*

    [315] MINN. STAT. ANN. § 144.7067(a) (West Supp. 2004).

states that they can freely discuss and report mistakes that occur in hospitals, nursing homes, and ambulatory surgery centers.

Pending legislation provides that protection. In 2004, the Senate and House overwhelmingly passed similar legislation to protect reporters and patient safety data.[316] The bills died in conference, but the Senate reintroduced its version earlier this year. The Senate bill provides that a health care facility may not take an adverse employment action against a person who, in good faith, reports adverse events or errors to a provider or patient safety center.[317] The legislation also contains broad federal protection from subpoena or discovery of data collected by patient safety organizations.[318] The Senate bill differs somewhat from the 2004 House bill in the scope of the privilege as well as in the data to be protected. The House bill shielded safety reports from subpoena or discovery in civil and administrative proceedings, while the Senate version also protects data in criminal cases.[319] Legislation passed by the House afforded a privilege for "patient safety work product," which is more narrowly defined than the Senate bill's "patient safety data."[320] Notwithstanding these differences, the legislation has received wide support in Congress and after five years of effort, deserves prompt reconciliation and passage.[321]

V. CONCLUSION

It has been more than five years since the IOM warned that medical errors were causing the death of a shocking number of patients in American hospitals. The findings were a wake-up call for the health

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[316] Patient Safety and Quality Improvement Act of 2004, H.R. 663, 108th Cong. § 922(g) (2004) (Senate version), *available at* http://thomas.loc.gov.; Patient Safety and Quality Improvement Act, H.R. 663, 108th Cong. § 922(b) (2004) (House version). The Senate version of H.R. 663 passed the Senate by unanimous consent and the House version passed 418-6. BILL SUMMARY AND STATUS FOR THE 108TH CONGRESS: H.R. 663, *at* http://thomas.loc.gov/cgi-bin/bdquery/D?d108:1:./temp/ ~bdYPY9:@@@D&summ2=m&|/bss/d108query.html (last visited May 15, 2005).

[317] Patient Safety and Quality Improvement Act of 2005, S. 544, 109th Cong. § 922(g) (2005).

[318] *Id.* § 922 (a).

[319] *Compare* former H.R. 663 § 922 (a)(1),(2) (House version), *with* S. 544, § 921(a)(1)(2).

[320] *Compare* former H.R. 663 § 921(5) (House version), *with* S. 544, § 921(a).

[321] Although beyond the scope of this article, alternatives to the current liability system also deserve continued study by politicians and health care policy analysts. Lawsuits do little to deter mistakes, but cause valuable information about medical errors to be suppressed because of fear of liability. *See* Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595 (2002).

care industry, the public, and the government. Although the IOM brought a welcome focus to the problem of patient safety in our health care institutions, it is debatable whether any real improvement has been made. Reducing medical error by a precise figure is a goal that cannot easily be attained because many errors cannot be measured with any degree of accuracy.[322] Many decisions made by professionals reflect the uncertainty inherent in medicine, and it is unlikely we will ever know the precise rate of error in health care settings because we rely on humans to be able to identify errors and to distinguish them from complications of appropriate treatment or the natural course of a patient's illness.

As currently implemented, most reporting systems are not able to identify medical error or monitor progress in the prevention of error. The full magnitude of the problem is still unknown and no one knows how many errors exist that are not being reported or whether reporting has had any positive impact on patient safety. The fundamental objective of any reporting system is to encourage discussion of both tragic and minor errors, so that health care professionals and organizations can learn from their mistakes. The lack of a uniform taxonomy of medical error and the failure to provide comprehensive legal protection of patient safety data remain as substantial impediments to the goal of preventing future errors in the health care system.

Ultimately, it may be unproductive to place trust in numbers that are so hard to achieve or to engage in debates about whether an event is an error or a bad outcome of appropriate care. Quality and safety in health care cannot be judged by statistics alone and because of its unique complexity, we cannot expect an error-free health care system.[323] Dollars now spent chasing elusive numbers may better be used to fund safety practices that are known to reduce harm to patients. For example, it is widely appreciated that adverse drug events continue to be a prevalent source of harm to patients. The FDA has recently implemented regulations mandating bar codes on all prescription drugs in an effort to reduce medication errors.[324] Requiring even

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[322] If states use exclusively the NQF list, a finite reduction in a limited number of errors may be achievable. However, the NQF list omits, by definition, a large number of preventable adverse events labeled errors by the IOM. *See* note 287 and accompanying text.

[323] Leape suggests that even if there were a ten-fold reduction in errors, achieving a 99.9% error-free system, it would still equate to two dangerous landings per day at O'Hare International Airport. Leape, *supra* note 4, at 1851 (citing W.E. Deming).

[324] Bar Code Label Requirements, 21 C.F.R. § 201.25 (2004). This type of safety measure is not inexpensive, however, and financial resources vary among hospitals expected to implement the regulations. *See* Markian Hawryluk, *FDA Tar-*

simple measures such as hand washing with alcohol-based rubs will significantly reduce hospital-acquired infections.[325]   Reporting systems designed to identify and measure rates of error should be seen as helpful tools and not as ends in and of themselves. Trying to achieve a specific, quantitative reduction may be less important than simply applying the lessons already learned to ensure the safety of patients in our health care system.

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gets Medication Errors by Requiring Bar Codes on Drugs, AM. MED. NEWS (Mar. 15, 2004), *at* http://www.ama-assn.org/amednews/2004/03/15/gvl10315.htm.
     [325] *See* Center for Disease Control, *Guideline for Hand Hygiene in Health-Care Settings Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force*, *available at* http://www.cdc.gov/handhygiene.