Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation

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ABSTRACT

Patients suffer surprisingly high levels of harm in U.S. hospitals. The causes are various, from overt physician errors to hospital system failures that do not implicate specific provider acts. Given the high level of patient harms, a new regulatory approach is needed to speed harm reduction in the nation’s hospitals. This Article defines adverse events for various regulatory purposes, examines the merits of stepped up detection approaches, and looks at new developments in adverse event detection approaches and measurement tools. It then proposes a new regulatory body, the Patient Safety Commission, with the power to work with hospitals to track adverse events and implement patient safety initiatives. Such an agency would mandate the use of computerized detection tools, disclosure to the public and to patients of adverse events, and link reimbursement to levels of adverse events. The agency would also develop a tiered approach to compensating patients who suffered adverse events, whether the harm suffered was small or substantial.

The goal of the Article is to move patient safety concerns to the forefront of hospital activities, in recognition of the fiduciary obligations of our hospitals to protect us from harms suffered within the hospital walls. The tools are still developing, and incentives are needed for hospitals to make patient safety a central concern. A strong, new federal regulatory body is the best solution, with the use of incentives and sanctions to force swifter responses by hospitals than we have seen since the Institute of Medicine report, To Err Is Human, was published over twelve years ago.

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INTRODUCTION

Patients are harmed frequently in hospitals, in as many as one-third of admissions.\(^1\) They die, suffer surgical injury, become infected, are disabled, are readmitted with problems, lose time from work, or otherwise experience what patient safety experts call “adverse events,” a term describing the sometimes lethal byproducts of health care. These patient harms, these adverse events, happen because of staff errors, system failures of coordination and management, drug mismanagement, and a hundred other reasons, many of which are discovered after the fact.\(^2\) Health care institutions injure and kill patients one at a time—unlike cruise ship disasters or airplane crashes. The casualties are scattered over almost six thousand hospitals, obscuring the volume of harms that occur. These adverse events come in dozens of forms, caused by a multiplicity of factors.\(^3\)

Complexity in medicine is producing more medical adverse events and errors than ever before. Mark Chassin and Jerod Loeb observe: “Hospitals house patients who are increasingly vulnerable to harm due to error, and the complexity of the care hospitals now provide increases the likelihood of

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2 See, e.g., Eric Nalder & Cathleen F. Crowley, Patients Beware: Hospital Safety’s a Wilderness of Data, HOUS. CHRON. (Mar. 22, 2010), http://www.chron.com/news/article/Patients-beware-Hospital-safety-a-wilderness-1702575.php (illustrating that hospitals often underreport adverse events and showing that, in some instances, hospitals have missed cases where patients were killed). This multi-part series on hospital errors, with many personal stories, uses public data to compare hospitals. It surveys states’ policies on adverse event reporting and chronicles the chaotic federal picture of adverse event reporting generally.

3 See VIRGINIA A. SHARPE & ALAN I. FADEN, MEDICAL HARM: HISTORICAL, CONCEPTUAL, AND ETHICAL DIMENSIONS OF IATROGENIC ILLNESS 4 (1998) (defining an “iatrogenic adverse event” as any “complication resulting from reactions to medication or procedures, physical injury or accident, psychological decompensation, nosocomial infections, and medical or nursing errors—including errors of omission”). The authors coin the word comiogenic to describe adverse effects that include “not only abnormal biological and physiological markers and patient mortality but also impairments to health status.” Id. at 121. This classification accommodates a broad spectrum of disease- and health-related outcomes but “would also be amenable to scaling by degrees of severity.” Id.
those errors.” Errors in drug prescribing continue to be a major source of patient harm, as are physicians who practice medicine contrary to clear practice guidelines. Progress in reducing the volume of patient harms is slow, in spite of growing evidence of patient injury. Patients who suffer adverse events, even severe ones, often do not realize what has happened, are not told about the adverse event, and often do not file a claim for compensation for serious harms suffered.

Patient harm at the hands of physicians has occurred as long as medicine has existed, from the early Greeks through today. Clinical iatrogenesis has a long history. Ivan Illich, the social critic and polemicist, cited Plinius Secundus, who wrote in *Naturalis Historia*: “To protect us against doctors there is no law against ignorance, no example of capital punishment. Doctors learn at our risk, they experiment and kill with sovereign impunity, in fact the doctor is the only one who may kill.” Illich wrote in *Medical Nemesis* about iatrogenic injuries, patient harms caused by the sickening features of the doctor-patient interaction. His “clinical iatrogenic disease” included “all clinical conditions for which remedies, physicians, or hospitals are the pathogens, or ‘sickening’ agents.” Adverse events are as old as medicine itself, and as medicine has become more technologically complex, its production of adverse events has also increased. And much of this production has shifted from individual physicians to the complex institutions, such as hospitals, where most high-

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5 See, e.g., Thomas T. Tsai et al., *Contraindicated Medication Use in Dialysis Patients Undergoing Percutaneous Coronary Intervention*, 302 JAMA 2458, 2463 (2009). In a study of 22,778 hemodialysis patients undergoing percutaneous coronary interventions (“PCI”) such as angioplasty, the authors found that 46.7% were administered enoxaparin, 64.1% were administered eptifibatide, and 10.9% received both medications. The use of both is contraindicated in dialysis patients due to excessive bleeding risk. Id. at 2461.

6 See William B. Borden et al., *Patterns and Intensity of Medical Therapy in Patients Undergoing Percutaneous Coronary Intervention*, 305 JAMA 1882, 1886 (2011) (“[L]ess than half of patients undergoing PCI are taking [optimal medical therapy (“OMT”)] before their procedure, despite the guideline-based recommendations to maximize OMT and the clinical logic of doing so before PCI so that the need for additional symptom relief from revascularization can be appreciated.”).

7 Lori B. Andrews et al., *An Alternative Strategy for Studying Adverse Events in Medical Care*, 349 LANCET 309, 309 (1997) (“Although 17.7% of patients experienced serious events that led to longer hospital stays and increased costs to the patients, only 1.2% (13) of the 1047 patients made claims for compensation.”).


9 Id. at 20.
risk care is now delivered.

I. Defining Adverse Events

The patient safety movement in health care aims to reduce the level of such adverse events. The Patient Protection and Affordable Care Act of 2010 ("PPACA") also added several patient safety reforms and grants authority to the Secretary of the Department of Health and Human Services to expand patient safety initiatives. As part of comprehensive quality management programs, patient safety compliance programs are being developed by private firms as well as hospitals. The tools for making modern health care safer are developing in tandem with the increased power of modern medicine to harm, as well as to cure, patients.

The history of the patient safety movement is a history of attempts to define and identify sources of patient injury at the hands of physicians. Iatrogenic harm, as it used to be called, was studied systematically by two pioneers in data collection on patient safety—Florence Nightingale and Dr. Ernest Codman. Nightingale was an early biostatistician and epidemiologist whose work on sepsis revolutionized early treatment of soldiers during wartime. As early as 1858, she developed the use of

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13 The goals of the patient safety movement are to: identify causes of patient injury, whether termed “errors” or not; identify and evaluate effective practices; identify, design, test, and evaluate practices that eliminate systems-related risks and hazards that compromise patient safety; educate, disseminate, and implement best practices to enhance patient safety; and maintain vigilance in monitoring and evaluating threats to patient safety. See generally Vincent, supra note 10.

statistical methodology to show the effects of unsanitary conditions in military field hospitals. Her approach laid the groundwork for standard statistical approaches for hospitals. Codman was a Boston physician who, by the 1920s, had become obsessed with collecting data on every patient in the hospital with the goal of learning what worked and what didn’t and how doctors contributed to bad outcomes. To Codman, patient harms due to infections or unnecessary or inappropriate operations were hospital “waste products.”

By the 1960s academic medical researchers began to systematically focus on the problem of patient harms in hospitals. E.M. Schimmel’s work at the Yale Medical School was one of the first sophisticated looks at safety in hospital practice. He looked at adverse episodes caused by acceptable diagnostic or therapeutic measures intentionally undertaken in the hospital. He found that twenty percent of the patients admitted to the medical wards at Yale experienced one or more adverse episodes—some severe—with 16 out of 240 episodes resulting in death. Surprised at the level of adverse events found and the number of harms caused by standard medical treatments, Schimmel called for physicians to better balance benefits and harms in the selection and use of therapeutic approaches.

This study relied on voluntary reporting by a dedicated staff involved in direct patient care. Such voluntary reporting has been the mainstay of approaches to detection of adverse events, but today it has largely failed in terms of reporting to regulatory authorities and patients. As I will show, better methods of detecting adverse events are necessary and are presently being developed.


16 See E.A. CODMAN, A STUDY IN HOSPITAL EFFICIENCY 54 (1996) (“[T]he Trustees of Hospitals should see to it that an effort is made to follow up each patient they treat, long enough to determine whether the treatment given has permanently relieved the condition or symptoms complained of.”). In Codman’s view, good results would lead to promotions, and poor results would lead to placing responsibility for failure on the responsible physician, the organization carrying out the treatment, the disease of the patient, or the patient conditions preventing cooperation. Id.; see also WILLIAM J. MALLON, ERNEST AMORY CODMAN: THE END RESULT OF A LIFE IN MEDICINE 52-62, 83-93(2000).


18 See id. at 63.

19 J.P. Burke, Commentary, Back to the Future, 12 QUALITY & SAFETY HEALTH CARE 63, 64 (2003), available at http://qualitysafety.bmj.com/content/12/1/63.full.pdf.
What is an adverse event? A common definition does not appear to exist, though one generally accepted meaning is “any injury caused by medical care.” A refinement to this definition is that there is “[a]n unexpected medical problem that happens during treatment with a drug or other therapy.” The National Cancer Institute has expanded upon this definition by detailing that an adverse event is “any unfavorable sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or intervention that may or may not be considered related to the medical treatment or intervention under investigation. The [adverse event] may be either unexpected or expected.” Such adverse events do not have to be caused by the drug or therapy, and are graded, on a scale of one to five, from mild to death, mild being a one on the scale and death being a five on the scale.

In the context of human subject research, Cornell University defines an adverse event as “any occurrence that has unfavorable and/or unintended effects on research subjects, regardless of severity or study-relatedness. AEs [adverse events] may manifest as new findings (signs, symptoms, diagnoses, laboratory results) or alterations in pre-existing conditions.” Yale uses a more nuanced definition, indicating that an adverse event is “[a]n undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.”

The Institute of Medicine (“IOM”) developed working definitions of “adverse event” and “medical error” in its now classic report, *To Err Is Human*. An adverse event is defined as “an injury caused by medical management rather than the underlying condition of the patient,” and a medical error is defined as “the failure of a planned action to be completed as intended . . . or the use of a wrong plan to achieve an aim . . . .” The Agency for Healthcare Research and Quality (“AHRQ”) defines an adverse event as “any injury caused by medical care,” essentially the same as the

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23 Id.


25 Id.

26 INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 28 (Linda T. Kohn et al. eds., 2000) [hereinafter IOM REPORT].
IOM’s definition. AHRQ cites the following examples of adverse events: “pneumothorax from central venous catheter placement,” “anaphylaxis to penicillin,” “postoperative wound infection,” and “hospital-acquired delirium (or ‘sundowning’) in elderly patients.”

The role of negligence in an adverse event is distinct from its role in an incident of malpractice. In a malpractice suit, the plaintiff must prove the physician’s negligence, and negligence is defined as some act or failure by a doctor to follow the standard of care that other physicians in the particular medical specialty follow. Examples of negligence in a malpractice action include the failure of a cardiologist to follow a practice guideline for treating a blocked artery in a patient or a surgeon’s error in operating on an incorrect organ of a patient.

Adverse event reporting has been flawed, since the categories of adverse events are often too narrow to capture the range of events that endanger patients and should be corrected. David Classen and his fellow researchers use the term “harm” as a replacement for “adverse event” to describe an “unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death.” Their language, “resulting from or contributed to by medical care,” is a causal test, not conditioned on a test of preventability. It adopts the modern view of patient safety that requires a relentless focus on safety, assuming that virtually all adverse events can be eliminated. This definition also moves the understanding of what constitutes an adverse event in the direction recommended by the Government Accounting Office (“GAO”), which proposes that “AHRQ and CMS [Centers for Medicare & Medicaid Services] should promote a

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27 AHRQ Glossary, supra note 20 (defining an adverse event as “any injury caused by medical care”).

28 Id. The AHRQ also notes:

Identifying something as an adverse event does not imply ‘error,’ ‘negligence,’ or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process. Thus, pneumothorax from central venous catheter placement counts as an adverse event regardless of insertion technique. Similarly, postoperative wound infections count as adverse events even if the operation proceeded with optimal adherence to sterile procedures, the patient received appropriate antibiotic prophylaxis in the perioperative setting, and so on.

Id.

29 Classen et al., supra note 1, at 583.

30 Id.

31 Id.
definition of adverse events that more fully encompasses harm resulting from medical care.” The tension between an inclusive definition of all harm and a definition that requires preventability has to be resolved as part of any regulatory solution developed to improve adverse-event frequency.

A. Merits of Detection

The hospital setting exposes patients to significant risks of iatrogenic illness. One early study found that more than thirty-six percent of the patients admitted to a hospital developed iatrogenic injury. Nine percent had major complications, and two percent of all patients died for reasons related to the iatrogenic illness. Exposure to drugs was an important factor in patient complications. Critics note that hospitals lack sufficient incentives to discover and reduce their adverse event rates. They fear disclosure because of malpractice risk, leading to either incomplete attention to discovery of adverse events or active concealment of such occurrences. And when adverse events are discovered and claims are

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32 OFFICE OF INSPECTOR GEN., DEPT OF HEALTH & HUMAN SERVS., OEI-06-09-00090, ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES 30-31 (2010) [hereinafter ADVERSE EVENTS IN HOSPITALS], available at http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf. AHRQ and CMS should broaden patient safety efforts to include all types of adverse events. Efforts to improve patient safety often focus on a small subset of events that harm hospital patients. For example, National Quality Forum (“NQF”) Serious Reportable Events or Medicare Hospital-Acquired Conditions (“HACs”) represented only a fraction of the adverse events identified in this report. Additionally, patient-safety provisions in the Patient Protection and Affordable Care Act (“PPACA”) often refer specifically to reducing medical errors, rather than to the broader range of adverse events. AHRQ and CMS should avoid focusing patient-safety efforts too narrowly on a small list of specific events. This narrow focus fails to address the wider array of events that lead to most instances of patient harm. See id.

33 Nathan P. Couch et al., The High Cost of Low-Frequency Events: The Anatomy and Economics of Surgical Misdiags, 304 NEW ENG. J. MED. 634, 635 (1981).

34 Knight Steel et al., Iatrogenic Illness on a General Medical Service at a University Hospital, 304 NEW ENG. J. MED. 638, 641 (1981); see also David W. Bates et al., The Costs of Adverse Drug Events in Hospitalized Patients, 277 JAMA 307, 310 (1997) (finding that an adverse drug event was associated with approximately $2600 in additional costs to the hospital, and for preventable adverse events the figure was almost twice as high); David C. Classen et al., Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Mortality, 277 JAMA 301, 302 (1997) (discussing adverse drug events associated with significantly prolonged lengths of hospital stays, increased economic costs, and an almost two-fold increase in the risk of death); Timothy S. Lesar et al., Factors Related to Errors in Medication Prescribing, 277 JAMA 312, 316 (1997) (suggesting that risks of adverse drug events can be reduced).

35 Daniel A. Pietro et al., Detecting and Reporting Medical Errors: Why the Dilemma?, 320 BRIT
filed, or costs are otherwise created, hospitals have largely externalized those costs to payers, or let the added costs fall on patients who are unaware of the causal links between harms they suffer and hospital care.

Our view of hospitals is changing—from largely non-profit institutions that do good to complex institutional systems that fail too often, injuring patients. This change in attitude has raised our expectations about hospitals—we want them to be safe and well managed. We have learned much more about medical errors, patient harm, and adverse events. The question is how the law can help to improve hospital performance. The threat of tort liability has had some effect in improving hospital-safety practices. The use of Medicare reimbursement carrots and sticks has also begun to ratchet up the pressure for hospitals to reduce hospital-acquired conditions. The level of patient harm remains very high however, and a high level of legal pressure will force hospitals to create what Timothy J. Vogus and his fellow writers call a “binding safety culture.” A consensus is developing that hospitals need to change rapidly to reduce hospital-acquired conditions. Dennis Wagner and Paul McGann note that quality data is reviewed only irregularly and that “[d]espite pockets of success—we still see massive variation in the quality of care, and no major change in the rates of harm and preventable readmissions over the past decade.”

MED. J. 794, 796 (2000) (describing the reading of 6000 prostate biopsies in the authors’ hospital after several biopsies were found to have been erroneously read, which had led to concerns of patient safety). In spite of hospital anxiety about revelations of errors, there were no negative repercussions:

Throughout this process, there was no measurable negative impact on the hospital’s workload or financial performance. Nor were the urologists adversely affected. Our openness reaffirmed our reputation for putting our patients first. Our patients were much more accepting of the inevitability of human error than we were, and they were impressed that we were doing something about it. Our experience suggests that putting patients first is also a good business strategy when addressing errors.

Id.

36 See Michelle M. Mello et al., Who Pays for Medical Errors? An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives for Patient Safety Improvement, 4 J. EMPIRICAL LEGAL STUD. 835, 850-52 (2007).
39 See Timothy J. Vogus et al., Doing No Harm: Enabling, Enacting, and Elaborating a Culture of Safety in Healthcare, ACAD. MGMT. PERSP., Nov. 2010, at 60, 73.
40 Dennis Wagner & Paul McGann, Partnership for Patients: Preventing Hospital Acquired
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The Center for Medicare and Medicaid Services (“CMS”) has begun to push for improvements, including major incentives to improve patient outcomes, such as putting more payment at risk, increasing transparency, increasing frequency of quality data review, and stepping up media scrutiny. 41

Detection of adverse events has significant benefits. Systematic data collection will spur improved safety practices, tracking improvement rates over time for everything from infections to drug adverse events. Such tracking efforts have already begun, as federal pay-for-performance programs condition a fraction of reimbursement on meeting performance standards. 42 The expansion of pay-for-performance—and the reduction of payments for nonperformance—will have some effect on hospital behavior, since income is important to hospitals with small margins of profitability. 43 Improved methods of adverse event detection also allow the evaluation of various patient-safety initiatives, reducing their evaluation cost and helping to develop a reliable arsenal of safety tools.

Adverse event detection is one of the most important ethical obligations of hospitals, as well as physicians. Providers take on a duty to do no harm to patients—defining, tracking, and reducing adverse events is crucial to producing safer hospitals that patients can be comfortable entering. The technical discussions of adverse event detection often disguise the core realities of the hazards patients face in modern hospitals and their right to be free, to the greatest extent possible, from such hazards. Modern medicine may not cure all ailments, but it should not make us worse through no fault of our own. 44


41 Id.


43 See Furrow I, supra note 11, at 1752-53.

44 See George J. Agich, Healthcare Organization Responsibility for Quality Improvement, in HEALTHCARE QUALITY IMPROVEMENT: ETHICAL AND REGULATORY ISSUES 55, 64 (Bruce Jennings et al. eds., 2007), available at http://personal.bgsu.edu/~agichg/Articles/HCO-QI.pdf (“[I]mproving quality of care is an important responsibility that falls to the [health care organization (“HCO”)] because of its historically distinctive place in the delivery of health care. Because complex contemporary healthcare often must be delivered in and through health-care institutions, the HCO is properly regarded as having responsibility for the quality of care.”).
B. Dilemmas of Accountability

Patients suffer injury from medical adverse events, particularly in hospitals where complex procedures are done. The problem is how to define adverse events. It will depend in part on the uses of that definition. We might, for example, define the term very broadly for purposes of tracking levels of harm across hospitals in order to show rates of improvement or deterioration. Here we want to detect problems for patient safety improvement. If the goal is to calibrate government reimbursement for Medicare or Medicaid patients, the definition might be narrowed for such use to avoid putting too much at risk when the definition may generate unfair levels of false positives. If we want to tie adverse events to mandated public disclosure, we again may want a precise and narrow definition because of potential reputational harm. Finally, if we want to design a compensation system for patients who suffered these harms, we may want to use a stratified “avoidability” test in order to justify using adverse events for compensation purposes.

The first major regulatory initiative to tackle the adverse event problem was the selection of twenty-eight Never Events, things that should never happen to a patient, such as wrong-site surgery. The phrase “never events” was coined to capture a range of hospital-acquired injuries that should never happen, that are “largely preventable, but also very serious.” An ordinary person can look at the result of wrong-site surgery and say, “that is not acceptable, that should never happen.” The concept bears a strong resemblance to the tort doctrine of res ipsa loquitur, which describes events that ordinarily do not occur in the absence of negligence, like the falling of an elevator. Never Events have been renamed “serious reportable events” by the National Quality Forum (“NQF”), although states that adopted the term “never events” are still using that term. Serious, reportable events are defined as “a compilation of serious, largely preventable, and harmful clinical events, designed to help the healthcare field assess, measure, and report performance in providing safe care.” These events are patient


46 See, e.g., MINN. DEP’T OF HEALTH, ADVERSE HEALTH EVENTS IN MINNESOTA: FIFTH ANNUAL PUBLIC REPORT 88 (2009), available at http://health.state.mn.us/patientsafety/a09ahereport.pdf (showing the state of Minnesota using the term “Never Events” in an annual health report).

harms caused by care management and not the underlying disease.

The Deficit Reduction Act in 2005 proposed Never Events for hospitals. CMS later implemented these Never Events under the authority of the Deficit Reduction Act to prevent Medicare payment to hospitals for certain Never Events or hospital-acquired conditions—conditions that were high volume, involved higher payment, and could be easily prevented. Hospital-acquired conditions, the current term used by Medicare as part of its 2006 reimbursement program, are no longer reimbursed at the normal rate for the costs of treatment, as they are presumptively preventable patient charges. Medicare has expanded these hospital-acquired conditions beyond the original twenty-eight Never Events, as it denies reimbursement for these conditions.

The concept of Never Events (now “serious reportable

42 U.S.C. § 1395ww(d)(4)(A)(iv)(I)-(III) (2006) (stating that the Secretary must assign diagnosis codes to conditions that: (a) are high cost or high volume or both; (b) result in higher payment when the condition is present as a secondary diagnosis; and (c) could reasonably have been prevented with evidence-based guidelines). On July 31, 2008, in the Inpatient Prospective Payment System (“IPPS”) Fiscal Year (“FY”) 2009 Final Rule, CMS included ten categories of conditions that were selected for the HAC payment provision. Categories of hospital-acquired conditions include: Foreign Object Retained After Surgery, Air Embolism, Blood Incompatibility, Stage III and IV Pressure Ulcers, Falls and Trauma, (Fractures, Dislocations, Intracranial Injuries, Crushing Injuries, Burns, Electric Shock), Manifestations of Poor Glycemic Control (Diabetic Ketoacidosis, Nonketotic Hyperosmolar Coma, Hypoglycemic Coma, Secondary Diabetes with Ketoacidosis, Secondary Diabetes with Hyperosmolarity), Catheter-Associated Urinary Tract Infection, Vascular Catheter-Associated Infection, Surgical Site Infection following surgeries such as coronary artery bypass graft, and Deep Vein Thrombosis (“DVT”)/Pulmonary Embolism (“PE”). Hospital-Acquired Conditions, CMS.GOV, https://www.cms.gov/HospitalAcqCond/06_hospital-acquired_conditions.asp (last visited Mar. 30, 2012).


events” or SREs in the NQF nomenclature) has filtered into federal and state law, requiring reporting and, increasingly, financial sanctions. Even the term “adverse event” neutralizes some of the emotional intensity of the phrase “patient harm,” and “serious adverse events” has replaced the categorical term “never events.” I will use the adverse event terminology in order to peel apart the dimensions of causation and determine what matters from a patient-safety and patient-harm perspective.

Provider acts cause harm to patients whether we see these harms as avoidable, erroneous, negligent, or otherwise branded with the fault characterization. Adverse events are patient injuries resulting from medical care, as opposed to adverse outcomes arising from underlying disease. Many who write about patient safety contend that “[n]ot all adverse events are preventable—those that are usually involve errors.”51 But it can be argued that all adverse events are preventable with attention and resources from a hospital-system perspective.52 A causal test such as that proposed by some reformers not conditioned on a test of preventability,53 adopts the modern patient safety view that virtually all adverse events can be eliminated with sufficient effort.54 Such a causal test may require a distinction between preexisting problems and a compensable adverse event but avoids connecting the event to negligence or preventable conduct as a condition of compensation.

Adverse event reporting systems are often not helpful. The scale of reporting in health care is potentially huge (by contrast to aviation, the paradigm of a successful safety model). Wachter observes:

[I]f all errors and near misses were being reported in American healthcare, this would almost certainly result in more than 30,000 reports per day—over 10 million reports per year! The system is

2011). Each state has to amend its State Plan to account for these HCACs and start refusing these Medicaid payments for hospitals. See id. Under the Proposed Rule, states may also adopt what each state considers to be a HCAC under the criteria of the Deficit Reduction Act. See id. at 9289-90. This can be considerably broader, allowing states to adopt their Medicaid HCACs even if broader than CMS definitions. Id. States can also adopt what CMS refers to as other provider-preventable conditions (“OPPCs”) which apply to other health care providers outside of the inpatient hospital setting. Id. at 9290. In CMS’ own words, these Never Event conditions “can occur in outpatient hospital, nursing facility, and ambulatory care settings, and other healthcare settings.” Id. This has the potential to expand the list considerably.

51 WACHTER, supra note 10, at 13.
52 See Classen et al., supra note 1, at 583.
53 Id.
simply far more complex, with far more opportunities for things to go wrong, and so the issues of prioritizing and managing the reports are far knottier.\textsuperscript{55}

Quality measurement and reporting are improving but are far from mature at this point.\textsuperscript{56} Health care organizations currently are uncertain as to proper approaches for measuring and reporting valid measures of adverse events.\textsuperscript{57}

Accountability measures can promote quality improvement if properly designed.\textsuperscript{58} Mandatory, confidential reporting to a larger organization (either a national one, such as the Joint Commission, or state entities, such as in Minnesota) is the first idea that has gained traction for identifying sentinel, or Never, Events—events that lead to patient deaths or significant disability—that should “never happen.”\textsuperscript{59}

The collection and reporting of hospital adverse events is a mess.\textsuperscript{60} The hospital data currently available in some states is “flawed by content gaps, inputting errors, failures by hospitals to conform to data-entry standards and inadequate government oversight of the data-collection process.”\textsuperscript{61} Congress enacted the Patient Safety and Quality Improvement Act in 2005 to encourage voluntary reporting through the creation of a system of patient safety organizations (“PSOs”).\textsuperscript{62} Reports of medical errors are sent to these organizations and kept confidential so that they cannot be used against the reporter in malpractice litigation. However, the Act fails to provide any incentives for reporting, and without incentives for physicians

\begin{footnotes}
\textsuperscript{55} WACHTER, supra note 10, at 160
\textsuperscript{56} See Peter J. Pronovost et al., The GAAP in Quality Measurement and Reporting, 298 JAMA 1800, 1802 (2007) [hereinafter The GAAP in Quality Measurement] (discussing a need for explicit systems to validate public-reporting measures, such as the Financial Accounting Standards Board, to set generally accepted accounting principles and the U.S. Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications standards of labeling). Pronovost and his fellow researchers recommend a panel to define standards; describe training for those measuring such care; design an auditing system to ensure accuracy; and promote accountability. Id.
\textsuperscript{57} Id.
\textsuperscript{58} Id.
\textsuperscript{60} WACHTER, supra note 10, at 160.
\textsuperscript{61} See David A. Hyman & Charles Silver, The Poor State of Healthcare Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?, 90 CORNELL L. REV. 893, 895-96 (2005) (discussing how doctors previously failed to acknowledge medical errors, but now fail to report because they fear litigation).
\textsuperscript{62} Nalder & Crowley, supra note 2.
\end{footnotes}
to report, these PSOs are unlikely to uncover adverse events.\textsuperscript{63}

I will use the term “serious adverse events” as a reasonable definitional compromise to capture the accountability issues. Causal issues such as preventability and avoidability are important for patient-safety programs, but less so for designed regulatory responses that include compensation for patient harm. The only major causal problem is distinguishing between a patient’s preexisting condition, its potential prognosis, and serious adverse events.

II. Detecting Adverse Events

The collection and reporting of hospitals’ adverse events is currently under- or undeveloped.\textsuperscript{64} The process of finding and measuring adverse events in healthcare is daunting. Federal efforts to improve such data collection have been limited. As stated above, the most recent effort, the Patient Safety and Quality Improvement Act, was enacted in 2005\textsuperscript{65} to encourage voluntary reporting through the creation of PSOs.\textsuperscript{66}

Current approaches to tracking adverse events include voluntary, sentinel event and Never Event reporting systems, often mandated either by state regulators or by the Joint Commission. These methods function poorly. A recent analysis of varied methods for adverse event tracking concluded that “these reporting systems fail to detect most adverse events. . . . Hospitals that use such methods alone to measure their overall performance on patient safety may be seriously misjudging actual performance.”\textsuperscript{67} Mandatory adverse event reporting is the ideal approach

\textsuperscript{63} See David A. Hyman & Charles Silver, The Poor State of Healthcare Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?, 90 CORNELL L. REV. 893, 898 (criticizing the plan because it is not adequately funded and because healthcare professionals have no significant incentive to make reports).

\textsuperscript{64} See id. at 896 (summarizing research showing that medical providers do not disclose errors).

\textsuperscript{65} Patient Safety and Quality Improvement Act, 119 Stat. at 425-26.

\textsuperscript{66} See Hyman & Silver, supra note 63, at 898 (describing the lack of incentives for health care professionals to report errors).

\textsuperscript{67} Classen et al., supra note 1, at 585 (footnotes omitted). The authors describe their findings as follows:

Our findings indicate that two methods commonly used by most care delivery organizations and supported by policy makers to measure the safety of care—enhanced voluntary reporting systems and the use of the Agency for Healthcare Research and Quality’s Patient Safety Indicators—fail to detect more than 90 percent of the adverse events that occur among hospitalized patients.

\textit{Id.}; see also ADVERSE EVENTS IN HOSPITALS, supra note 32, at 5-6.
to full discovery of adverse events, but it is often limited by poor compliance resulting from weak enforcement sanctions and provider anxiety about litigation risks.

Most current approaches to adverse event detection may be viewed as first-generation tools. Computer-driven data collection is the next, second generation of adverse-event collecting. Adverse event measurement is developing rapidly as new tools develop. The development of electronic medical records promises a fully electronic hospital, in which an electronic medical record system would facilitate the use of multiple parallel adverse event detection methods, including automatic analysis of administrative coding measures, treatment details, and data-mining strategies.

A. Measurement Tools

A range of tools are available to detect and measure adverse events. Eight distinct methods can be used to discover adverse events: morbidity and mortality conferences and autopsies; malpractice claims analysis; error reporting systems; administrative data analysis; chart review; electronic medical records; observation of patient care; and clinical surveillance. Each approach has advantages and disadvantages and can be combined in a variety of ways to maximize detection. Eric Thomas and Laura Petersen note:

Although these methods can provide important and actionable information about systems, they also have weaknesses. They are incapable of providing error or adverse event rates because they are imprecise, primarily because of the various factors that influence whether an error or adverse event leads to a claim incident report, or autopsy. Therefore, they should be used sparingly, if at all, to assess the efficacy of interventions to improve patient safety.

Other commentators also note the measurement problems with rates due to the infrequency of many adverse events, limits on surveillance methods, and other factors.

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69 Thomas & Petersen, supra note 68, at 65.


A prime challenge in measuring safety is clarifying indicators that can be validly measured as rates. Most safety parameters are difficult or impossible to capture in the form of valid rates for several reasons: (1)
Harvey Murff and his coauthors survey the detection tools by breaking down the tools into manual methods and combined modalities. The manual methods include voluntary reporting methods, such as incident reporting. This is the voluntary reporting of an adverse event by a healthcare provider. Detection is poor with only 1.5% of adverse events and only 6% of adverse-drug events detected through incident reports. In spite of this, it is still the dominant approach in most hospitals. Prompted spontaneous reporting has also been tried as a way to increase voluntary reporting, using prompts such as email reminders to stimulate more reporting. This still misses most events.

Involuntary reporting methods include chart review, trained observers, and patient interviews. Chart review has typified the large studies, such as the Harvard Medical Practice Study. Predictive value and reviewer agreement on causation are poor with this approach. Observer approaches use trained observers to detect adverse events in the intensive care unit and surgical care floors. Patient interviews have also been tried and provide a good source for adverse event detection.

Medical-record trigger tools are the most recent approach to record review, offering a more practical and less labor-intensive approach to assessing patient safety. Developed by the Institute for Healthcare Improvement, NQF is studying Patient-Reported Outcomes—tools to assess “patient-reported health status for physical, mental, and social well-being.”

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Id.

71 Murff et al., supra note 68, at 132.


73 Murff, supra note 68, at 134.


75 See Introduction to Trigger Tools for Identifying Adverse Events, INST. FOR HEALTHCARE IMPROVEMENT, http://www.ihi.org/knowledge/Pages/Tools/IntrotoTriggerToolsforIdentifying
Improvement, the Global Trigger Tool is based on close chart review, looking at discharge codes and other entries to see if there is a “trigger” in the chart, such as a medication stop order or an abnormal lab result. A trigger then leads to further investigation of the adverse event. A recent study compared three approaches—the hospital’s voluntary reporting system, the AHRQ’s Patient Safety Indicators, and the Institute for Healthcare Improvement’s Global Trigger Tool. They concluded that the Global Trigger Tool uncovered far more adverse events than the other two approaches.

The second major approach combines detection modalities. It relies on both electronic and manual review processes to identify an electronically stored “signal”—a laboratory abnormality and use of a medication along with development of a symptom—to screen charts for further review. This requires manual review, applying screening criteria to identify charts for further review. These systems generally require less reviewer time and thus are less expensive to operate than manual systems, but suffer from low specificity.

An adverse-event-detection system can use either a single-data source or an integrated-data source. A single source could include discharge summaries, with the adverse-event measure relying on an automated review of discharge codes to detect adverse events. A more powerful integrated-source approach would search patient administrative data, medication history, and a clinical narrative from a visit note to identify adverse-drug events. However, other targeted tools have been nosocomial infection and adverse-event monitors using computer surveillance, as well as single- and integrated-data sources. More sophisticated record reviews are being developed. A recent study used four different patient safety case-finding tools and applied them to multiple linked data sets. The authors noted that “triangulation of multiple tools was needed to capture potential patient safety events more
completely and, by eliminating duplication, more accurately.”

The tools used were a software package available through the AHRQ website and voluntary error-reporting systems. The authors found that triangulation through data linkage was a workable balance between chart review (effective but expensive to carry out) and a readily available, if imperfect, data set.

The final tool under development is a fully automated detection system, without any form of manual review. Intra-operative monitors, inpatient-fall monitors, and other programs can match and improve upon chart review success. Such tools are exemplified by patient-fall-detection programs that use natural language processing of the electronic medical record to detect inpatient falls. These tools search all inpatient radiology reports, excluding those performed during the first two days of an admission, to identify those that had been requested as a result of a fall. It could then determine in which reports a fracture had been diagnosed. The fall rates detected through this fully automated tool are similar to fall rates reported within the medical literature.

A recent report from the IOM supports the importance of systems design by acknowledging that most errors and adverse events are caused by system process problems rather than provider fault and that information technology is crucial in detecting and preventing the consequences of such errors. The use of combined and automated electronic search strategies is becoming standard in government regulatory approaches, given the ease of use and automated mining of administrative and financial databases. CMS and the states have begun to use these measures to compare or benchmark hospitals’ performances for patient safety.

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83 Id. at 393.
85 See Taylor, supra note 82, at 393.
B. Information Technology

The expansion of electronic records under pressure from the federal government, market forces, and financial inducements of the American Recovery and Reinvestment Act of 2009 (“ARRA”)³⁸ hold out the promise of improved adverse-event detection.²⁹ As noted above, spontaneous voluntary reporting of adverse events misses the vast majority, while in contrast information technology approaches have the potential to identify a larger proportion of all adverse events that occur. As the tools are refined with the emergence of universal electronic-medical-records adoption through the pressure of the HITECH Act and the money supplied by the ARRA, automated detection is becoming the primary candidate for adverse-event reduction. As David Bates and his coauthors note, “tools that allow detection of a wide array of adverse events are needed.”⁹⁰

Once computer-driven search tools are developed to search hospital files, we are much closer to connecting adverse events to the patients who suffer them, in order to incentivize hospitals to treat patients safely.

III. Institutional Adverse Event Uses

A. A New Regulatory Agency—The Federal Patient Safety Commission

A new federal agency should be created to move patient safety to the center of federal regulatory concerns about patient harms.⁹¹ It might be

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⁹⁰ Bates et al., supra note 89, at 227.

⁹¹ The PPACA created the Center for Quality Improvement and Patient Safety, section 3501, to “identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices . . . in health care quality, safety, and value” in collaboration with other federal agencies. 42 U.S.C.A. § 299b-33(b)(1)-(2). Among the Center’s purposes is the redesign of systems to improve outcomes and patient safety, as well as to limit medical errors. **id. § 299b-33(b)**. It is primarily a research center, tied to the establishment of a
called the *Patient Safety Commission*. This agency would collect data on medical care, publish it, set rules, and impose penalties. It can be modeled, as Peter Pronovost had argued, on existing agencies such as the National Highway Transportation Administration, the Securities and Exchange Commission, or the Federal Aviation Administration.

This new agency would have a range of powers. It would mandate safety-data collection, as the government does now for reimbursement purposes, with penalties for provider failure or intransigence. Hospitals, clinics, or individual physicians’ offices would be obligated to move toward electronic medical records to do so. The agency would develop explicit systems to validate public reporting measures, as exemplified by the Financial Accounting Standards Board’s generally accepted accounting principles or the U.S. Food and Drug Administration’s Division of Drug Marketing, Advertising, and Communications standards of labeling. It would create a board to define these standards; training programs for those measuring such care; and an auditing system to ensure accuracy. This agency would be designed to promote hospital accountability for adverse events. Possible divisions within this agency might be Provider Management (including adverse-event detection and measurement disclosure); Enforcement (disclosure, compensation, and compliance); and Accreditation (oversight of self-regulatory organizations such as the Joint Commission). The agency would also monitor compensation for adverse events, helping to develop standardized compensation schedules that include both economic and noneconomic losses for eligible patient harms suffered as the result of adverse events.

**B. Institutional Safety Improvements**

1. **Learning—Tracking Event Rates**

   The patient safety movement is driven by information about patient harms and improvements and information about what does and does not work. The goal is institutional learning. This is harder than it seems. Hospitals have been described as “obtuse” institutions—they fail to learn from experience and data due to their institutional culture and the

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92 One reason to create a new regulatory agency is to more clearly define a set of regulatory powers that are different from those exercised by the CMS, which has traditionally been primarily a reimbursement-driven agency, slow to take on broader regulatory power.

93 Dr. Peter Pronovost has argued for such a new regulatory agency with the ability to mandate changes in hospitals. Nalder & Crowley, *supra* note 2, at 4.

94 See *The GAAP in Quality Measurement*, *supra* note 58, at 1802.
structural features inherent in their composition and history. Hospitals must discover errors and their causes, and it takes money and time to do so. It also requires overcoming the myths about concealing adverse events for fear of devastating malpractice attacks by patients and their lawyers. There is no doubt that more claims will be made if more adverse events are detected and revealed, but a balanced-compensation system and the higher level of improvements driven by such disclosures will force safety measures that will lower claims over time.

2. Improving—Implementing Patient Safety Initiatives

Hospitals and other institutions need leadership tools to fix mistakes systematically. Safety improvement requires staffing adequate to the job, money spent on electronic medical records and staff to detect and measure adverse events, and high-level scrutiny of such events by administrators and boards of directors. The following sections will present several ideas for improving detection and event reduction, in the spirit of improving hospital-based healthcare.

C. Regulatory Strategies for Safety Improvement

1. Mandating Computerized Detection Tools

Hospitals need a boost in monitoring adverse-drug events, infections, and particularly other kinds of patient harms. It should be routine for health care systems to use a variety of tools, including various computerized detection systems to identify adverse events. Incentives are

95 “Obtuse” is used by Amy Edmondson, a specialist in organizational behavior, to describe how hospitals often fail to learn from their mistakes. See Craig Lambert, Obtuse Organizations: Secret Errors Kill, HARV. MAG., Mar.-Apr. 2001, at 11, available at http://harvardmagazine.com/2001/03/secret-errors-kill.html. Edmondson, an assistant professor at the Harvard Business School, teamed up with two colleagues to study factors that encourage, or inhibit, surfacing errors in small work groups. Id. Leadership that encourages the surfacing of errors can reduce mistakes. As Edmondson found: “You don’t find yourself repeating the same mistake—since you didn’t know about it—that a colleague made last week. . . . When errors aren’t surfaced, an individual may be learning, but the group doesn’t learn. Obtuse organizations can make the same mistake again and again.” Id. (internal quotation marks omitted); see also Anita L. Tucker & Amy C. Edmondson, Why Hospitals Don’t Learn from Failures: Organizational and Psychological Dynamics that Inhibit System Change, 45 CAL. MGMT. REV. 55, 63–64 (2003) (discussing how the individual vigilance and staffing shortages that pervade the industry create barriers to organizational improvement).

96 Lambert, supra note 95, at 11 (“Leadership that encourages the surfacing of errors can actually reduce mistakes significantly in the long run. If errors surface and are publicly discussed, team members can help each other avoid the booby traps hidden in their work environment.”).
not enough, although higher payments for use are desirable; conditions of participation are needed, with penalties for failures to implement detection tools of proven value.

The government can continue to make monitoring tools available. Mandatory adverse event reporting (discussed below) is one component of a regulatory approach to full discovery of adverse events, but it is often limited by poor compliance as the direct result of weak enforcement sanctions. Other approaches to detection of adverse event patterns include the Institute for Healthcare Improvement’s Global Trigger Tool and the use of data mining software programs, such as Midas and other vendor programs, to mine hospital records. Such tools are designed to detect outlier problems in care that may otherwise be invisible to medical staff and administrators. They are unlikely, however, to pick up the range of adverse events that nurses and other providers would detect in their own patient care.

Studies analyzing the actual incidence of negligent events in hospital wards found that many adverse events were not reported in hospital records as required—especially when the main person responsible for the error was a senior physician. Such concealment of adverse events requires strong sanctions to prevent, since it reduces the effectiveness of automated-computer screening for adverse events. It most likely will require a new government agency or department focused solely on adverse event detection, measurement, and reduction.

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97 Introduction to Trigger Tools for Identifying Adverse Events, supra note 75.
98 See generally JIAWEI HAN ET AL., DATA MINING: CONCEPTS AND TECHNIQUES (3d ed. 2012) (discussing different techniques for analyzing data); see also Barry R. Furrow, Data Mining and Substandard Medical Practice: The Difference Between Privacy, Secrets and Hidden Defects, 51 VILL. L. REV. 803, 820 (2006) [hereinafter Furrow III].
99 Furrow III, supra note 98, at 819-20.

[T]he finding that most medical malpractice claims are not based on either iatrogenic injury or provider negligence stands on a small and precarious empirical base. Indeed, the HMPS data are as likely to support a very different finding, namely that most malpractice claims are reasonably related to medical management injuries and provider negligence.

Id.
101 Taylor et al., supra note 82, at 393.

Patient safety surveillance systems should be housed in a governmental
2. Mandating Public Adverse Event Disclosure

Adverse event reporting is a central component of patient safety, identifying threats to patient safety, and providing crucial information for fixes. Mandatory reporting with sanctions for failures to report—properly designed—would increase the level of reporting dramatically. Critics argue that such reporting would drive errors underground and deter physicians from reporting. The evidence for this assumption is weak at best, and there is evidence to the contrary indicating that full disclosure in a properly designed framework reduces litigation risk and settlement and payout costs. Tom Baker and Timothy Lytton observe that “[t]he claim that medical malpractice liability discourages error reporting has never been documented by empirical research, and a recent, careful review has thoroughly discredited this conventional wisdom.”

institution providing affordable, easy access to the data, the analysis of which should produce new interventions. Comprehensive surveillance should provide the basis for optimal policy development and research funding, interventions and benchmarking to ensure we are making progress in improving patient safety.

Id. 102 Lucian L. Leape, Patient Safety: Reporting of Adverse Events, 347 NEW ENG. J. MED. 1633, 1633 (2002). Leape writes that:

The primary purpose of reporting is to learn from experience. Many other methods are also used to identify threats to safety, but a good internal reporting system ensures that all responsible parties are aware of major hazards. Reporting is also important for monitoring progress in the prevention of errors. Thus, the reporting of close calls, as well as adverse events, is valuable. External reporting allows lessons to be shared so that others can avoid the same mishaps. State-run mandatory reporting systems have an additional purpose: to hold hospitals accountable for safe practices.

Id. 103 See Bryan A. Liang, 2005 Institute Healthliners, INST. OF HEALTH L. STUD. (June 2, 2005), http://www.ihls.org/healthliners_05.html.

104 Leape, supra note 102, at 1635.

The fear of litigation may also be overblown. No link between reporting and litigation has ever been demonstrated. In addition, hospitals have an ethical obligation to inform patients fully of the causes of their injuries, and such disclosure was recently made a requirement by the JCAHO. If patients know, then so could their lawyers. In fact, several reports indicate that full disclosure reduces the risk of litigation.

Id.; see also Steve S. Kraman & Ginny Hamm, Risk Management: Extreme Honesty May Be the Best Policy, 131 ANNALS INTERNAL MED. 963, 966 (1999).

105 Tom Baker & Timothy Lytton, Allowing Patients to Waive the Right to Sue for Medical
Physicians who are not exposed to liability are no more likely to report errors than physicians who are exposed to liability.

Reporting hospitals’ comparative outcomes would be valuable.\footnote{See, e.g., Martin N. Marshall et al., The Public Release of Performance Data: What Do We Expect to Gain? A Review of the Evidence, 283 JAMA 1866, 1867 (2000) (reviewing studies that analyzed the impact of publicly releasing healthcare performance data and finding that consumer use was minimal at best); Eric C. Schneider & Arnold M. Epstein, Use of Public Performance Reports: A Survey of Patients Undergoing Cardiac Surgery, 279 JAMA 1638, 1641 (1998) (assessing patient use of a publicly available report card listing hospital mortality rates for cardiac surgery and finding that patients rarely used such information when choosing between healthcare providers).} Public reporting may stimulate quality-improvement activity by hospitals, although a strong correlation between public-reporting obligations and clear evidence of safety improvement is not yet established.\footnote{See Constance H. Fung et al., Systematic Review: The Evidence that Publishing Patient Care Performance Data Improves Quality of Care, 148 ANNALS INTERNAL MED. 111, 121 (2008) ("We conclude that studies of the effect of public reporting on outcomes provide mixed signals, and the usefulness of public reporting in improving patient safety and patient-centeredness remains unknown because few studies assessed these end points. . . . We found additional support for the conclusion that public reporting stimulates hospital quality improvement activity, although studies were mostly descriptive in nature and had low global ratings.").} The data is likely to improve over time under the pressure of private and government payers.\footnote{See id.} Comparative data needs to be carefully extracted and presented; while it may not be easy to evaluate and compare institutions,\footnote{See id. at 274 (noting the “hard work that lies ahead” in expanding and refining healthcare comparative data analyses).} the technologies of data comparison can only improve under external pressure to disclose such data.\footnote{See Ashish K. Jha et al., Care in U.S. Hospitals—The Hospital Quality Alliance Program, 353 NEW ENG. J. MED. 265, 272-74 (2005).} The marketplace has been willing to offer such comparisons as specialty groups reach agreement about what are relevant data. In one recent example, the magazine Consumer Reports partnered with the Society of Thoracic Surgeons to rank over two-hundred heart-bypass groups on a scale of one star (the worst) to three stars (the best) based on their performance against their peers.\footnote{iHeart-Bypass Surgery: 50 Top-Rated Surgical Groups, CONSUMER REP., Oct. 2010, at 40. Only subscribers of ConsumerReportsHealth.org have access to the full rankings and the detailed statistical information used to rank the surgical groups, but the top fifty groups are listed in the October 2010 edition of Consumer Reports. Id. For more background and a critical assessment of the rankings, see generally Timothy G. Ferris & David F. Torchiana, Public Release of Clinical Outcomes Data—Online CABG Report Cards, 363 NEW ENG. J. MED. 1593, 1595 (2010).}
The PPACA and current CMS initiatives further develop such disclosure requirements even though causation is not yet established between disclosure and strong improvements.\textsuperscript{112} The public reporting of performance information is a central feature of the patient-safety provisions of the PPACA.\textsuperscript{113} The PPACA establishes a wide range of demonstration projects and awards to fund research on outcomes and effectiveness. Once that data becomes available, the PPACA mandates its wide dissemination to other government agencies, providers, and the public generally.\textsuperscript{114} Comparative information moves beyond disclosure to patients or future patients of adverse events to a much broader set of comparative factors to aid in selecting a health-care provider. For example, the Physician Compare website will include not only patient outcomes and functional status but also efficiency, patient and family experiences, effectiveness, and timeliness of care.\textsuperscript{115} The PPACA creates several new entities to disseminate findings.\textsuperscript{116}

3. Calibrating Reimbursement to Adverse Event “Waste”

Adverse events may be hard to detect and measure; they may be hard to eliminate in many cases. They should however be viewed as a waste product of hospitals, one that is both harmful and inefficient. Ernest Codman first used the term “waste” to describe patient harms. He argued that hospitals must track their practices and evaluate outcomes of their patients, since he felt that patient harm due to infections and unnecessary or inappropriate operations was a hospital “waste product.”\textsuperscript{117} He admonished hospital managers:

You hospital superintendents are too easy. You work hard and faithfully reducing your expenses here and there—a half cent per pound on potatoes or floor polish. And you let the members of

\textsuperscript{112} See Furrow I, supra note 11, at 1749-52.


\textsuperscript{114} Id.

\textsuperscript{115} Patient Protection and Affordable Care Act, 42 U.S.C.A. § 1395w-5(a)(2) (West 2010).

\textsuperscript{116} The Center for Quality Improvement and Patient Safety is required by section 3501 to make its findings available to the public “through multiple media and appropriate formats to reflect the varying needs of healthcare providers and consumers and diverse levels of health literacy.” Id. § 299b-33(d)(1) (2010). Its research findings are to be shared with the Office of the National Coordinator of Health Information Technology and “used to inform the activities of the health information technology extension program under section 3012, as well as any relevant standards, certification criteria, or implementation specifications.” Id. § 299b-33(d)(2) (2010).

\textsuperscript{117} See SHARPE & FADEN, supra note 3, at 31-32.
the [medical] staff throw away money by producing waste products in the form of unnecessary deaths, ill-judged operations and careless diagnoses, not to mention pseudo-scientific professional advertisements.\textsuperscript{118}

The framing of adverse events as “waste” properly orients regulation toward an attitude of intolerance of unnecessary patient harms. The movement by the federal government and the states to link reimbursement to quality measures is accelerating and can be viewed as addressing Codman’s screeds about waste in hospitals. The PPACA simply follows regulatory initiatives already in place and accelerates further initiatives to improve and disseminate them. Subsection 1311(g) of the PPACA, “Rewarding Quality Through Market-Based Incentives,” mandates a payment structure that is quality and health outcome based, providing increased reimbursement or other incentives for improvements in health outcomes through quality reporting and a range of other coordination initiatives found elsewhere in PPACA.\textsuperscript{119} Its most relevant patient safety language can be found in subsection (1)(C), which requires quality payments for “the implementation of activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage.”\textsuperscript{120}

IV. Patient Centered Adverse Event Regulation

The Patient Safety Commission described above would be in charge of enforcing disclosure of serious adverse events to patients (much as the Veterans Administration is today for its hospitals) and enforcing hospital compensation of patient harm caused by serious adverse events.

A. Disclosing Serious Adverse Events to Patients

Patients desire access to information about injuries they experience, especially serious and preventable ones. Data on adverse events facilitates consumer choice and alerts patients to opportunities to seek compensation for their injuries. Providers are afraid that disclosure will increase their liability exposure, particularly in mandatory disclosure systems.\textsuperscript{121} An

\textsuperscript{118} CODMAN, supra note 16, at 16.


\textsuperscript{120} Id. § 1311(g)(1)(C), 124 Stat. at 180 (codified at 42 U.S.C.A. § 18302(g)(1)(C) (2011).

\textsuperscript{121} David M. Studdert & Troyen A. Brennan, No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention, 286 JAMA 217, 218-19 (2001), http://jama.ama-assn.org/content/286/2/217.full.pdf (discussing the merits of the Swedish model of no-fault
obligation of a hospital to disclose adverse events to patients arises from the role of the hospital as a co-fiduciary, with its physicians and staff taking on a higher duty to protect patient safety and health than is normally required by medical-liability doctrines. Courts have noted that patients rely on hospitals, just as they rely on physicians, to treat their condition with loyalty and skill. When selecting a hospital, patients in most cases will rely on the hospital’s reputation.

Disclosure is part of a movement to honor patients by respecting their need to receive full information. Such transparency makes sense: it respects patient autonomy and their right to the truth about harms suffered in health care institutions. Such disclosure will of course have its costs. As David Studdert and his coauthors observed,

 Disclosure is the right thing to do; so is compensating patients who sustain injury as a result of substandard care. Continuing moves toward transparency about medical injuries will expose tensions between these two objectives. That severe injuries are prevalent and that most of them never trigger litigation are epidemiological facts that have long been evident. The affordability of the medical malpractice system rests on this fragile foundation, and routine disclosure threatens to shake it. Movement toward full disclosure should proceed with a realistic expectation of the financial implications and prudent planning to meet them.

The best current model of adverse event reporting is that of the Veterans Administration (“VA”) System. As of 2005, the VA required disclosure of adverse events to patients and their representatives, including adverse

compensation, in which successful claims are paid in a uniform manner using a fixed-benefits schedule and include compensation for both economic and noneconomic (pain and suffering) losses. Eligibility for compensation requires at least ten days in the hospital or endured more than thirty sick days. This “disability threshold” eliminates the minor claims that would not require significant compensation, but would, if processed, add considerably to administrative expenses.

events that have—or are expected to have—a clinical effect on the patient or necessitate a change in the patient’s care. The Joint Commission’s disclosure standard also requires that “[p]atients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes.”

Another example is Pennsylvania’s Patient Safety Authority (“Authority”), modeled on the VA system, which mandates adverse reporting to both the Authority and to harmed patients. All “serious event[s]” must be reported, and fines are levied for failures to report. Also whistleblower protections exist for those who report nondisclosure of adverse events. Pennsylvania also adopted a patient-notification requirement. Despite some modest regulatory tools to penalize reporting failures, Pennsylvania still has a low and erratic level of adverse-event reporting. The approach however has at least developed some regulatory muscle, but clearly more is needed.

Reporting to patients is essential to sharpen sanctions on providers. We know that patients who suffer significant adverse events often do not file claims. When injury is relatively minor, a lawyer lacks financial incentive to bring a suit, given his dependence on a contingency fee to recover his costs. Also, the patient is often ignorant of the link between his injury and a hospital’s system failure. The provider arms the patient with information through disclosure. If the provider fails to disclose, the patient has little capacity to learn about the role his provider played in causing the patient’s injury. A regulatory agency can mandate reporting of adverse events to solve the problem of underreporting in voluntary systems. State studies

127 See VETERANS HEALTH ADMIN., supra note 54, at A-1.

Adverse events that have had or are expected to have a clinical effect on the patient that is perceptible to either the patient or the healthcare team. For example, if a patient is mistakenly given a dose of furosemide (a diuretic that dramatically increases urine output), disclosure is required because a perceptible effect is expected to occur.

Id.

128 THE JOINT COMM’N, REVISIONS TO JOINT COMMISSION STANDARDS IN SUPPORT OF PATIENT SAFETY AND MEDICAL/HEALTHCARE ERROR REDUCTION RL1.2.2 (2001), available at http://www.dcha.org/JCAHOREvision.htm. The intent statement provides, “[t]he responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatments or procedures to the patient and, when appropriate, family, whenever those outcomes differ significantly from the anticipated outcomes.” Id. This practitioner is someone with clinical privileges, typically the patient’s attending physician. Id.

129 40 PA. CONS. STAT. ANN. § 1303.308(a) (West 2011).

130 Id. § 1303.308(c).

131 Id. § 1303.308(b).
have found self-reporting of adverse events in voluntary systems to be ineffective.\textsuperscript{132} Patient-notification requirements are intended to force hospitals to gather data and share it with the public. The sanctions currently imposed in some states, and by the Joint Commission, are mild and difficult to enforce.\textsuperscript{133} An intentional failure to disclose a serious adverse event, if discovered, might impose a federal penalty of up to $10,000 per day. This would be coupled with a treble damages or punitive damages claim in a malpractice suit by any patient suffering adverse harm due to nondisclosure of an adverse event.

This form of transparency regarding adverse events and error reporting represents an evolution in the kind of fiduciary duty the hospital owes its patient population. It will also promote more medical malpractice claims as a necessary result. Such liability litigation is an outcome-driven, patient-safety mechanism, awaiting evidence of patient injury before crossing the threshold for a possible claim. It does not reveal “near misses” or cases of predictable side effects of drugs, therapies, or surgeries. The low number of claims suggests that lawsuits under-deter, rather than over-deter, in most medical specialties, despite physicians’ exaggerated complaints about defensive medical practices. Even when a suit is filed, evidence indicates that recoveries for noneconomic damages are, on average, too small in states without statutory limits on such damages.\textsuperscript{134} Increasing a patient’s awareness of adverse events allows the improvement of a tort suit’s performance as a parallel patient-safety strategy.

\textbf{B. Compensating for Adverse Event Harm}

The final regulatory strategy for improving the handling of adverse events is the most painful one from the provider perspective but the most important when considering patient harms. \textit{Serious adverse events should be}

\textsuperscript{132} Florida, for example, tried to encourage voluntary reporting several years ago to provide concrete teaching examples for providers. After spending one million dollars on the project, the state found that ninety percent of state hospitals reported no adverse events. Sally Kestin & Bob LaMendola, \textit{Efforts to Improve Patient Safety Not Enough, Critics Say, SUN-SENTINEL}, July 31, 2011, at 1A, available at http://articles.sun-sentinel.com/2011-07-29/health/fl-hk-medical-mistakes-overview-20110710_1_wrong-site-surgeries-medical-mistakes-wrong-body-part.

\textsuperscript{133} See Nalder & Crowley, supra note 2. Washington’s program also is among the worst in the nation for enforcing its reporting requirements. At least sixteen of twenty-seven states with mandatory error reporting programs investigate hospital compliance by comparing medical-error reporting rates with other data, like patient complaints and medical malpractice settlements, according to the HHS inspector general report. Four states conduct onsite audits.

subject to a set of compensation rules that mandate payment to injured patients. A stratified penalty-compensation regime should be considered to provide a fairer and more robust response to patient harms in healthcare institutions while shifting the compensation focus away from physicians. The new Patient Safety Commission, applicable to the Medicare population, would administer the system.

Sophisticated no-fault compensation for patients can operate in tandem with pay-for-performance pressures and other drivers of patient safety improvements. However, I propose that we move beyond pay-for-performance initiatives through the Medicare program. The expansion of patient-safety efforts requires more pressure on hospitals. The adverse events now used as a basis of hospital-acquired conditions are very limited (although expanding) and miss the vast majority of patient harms in hospitals. Many of those harms are not discussed or revealed to patients. It is time to develop a “disclosure and payment system” with both penalties for non-disclosure and no-fault compensation for patients who suffer detectable, adverse-event harm. First, discovery and disclosure of adverse events that cause patient harm needs to be developed and mandated, including penalties when hospitals fail to reveal their level of adverse events. Second, medical liability needs a no-fault option that connects adverse events to patient harms and places compensation responsibility on hospitals for patient harms. Substantial financial costs in the form of damage awards need to be added to other forces to channel hospital practice toward lower levels of harm. Some patient safety analysts have recognized the merits of such an approach, if the incentives can be properly balanced. Too many patient safety scholars fear lawsuits, overrate the

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135 See INST. OF MED., BEYOND MALPRACTICE: COMPENSATION FOR MEDICAL INJURIES 29-42 (1978) (discussing no-fault compensation system among other alternatives to traditional medical malpractice litigation); John Harl Campbell, Enterprise Liability—An Adjustment of Priorities, 10 FORUM 1231, 1231-32 (1975); Robert E. Keeton, Compensation for Medical Accidents, 121 U. PA. L. REV. 590, 590-91, 593, 595, 597 (1973) (analogizing criticisms of the fault-based system for compensation of car-accident victims, which led to the adoption of the no-fault system in that field, to medical malpractice cases); Jeffrey O’Connell, Expanding No-Fault Beyond Auto Insurance: Some Proposals, 59 VA. L. REV. 749, 767-70, 793 (1973) (asserting that no-fault liability is a more successful deterrent than the traditional system and suggesting its adoption in medical malpractice cases); Jonathan Chait, Comment, Continuing the Common Law Response to the New Industrial State: The Extension of Enterprise Liability to Consumer Services, 22 UCLA L. REV. 401, 430 (1974) (forecasting the application of enterprise liability to medical-malpractice cases).

136 See Furrow I, supra note 11, at 1752 (suggesting tort liability has been the primary, if not only, method that forces hospitals and providers to internalize the costs).

137 Wachter, for example, suggests implementing:
risks they create, and are overprotective of institutions. Lawsuits can be powerful tools of deterrence if they capture the maximum number of valid claims possible. They affect both provider behavior and patient choices. Lawsuits are neither random nor unfair, and liability tends to alter the behavior of health care providers.\textsuperscript{138} Physicians and hospitals both learn from the experience of facing claims.\textsuperscript{139} Physicians respond to claims initiation more than claims resolution.\textsuperscript{140} One study concluded that most tort reforms would have little effect on physician behavior, with the exception of reforms aimed at reducing uncertainty about claims initiation—such as the use of practice guidelines.\textsuperscript{141} The authors also found that claims affected consumer behavior, noting that: “The resolution of a malpractice claim provides public information that consumers can use when choosing a provider, and we provide some evidence that they do use this information—physician volume drops following the disposition of a large claim.”\textsuperscript{142}

Organizational liability for hospitals and other institutional providers has long been a meritorious model for malpractice reform.\textsuperscript{143} The American Law Institute (“ALI”) proposed a “channeling” model of organizational liability over twenty years ago.\textsuperscript{144} Organizational liability, as defined by the ALI, would make a hospital liable for physician negligence that injures a compensation scheme that transcends the malpractice framework. If nosocomial infections and other hospital-related harms can be compensated from a fund outside of the framework of malpractice then in principle, the most compelling incentive that hospitals have to seek anonymity and confidentiality regarding the quality of healthcare delivery would be removed. [The] concern is that fear of liability drives providers to conceal bad behavior, including adverse events that are less than disastrous for patients.

\hspace{1em}WACHTER, supra note 10, at 170.

\textsuperscript{138} Darren Grant & Melayne Morgan McInnes, Malpractice Experience and the Incidence of Cesarean Delivery: A Physician-Level Longitudinal Analysis, 41 INQUIRY 170, 171 (2004) (“[P]hysicians experiencing malpractice claims that lead to substantial indemnity payouts increase their risk-adjusted cesarean rates by about one percentage point.”).

\textsuperscript{139} Id. at 185.

\textsuperscript{140} Id.

\textsuperscript{141} Id.

\textsuperscript{142} Id.


\textsuperscript{144} See [2 Approaches to Legal and Institutional Change] ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 113-19 (1991) [hereinafter ALI Study].
patients within the hospital.\textsuperscript{145} It now appears that adverse events are the progeny of poor system management with physicians in need of more help as the patient-safety movement has gained momentum.

The role of information technology and electronic medical records is central to a true no-fault system of medical enterprise liability that evolves toward a requirement of proof of a serious adverse event, with only limited “preventability” tests applied. Pronovost writes: “Robust information technology systems are needed to promote efficient measurement and feedback at various levels, including practicing clinicians, hospital leaders, regulators, accreditors, payers, and patients. This goal is achievable.”\textsuperscript{146} Classen and his coauthors believe that effective tracking of adverse events through electronic means is already possible. They write:

Because of prior work with Trigger Tools and the belief that ultimately all adverse events may be preventable, we did not attempt to evaluate the preventability or ameliorability (whether harm could have been reduced if a different approach had been taken) of these adverse events. A health system has recently accomplished such automation of this tool. The increasing adoption of electronic health records may make such adverse event detection tools more generally available, especially if policy makers incorporate the use of such tools into future meaningful-use criteria for record adoption.\textsuperscript{147}

The approach would have different levels of regulatory responses to adverse events, ranging from claims so serious that strict liability results, to claims that must satisfy criteria for compensation, leaving other events to traditional claims for the present.

1. Serious and Obvious Adverse Events

Serious and obvious adverse events are those patient injuries that are caused by obvious errors. This is derived from the earlier concepts of Never Events—the idea that some harms are simply not tolerable even though they may not yet be obviously preventable, or causation may be uncertain. The definition would not include “avoidability” or traditional “error” criteria. This is pure-enterprise liability. It is based on the obviousness of the harm; it is aimed at the hospital rather than individual physicians; and it gives patients additional claims for damages at all levels with few or no defenses possible.\textsuperscript{148} The general idea of enterprise liability

\textsuperscript{145} Id. at 113-14.
\textsuperscript{146} Tracking Progress in Patient Safety, supra note 70, at 699.
\textsuperscript{147} Classen et al., supra note 1, at 3, 6.
\textsuperscript{148} A defendant could show as an affirmative defense that the adverse event was not an unavoidable complication regardless of treatment or non-treatment. See Actions Against
Preventable, serious adverse events are measurable, preventable, and important with few false positives. It can be argued that Never Events are obvious and do not need further evidentiary justification, but other adverse outcomes are more difficult to link to particular interventions. Pronovost and his fellow researchers worry about designing systems that impose heavy burdens on hospitals, such as pay-for-performance. These concerns are intensified when an obligation to compensate accompanies the reimbursement penalties. They want adverse events that “are important and measurable and truly are preventable.” One could argue that a “preventability” or “avoidability” test misses the point of true enterprise liability. Bad outcomes should simply require a regulatory reaction of disclosure and payment. The tension between preventability and strict
liability is clear. Liability for all adverse events, broadly defined, may be counterproductive:

Nonpayment for complications that are truly not preventable may destroy trust in quality improvement programs, reduce access for patients at risk for these complications (e.g., obese patients at increased risk for decubitus ulcers, deep venous thrombosis, and infections may be shunned), reduce the frequency of diagnosis after admission, and misinform the public when safety and quality results are publicly reported.\footnote{Id. at 2199.}

The problem is that health care is more complicated than, for example, defective product injuries. We need a preventability test that does not over-deter health care providers but is rather based on generally agreed principles of evidence-based medicine whenever possible. With these constraints in mind, preventable serious adverse events can be determined by one of two measures. First, complications are preventable if a “minimally biased effectiveness study with robust measurement from a variety of health care organizations demonstrates that most complications can be prevented.”\footnote{Id. at 2198.} Central-line infections would satisfy this test. Comparative effectiveness research findings are likely to expand this category rapidly with regard to hospital-based complications.

Second, complications are preventable if “substantial variation in complication rates were found among hospitals, assuming those rates were accurately measured.”\footnote{Id.} This sets up a standard of best practice based on measurable rates, allowing for more likely acceptance by the regulated parties. The second component of this test—serious-adverse events that reflect substantial variation among hospitals, teams, or practice areas within hospitals—requires use of comparative data in order to decide what the optimum level of adverse events can be in terms of what successful hospitals are doing. This buys time for below-average hospitals to improve and set goals, and it fits within current Medicare pay-for-performance principles.

3. Serious Adverse Events Lacking Current Evidence of Preventability

Serious adverse events lacking certainty about preventability are still bad outcomes. These adverse events would require: (1) disclosure to regulators and patients; and (2) hospital payment of the economic costs of making patients whole but without noneconomic costs such as pain and
suffering, as well as receiving less reimbursement from Medicare for such failures.

CONCLUSION

Increases in claims against hospitals for the adverse events they generate, coupled with loss of reimbursement, are just what the doctor ordered. Hospitals are implementing new electronic medical record systems; they are developing elaborate compliance programs to satisfy Medicare reimbursement rules; and it is time they focus more intensely on adverse event reduction. Hospitals need to detect, measure, and eliminate these events, or pay for their occurrence. The tools are developing, federal regulators are improving their own regulatory strategies, and the new payment-compensation model of adverse event penalties, monitored by the Patient Safety Commission, will finally approach the system that Ernest Codman and other pioneers of patient safety hoped for a hundred years ago.