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An Ethical Model for Mandatory Reporting to Avoid Preventable Adverse Harm in Health Care

Kate A. Molchan

AN ETHICAL MODEL FOR MANDATORY REPORTING TO AVOID PREVENTABLE ADVERSE HARM IN HEALTH CARE

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By

Kate A. Molchan, JD, MA

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Kate A. Molchan, JD, MA

Approved November 8, 2018

Gerard Magill, PhD The Vernon F. Gallagher Chair Professor of Healthcare Ethics (Dissertation Director)	Henk ten Have, MD, PhD Professor of Healthcare Ethics (Committee Member)
Joris Gielen, PhD Associate Professor of Healthcare Ethics (Committee Member)	Joris Gielen, PhD Director, Center for Healthcare Ethics Associate Professor of Healthcare Ethics
James Swindal, PhD Dean, McAnulty College and Graduate School of Liberal Arts	

ABSTRACT

AN ETHICAL MODEL FOR MANDATORY REPORTING TO AVOID PREVENTABLE ADVERSE HARM IN HEALTH CARE

By

Kate A. Molchan, JD, MA

December 2018

Dissertation supervised by Professor Gerard Magill

The goal of the dissertation is to undertake an analysis in healthcare ethics that focuses upon organizational ethics to resolve problems related to medical error in the U.S. The ethical argument focuses upon justifying a model of mandatory reporting nationally.

While countless others have argued in favor of the implementation of a mandatory reporting system, this dissertation presents its model through the lens of organizational theory; arguing first that healthcare organizations are ethically required to invest in patient safety. This premise frames the foundation for this dissertation's central argument; namely, that U.S. healthcare organizations have an ethical imperative to protect the public from undue harm. Only after having established this normative foundation does this dissertation address the primary obstacle to improving patient safety (the current culture of medicine) and offer suggestions for how to begin to build a business case to incentivize decisive action to develop a culture of safety.

This dissertation explores the ethical justification for developing a centralized, mandatory, non-punitive reporting system that can collect and disseminate adverse event information to a national audience. The analysis relates two foundational concepts to advance this argument: namely, the system-based approach to patient safety and institutional moral agency. The discussion of the systems-based approach to patient safety informs the stance that healthcare organizations are uniquely situated to intervene to reduce medical error. This approach emphasizes the role of system defenses, barriers, and safeguards in preventing errors; recognizing that, because humans are fallible and cannot be made perfect, reform efforts need to focus on system design to prevent harm. The second concept provides a normative framework to hold healthcare organizations morally accountable for failures in system design. Without moral agency, organizations cannot be held accountable for their *institutional practices* or use of systems. Together, these concepts provide an ethical framework to advocate for greater transparency and the nationwide implementation of a mandatory reporting system for preventable adverse harm.

DEDICATION

To the many families who have suffered unimaginable pain and loss as the result of preventable harm.

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CHAPTER ONE: INTRODUCTION

The phrase "adverse harm" in the dissertation title may appear somewhat strange but it has become widely used in healthcare to combine two concepts related to medical error: adverse events and harm. The goal of the dissertation is to undertake an analysis in healthcare ethics that focuses upon organizational ethics to resolve problems related to medical error in the U.S. The ethical argument focuses upon justifying a model of mandatory reporting nationally. The ethical justification for the codification of a mandatory reporting system is explained by discussing these issues: the history of the current patient harm epidemic (Ch.2); the ethical imperative to improve patient safety (Ch.3); the theory of organizational moral agency (Ch.4); the relevant law and the history of the debate over error reporting in the United States (Ch.5); the application of the foundational concepts to present a model for error reporting (Ch.6).

Error within the healthcare system is a major social policy problem. In recent decades, iatrogenic (or inadvertent) harm has emerged as one of the nation's most pressing healthcare challenges.[1] Nearly two decades have passed since the landmark Institute of Medicine (IOM) report, *To Err is Human*, *Building a Safer Health System* first made the general public aware of the severity and pervasiveness of medical harm.[2] The IOM Report, in 1999, galvanized attention on the problem of medical error. The IOM Report is famous for its alarming claim that as many as 98,000 people in U.S. hospitals were dying every year from medical error. Even more notorious was its jumbo jet analogy; the IOM report was credited with the analogy that the number of deaths in the U.S. from medical error is equivalent to one Boeing 747 crashing every day. These estimates did not even include serious, but non-fatal injuries—only deaths.

The IOM report, modeled after highly successful efforts in the aviation industry, recommended implementing a two-tiered system of reporting to tackle the error epidemic:

voluntary reporting of minor or harmless errors, and mandatory reporting of all serious errors.[3] To date, however, the United States still lacks any centralized, national reporting structure to investigate and reduce the occurrence of medical errors. This dissertation explores the ethical justification for developing a centralized, mandatory, non-punitive reporting system that can collect and disseminate adverse event information to a national audience.

The analysis relates two foundational concepts to advance this argument: namely, the system-based approach to patient safety and institutional moral agency. The discussion of the systems-based approach to patient safety informs the stance that healthcare organizations are uniquely situated to intervene to reduce medical error. This approach emphasizes the role of system defenses, barriers, and safeguards in preventing errors; recognizing that, because humans are fallible and cannot be made perfect, reform efforts need to focus on system design to prevent harm. The second concept provides a normative framework to hold healthcare organizations morally accountable for failures in system design. Without moral agency, organizations cannot be held accountable for their *institutional practices* or use of systems. Together, these concepts provide an ethical framework to advocate for greater transparency and the nationwide implementation of a mandatory reporting system for preventable adverse harm.

Though the United States has not followed the IOM recommendations, the report did motivate the passage of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).[4] Progress has been slow. The Patient Safety Act—which became effective in 2009—contemplates the creation of a voluntary reporting system for health care providers to share safety event reports on a privileged and confidential basis. The success of the Patient Safety Act depends on the establishment of independent Patient Safety Organizations (PSOs) to collect and analyze safety event information from health care providers.[5] Curiously, however, the Patient

Safety Act fails to offer substantial guidance or funding for PSOs to carry out this work.[6] As of 2009, the Agency for Healthcare Research and Quality (AHRQ) had certified 65 PSOs, although few had begun collecting data.[7] In fact, many of the PSOs did not even have any contracts in place to collect information from providers. Officially, in 2010, the Government Accountability Office (GAO) concluded that it could not comment on the effectiveness of the Patient Safety Act because the law is still in the process of being implemented.[8]

To purportedly support PSOs, the Patient Safety Act also mandated the development of a Network of Patient Safety Databases (NPSD)[9] to collect and aggregate non-identifiable patient safety data from PSOs.[10] However, nearly ten years later, and there is still no word on when the NPSD will begin collecting information.[11] AHRQ entered into a three-year contract with Westat, effective September 2007, to establish the NPSD. In 2010, AHRQ and Westat officials reported to the GAO that they expected that the NPSD could begin receiving data by February 2011, however, they also noted that this depends on both the development of common formats and on the development of a method of de-identifying patient safety data.[12] According to a Federal Register notice, as of January 2014, AHRQ is still soliciting feedback and meeting with software developers to finalize development of the Common Formats.[13] Still without a method to de-identify patient safety data in September 2012, AHRQ awarded a new five-year contract to ActioNet. At the conclusion of that contract, ActioNet later submitted the only bid on a recent four-year contract (awarded August 2017) to further maintain the Patient Safety Organization Privacy Protection Center (PSOPPC) and NPSD. While the plan was to utilize the PSOPPC to de-identify PSO data in order to meet the confidentiality requirements for submission to the NPSD, the full solicitation for contract HHSA290201700002C clearly confessed that "AHRQ has not yet built or implemented the NPSD environment nor received any data in the NPSD

environment."[14] Moreover, the GAO also recognized that, even if the AHRQ develops effective strategies and a working NPSD, the Patient Safety Act also relies on the *voluntary* participation of providers and PSOS.[15] Not surprisingly, it is unclear whether the Patient Safety Act framework will be successful given the lack of incentives, federal funding, and legal precedent.

Thus, while the IOM report generated widespread awareness and stimulated collective outrage, the public outcry has not been loud enough to break the cycle of inaction. The United States healthcare system is still failing to reduce the occurrence of medical error. Shockingly, at the same time, the death toll actually seems to be rising. Recent studies have suggested that medical harm occurs in as many 1 in 3 admissions—most of which are preventable. To this point, a 2013 study concluded that the current number of premature deaths associated with preventable harm is estimated at more than 400,000 per year[16]—more than four-fold the original IOM estimate. To borrow the notorious jumbo jet analogy from the IOM report, this is comparable to, not one, but, *three* Boeing 747 aircrafts falling from the skies every day.

It is clear that current efforts, including voluntary reporting systems, are failing to motivate healthcare providers to report or reduce errors. Though the IOM report initially provoked patient anxiety, there has been all too little change in the healthcare industry. It is understandable why—even if a patient's family does learn that their loved one's death was preventable (a disclosure that happens infrequently) the problem of preventable deaths occur one patient at a time, in one hospital at a time. If these figures had to be reported nationally, the public would be shocked and healthcare would be forced to make the necessary changes to avoid so many preventable errors and deaths. To truly tackle the problem of medical error, the U.S. healthcare system must be held accountable for this epidemic harm. It is time to take decisive action to prioritize patient safety.

The purpose of this analysis is to approach the problem of medical error from the perspective of organizational ethics in healthcare. Since the IOM report, experts have concluded that individual providers are not responsible for most errors. Of course, there will always be some individuals whose incompetence or negligence justifies a malpractice lawsuit; but studies have convincingly concluded that poorly designed organizational systems (e.g., long work hours, insufficient safeguards, understaffing) are the root cause of medical harm. Starting from this widely accepted understanding of error management, which focuses on changing the conditions within the system to anticipate and prevent errors, this dissertation adopts a similar approach in organizational ethics to argue for a nationally mandated reporting system that will significantly reduce the occurrence of medical error.

The analysis adopts a systems approach in organizational ethics to explain the need for and contribution of a nationally mandated reporting system. While countless others have argued in favor of the implementation of a mandatory reporting system, this dissertation will be the first bioethics analysis to present an argument from the perspective of organizational ethics in healthcare. This dissertation presents its model through the lens of organizational theory; arguing first that healthcare organizations are ethically required to invest in patient safety. This premise frames the foundation for this dissertation's central argument; namely, that U.S. healthcare organizations have an ethical imperative to protect the public from undue harm. Only after having established this normative foundation does this dissertation address the primary obstacle to improving patient safety (the current culture of medicine) and offer suggestions for how to begin to build a business case to incentivize decisive action to develop a culture of safety.

The argument begins with a comprehensive summary of the extent of patient harm in the United States. Chapter two provides a critical analysis of the problem of medical error, through

which this research has concluded that healthcare organizations have an ethical obligation to implement solutions in a more genuine effort to protect the public interest. To fully appreciate the severity of the ethical issue, chapter two further examines the frequency and taxonomy of medical errors, noting the complex intersection of multiple factors. Not surprisingly, safety improvement efforts have failed to prevent thousands of tragic deaths due to medical error. To an extent, this shortcoming can be attributed to the intricacy of human error. Chapter two aims to provide a comprehensive overview of these complexities, paying attention to the identification, frequency, and causation of errors.

This picture of error and its causes provides a contextual basis to approach systems thinking within healthcare systems. As medical education began improving and providers were able to employ more interventions and procedures, the healthcare system began attaining greater influence and ability to cause harm. As early as the mid-1950s researchers were warning about problems with patient safety.[17] Many of the early patient safety reforms resulted from public outrage in response to high profile, horrific errors. In the 1980s, the death of Libby Zion led to public scandal about poor supervision and sleep-deprivation among medical residents. [18] After a massive overdose of chemotherapy in the early nineties, prominent health reporter Betsy Lehman died at the Dana-Farber Cancer Institute in Boston—one of the country's most renowned cancer institutions. Then, in 1995, it was the Willie King case; where a surgeon at University Community Hospital in Tampa amputated the wrong leg. In that same year, a New York woman died when her doctor used her catheter as a feeding tube; a surgeon in Grand Rapids, Michigan performed a mastectomy on the wrong breast; and a therapist in Tampa erroneously disconnected a 73-year-old's ventilator.[19] Although these cases have had a profound impact on the practice of medicine, this type of specific headline exposure tended to suggest that medical errors—while

appalling—were rare, infrequent accidents. The publication of the IOM report, however, signaled a new approach to error—it was the rise of the patient safety movement.

Accordingly, the third chapter explores the history and evolution of the patient safety movement, with a focus on contemporary terminology and methods. Armed with a basic understanding of the modern approach, this chapter also examines the contention that a prevailing culture of blame is primarily responsible for the high rate of medical error. Informed by systems theory, proponents of this contemporary approach contend that healthcare organizations must abandon the practices of blaming individuals in order to improve safety. This chapter helps to frame the foundation for this dissertation's argument that preventing unintended injury requires a systems-based approach; one that can identify and eliminate the latent defects within the current health care system that permit obvious, but often irreversible, human error.

To successfully implement such an approach, it is essential to develop a solution that simultaneously fosters organizational accountability. This dissertation argues that the failure to address this element is one of the leading reasons as to why the patient safety movement has made so little progress in reducing the occurrence of medical error. To support this argument, the fourth chapter critically examines the application of organizational moral agency as a mechanism to develop normative methods to improve the quality and safety of healthcare. This analysis further reveals that, safety improvement efforts are not only failing, but also that future efforts are unlikely to succeed given the lack of financial incentives for healthcare organizations to take the issue more seriously.

Before addressing how to better incentivize the development of robust patient safety systems, the fourth chapter tackles the question of whether healthcare organizations are ethically required to invest in patient safety. Through establishing the necessity for a systems-based

approach to prevent unintended injury, this chapter provides a foundation for the argument that healthcare organizations must get involved—indeed, if the public could individually curtail the incidence of harm, medical malpractice should have already been wildly successful. Though there are many, the major failing of medical malpractice is that it only tackles the problem of preventable harm one patient at a time, in one hospital at a time. Even when the family and public learn of harm (something that hospitals and other facilities can easily cover up in most cases), because the incident is presented as a single occurrence, it does not convey the severity of the harm epidemic. In this way, the notion of accountability is critical to safety reform. If healthcare organizations were required to report incident rates nationally, the public would be shocked. The entire healthcare system would be forced to make the necessary organizational changes to avoid such rampant preventable harm. A single incident, however appalling, will never be able to match the demand for a national level of systemic intervention—it simply does not seem necessary. Societal expectations and judgments regarding health care are formed, in part, in relation to an understanding of accountability. Accordingly, section B explains the emergence of organizational ethics within health care and clarifies how organizational moral agency can offer a framework to guide societal expectations.

Having established that organizations must take patient safety more seriously, chapters five and six consider how to develop a solution to identify and eliminate defects within the healthcare system while simultaneously fostering organizational accountability.

Within this context, the fifth chapter critically examines the ethical and legal debate on the centralized reporting of medical errors. Opponents advance a number of arguments, but most center on the ineffectiveness of current mandatory systems; contending that mandatory reporting systems actually worsen participation in error management. This chapter explores those

arguments, making clear that the true problem is that the existing systems (both mandatory and voluntary) were designed to force compliance and impose punitive measures. To truly realize positive change towards improving patient safety, error reporting systems must be designed to achieve those goals—these systems must be primarily concerned with collecting information to improve patient safety. Instead, empirical evidence tends to show that the current mandatory reporting systems in place are underfunded and poorly executed. Not surprisingly, these systems are unable to foster buy-in and help stimulate meaningful change. While critics have helped to pinpoint many weaknesses in the current systems, these are not problems that cannot be overcome with a well-designed reporting system. Far from an argument against mandatory reporting, this ongoing problem, instead, highlights the importance of garnering greater administrative support.

To that end, the sixth chapter recommends a series of reforms that introduce mandatory reporting and encourage accountability through public awareness and the implementation of incentive programs. However, change does not always come easy—particularly when the majority of healthcare organizations continue to ignore both the safety behavior and management dimensions of safety culture. To achieve safe health care, this chapter provides a mechanism to cultivate a sense of responsibility for safety. Given the fact that patient safety initiatives must compete for resources with other priorities, it is critical that any reform effort offers a compelling business case for patient safety. Fully engaging the public, transparent accountability for harm, and systemically correcting the root causes of harm will be necessary to curtail this epidemic of harm. To that end, this chapter articulates important mechanisms that must be incorporated into the centralized, mandatory reporting system: (1) incentivize safety efforts, (2) protect providers and institutions from unfair punitive measures, (3) integrate the reporting mechanism within

existing systems to streamline reporting, (4) ensure reporting mandates are clear and easy to interpret, and (5) provide meaningful feedback to encourage continued reporting. Congress should pay particular attention to the importance of embedding the recommended incentives. It is time to break the cycle of inaction and create a safer health system.

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CHAPTER TWO: PATIENT HARM: AN EPIDEMIC

> The United States loses more American lives to patient safety incidents every six months than it did in the entire Vietnam War.[1]
>
> —HealthGrades, "Patient Safety in American Hospitals"

A. The Beginnings

Prior to the scientific progresses of the industrial revolution, society often regarded the medical practitioners of the 19th century with caution. Given the lack of training and basic understanding of anatomy that marked the medicine of that era, it is not surprising that there was great suspicion surrounding the field—a field that was more often considered quackery.[2] Yet, towards the end of the century, medical education was improving.[3] By the early 20th century, the profession self-organized and significantly repaired its public image. These new-century doctors embraced a code of ethics and abided by licensing requirements. In the public mind, the American physician—adorned with an air of moral probity—was held in high esteem.[4] Possibly the most revered of all was the small-town doctor; the lone physician that cared for entire rural towns with a single, characteristic black bag. This image embodied the 'Country Doctor:' an "empathetic portrait of an American folk hero."[5]

When making judgments about appropriate professional conduct, these new-century physicians consulted a single source: the Hippocratic code.[6] Although it is commonly called the 'Hippocratic Oath,' the Hippocratic ethic is a verbalized codification of a set of moral precepts—more than an oath, it is a code. As a code, it describes the expectations of ethical behavior and professional decorum for physicians.[7] In solemnly swearing to abide by the Hippocratic ethic, the code and oath coincide, but the ethic does not lose its identity as a code. In its entirety, the code represented the Hippocratic tradition, which was the standard of medical ethics.[8]

Establishing an ethical system within a code is not a traditional methodology, but instead follows from the rhetorical method of the argument from authority.[9] In this way, the Hippocratic tradition exist as self-evident and self-justifying moral precepts.[10] In classical logic, an argument from authority was accepted out of deference for the presumed expertise or prestige of the person or institution. As such, the strength of such a claim varies based on the validity of the authority at issue.

In this instance, the tradition gained moral authority as theories of common morality that were generally accepted and recognized as universal truths within the medical profession of that era. Theories of common morality focus on a set of moral norms that are widely accepted within the social system. A norm is a rule or pattern, which is usually related to expected social behavior, that is typical within a population. While also describing expected social behavior, unlike a social norm, a moral norm includes a normative expectation that persons are morally obligated to abide. All common-morality accounts share several philosophical underpinnings. First, each account begins with shared norms—these are typically established empirically. This empirical investigation is non-normative, *descriptive* ethics because its objective is to uncover what factually occurs rather than establish what should ethically happen.[11] Second, systems of common morality assume that the set of accepted rules or principles are universal and implicit. Principles are slightly more abstract than rules, but both order, classify, and group moral norms.[12] Finally, these theories are pluralistic, as the proponents offer at least two (though, usually more) principles or rules as the basis for the ethical framework.[13]

A weakness in this approach is its reliance upon the sustained common morality. Many philosophers accept W.D. Ross's contention and agree that a system of morality can be founded on a common set of widely accepted moral principles, yet the endurance of any such moral

framework is dependent upon an undisturbed sense of common moral ideals. Because a common morality builds from a set of moral norms, as a society becomes more pluralistic, the approbation of the common morality could deconstruct.[14] Faced with the erosion of commonalities, a moral guideline based on common morality must develop a new basis of normative authority or be relegated to exist as a social construct without any moral force.[15]

While medical technology advanced, the common morality deteriorated as physicians faced increasingly complex ethical dilemmas. The Hippocratic tradition did not provide any insight into matters of medical futility or, as healthcare costs skyrocketed, the distribution of care. After World War II prompted huge advances in medical knowledge and techniques, however, medical commentators began expressing concerns about unintended problems.[16] Similarly, the public trust faltered; the introduction of technology had transformed the doctor-patient relationship in ways that portrayed doctors as uncaring, greedy, and self-interested.[17]

In the mid 1950s things worsened, as researchers began publishing studies warning of problems with patient safety.[18] Despite repeated revelations about patient deaths and injuries, they elicited almost no effect on the actual practice of medicine.[19] The medical paradigm successfully combatted change using two rather effective safeguards.[20] First, relying on public perception of doctors as well-intentioned and caring, it asserted that some level of inadvertent patient harm was simply unavoidable given the advanced level of technology. As these injuries were unavoidable, there was no impetus to take any corrective action. Secondly, in the unusual instance when it was too difficult to suggest that an injury was unavoidable, the practitioner was cast as the problem. The medical paradigm was safely entrenched.

As Thomas Kuhn described, even without these safeguards, altering a paradigm is a revolutionary process; “each [new revolution] necessitated the community's rejection of one

time-honored scientific theory in favor of another incompatible with it."[21] To be accepted as a paradigm, a theory does not need to be complete or explain all counter-instances. It takes a true crisis to shake up the stereotypes and pave the way for a fundamental paradigm shift.[22] It will only occur when a profession can no longer evade anomalies—these are the tradition-shattering turning points. In the case of the medical tradition, it will take significant pressure to penetrate the self-protective shell of rationalizations. One expert, Michael Millenson, argues that the news media has successfully subverted the old paradigm and ushered in a new era of patient safety.[23]

1. High-Profile Errors

Indeed, with the medical tradition ignoring the studies, the major push for reform came from the general public (after being informed by the media). With high profile cases gaining intense coverage, the outcry was deafening.

White Coat Criminals: The Libby Zion Case

In the 1980s, the death of Libby Zion—daughter of well-known investigative journalist and former attorney, Sydney Zion—led to public scandal about poor supervision and sleep-deprivation among medical residents.[24] The case, itself, is both confusing and contested, and almost every witness in the eventual court trial presented a differing account of the facts.[25] At least four different narratives, occasionally overlapping, emerged to explain the event: (1) The doctors and hospital, to varying degrees, are responsible for Libby Zion's death, which resulted solely from medical malpractice. (2) Libby Zion died because a broken hospital system allowed inexperienced and overworked trainee doctors to manage her care. (3) Libby died as a result of her own failure to provide a full medical history, specifically, by concealing her illicit cocaine use. (4) Libby Zion died an unpreventable death from an unidentifiable cause.[26] That said, there are some undisputed facts.

Late Sunday night, March 4, 1984, Libby Zion, an 18-year-old college student at Bennington College, presented to New York Hospital with a fever, agitation, and odd jerking movements.[27] She had been ill at home for several days with a low-grade fever and an earache—possibly related to a recent tooth extraction on Thursday, March 1—and had already been taking erythromycin, an antibiotic. Her condition worsened. Libby began to act strangely, writhing her body and periodically seeming disoriented. Sidney contacted his doctor, Raymond Sherman, an attending at New York Hospital, who suggested that they bring her to the emergency room.[28]

The Zions arrived at the New York Hospital emergency room shortly before midnight—the time on the emergency pavilion record was 11:43 p.m. During an initial assessment an emergency-room nurse, Anne Gallagher, logged a temperature of 102.9° F. Nurse Gallagher recalled that Libby was unable to sit still. She noticed that Libby was shaking and appeared very uncomfortable. At some point during the two-hour examination, Sidney thought he overheard a nurse say the fever had risen to 103.5° F. Not being able to find a clear diagnosis, the emergency room physicians admitted Libby at 2 a.m. for further observation.[29] Though it was never charted, Myrna Blade, a nurse assigned to Libby's care after she was admitted, noted that she was throwing herself around the bed and swearing incomprehensibly, as though she was a little delirious.[30] It made it difficult to communicate with her.

On that evening, the only staff member on call was Dr. Luise Weinstein, a first-year intern with eight months of experience.[31] During the week, a house-staff usually comprised of three interns and one resident; but it was routine to be understaffed on Sundays. The emergency room Dr. called ahead to advise her of the new admission and briefly discuss her case.[32] Dr. Weinstein told her immediate supervisor, Gregg Stone—a second-year resident—and they decided to meet and examine Libby together. Weinstein, who routinely worked between 95 and

110 hours every week, was already covering nearly forty patients, and both residents had been working for roughly eighteen hours when they began examining Libby.[33] Stone arrived first, and had completed his assessment before Weinstein arrived, although he remained elsewhere on the floor to write up his notes. Sidney and Elsa said that Dr. Weinstein and nurse Blade were already at Libby's bedside when they finally reached her room, after getting slightly lost. Dr. Weinstein complained that Libby was a poor historian, hardly surprising. At one point, Libby was so disoriented that she told Dr. Weinstein that she only had one brother. Libby did disclose that she was taking Nardil, an anti-depressant, but repeatedly denied using any illegal drugs (except for marijuana).

Shortly before 2:45 a.m., Drs. Stone and Weinstein settled on a "plan of conservative care" (as Dr. Stone later put it).[34] The plan, which the attending physician approved by phone, was to administer intravenous fluids and Tylenol for her fever while observing her and awaiting results from other tests.[35] At the time, the preferred diagnosis was "a viral syndrome with hysterical symptoms."[36] Though this was still a preliminary assessment, neither resident was particularly alarmed—ordering routine vitals (temperature, pulse, and blood pressure) to be taken every four hours. Feeling assured that their daughter was all right, Sidney and Elsa Zion went home at around 3 a.m. Much of what transpired in the following three and a half hours are contested, but the charts reveal a general timeline.

Per Dr. Weinstein's orders, nurse Blade administered a sub-therapeutic dose of Demerol, an opiate, around 3:30 a.m. to help control Zion's shaking movement.[37] Blade, a registered nurse for over seventeen years, was the only provider involved in Libby's care who knew that Demerol was contraindicated with Nardil; unfortunately, she reportedly had not reviewed the emergency-room sheet to realize that Libby was taking Nardil at that time.[38] Weinstein stated that she

looked up Nardil in a physician's reference book, but overlooked any contraindication for Demerol. Around 4:15 a.m., shortly after Weinstein left the floor to see other patients, Libby was increasingly agitated, swearing, and trying to climb out of bed. Nurse Blade asked Jerylyn Grismer, a 1983 graduate from nursing school, to call Weinstein to ask her to return and evaluate Libby because she was worsening.[39] After observing Libby pull off her covers, try to remove her hospital gown, and attempting to scale the bed's side rails, Nurse Grismer called Weinstein to suggest that Libby should be retrained. Evidently believing the agitation and shivering to be consistent with the prior symptoms she observed, Weinstein orally ordered restraints. The nurses first utilized a Posey restraint that secured Zion's waist and chest to the bed. When the Posey failed to contain Zion, the nurses also tied her wrists and ankles (supposedly, they failed to communicate this decision to Dr. Weinstein, who later said it was not appropriate).

Not satisfied, Grismer called Weinstein again and asked her to come evaluate Libby personally. Weinstein refused, explaining that she had just seen Libby and was with another sick patient. Weinstein reportedly felt comfortable with nurse Grismer's assessment that, despite the persistent agitation, there were no changes to Libby's appearance and respiration, and orally ordered 1 mg of Haldol—an antipsychotic tranquilizer.[40] Sometime shortly after the nurses administered the Haldol, Zion finally calmed and fell asleep. Myrna Blade, the senior nurse, stated that she woke Zion at 6 a.m. to take two Tylenol tablets. Blade recalled that Libby was flushed, and she could tell that she was feverish, though she did not believe it was "that high."[41] Just one half hour later, during the routine morning temperature checks, Zion's temperature was between 105.8° and 107.8° F. The nurse's aide reportedly had a difficult time obtaining a temperature, as Libby kept thrashing and would not open her mouth. The aide eventually obtained a temperature from Libby's armpit. However, because an axillary (i.e., armpit) reading

is one degree(s) lower than an oral reading and two degrees lower than a rectal reading, Libby's internal temperature was as high as 110° F. Nurse Grismer immediately called Dr. Weinstein, who ordered cold compresses and a cooling blanket. Ten minutes later, at 6:40 a.m. Libby was in cardiac arrest. Despite extensive resuscitative efforts, Zion passed away.[42]

Even after her death, however, everyone remained puzzled.[43] Eventually, the hospital would attempt to shift the blame to Libby. Drs. Leonard (the emergency room doctor), Stone, and Weinstein only knew about the Nardil, erythromycin, and Libby's occasional marijuana use. In truth, Libby was taking far more drugs: her dentist prescribed 20 tablets of Percodan (only 5 were left), her psychologist prescribed 30 Valium and 30 Dalmane, her pediatrician prescribed Chlor-Trimeton (an antihistamine), and she purportedly used cocaine (at least according to one toxicology report). After conducting his investigation, Dr. Joseph Ruggiero, the chief resident, concluded that Libby's condition stemmed from a drug interaction between Nardil and one of the drugs that she ingested prior to admission—likely cocaine.[44] Sidney was irate.[45]

Sidney Zion wanted the doctors to be charged for criminally negligent homicide. Libby's cocaine usage—or lack thereof—was widely contested. A supplemental report attached to the initial toxicology report, stated that the blood samples were retested and found to be negative for cocaine. Sidney maintained that Libby died from a deadly interaction of the hospital-administered Demerol with Nardil:

> I learned that they gave her Demerol, which the physicans handbook says you do not give against Nardil, that when she began writhing around, trying to break loose or whatever, trying to get out of that bed, Luise Weinstein refused to come down and see her and ordered a bed thing put around her, a restraint put on her, without examining her; that when Libby broke that restrain Luise Weinstein coldly ordered another one, another

> restraint… Luise Weinstein still refused to come down and see the kid, ordered her hands and feet tied to the bedpost and then had her hit with a drug called Haldol, and Luise Weinstein never saw her again until they put in the code. …It is my definition of murder.[46]

Sidney raged. With his media connections, he had immense influence over the news coverage, and he positioned the doctors involved as murderers in every interview.[47]

Though it is difficult to learn of this case and believe that Libby's death was unpreventable, it was not until later that experts could explain why—Libby died from a form of drug poisoning called serotonin syndrome.[48] Despite its relative obscurity, this deadly interaction was first described in 1959 in a patient with tuberculosis who was treated with meperidine (Demerol)—the interaction was not named serotonin syndrome until 1982. The combination of Nardil and Demerol (or possibly another drug) may have likely raised the level of circulating serotonin to dangerous levels. As she became agitated, exhibiting classic early symptoms, she was restrained. The resulting muscular tension is believed to have sent her fever soaring to lethal heights. Though the condition was discovered, until the Zion case, the overwhelming majority of physicians in the United States had not heard of the interaction. At that time, there were only 20 reported cases since the 1950s. In fact, according to their testimonies, none of Libby's doctors were aware of the interaction. Dr. Weinstein reportedly consulted the *Physician's Desk Reference*, but had not noticed the warning that "death can result" from that drug combination.[49]

Interestingly, despite this, Sidney Zion was consumed by anger and would not stop until New York Hospital admitted it killed his daughter. Though his crusade helped to spur reforms, especially in limiting the hours residents can work per day,[50] Sidney arguably failed to push the

system to change in any meaningful way to prevent a similar error in the future. Indeed, these interactions continue to kill patients today—even with hours restrictions. What the system needs is a dramatic restructuring of how we provide care; from the improved utilization of technology to monitor and warn of potentially uncommon interactions to a new mindset for how young doctors are mentored and supervised. To realize meaningful gains the commitment to patient safety must be systemic and engrained. The fervor to again reform safety re-emerged after a similar high-profile tragedy a decade later.

Betsy Lehman: Not the Only Victim

> [M]ay I appeal to you to pause for a moment, if you will, in your important task. For in the wings outside your busy meeting rooms may be heard the murmurings of patients gone now due to fatal medical error, or harmed by a medical system they trusted. They are the ones absent…. Among them is my young, brilliant daughter suddenly lost…. Patient safety must be utmost and constant, both ingrained into the system you seek to strengthen, and into caring hearts.[51]
>
> —Mildred Lehman

On March 23, 1995, the *Boston Globe* published a chilling front page article warning that "Doctor's orders killed cancer patient." In the exposé, veteran reporter Richard Knox wrote:

> When 39-year-old Betsy A. Lehman died suddenly last Dec. 3 at Boston's Dana-Farber Cancer Institute, near the end of a grueling three-month treatment for breast cancer, it seemed a tragic reminder of the risks and limits of high-stakes cancer care. In fact, it was something very different. The death of Lehman, a Boston Globe health columnist, was due to a horrendous mistake: a massive overdose of a powerful anti-cancer drug that ravaged her heart, causing it to fail suddenly just as she was preparing to go home to her husband and two young daughters. The error was discovered only last month by Dana-Farber clerks, not clinicians. Lehman was not the only victim.[52]

The media frenzied, with 28 front-page headlines devoted to the heartbreaking error.[53] After a massive overdose of chemotherapy, prominent health reporter Betsy Lehman died at the Dana-Farber Cancer Institute in Boston—one of the country's most renowned cancer institutions. The circumstances leading to her death are undisputed.

Lehman sought out an aggressive (and experimental) four-day chemotherapy protocol at Dana-Farber for metastatic breast cancer.[54] She was to receive an almost lethal dose of chemotherapy, which she believed would give her a 20 percent chance of surviving for another 5 years. Unfortunately, the protocol summary failed to clarify whether the specified dose of cyclophosphamide (6,520 milligrams) was intended to be administered as the daily dose or the cumulative dose over the course of the 4-day treatment. Because the prescription was on a note used for daily doses, Betsy was given 16 days' worth of treatment in four days. Less than three weeks later, she died as a result of cardiac toxicity from the overdose.

Unlike in the Zion case, the error killing Betsy occurred multiple times over the course of multiple days, under the supervision of at least a dozen experienced physicians, nurses, and pharmacists. It was her third round of chemotherapy and Betsy was alarmed at the severity of the side effects. It was far worse than she had experienced in the prior rounds; she was vomiting sheets of tissue lining from her gut. Despite her complaints, doctors overlooked the signs of the overdose, interpreting the severe side effects as normal reactions to the intentionally aggressive treatment.

Shortly before she was to be discharged, Betsy called Hester Hill, a friend who was also a social worker at the nearby Beth Israel Hospital. When Hester failed to answer, Lehman left a message explaining that she was calling because she was feeling very frightened: "I don't know what is wrong, but something's wrong."[55] Less than an hour later she was found dead.

Worse still, just days before Lehman's first dosage, another woman was given the same four-fold overdose. Maureen Bateman, a fifty-two-year-old patient, suffered irreversible heart damage, yet recovered and survived for another three years. The news of these errors was a strong wake-up call:[56] the Dana-Faber Cancer Institute was not just any institution, it was a world-class facility. Given the institute's prominence within the community, news of the nearly simultaneous and deadly errors was met with profound shock.

As Knox recalled, the errors were "so irrevocably bald" that the Boston medical community made no attempt to defend itself.[57] Millenson argues that, as a result, the Lehman incident became the unavoidable anomaly that subverted the existing paradigm. To his point, within six months, the Massachusetts Hospital Association ("MHA") launched a medication safety project. A year later, the MHA started forming a Coalition for Prevention of Medical Errors. This was around the same time that the AMA was finalizing its plans for a new safety foundation. Millenson contends that the support of influential groups such as the MHA and AMA bolstered the patient safety movement, making it easier to publish accounts illustrating the old paradigm's failure to protect patients.

Though Millenson's contention is compelling, the fact remains that these errors continue to persist without any genuine evidence of a paradigm shift. Looking just at medication overdoses (similar to that causing Besty Lehman's death), it is plain that little has improved over the years.

More than a decade after Lehman's tragic passing, on November 9, 2006, 21-day-old Alyssa Shinn died after being prescribed a lethal dosage of zinc.[58] Alyssa was born 14 weeks premature. In order to boost her metabolism, the hospital intravenously administered total parenteral nutrition (TPN). TPN is a necessary way to provide nutrition for infants, particularly

pre-term, whose bodies cannot absorb sufficient (or sometimes, any) nutrition through their stomach or intestine. TPN allows fluids to enter the body intravenously, bypassing the GI tract. The dosage includes a combination of protein, carbohydrates, fats, vitamins, minerals, and electrolytes. Late on the evening of November 8, the lead pharmacist, Pam Goff began mixing an order for 330 micrograms of zinc. However, when she entered the order in the machine that mixes the compound, she accidentally selected milligrams (instead of micrograms) from the drop-down menu. This lead to a 1,000-fold increase beyond the prescribed dosage. That evening, nurses started Alyssa on this new dose. By 6:30 a.m. the next morning, the pharmacist sent a memo warning of a possible medication error, "send new TPN stat." Sadly, due (in part) to staffing shortages, the team failed to change her IV until 1 p.m. Nurses immediately began flushing Alyssa's small body with an antidote, but it was too late—Alyssa died. Upon being summoned to see her supervisor, Pam said: "I just broke down into tears and started to shake… I just sobbed uncontrollably. I went back to my desk and started to vomit and cry and shake." An investigation later revealed that a safety stop on the mixing machine had not been set, two other pharmacists failed to check Goff's calculation, and the technician neglected to raise any alarms at needing to replenish the machine 11 times for it to complete filling the infant's TPN bag with 48 vials of zinc. The nursing staff also did not seem to notice that the bag was significantly larger than usual. These cases are not rare.

In 2006, an Indianapolis hospital accidentally dosed 6 infants with 1000 times the prescribed dose of heparin—three died.[59] Just a year later, in November 2007, Dennis Quaid and his wife, Kimberly, almost lost their twins, Thomas Boone and Zoe Grace, to a similar overdose. Heparin, which functions as an anticoagulant, is routinely used in neonatal intensive care units to prevent the formation and extension of blood clots.[60] The arterial lines, which are commonly

used to monitor neonates, are associated with clinically significant risks of catheter occlusion (i.e., the plastic tubing is obstructed) and thrombosis (i.e., blood clots within blood vessels). Often the catheter occlusion is secondary to thrombosis. To reduce these complications, most neonatal intensive care units prescribe some form of heparin infusion to maintain the patency or openness of the catheter. In many cases involving heparin overdoses, technicians are mistaking 10,000 unit per millimeter vials for the prescribed 10 unit per millimeter heparin vials. Though horrifying, the frequency of these errors clearly demonstrates that these errors are due to a larger system error. In this particular case, the manufacturer packaging for the doses look very similar: both packaged in similar size vials with shades of blue as the main background color on the label.[61]

That same year, another nurse, Julie Thao, was arrested and charged with felony manslaughter after a medication error lead to the death of a young mother.[62] Julie was a veteran nurse with 15 years of service in a high volume obstetrics unit at St. Mary's Hospital. During a busy holiday season, Julie offered to work extra shifts to help cover a coworker's family medical leave. At the time of the error, she had just finished a 16.75-hour double shift less than six hours before starting her third shift at 7 a.m. During the second half of her third shift, Jasmine Grant was admitted to give birth. Following a formalized workaround, Julie began preparing an epidural before the anesthesiologist arrived. This to-do list was implemented to minimize the amount of time that the anesthesiologist needed to be in the unit. The nurses were to obtain the necessary medications, insert and prime the tubing, and place the medications on the infusion pump before the anesthesiologist arrived and actually wrote the necessary order. At the same time, Julie was supposed to administer IV penicillin to treat a streptococcal infection. Confusing the two infusion bags, Julie mistakenly delivered the epidural medication through the IV meant

for the antibiotic. Tragically, Jasmine suffered a cardiac arrest and died. As a result, Nurse Thao was terminated from her position without severance and charged with felony criminal neglect.

Facing jail time and unable to pay legal fees for a stronger defense, Thao pled no contest to two misdemeanors. Though this allowed her to avoid a jail sentence, the Board of Nursing suspended her license for 9 months, and her convictions barred her from practicing in any federally funded health care organization for five years.[63] Interestingly, a further condition of the Nursing Board's sanctions, prohibited Thao from working for more than 12 hours per day.[64] This sanction tends to suggest that the Board believed that Thao was uniquely unable to work fatigued without an elevated risk of error, yet somehow other nurses are similarly unaffected.

In the specific case of St. Mary's Hospital, a root cause analysis report revealing systemic defects allowing for the error partially vindicated Thao. Most notably, the report clarified that nurses prepared epidurals early (a violation of hospital policy) in response to pressure from anesthesiologists.[65] In response to those defects, St. Mary's now requires signed orders for epidurals, has greatly increased the use of technology to limit error, and requires nurses working longer than 16 hours to take 12 hours off before returning to work. Any one of these protections would have prevented Jasmine Grant's tragic passing.

Although these highly publicized cases have had a profound impact on the practice of medicine (particularly on an institutional or case-specific level), this type of exceptional headline exposure also tends to suggest that medical errors—while appalling—are rare, infrequent accidents. The public and community are initially appalled, but quickly pacified at the first sign of corrective action. After all, the stories appear to be newsworthy because they are unique in some way, lending to the belief that the tragedies are horrific, but isolated incidents.[66] However, a turning point for the error prevention movement came in late November, 1999.

2. The IOM Report, *To Err is Human*

In 1999, the Institute of Medicine (IOM) published a comprehensive 223-page report on medical errors that astonished the nation. Its goal was to break the unacceptable cycle of inaction. According to the report's most famous and disturbing claim, as many as 98,000 people were dying in U.S. hospitals each year from medical error.[67] These estimates did not even include serious but non-fatal injuries—just deaths.[68] As it put it, "to err is human, but errors can be prevented."[69] *To Err Is Human: Building a Safer Health System* was the first publication to offer broad transparency into the shockingly high rate of medical error—not just by way of a singular, isolated tragedy, but with comprehensive numbers.[70] Because of this, some experts even went so far as to suggest that *To Err is Human* represents the 'discovery' of the epidemic of medical mistakes.[71]

Interestingly, even though *To Err is Human* merely republished decade-old results from other studies, it was the first document that vaulted patient safety into the mainstream media.[72] Specifically, *To Err is Human* relied on two prior studies: a then unpublished study of adverse events in Colorado and Utah, and the well-known Harvard Medical Practice Study of iatrogenic injury in New York hospitals. The Harvard Medical Practice Study was a retrospective review of 30,121 medical records from patients discharged from acute care hospitals throughout New York in 1984.[73] The Utah-Colorado Medical Practice Study similarly reviewed discharge records from twenty-eight hospitals in Utah and Colorado in 1992. When the results of these studies were extrapolated to the 33.6 million hospital admissions in the U.S. in 1997, the Utah and Colorado study suggested that as many as 44,000 patients were dying yearly as a result of hospital error. The New York Study had a higher death toll, suggesting that the number might be as high as 98,000. Press coverage quickly dropped the lower figure, reporting instead the high-

end estimate. Further, few journalists conveyed the subtleties of the report; neglecting to mention that the numbers came from data that was already more than fifteen years old.

Many experts also credit the IOM with an even more notorious jumbo jet analogy. As it goes, *To Err is Human* provided a tangible icon for the magnitude of the problem (one that, some argue, managed to shake the nation out of its collective inattention), pointing out that the number of deaths in the U.S. from medical error is equivalent to one Boeing 747 crashing every day.[74] In fact, Lucian Leape first published this analogy in a 1994 *JAMA* article. Writing about the 1991 Harvard Medical Practice Study (the same study that the IOM report cited), Leape wrote:

> Also in 1991, the Harvard Medical Practice Study reported the results of a population-based study of iatrogenic injury in patients hospitalized in New York State in 1984. Nearly 4% of patients suffered an injury that prolonged their hospital stay or resulted in measurable disability. For New York State, this equaled 98,609 patients in 1984. Nearly 14% of these injuries were fatal. If these rates are typical of the United States, then 180,000 people die each year partly as a result of iatrogenic injury, **the equivalent of three jumbo-jet crashes every two days** (emphasis added).[75]

Even more curious, the mainstream media did accurately report on Leape's article in 1994, however, it failed to garner the same attention that the IOM report would later stimulate. By March of 1995, Newsweek altered the quote, simplifying the formulation to just one jet crashing every day.[76] Nearly 6 years later, Leape (a co-author on the IOM report) was continuing to emphasize his jumbo jet analogy during interviews. Reporters, having not read the IOM report, mistakenly credited Leape's 1994 jumbo jet analogy to the IOM report (as opposed to the earlier article). This makes it even more interesting that the IOM report had such a significant impact—not only was the data decades old, but even the sensationalized sound-bites were recycled from

prior articles. Nevertheless, for some reason, the IOM report was able to initiate action in a way that prior reports could not.

PATIENT SAFETY MOVEMENT – HIGHLIGHTS

1959: Moser's book *Diseases of Medical Progress.*
1978: Cooper: *Preventable Anesthesia Mishaps* published.
1982: *20/20* "The Deep Sleep" airs.
1984: Libby Zion dies.
1985: Anesthesia Patient Safety Foundation formed.
1991: Harvard Medical practice studies published in the *New England Journal of Medicine.*
1994: *JAMA* publishes Leape's seminal article, "Error in Medicine"
1995: *Boston Globe* columnist Besty Lehman dies.
1996: First Annenberg Patient Safety Conference held.
1997: National Patient Safety Foundation formed.
1999: Institute of Medicine published *To Err is Human.*

FIGURE 2.1. History of the Patient Safety Movement.

Before the IOM report, the entire profession (including governments and academic constituents) seemed committed to downplaying the frequency of error within health care.[77] Whether it was deliberate neglect or simple ignorance, providers, healthcare organizations, and policy makers were not taking seriously the need to improve safety. Though the jumbo jet analogy had been reported in the news nearly five years before the IOM report, a major difference that could account for the significantly different reaction to the IOM report is that, though the prior studies and articles received some mention, the IOM report was splayed across front-page covers and was given significant airtime during mainstream nightly news features. As expected, this exposé caused a media frenzy that seized the public's attention. Though this did not start the patient safety reform moment (see figure 2.1), it did propel it to the forefront of the nation's focus.

Not surprisingly, the IOM report provoked patient anxiety on a much larger scale than the individually reported errors could muster in the past. The public demanded swift action. Safety instantly became a central focus, making the IOM report perhaps the single-most instrumental publication in igniting the patient safety movement.[78] Aside from drawing attention to the epidemic, the IOM report offered a comprehensive strategy to improve patient safety. Utilizing a four-tiered approach, the IOM report issued the following recommendations:

- Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- Identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
- Raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- Creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all of the recommendations.[79]

Specifically, in order to develop a national focus, the report tasked Congress with establishing a Center for Patient Safety within the Agency for Healthcare Research and Quality ("AHRQ"). This new center, it explained, should be responsible for developing knowledge and understanding of errors within healthcare, and setting nationwide goals to prevent errors and improve patient safety. It should monitor progress in meeting those goals and issue an annual report to the President and Congress. The IOM report also emphasized the importance of

adequately funding the Center, especially as it also directed that the Center should oversee the allocation of research dollars to test and evaluate best practices for preventing errors.

To aid the Center for Patient Safety in meeting its goals, the IOM report urged Congress to establish reporting systems.[80] Without these systems to collect data, the Center would struggle to evaluate progress toward national goals. The report envisioned that two systems would work conjointly: a nationwide mandatory reporting system that collects a limited set of standardized information about serious adverse harm, and a network of voluntary reporting systems that collect more detailed data about broader causes of harm. To encourage reporting, the IOM report also recommended that Congress pass legislation extending the peer review privilege to protect data related to patient safety.[81]

Simultaneously, the IOM report recognized that health care organizations will need multi-faceted external pressures to devote more attention to patient safety.[82] To this end, the report urged regulators, accreditors, and payers to hold organizations more accountable. It advised regulators and accreditors to require organizations to develop patient safety programs. The report also pointed out ways that purchasers could influence health care organizations; most notably, it suggested they require a commitment to safety standards as a term in contracting decisions. Finally, the IOM report called on licensing bodies and the Food and Drug Administration to heighten their scrutiny.

Lastly, the report recognized that, in order to truly make a meaningful impact, health care organizations *themselves* must make a genuine commitment to becoming safer. The organizations and the leadership overseeing them must be independently driven to establish patient safety programs. The establishment of these programs should be motivated by a sincere desire to improve patient safety, not merely as way to meet the bare minimum requirements.

While past reform efforts were disjointed and isolated, after news of the IOM report, Congress promptly appropriated $50 million annually for patient safety research, established a Center for Quality Improvement and Safety, and (eventually) signed into law the Patient Safety and Quality Improvement Act of 2005.[83] Additionally, within a year, over twenty states had passed some variation of reporting laws. The Joint Commission on Accreditation of Healthcare Organizations committed to developing safety standards and enforces those initiatives through comprehensive inspections.[84] A number of other accreditors became involved as well, including the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS).[85]

By all accounts, the IOM managed to make a major impact on the industry in a very short timeframe—with many of its recommendations being implemented. Unfortunately, in spite of these efforts, progress has remained frustratingly slow.[86] Explaining why is a complicated task. As the report itself acknowledged, healthcare organizations are increasingly complex institutions and improving safety requires a multidimensional approach.[87] Even so, the fundamental problem (from a broad perspective) is remarkably simple: there is just not enough pressure on the industry to change. Repeated publications in medical journals had virtually no effect on the overall practice of medicine at all. Not because providers are wildly unethical, but rather that even ethical people tend to tolerate unethical behavior when they feel powerless to effect any meaningful change.[88] As the IOM Report explained, to prevent errors, the entire systems need to change.

The systems need to be re-designed to make it difficult to make mistakes or do the wrong thing, and easy to do the right thing. For instance, take the issue of alertness: when faced with an impossible choice between working too many consecutive hours or being fired, most providers

feel forced to tolerate the conditions, fueled with the confidence that, because they are committed to providing quality care, they can prevent any performance errors. Providers are not independently choosing to put patients at risk, but that can be an end-result. Given these constraints, almost all of the advancements within patient safety resulted because of sustained public outrage because that level of pressure mobilized high-level action.[89] However, the motivating pressure quickly dissipates. As much as it is difficult to admit, these organizations will continue causing harm without a massive restructuring to address deeply systemic flaws. In this light, while there are a growing number of professionals dedicated to improving safety and quality, it is not simply not enough.

At each significant anniversary of *To Err is Human*, commentaries have also looked back and analyzed our progress; mostly exploring our failure to live up to the original call to action. In his five-year review, Robert Wachter gave the patient safety efforts an optimistic C+. He noted that, while institutions are finally starting to invest in safety, there is still a long way to go. Wachter specifically bemoaned the lack of federal funding, noting that the Agency for Healthcare Research and Quality only received $60 million in contrast to the $27 *billion* allocated for the National Institutes of Health.[90] In other words, he criticized the government for only invested $1 towards safety for every $500 it spent on advancing diagnoses and treatments. Most troubling is the fact that, despite being grossly underfunded for the task, funding the Center for Patient Safety is the federal government's single largest investment in patient safety.[91]

Leape and Berwick, however, took a more positive approach.[92] Noting setbacks, they still pressed a belief that the industry would begin to dramatically increase its pace. Further, they applauded three important accomplishments of the IOM report in the first five years: framing error prevention, enlisting stakeholder support, and changing practices. Most importantly, they

first credited the IOM report with fundamentally changing the way that providers view and discuss medical errors. While acknowledging that there are skill plenty of skeptics, Leape and Berwick were encouraged by how many health care leaders were beginning to adopt the understanding that bad systems (not bad people) lead to the majority of errors. The second important outcome was the broad array of stakeholders that emerged: the federal government, the Veteran's Health Administration, the Joint Commission on Accreditation of Healthcare Organizations, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the American College of Physicians, the National Patient Safety Foundation, the American Medical Association, the Accreditation Council on Graduate Medical Education, the American Board of Medical Specialties, the Institute for Healthcare Improvement, regional collations, the Leapfrog Group, and the thousands of devoted providers. Lastly, Leape and Berwick credited the IOM report with accelerating changes in best practices.

At ten years, Dr. Carolyn Clancy (director of the Agency for Healthcare Research and Quality) lamented the slow progress.[93] Clancy suggests that, while there are many factors, one of the most important reasons for the underwhelming improvement in patient safety is the fragmented nature of the industry: improvement efforts are largely hospital-based, leaving it up to individual organizations to invest—or not—in the undertaking. That said, there had been many accomplishments throughout those five years. As Wachter notes, from 2004-2009 the U.S. created the first federal initiative to computerize health care (through the Office of the National Coordinator for Health IT), the World Health Organization formed the World Alliance for Patient Safety, the Institute for Healthcare Improvement launched its first national campaign (the 100,000 Lives Campaign), Congress authorized the creation of Patient Safety Organizations (PSOs) to promote error reporting and shared learning, the Michigan ICU study was published

noting remarkable reductions in catheter-related line infections using a safety checklist, and Medicare announced a "no pay for errors" initiative. These modest improvements led Wachter to raise his overall grade from a C+ to a B- (his full assessment is reproduced below in table 2.1).

TABLE 2.1. Assessment of progress in ten patient-safety domains, 1999-2004 and 2004-2009

Safety Category	2004 grade	2009 grade	Comments
Regulation / Accreditation	A-	B+	An important early driver, but much of the low-hanging fruit has now been picked
Reporting Systems	C	B+	Key intervention was the adoption of the NQF list to support error reporting; some improvement in analytical abilities at provider organization and state/national levels
Health information technology	B-	C+	Surprisingly low uptake over past 5 years; increasing evidence of health IT-related safety hazards and implementation challenges; new infusion of federal dollars should promote health IT adoption
Malpractice system and accountability	D+	C+	Increased pressure for accountability has led to more emphasis on "Just Culture"; more accountability at leadership level as well; practical approaches for balancing "no blame" and accountability still lagging
Workforce and training issues	B	B-	Limited but increased engagement by providers; evidence regarding impact of residency duty-hour limits mixed; nurse shortage eased but primary care shortage worse; few organizations adopting robust teamwork, culture change, or simulation programs
Research	-	B-	Stronger methods are emerging; moderate, but insufficient, increase in funding; still limited data on what works; field still debating fundamental questions regarding evidence standards for safety studies
Patient engagement and involvement	-	C+	Patient advocacy movements small; impact of "how can patients protect themselves?" efforts uncertain; significant progress on disclosure policies and practices
Provider organization leadership engagement	-	B	Stronger focus on safety by boards, "C-suite," as business case becomes more robust; uptake of strong leadership interventions (root-cause analysis, Executive Walk Rounds) improved but spotty
National and international organizational interventions	-	A-	Much stronger engagement by AHRQ, NQF, Joint Commission, ACGME, WHO, IHI, and others; better dissemination of tools, training, and requirements; some wide-scale change efforts (IHI campaigns, Michigan and WHO checklist studies) have illustrated capacity for broad engagement and measurable progress
Payment system interventions	-	C+	Impact of P4P in quality uncertain; P4P not yet applied to safety

			because of measurement challenges; Medicare's "no pay for errors" is a provocative initiative; no evidence yet about impact and concerns regarding unintended consequences
Overall grade for progress in patient safety	**C+**	**B-**	**Most striking improvements in reporting and leadership; gaps in IT and accountability are most concerning, but both areas should see significant progress driven by new funding (IT) and emerging consensus (accountability)**

Source: Adapted from Robert Wachter, "Patient Safety at Ten: Unmistakable Progress, Troubling Gaps," *Health Affairs* 29, no. 1 (2010): 166.

Though Wachter has not published an updated grade since his ten-year review, in an interview with Healthcare IT News in April 2018, his comments echoed a similar sentiment: patients are safer than they were, but there is still significant work to accomplish.[94]

At fifteen years, researchers from Johns Hopkins and Australian National University interviewed 11 leading international authorities (three of whom directly contributed to the IOM Report) on patient safety to assess the IOM Report's impact on current practices.[95] All of the experts echoed a similar initial reaction: the IOM Report, *To Err is Human*, generated widespread eagerness, which instilled a genuine hope that the publication would bring about safer patient care. While the interviewees had great insights and suggestions for areas for improvement, many still expressed disappointment about the lack of meaningful progress towards safer patient care. All agreed that for patient safety to improve healthcare organizations must do more to learn from adverse events. Collectively, the interviews revealed five key challenges for why incident reporting systems have failed to facilitate the type of learning that organizations need: (1) inadequate processing, (2) inadequate engagement of clinicians, particularly physicians, (3) insufficient action in response to reports, (4) inadequate funding and institutional support, and (5) inadequate utilization of health information technology developments.

As a result, even though the IOM report generated widespread awareness that medical errors continue to occur throughout health care, it failed to "break [the] cycle of inaction."[96] The widespread public attention was met with two forms of resistance.[97] The first questioned the validity of the patient safety movement as a unique endeavor; after all, the quality improvement (QI) movement had already taken hold. Beginning in the late 1980s, the QI movement had already attained legitimacy. Rather than focus on harm, however, the quality movement sought to uncover best practices to improve access and decrease costs.

The second, and more detrimental, resistance was the argument that the IOM report grossly exaggerated the occurrence of harm. Motivated by denial, these critics attacked the loose language of errors, challenging both the vague definitions and the pseudoscience philosophy of the safety sciences. To make matters worse, the initial shock dissipated. Paired with the strong Congressional response, promising reform and a safer health system, the public was left to assume that no news, is good news. Indeed, just three years after *To Err is Human* provoked overwhelming and widespread anxiety, a study found that the majority of physicians and the general public believed that fewer than 5,000 deaths occurred in hospitals each year due to error.[98] In reality, this could not be further from the truth.

B. The Current Crisis

As if 98,000 annuals deaths were not chilling enough, contemporary studies continue to find that the incidence of harm is far greater than previously measured. More recent studies have suggested that medical harm occurs in as many 1 in 3 admissions—half of which may be preventable.[99] In fact, contributing to more than 400,000 deaths, medical error is rivaling tobacco use as the primary cause of preventable mortality in the United States.[100] Positioning medical harm as the third leading cause of death in the United States,[101] this amounts to 7,692

deaths per week or more than 1,095 deaths per day (Table 2.2). Worldwide, iatrogenic harm (avoidable harm caused by healthcare, rather than an injury or illness) in acute-care settings (10,000) accounts for more deaths per day than HIV/AIDS (8,000), road traffic accidents (3,000), natural disasters (100), and terrorism (20).[102] This alone is unacceptable, and these numbers do not even take into consideration the tens of thousands of patients who suffer serious, but non-fatal complications.

TABLE 2.2. Leading Causes of Death in the United States in 2016

Cause of Death	No. of Deaths	Percent of Total Deaths
1. Heart Disease	635,260	23.1
2. Cancer	598,038	21.8
3. Medical harm	400,000	14.6

Source: Adapted from Kenneth Kochanek, Sherry Murphy, and Jiaquan, Elizabeth Arias, *Mortality in the United States, 2016*, NCHS Data Brief, no. 293, (Hyattsville, MD: National Center for Health Statistics, 2017); for 400,000 statistic, John T. James, "A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care," *Journal of Patient Safety* 9, no. 3 (Sept. 2013): 122-128.

Admittedly, there are some reviewers who challenge the validity of these studies. As they point out, many of the contemporary estimates of deaths due to medical error (and even the IOM report itself) reference source studies that did not offer any methodology for estimating mortality based on medical error.[103] Instead these source studies, as the critics argue, only sought to measure the prevalence of harm caused by health care. As such, skeptics argue that the data is too limited to be able to estimate the causal relationship between a preventable adverse event and subsequent death. Some recent studies, however, did set out with the primary purpose of measuring the prevalence of death due to medical error (namely, estimates from HealthGrades[104] and Leapfrog[105]). These studies, commentators contend, are epidemiologically

flawed. Confounding makes it incredibility difficult to parse out the harm caused by poor medical management versus that caused by the patient's underlying illness, especially when considering the fact that patients at the highest risk for being exposed to hospital-acquired conditions (such as central line infections) are also at a higher risk of dying because of their underlying condition. In this light, there is a real necessity to develop a reliable means of quantifying and classifying adverse harm and preventable death. Without this basis, not only will it be impossible to measure any meaningful level of progress, it will be nearly impossible to identify key problems in order to appropriately intervene to improve patient safety.

1. Understanding 'Error' in Medicine: Definitions, Classifications and Methods

> Human error is a very large subject, quite as extensive as that covered by the term human performance.[106]
>
> —James Reason, *Human Error*

Definitions

Not surprisingly, disagreement over how to measure medical error complicates efforts to improve safety.[107] Indeed, defining *error*—or simply identifying it—is a difficult task.[108] The term error has become part of the common vernacular within health care (especially when referring to human error), yet it lacks a common definition. To complicate matters, neither laypersons nor professionals can even agree on what terminology to use, using the terms accident, mistake, failure, error, negligence, adverse event, and malpractice interchangeably.[109] Without a standard nomenclature, it is difficult (if not impossible) to interpret or report findings.

From an etymological perspective, *error* is derived from the root *err*. Dating to circa 1300 from the Old French word *errur* from the Latin *errare*, the root concept of error is to

wander or stray. The Oxford English Dictionary First Edition (1891) offers the following:

> 1. The action of roaming or wandering; hence a devious or winding course, a roving, winding. Now only *poet.* 2. Chagrin, fury, vexation; a wandering of the feelings; extravagance of passion. *Obs.* 3. The condition of erring in opinion; the holding of mistaken notions or beliefs; an instance of this, a mistaken notion or belief; false beliefs collectively. 4. Something incorrectly done through ignorance or inadvertence; a mistake, *e.g.,* in calculation, judgment, speech, writing, action, etc. 5. A departure from moral rectitude; a transgression, wrong-doing.[110]

Merriam-Webster defines *error* as "an act involving an unintentional deviation."[111] In a sense, this contemporary definition still reflects the root notion of straying—such that there is a departure from the actor's intended course. This understanding of error tends to view an act based on its outcome.

Historically, this is how researchers first approached harm within medicine. Early investigators embraced an outcome-dependent definition of medical error, studying adverse patient outcomes rather than medical error itself, regardless of outcome.[112] Thus, human error(s) that did not result in a deviation from the intended outcome were excluded from consideration. Some speculate that this tendency stems from the influence of the Hippocratic oath charging physicians to "do no harm."[113] In this light, investigators may not have been concerned with acts that did not violate this principle. Paradoxically, however, the earliest studies concerning this topic actually dismissed medical errors as the price society must pay for medical progress.[114]

In 1964, Elihu Schimmel first acknowledged the unavoidable dangers within modern medicine, while still calling for greater care in a pioneering study of the incidence of error, "Hazards of Hospitalization."[115] Though he did not attempt to identify which errors were

preventable, the Schimmel study was the first prospective assessment of the risks accompanying modern healthcare. Schimmel uncovered that, during an 8-month period, medical treatment was causing complications in one out of every five patients. Not wanting to imply that this level of harm was necessarily preventable, Schimmel used the term *episodes* to refer to all "untoward events, complications, and mishaps." Importantly, the study only included episodes that "arose from acceptable diagnostic or therapeutic measures," and excluded any complications arising from inadvertent errors. Though the discovery was startling, it did not have a strong impact on the practice of medicine.

Several decades later, three publications gave prominence to the use of the term *adverse event* to describe the harmful outcomes from medical error. Still some of the most extensive investigations concerning iatrogenic injury, the Harvard Medical Practice Study, the Quality in Australian Health Study, and the Utah and Colorado Medical Practice Study, helped to proliferate the term adverse error. Both the Harvard Medical Practice Study (1991) and the Utah and Colorado Medical Practice Study (1999) defined adverse events as unintended injury, which was caused by medical management (as opposed to an underlying illness), and resulted in measurable disability[116] (the Utah and Colorado Study clarified to this to include either a prolonged hospital stay or disability at discharge).[117] The Harvard Medical Study additionally evaluated and ranked each instance of adverse error based on the occurrence and severity of any negligence, which it defined as a failure to meet the standard of care for a reasonable physician.

The Quality in Australian Health Study (QAHCS) rejected this criterion, instead measuring *preventability* in place of *negligence*.[118] In explaining this modification, the QAHCS study noted that few adverse patient outcomes result from negligence. In this light, and with the stated goal of improving quality, QAHCS focused instead on *preventability*. The study suggests

that this approach will also cast its results in a more positive and constructive light, as opposed to a potentially antagonistic one. The Australian study assessed *preventability* (with respect to an adverse event) as an error that resulted from a failure to follow accepted medical practice—either at an individual (judged by the expected performance for the average practitioner) or system level. While this definition of *preventability* essentially renames the Harvard Medical Practice Study's definition of *negligence* (with both definitions focusing on the adherence to the accepted standard of care), the underlying suggestion is warranted. Taken together, these seminal studies offer a critical combination with respect to defining adverse error. Regardless of the terminology used, a definition of medical error should combine the key elements from each of these studies: that is, the definition must still measure harm and consider outcomes, but not to the exclusion of understanding the process that contributed to the end result. The definition must aim to reduce all deviations (even when harm is only minimal or avoided entirely) without specifically focusing on whether providers adhered to accepted practices. This approach offers important insights into the total cost and magnitude of the harm, while still providing the necessary knowledge to meaningfully intervene to reduce the overall harm.

To exemplify this point, consider the following prospective study. Khan and Arsanious collected data over a 10-week period with the aim of determining whether UK medical students, junior doctors, and consultants had divergent perceptions of the severity of a clinical error.[119] The participants were asked to rank eight different hypothetical scenarios using a numerical scale (1-10) based on the severity of error. A response of 1 indicates that there is no error, whereas 10 denotes the most severe possible error. Interestingly, nearly all of the responses suggested that the respondents highly factored the outcome into determining whether an incident qualified as an error. However, the there was a clear line between those who considered an incident as easily

made (resulting in a low ranking) versus viewing that incident instead as being easily preventable (contributing to a higher ranking). For instance, in one such scenario two patients presented with similar names. At the end of the ward round, a junior doctor accidentally switched the patients' drug charts. Later that day, the nurse begins dispensing their drugs according to the charts' instructions, only to be stopped because one of the patients questioned why her tablets were a different color. The nurse apologized and administers the correct medication to both patients. In this case, though the patient prevented any potential harm, the potential severity of the harm is great. Participants who viewed this as being an easily made mistake (e.g., "drugs charts can easily get moved around") rated this very low (2) given the potential for harm. Conversely, respondents who noted that this breach was easily avoidable rated the error very severely (9). This example alone makes clear that it is not enough to only consider error based on whether a patient suffered measurable harm. While, in this particular instance, the patient prevented any occurrence of harm, not labeling this as an error significantly hinders any genuine attempt at reducing the overall rate of error. Left ignored, this gap in care will almost surely result in eventual harm at some point. Additionally, it is not prudent to excuse and tolerate certain harms because of a low-perceived degree of evidence for preventability.

As explained, it is important that our definition for medical error includes both acts that actually result in harm, as well as those that have the potential to cause harm (but failed because of some intervention). Some use separate terms to refer to these outcome-based categories of medical errors: referring to error that results in harm as an *adverse event*, while referring to an event that could have resulted in an adverse patient outcome but did not ultimately result in injury as *near misses, close calls*, *potential adverse events*, or *warning events*.[120]

This leads to the following definition for *medical error*: an act or omission during planning or execution that contributes (or could contribute) to an unintentional deviation.[121] This incorporates the essential elements discussed above, and is in keeping with prevalent definitions:

> *Leape:* "Error may be defined as an unintended act (either of omission or commission) or one that does not achieve its intended outcome."[122]
>
> *Joint Commission*: "Error: An unintended act, either of omission or commission, or an act that does not achieve its intended outcome."[123]
>
> *Dana Farber Cancer Institute:* "Error is an event of act of commission or omission with unintended, potentially negative consequences for the patient."[124]
>
> *Institute of Medicine* and *The Agency for Healthcare Research and Quality*: "An error is defined 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).[125]

Note the specific inclusion of intentionality in the definitions adopted by the Dana Farber Cancer Center, Institute of Medicine, and Agency for Healthcare Research and Quality. As these definitions suggest, determining whether an action constitutes an error cannot be judged based on outcome alone. Simply because there is a bad outcome, does not automatically mean there was an error. In this light, an error only occurs when a person, attempting to do the right thing, does the wrong thing. The key element is that the person was intending to do the right thing, but there was a deviation that was not deliberate. A deliberate or intentional injury would be a very different form of abuse. In this way, the notions of intention and error are intimately linked.[126] One useful way of qualifying intentional behavior, from a psychological perspective, is to apply a simple, three-question algorithm:

> *1. Were the actions directed by some prior intention?*

2. Did the actions go as planned?

3. Did the actions achieve their desired consequences?

Unlike trying to discern someone's basic motivation, these questions can all be easily answered. Because error can only be used to describe intentional actions, human error can only be corrected on the basis of the answers to the second and third questions. Actions that do not go as planned (question 2) can be separated into two subsets: those that nevertheless achieved their outcome, and those that failed. Though it is possible for the actions-not-as-planned to still meet their desired goal, it is highly improbable. For instance, consider the famous case of *Thabo Meli v. The Queen* (1954). In *Thabo Meli*, a gang of four men plotted to kill another man and cover it up by making it look like a drunken accident. The men invited the poor victim to a hut, got him heavily drunk, and hit him on the head with the intent of killing him. As it turns out, the victim was only knocked unconscious. Believing they had killed him, the men threw the victim's body over a nearby cliff and arranged items to make it appear as though he had inadvertently walked off the side of the cliff. He also survived the fall! Though, the victim did later die from exposure. Though none of the actions went as planned, inexplicably, the man did later die as a consequence of the gang's actions. These unusual cases are possible, though very unlikely. Even actions that do go as planned, however, do not always achieve their desired consequences (question 3). In these cases, the problem is not with the lack of intention, but with the plan itself.

However, as Dr. John Banja points out in *Medical Errors and Medical Narcissism,* this singular focus on intentionality can also be problematic. Banja offers the following example:

> Dr. Jones, who is considered the finest surgeon at Ajax Hospital, is about to repair Mr. Green's abdominal aortic aneurysm. Because Mr. Green has undergone numerous

> abdominal operations, Dr. Jones realizes that this surgery might be extremely complex because of scarring and anatomical reconfiguration in the surgical site. Although Dr. Jones exercises enormous patience and skill during the operation, he nevertheless lacerates Mr. Green's bowel, which necessitates additional surgery.[127]

Banja rightfully points out that most health professionals would not categorize this as an error, as this is more appropriately labeled a surgical complication. Nevertheless, the limitation of most definitions for error is that they include these types of negative outcome within their definition. Indeed, only using intentionality to limit the scope of incidents that fall within the realm of medical error will inadvertently include known or even likely complications that (may have even been disclosed to the patient during the informed consent process) simply because the health provider did not intend them. Consequently, this dissertation defines *medical error* as an act or omission during planning or execution that contributes (or could contribute) to an unintentional and unreasonable deviation.

Classifications of Error

Armed with a definition for medical error, it is important to be able to understand and identify errors as they happen. Sorting errors into classifications allows observers to identify, quantify, and possibly prevent broad categories of error. Due to the complexity of healthcare errors, there have been a number of innovated approaches to classifying error.[128] There is no single taxonomy, with different classifications serving different needs.[129] Despite this, all existing taxonomies correspond to three basic levels of classification: contextual, modal, or psychological.[130]

Contextual classification is an approach that focuses on specific contextual information (e.g., time, place, people, procedures). This taxonomic form describes errors based upon the

particular actions and environment.[131] Because of this singular focus on a particular scenario, a contextual taxonomy cannot offer a predictive account of error in general. This kind of taxonomy instead offers a completely context-dependent descriptive account, which may offer insights in the risks of error for a specific set of tasks in a particular environment. Lucian Leape offered a contextual taxonomy for understanding medical error by categorizing errors in terms of which types of errors occur in which environments.[132] According to this classification scheme, there are three main categories of medical error: diagnostic errors, treatment errors, preventative errors, and other complications (see table 2.3).

TABLE 2.3. Types of Medical Error

Types of Error by Category	
Diagnostic Error	
	Error or delay in diagnosis
	Failure to perform indicated tests (no tests or inappropriate tests)
	Failure to act on test or monitoring results
Treatment Error	
	Error in the performance of an operation, procedure, or test
	Error in the administration of a treatment
	Error in medication use, dose, or method
	Avoidable delays in responding to abnormal test or providing treatment
	Inappropriate (not indicated) care
Preventative Error	
	Failure to provide prophylactic treatment
	Inadequate monitoring or follow-up treatment
Other Error	
	Communication failure
	Equipment failure
	Other system failure

Sources: Adapted from Lucian Leape et al., "Preventing Medical Injury," *Qual. Rev. Bull.* 19, no. 5 (1993): 144-149.

Modal classification examines the ways that error occurs on a behavioral level (e.g., did the error occur through an act or omission), seeking to understand the manner in which the act was performed. This context-free classification is sometimes called the "mode" of an error.[133] Rather than focus on the describing the specifics involved, this taxonomy would instead sort an error based on the it's mode (e.g., omission, substitution, insertion, repetition). This approach offers insight into which modes of error are more common and makes it possible to calculate error probabilities; however, it cannot meaningfully improve error prevention because it does not provide any information about how the categories of error manifest. One particular modal classification scheme, the Predictive Human Error Analysis (PHEA), integrates errors of omission, errors of commission, and extraneous errors (resulting from an unnecessary act).[134] While it can be useful for researchers to group errors according to outcome, examining errors from a psychological perspective can yield better insight for developing effective prevention strategies (a major shortcoming of modal classifications).[135]

The third level does just that: looking beyond the observable characteristics of the error or its context, instead employing psychological principles to understand the nature of the error. Most experts prefer this approach, as it helps to explain events rather than merely describe them.[136] In this form, the investigator attempts to discern where throughout the chain of events an error occurred, and then understand why.[137] This attempt to make inferences about the underlying mechanisms that allow for certain errors, positions psychological taxonomies to offer generalizable and predictive insights.

In this respect, James Reason notes that psychologists make a distinction between *error types* and *error forms.*[138] According to Reason, *error type* relates to the presumed origin of an error within a corresponding cognitive stage at which it occurred during the action sequence.

Reason identifies three main cognitive stages: planning, storage, and execution. Error forms, conversely, are not tied to any one specific underlying cognitive stage. Instead, *error forms* represent the recurrent varieties of fallibility that surface during all types of cognitive activity regardless of the specific error type.

TABLE 2.4. Error Types According to Cognitive Stage

Cognitive Stage	Primary Error Type
Planning	Mistakes
Storage	Lapses
Execution	Slips

Source: Adapted from James Reason, *Human Error* (Cambridge University Press, 1990) 12-14.

Of the three main error types, planning refers to the cognitive processes involved in identifying a goal and then determining the appropriate means to achieve it. Most often, people do not immediately act upon their plans. Because of this, there is a likely storage phase that occurs between formulating a plan and executing the plan. Finally, the last stage concerns the processes involved in actually executing the stored plan.

As Reason explains, a mistake (a planning failure) is distinctly different from a slip, or lapse (an execution failure).[139] Essentially, this means that there are two basic ways a failure can occur: (1) the plan is adequate, but the actions deviate from the intention, or (2) the actions go entirely as planned, but the plan was faulty. This distinction hinges on the difference between conscious (intended) and automatic (unintended) behavior. A slip is an error of action, which results from some degree of inattentiveness during the performance of a routine and largely automatic task. Similarly, a lapse often occurs during a routine task, but it relates to an internal failure of memory. For both, a person intended a certain action that does not go according to plan. These execution failures are regularly associated with some level of distraction or

preoccupation. Given their distinctions, it is possible to externally observe a slip (e.g., slip of the tongue, slip of the pen). By contrast, because lapses largely relate to memory failures, these error forms are more covert. Lapses may only be readily apparent to the actor involved.

Conversely, a mistake is a conscious error of knowledge or planning. Here, the action itself goes exactly as planned but fails to achieve the intended outcome; the error occurred when planning the action. Reason defines mistakes as:

> *deficiencies or failures in the judgmental and/or interferential processes involved in the selection of an objective or in the specification of the means to achieve it, irrespective of whether or not the actions directed by this decision-scheme run according to plan.*[140]

Given this definition, mistakes are even more likely to be less understood than slips—being subtler and more complex. Because of their nature, mistakes will also be harder to detect. Human consciousness is quite well trained to notice departures from intention, however, the quality of a plan is a matter of debate. As such, mistakes present a far greater danger.

Nevertheless, the primary distinction between mistakes and slips (or lapses) is quite simple: "if the intention is not appropriate, this is a mistake. If the action is not what was intended, this is a slip (or lapse)."[141] Mistakes can be further categorized into (a) failures of expertise, where some pre-established rule or standard is applied inappropriately (i.e., rule-based mistakes), and (b) a lack of experience, where the individual lacks relevant knowledge (i.e., knowledge-based mistakes. These errors are often compounded by the heavy emphasis on memorization within health care practice.

Failures of expertise and lack of experience correspond closely to Rasmussen's skill-rule-knowledge behavior classification for describing human cognitive control. Reason derives his conceptual framework from Rasmussen's work, yielding the parallels depicted in table 2.5.

TABLE 2.5. Performance Levels and Error Types

Rasmussen's Classification	Primary Error Type
Skill-based	Slips (and lapses)
Rule-based	Mistakes
Knowledge-based	Mistakes

Source: Adapted from James Reason, *Human Error* (Cambridge University Press, 1990) 53-56.

Rule-based mistakes occur in relation to familiar problems—problems that providers train to handle. A large part of medical practice is built on this system of corresponding rules or heuristics: if *x* (patient presents with high fever and sharp pain in the lower right abdomen), then it is probably *y* (appendicitis). When used appropriately, a simple heuristic approach performs surprisingly well, out-performing both predictive instruments and physicians.[142] However, this process can go awry in a number of ways: providers can apply a bad rule, fail to apply a suitable rule, or misapply a useful rule by failing to consider the contraindications. These errors are compounded by the heavy emphasis on memorization within health care practice

For instance, consider the case of Blanche Begaye (a pseudonym).[143] Blanche, a Navajo woman in her sixties, presented to the emergency room in respiratory distress. She reported that she had been feeling ill for a few days. Though she originally attributed it to a bad head cold, she came to the emergency room because her systems continued to worsen after drinking tea and taking a few aspirin. On exam, Begaye had a fever of 100.2° F and she was breathing rapidly. Her lungs were clear and white-blood-cell count was normal, but a blood test showed slight acidity. At the same time, however, a chest X-ray showed no indication of viral pneumonia. Nevertheless, the emergency room physician diagnosed Begaya with subclinical pneumonia. He determined that she must be in the early stages of the infection, which he used to disregard the

data that contradicted his diagnosis (namely, the absence of rhonchi and white streaks on the chest X-ray and normal white-blood-cell count).

Knowledge-based mistakes occur when a provider encounters a novel situation, outside of the realm of his or her problem-solving heuristics. In this instance, the practitioner is forced to reason through the problem without any specific preparation. This is a slow, effortful, and extremely error-prone process. Not only do these situations require providers to make decisions without any mental model to guide them, they are attempting to solve a problem with incomplete or incorrect knowledge (making knowledge-based mistakes the most complex error type). For instance, a surgeon may be forced to guess at the source of the bleeding during a high pressure operation.[144] Cognitive psychologists have found that health professionals frequently commit knowledge-based mistakes due to stress or immense time constraints.[145] Some common types of knowledge-based mistakes include: the availability heuristic, using the first information that comes to mind; confirmation bias, seeking only evidence that supports an opinion to the exclusion of any contradictory information; and overconfidence tendency, which is believing the validity of a determination without any justification or evidence to support it.[146]

These three basic error types (mistakes, slips, and lapses) are also distinct from violations. Violations are deviations (mostly deliberate, though they can also be erroneous) from the safe and accepted operating standards.[147] Whereas errors primarily result from limitations in thinking and remembering, violations arise because of attitudes about motivation or how to behave in a work environment. Because violations do not result from human limitations, it is only possible to understand them in relation to the social context in which humans behave.[148] In the case of violations, the actions (though not the possible bad outcomes) were intended; the act did not result from a mistake or accident. Accordingly, James Reason defines violations as

deliberate deviations from an organization's proscribed safety practices and regulations.[149] While deliberate, violations do not necessarily reflect a malicious intent. Instead, violations are byproducts of the ways individuals cut corners in everyday tasks to accomplish a competing objective—usually to save time. There are three main groups: routine, optimizing, and situational (or necessary) violations.

Routine violations are largely habitual and can include virtually subconscious acts. Two factors tend to influence the occurrence of habitual violations: (a) the human tendency to take the quickest and most convenient path, and (b) an apparently trivial procedure (especially within an organization that is relatively indifferent to violations). Optimizing violations are undertaken for personal gain rather than task-related goals (e.g., to get home early or alleviate boredom). A necessary or situational violation occurs when someone disregards a rule because it is seemingly impossible to follow under those circumstances. For instance, a nurse may administer a drug without first using the hospital's medication scanner to check for errors because the technology is not working properly at the time. While the nurse is choosing to knowingly violate the procedure in the patient's best interest, these violations can be disastrous should something else go wrong (e.g., the infusion bag is for the incorrect dosage).

Because all violations increase risk, they also increase the likelihood of error and the propensity of harm. As such, the boundaries between errors and violations are not fixed. For instance, it is difficult to discern how a subconscious violation is different than a slip. Although the margins will always be blurred, one possibility is to simplify the distinction based on intent.[150] While skill-based slips (errors) are almost always isolated events, routine violations tend to re-occur daily. Even though routine violations could eventually become subconscious, at

one point in time the actor still made a conscious choice to engage in that behavior. Choice is the key element.

Further, given the ways that violations differ from errors, each require different interventions. [151] Whereas errors primarily arise as informational problems, violations are commonly associated with motivational problems (e.g., low morale, poor leadership, perceived lack of concern). Thus, while errors can be reduced by improving the quality and delivery of information within the healthcare system, violations necessitate motivational and organizational changes.

Finally, there is a third distinction that influences the way that people contribute to accidents: the difference between latent and active failures. James Reason credits the distinction between these types of failures to Mr. Justice Sheen's observations regarding the capsize of the *Herald of Free Enterprise*. Mr. Sheen was investigating the capsize of the roll-on-roll-off ferry, which sank in shallow water off the coast of Zeebruge, Belgium in March of 1987, killing 189 passengers and crew. Sheen wrote:

> At first sight the faults which led to this disaster were the… errors of omission on the part of the Master, the Chief Officer and the assistant bosun … But a full investigation into the circumstances of the disaster leads inexorably to the conclusion that the underlying or cardinal faults lay higher up in the Company … From top to bottom the body corporate was infected with the disease of sloppiness.

Reason uses this excerpt to clearly exemplify the difference between active and latent failures. The active failures (the various errors on the part of the ship's crew) were immediately clear. But, as the inquiry ultimately uncovered, the *Herald* was a "diseased" ship long before it sailed on that fateful day. In this light, active failures are the unsafe acts (both errors and violations)

that are committed at the "sharp end" of the system. Analogous to the *Herald*, these are the immediate providers (e.g., the nurses, surgeons, internists) whose actions have immediate, adverse consequences. Latent failures, by contrast, result from the executive organizational decisions upper management. These failures may lay dormant for long periods before ever encountering a situation that breaches the underlying deficiencies. In the example of the *Herald*, the triggering factors were the spring tide and loading difficulties at the Zeebrugge harbor. Thus, active and latent failures are distinguishable based on (1) the length of time before the failures contribute to a bad outcome, and (2) the level at which the failure occurs.

To recap, though human error is markedly complex, cognitive psychologists (errorologists, specifically) offer a valuable taxonomy for understanding human error. According to that taxonomy (see figure 2.2.), accidents arise because of active or latent failures within a system. There are three main error types, which can be divided based upon the corresponding cognitive stage—either the failure occurred during planning or execution. Planning failures are known as mistakes, wherein the actions went according to plan, but failed to achieve the desired result because the plan itself was deficient. Execution failures can be either slips or lapses. Though both involve a deviation from the intended plan, slips (of action) tend to result from attentional failures, whereas lapses are associated with memory failures. Slips and lapses occur during the largely automatic performance of a routine task, which is almost always associated with some level of distraction. Slips, which are inadvertent, happen most often when people put a task on autopilot because they are distracted with other matters. Mistakes, conversely, are decision-making failures that result from making incorrect choices. Typically, these mistakes result from incomplete or inaccurate information. Rule-based mistakes happen when the actor already knows the appropriate rule through training or experience but

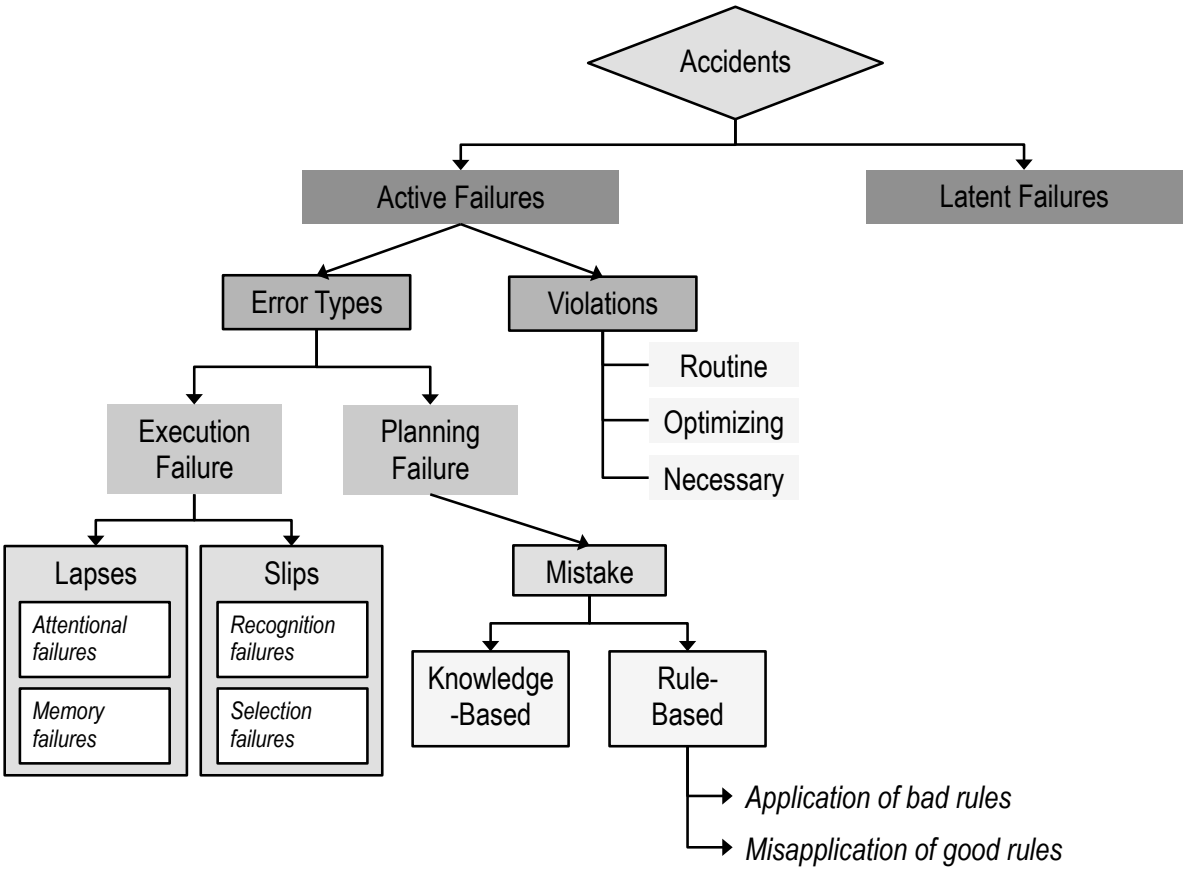

FIGURE 2.2. Organizational Accident Taxonomy

misapplies the rule. Knowledge-based risks arise in novel situations when the person is unfamiliar with the scenario. Slips, lapses, and mistakes all differ from violations. Violations are deliberate deviations from standard operating procedures, standards, or rules.

Methods

To better understand how to study human error within the medical field, it is also useful to consider how experts analyze human error generally. Reason listed five main approaches for studying accidents: corpus gathering, questionnaire studies, laboratory studies, simulator studies, and case studies.[152] These five approaches provide a basis to understand the specific methods for investigating medical error.

For decades, psycholinguists and cognitive psychologists have been 'corpus gathering' to better understand human error. This is a naturalistic method of investigation that is concerned with the identification and classification of naturally occurring slips and lapses. This methodology focuses on describing and observing naturally occurring phenomena—in this instance, everyday human errors. With a large enough corpus, this approach provides a robust and comprehensive representation of the species of error. This analysis enables researchers to identify recurrent error patterns. However, the limitation of this approach is that, with such a broad qualities account, it is difficult to draw scientifically sound conclusions—the causal chain is simply too attenuated.

Another method asks subjects to self-disclose information about their own experience with slips and lapses through the use of questionnaires. Though questionnaires can be useful supplements to naturalistic investigation, this method is also limited by the biases and distortion of each subject's perspective. That said, studies have confirmed that these self-reports correlate to genuine behavior.

Laboratory studies and experiments offer a path to attempt to better control for the weaknesses inherent in naturalistic observation and self-reporting. While this methodology is the gold standard in some scenarios, in the case of eliciting human error, it is difficult to recreate the natural conditions and pressures that tend to evoke cognitive failure in everyday life. Computer-based simulation studies attempt to better mimic the dynamic features of real-life, complex decision-making that was impossible to capture in a static experimental study.

Finally, case studies examining instances of catastrophic errors offer a lens into the circumstances that led to a particular event or accident. This allows investigators to examine the interaction and responses in an extended sequence that would be nearly impossible to recreate by

other means. Naturally, the difficulty in this approach is again the reliance on the individuals involved to provide accurate reports. Not only do most accident reports tend to focus on shifting blame, but each person typically has an inaccurate or limited understanding of the events.

Within the context of investigating medical error, Thomas and Petersen categorized eight healthcare-specific methods of study: administrative data analysis, record review, electronic medical record (EMR) review, direct observation, clinical surveillance, autopsy, root cause analysis, claims analysis, and error reporting systems.[153] These eight methods apply the five general approaches for studying human accidents to the healthcare industry. As table 2.6 depicts, each method offers its own set of advantages and disadvantages.

TABLE 2.6. Methods for measuring medical errors

Study Method	Advantages	Disadvantages
Administrative Data Analysis	The data is readily available Inexpensive	The data may be incomplete or inaccurate The data is unconnected to the clinical context
Record Review	The data is readily available Commonly used	The provider's judgments may not be reliable The medical record may be incomplete Hindsight bias
EMR Review	Inexpensive (after initial investment) Can monitor in real time Integrates multiple data sources	Susceptible to data entry / programming errors Expensive initial investment
Direct Patient Care Observation	Potentially accurate / precise Provides data otherwise unavailable Detects more active errors	Time consuming and expensive Difficult to train reliable observers Could risk confidentiality Possible to be overwhelmed with information
Active Clinical Surveillance	Potentially accurate and precise	Time consuming and expensive

Autopsy	Can suggest contributory factors Familiar to health care providers	Hindsight bias Reporting bias Focused on diagnostic errors Infrequently used
Case / Root Cause Analysis	Can suggest contributory factors Structured systems approach Includes recent interview data	Hindsight bias Tends to focus on severe events Insufficiently standardized
Claims Analysis	Provides multiple perspectives (e.g., legal, providers, patients)	Hindsight bias Reporting bias Non-standardized data source
Error reporting systems	Can provide multiple perspectives over time Can incorporate into routine operations	Hindsight bias Reporting bias

Sources: Adapted from Charles Vincent, Patient Safety, 2nd ed. (Hoboken: Wiley-Blackwell, 2010), 53-56.

These methods differ in a number of ways. First, some focus on detecting the incidence of error, while others are oriented towards understanding their causes and contributory factors. Second, each method relies on different sources of data: some use first-person observation, others voluntary reports, and still others various forms of existing records. In this light, no single method is foolproof—each only painting a partial picture.

Because the Joint Commission mandates RCA after every *sentinel event*, it is one of the more familiar methods of investigation in the United States.[154] The United States Department of Energy originally developed root cause analysis (RCA) to investigate industrial accidents.[155] In an earnest attempt to learn from other high-risk industries, healthcare systems adopted RCA as a method for structured risk identification and management following an adverse event. RCA is not a single technique, but a range of approaches and tools[156] that aims to identify the true cause

of a problem and suggest solutions to prevent similar problems in the future.[157] One limitation with RCA is the implicit implication that there is only one single root cause; rather than promote a global investigation of all of the latent and active factors that contributed to an adverse error, some RCA techniques tend to result in a linear narrative that is far too simplistic to capture the system's complexity.[158] RCA is also susceptible to hindsight bias and sometimes lacks the structure needed to produce effective results (see figure 2.3).[159]

CASE SUMMARY

This case example demonstrates how a hospital may fail to learn from an incident in spite of RCA.

A patient presented to a large, acute hospital for a routine cataract surgery—a relatively low-risk procedure. Though an experienced ophthalmologist performed the procedure, the wrong lens was inserted. After discovering the error, the patient underwent a second procedure to correct the error, which was successful.

A RCA identified that there were two lenses in the OR: one brought by the surgeon (the correct one) and one by an operating department assistant. The investigation concluded that the incident occurred because of both the duplicate lens in the OR and a failure to follow the double-check protocol. The action plan called for the development of a new protocol that emphasized the surgeon's individual responsibility to select the appropriate lens and had posters made to remind providers of the importance of double checks.

One year later, a different surgeon made the same error (implanting the wrong lens); however, in this instance, the surgeon selected the wrong lens.

FIGURE 2.3. Lessons from RCA

As it happens, many of the methods for measuring harm are susceptible to bias—particularly hindsight bias. Hindsight bias (the inclination to overestimate error in cases with worse outcomes) is a particularly troubling problem for retrospective analysis of medical error. In fact, several experts posited that "hindsight bias is the greatest obstacle to evaluating the performance of humans in complex systems after bad outcomes."[160] Hindsight bias, or the

"knew it all along" effect encourages people to overestimate their ability to control future events.[161] When observing past events, this bias leads people to exaggerate what other people should have been able to anticipate in foresight and embellish what they knew themselves. This phenomenon is further fueled by how unaware people are of the extent to which outcome knowledge influences their perceptions of the past. For those striving to make sense of past events, knowledge of the outcome provides an unconscious schema for historical judges to assimilate prior facts. In the moment, however, the series of events do not present themselves in such a linear fashion; each participant would tell a different story based on their immediate concerns. Hindsight bias tempts observers to view the convergent narrative as having been the expected or obvious outcome.

With respect to medical harm, hindsight bias also tempts researchers to label the events leading to an accident as errors simply because of the negative outcome. This is also sometimes called outcome bias.[162] As the harm from an accident increases, so does the likelihood that the events leading to the harm will be considered erroneous.[163] With the bias of already knowing the end result (and believing the outcome to be more foreseeable), even 'objective' reviewers will overestimate how easily someone could have prevented the outcome in real time.

Given the limitations of the methods for studying medical error when used independently, there is a greater case to be made for utilizing a large-scale, national reporting database. While the database will be subject to the limitations of error reporting systems, generally, it is possible to develop a system that could potentially allow for greater access to a more comprehensive picture of error. With this in mind (and given this dissertation's central thesis), let us more closely examine the use of error reporting systems as a methodology for studying error.

In the most basic sense, error reporting systems are relatively straightforward: regardless of their scope, these systems are intended to serve as a repository of information to solve a stated problem. Beyond this general goal, there is extensive disagreement at almost every level. Experts disagree on whether the system should be voluntary or compulsory, whether it should solicit any and all information or institute limiting factors, and more. As stated, the IOM report called for the establishment of both a voluntary and mandatory reporting system, to be operated separately.[164] In their view, the mandatory system should be primarily concerned with the prevention of only the most severe errors (i.e., errors that have a strong likelihood of causing serious bodily injury or death). Voluntary systems, by contrast, are encouraged to continue to focus on the overall goal of improving patient safety.

Though, like most other methods, error reporting systems are susceptible to bias, designing a user-friendly, effective system that providers will readily use is their biggest obstacles. Indeed, the level of bias within a report is irrelevant if entities are failing to even submit the reports to begin with. In this light, the success or failure of this approach is highly dependent on the level and adaptability of the system's technological design. Like any technology, the user must not only accept the program, but must be motivated to engage and use the technology. Here, that translates to both agreeing that an error reporting system has the potential to improve patient safety, and believing that the system offers more benefits than disadvantages. When polled, participants identified several key features that would motivate them to utilize a reporting system (see table 2.7). Of note, the participants felt that the reporting system must not only be time-efficient, it should also be incorporated into their current work structure. This poses a technical challenge but offers the greatest promise in addressing concerns about time constraints and underreporting.

TABLE 2.7. Motivators and Barriers Related to a Medical Error Reporting System

Motivators		Concerns	
Feedback	"There has to be… a high likelihood of getting some positive benefit… rather than just another place… reports are sent [to] vanish"	**Ease of Use**	"Ease of use so that we're not talking about adding 10 min or more of paperwork per day to the schedule."
	"I think the real plus… would be if there would be some way to get instantaneous feedback… [b]ecause I suspect that most errors that people would report have occurred before."	**Privacy**	"I don't trust confidentiality. It's breached too often."
Mandatory System	"…are you going to take extra time out in an extremely busy day to say, 'Oh, yeah, I get to go report this to a voluntary committee?' I don't think so."	**System Abuse**	"I'm not sure how to present this in a way that it's not going to be used for legal reasons… And that, I think, is my biggest fear… that this would eventually come out and be able to be used against us."
	"I almost think if you don't make it mandatory you aren't going to get much information."	**Length of Report**	"Well, if you're going to have pages upon pages to fill out, you know, it's not going to get done."
	"There are so many things to do in the day that some voluntary things, you'd almost have to have missionary zeal…"		"My biggest concern would be that [it seems that errors] would be more likely on the days when we're busiest, and I would be worried that any system that we'd come up with would be cumbersome and therefore just not used."
Financial Incentives	"I think it would taint [the reporting if] we're not… [reporting] for professional pride or trying to fix a recognizable problem, that we have to be bought in order to do something."	**Punishment**	"Why should they report anything, if there is going to be any retaliation or punitive things happening."

Other Incentives	"…perhaps by having reported an error early, you would get some sort of recompense or whatever from whatever malpractice action might occur or, you know, disciplinary action might occur within your facility."	**Reporting Near Misses**	"Well, unless there was an adverse outcome, I don't think people are going to take the time to report."

Sources: Adapted from Ben-Tzion Karsh, Kamisha Escoto, John Beasley, and Richard Holden, "Toward a Theoretical Approach to Medical Error Reporting System Research and Design," *Appl Ergon* 37, no. 3 (May 2006): 283-295.

Regardless of the method used, it is incredibly difficult to obtain a clear understanding of the overall magnitude of harm because of the challenges of measuring error; perhaps the greatest of which is defining harm.[165] Because error depends on intentionality, it is difficult for researchers to uncover and separate instances of error—even more so when those researchers are not employing a robust program. Even if investigators only focus on outcomes, it is hard (if not impossible in some instances) to select indicators that could isolate cause and effect. Injury in medicine is simply not that straightforward. For instance, it is difficult to discern what injuries were due to medical management from the harm that was caused by the disease process itself. Even when it is possible to identify error, professionals frequently disagreed about the extent of the harm from the medical error.[166] While this difficulty is no reason to shy away from the task, it is important to always be cognizant of the ways that the selected method will depict overall error frequency. Kaveh Shojania calls this is the "elephant of patient safety," such that the picture of harm is predicated on what part of the animal you are looking at.[167] To combat this limitation, it is imperative that healthcare systems integrate various methods.

2. The Psychological and Financial Impact of Medical Errors

However you define, classify, or study it, medical harm is a major cause of human suffering. For the families of victims, the devastation is all too obvious. However, health care providers also often experience a range of emotional and psychological repercussions—sometimes referred to as the "second-victim" phenomenon.[168] For providers like Kimberly Hiatt, the feelings of guilt and self-doubt are unbearable.[169] After an unblemished, 24-year career as a registered nurse, Kim was fired from Seattle Children's Hospital when she accidentally gave an infant a potentially fatal dose of calcium chloride. Intending to dispense 140 milligrams of calcium chloride, she accidentally miscalculated the dosage when converting the milligrams to mL and drew up a 14-mililiter dose, dispensing 1.4 grams. That same day, she reported the error in the hospital's feedback system, admitting that she may have made the error because she was distracted, since she was talking to someone while she was drawing up the medication and making her calculations. She vowed to be more careful in the future and admitted that she felt sick about the error. Despite this, the hospital had Hiatt escorted from the property and immediately placed on administrative leave. Within a few weeks, she was fired. The hospital's notes suggest that Kim failed to appreciate her responsibility for the error, stating that she did not show an appreciation for how her deviation from hospital policy caused the error. The note further suggests that a veteran nurse, such as Kim, should have greater precision and attention to detail—seemingly implying that accidents are only expected at the very beginning of a nursing career. Interestingly, just two weeks prior to the overdose, an evaluation lauded her as a "leading performer." Ultimately, it was never even clear whether the mistake was directly fatal, though it may have exacerbated the child's cardiac dysfunction, which likely contributed (at least in a small part) to her death five days later.

After the patient's death, hospital notes detailing Kim's termination meeting are concerning.[170] In one section, ICU Director Cathie Rea, is put off by what she describes as Hiatt being incredulous, noting that Kim reacted to the termination in disbelief: "I am a 24-year employee—I make 1 mistake in 24 years and I lose my job? This is brutal—we all agree this was human error, right?" Cathie writes that she responded, "no—we all agree you did not follow policy." Though the state nursing commission allowed Kim to keep her license, with the condition that she complete a four-year probation specifically forbidding her from dispensing any medication without being supervised, these restrictions made it difficult for her to find a new job. Wrecked with grief and feeling utter despair about the likelihood of regaining employment in health care, Kim hanged herself.

In addition to millions of deaths and injuries, medical errors also result in astronomical financial loss. One 2010 study estimated that, in 2008, the total cost of measurable medical errors in the United States equaled $19.5 billion.[171] About $17 billion (or 87 percent) were directly attributable to additional medical costs, including: prescription drugs, ancillary services, and inpatient and outpatient care. $1.1 billion accounts for the cost of ten million sick days.

Since 2004, one organization (HealthGrades), has been regularly measuring patient safety with a specific emphasis on extrapolating these costs to individual hospitals.[172] Using data related to 13 of the most common patient safety incidents, which cost the U.S. health care system nearly $7.3 billion and 79,670 deaths in the Medicare population between 2007 and 2009, the study parsed out the real costs based on patient safety hospital performance (table 2.8). According to their findings, they concluded that Medicare could have saved nearly $1.8 billion—and prevented 20,688 deaths—had all of the patients been admitted to the best performing hospitals.

TABLE 2.8 Comparing Different Performance Categories (2007-2009)

Patient Safety Indicator	Top Hospitals	Bottom Hospitals	Relative Risk Decrease with Top Hospitals Compared to Bottom Hospitals	# of Potentially Avoidable Deaths
Death in low mortality DRGs*	.691	1.200	42.40%	1,266
Pressure ulcer	.731	1.249	41.49%	7,163
Failure to rescue*	.808	1.150	29.74%	4,179
Foreign body left after procedure	.447	1.729	74.16%	3
Iatrogenic pneumothorax	.835	1.193	30.01%	239
Catheter-related bloodstream infections	.693	1.459	52.48%	394
Post-OP hip fracture	.629	1.580	60.15%	32
Post-OP hemorrhage or hematoma	.825	1.219	32.35%	130
Post-OP physiologic and metabolic derangements	.612	1.628	62.38%	441
Post-OP respiratory failure	.771	1.348	42.81%	3,663
Post-OP pulmonary embolism or DVT	.805	1.318	38.92%	1,676
Post-OP sepsis	.717	1.487	51.80%	1,387
Post-OP abdominal wound dehiscence	.754	1.317	42.72%	115

Sources: Adapted from "Health Grades Quality Study: Patient Safety in American Hospitals," *Health Grades*, March 2011, http://patientsafetymovement.org/wp-content/uploads/2016/02/Resources_Reports_Patient_Safety_in_American_Hospitals_Study.pdf

Another study—using the benchmark (and arguably outdated) figure of 98,000 deaths from the Institute of Medicine (IOM) report—estimated that the economic cost in terms of lost earnings and other contributions was as much as $98 billion in Quality-Adjusted Life Years.[173] Applying the same formula to data from studies that argue that medical error contributes to far more death than the IOM considered, the economic impact may reach nearly $1 trillion—in terms of lost human potential.

Somewhat paradoxically, several other researchers uncovered a negative relationship between a hospital's fiscal health and patient safety.[174] As hospital profit margins decline, adverse patient safety events increase significantly. Though the exact impact is unknown, the researchers hypothesize that financial pressures reduce costly investments in patient safety improvements and detract from a strong safety culture. The relationship between patient safety and profit margins can be tricky, however. On the one hand, lower profit margins will induce hospitals to cut costs. The more severe the financial problems, the more likely the hospital is to employ cost-cutting measures that impacts patient care (e.g., cuts in nursing staff). While this makes logical sense, it fails to demonstrate that poor patient safety is causally tied to poor fiscal health.

That said, however, with excess inpatient costs soaring at $17-29 billion per year, it is easy to imagine how these costs might worsen a hospital's financials. Not surprisingly, patient safety advocates urge hospitals to invest in safety improvements to reduce the high costs they incur as a result of adverse events—an argument sometimes called the business case for patient safety. Yet, it is important to consider the extent to which hospitals themselves actually absorb these costs.

In examining the rate to which hospitals do incur the costs of adverse events, Mello et al. found that hospitals shift the majority of the costs (not including indirect costs, such as negative publicity) related to medical harm to external parties.[175] For the purposes of the study, Mello et al. considered two main types of direct costs: un-recoupable costs for extra medical services that cannot be billed and compensation related to malpractice claims. On average, hospitals externalized approximately 78 percent of the costs of all injuries, and 70 percent of the costs of negligent injuries.[176] These costs average between $1,246 and $2,013 (depending on the type of injury), but hospitals externalize the bulk of the burden. After passing the majority of these costs to the injured patient, their families, and their health insurers, the hospital is only responsible for 22 percent of the costs. These findings could suggest that the hospital's share of the direct costs of medical error is too minimal to create strong enough incentive to improve patient safety.

Even still, the tide may be quickly changing. Public and private payers continue to modify their reimbursement policies to exclude payments for care resulting from preventable injury. In 2005, Congress enacted a statue permitting the Centers for Medicare and Medicaid Services to adjust its payment system to incorporate incentives for hospitals to prevent errors.[177] Medicare implemented the Hospital-Acquired Conditions policy in 2008, eliminating additional diagnosis related group (DRG) payments for 10 types of complications thought to be preventable. Similarly, insurers nationwide began testing their own non-reimbursement policies. Aetna no longer reimburses for any of the 28 National Quality Forum listed "never events."[178] Even more aggressive is the 2012 implementation of Medicare's Value-Based Purchasing (VBP) and Hospital Readmissions Reduction Program (HRRP). Under the Hospital VBP program, a byproduct of the Affordable Care Act, Medicare withholds a small percent of base hospital DRG payments (the amount is 2% as of FY 2018), which is redistributed to hospitals based on the

quality of care provided. At the same time, the HRRP penalizes hospitals for higher-than-expected readmission rates. For fiscal year 2018, 2,573 hospitals are being penalized—a small decline from the 2,597 hospitals in 2017. While that might seem like slow progress, the news overall is encouraging: not only did the readmission rate fall from 21.5% in 2007 to 17.8% in 2015,[179] studies also found that the readmission rate fell more quickly at hospitals affected by the HRRP when compared with exempt hospitals.[180]

The question still remains, however, is such a small overall bonus (2% for the Hospital VBR) sufficient enough to drive a meaningful culture shift? Is the amount lost comparable to the amount of investment required in safety improvements to prevent injuries? While patients, health insurers, and third-party payers have strong financial incentives for safety, healthcare organizations still may appear to benefit by not investing in patient safety. This provokes two critical public policy questions. First, do healthcare organizations have an obligation to develop patient safety systems? Second, if so, is it important to provide economic incentives for patient safety?

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[8] Pellegrino, 93.
[9] Pellegrino, 93-95.

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[11] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (Oxford: Oxford University Press, 2001), 2.
[12] Beauchamp and Childress, 373.
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[14] Pellegrino, 93-97.
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CHAPTER THREE: THE ETHICAL IMPERATIVE TO IMPROVE PATIENT SAFETY

> The public should be screaming that we deserve better.[1]
>
> —Dr. Peter J. Pronovost

Hazards in the healthcare setting are matters of public safety. As such, the public is justified in expecting—and even demanding—that healthcare organizations act to prevent continued public harm. It is no longer appropriate—both from a practical and an ethical standpoint—to attempt to hold individual practitioners accountable for harm that is attributable to the organization. The standard is clear: healthcare organizations have a moral obligation to develop patient safety systems.

To provide a context for understanding the responsibility healthcare organizations owe to patients in improving and developing patient safety systems, this chapter first explores the history and evolution of the patient safety movement. In order to appreciate the way forward, it is critical to understand the terminology and methods that guide the modern approach to patient safety. This begins with examining the debate as to whether patient safety should concern itself with reducing errors or preventing harm.

In spite of this clash over terminology and goals, patient safety is perhaps best characterized as a movement focused on transitioning to a systems-based approach to safety. At its core, this movement reinforces the assertion that, both from an ethical and practical standpoint, health care organizations must evolve into safer organizational systems. That is, the patient safety movement reveals, that although human error may be attributable for the majority of adverse events within health care, the solution lies in redesigning the system itself. This is the foundational element that embodies the systems-based approach to patient safety. Section A(2) examines this theory, and reveals that preventing unintended injury depends on applying a

systems-based approach to identify and eliminate deficiencies within the organizational systems that permit obvious, but often irreversible, human errors.

Armed with this understanding, Section B focuses on the application of a systems-based approach to develop a safer health system. Within this context, this section examines how organizations can apply systems thinking to organize a patient safety program. A prevalent argument is that the widespread culture of blame within healthcare organizations is principally responsible for the abundance of medical errors. Informed by system theory, proponents of this approach contend that healthcare organizations must first stop blaming individual clinicians in order to improve safety. Section B(1) (avoiding a culture of blame) examines this contention, noting the strengths of this position while also explaining why improving quality and safety requires a more comprehensive understanding of organizational attributes. Organizational culture is complex and the promotion of safety hinges on the development of additional dimensions (beyond just blame). In this light, Section B(2) (creating a culture of safety) further analyzes the broader notion of safety culture.

A. The Modern Approach to Patient Safety

As examined in chapter 2, the traditional approach to medical errors within the healthcare system has been to focus blame on the individual provider and treat the accident in accordance with the civil or criminal system of jurisprudence. Somewhat paradoxically, a popular argument within patient safety literature is that this prevailing culture of blame is primarily responsible for the high rate of medical error.[2] The basis for this claim is that a culture of blame misdirects responsibility from the system to the clinician.[3] By blaming individuals that are not ultimately responsible for the error, the underlying factors and conditions that did contribute to the error will remain unchanged—making it likely that the same error will continue to proliferate and

recur. Proponents of this approach recognize that healthcare organizations must abandon this practice of attributing blame to individual providers and instead begin to critically examine the defects within the system. In this way, the modern patient safety movement replaces blame with systems thinking.[4]

Within this context, patient safety is best described as the avoidance, prevention, and amelioration of adverse outcomes or injuries from the delivery of health care.[5] This definition reflects the fact that patient safety is concerned with more than the overall quality of care—that examination is a focus for the quality improvement movement. Though there are some areas of overlap between the two movements, the patient safety movement is more specifically concerned with eliminating care that is actually harmful. At the same time, patient safety involves more than merely trying to avoid damage—it is not just another phrasing for disaster management.[6]

Formed in 1997, the National Patient Safety Foundation (NPSF) is an independent, nonprofit organization dedicated to the improvement of patient safety. In 2000, the NPSF sought to articulate the defining characteristics of patient safety and set an "agenda" for forthcoming research and development within the field. The NPSF first aimed to delineate a common definition, being careful to distinguish patient safety from the overlapping study of quality improvement. The NPSF outlined that:

1. Patient safety has to do primarily with the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care itself. It should address events that span the continuum from what may be called "errors" and "deviations" to "accidents."
2. Safety emerges from the interaction of the components of the system. It is more than the absence of adverse outcomes and it is more than avoidance of identifiable

"preventable" errors or occurrences. Safety does not reside in a person, device or department. Improving safety depends on learning how safety emerges from the interactions of the components.

3. Patient safety is related to "quality of care," but the two concepts are not synonymous. Safety is an important subset of quality. To date, activities to manage quality, such as quality assurance, continuous quality improvement, total quality management, etc., have not focused sufficiently on patient safety issues.[7]

In characterizing the distinction between accidents, near misses, errors, and deviations, the NPSF referenced a model that compares the correlation to an iceberg (see figure 3.1). This analogy has been used to describe the relationship between accidents and the active or latent conditions that ultimately cause them because of just how many of these combinations of conditions are lurking below the surface. The problem may look small at first glance, particularly when only investigating the rare, visible accident, but the bulk of the iceberg (as it were) is not immediately visible below the surface.

Though the (relative) rare occurrence of error in contrast to the high numbers of error-causing conditions may initially seem beneficial or even positive, it poses a real challenge for high-risk systems.[8] Here, the infrequency of accidents (as compared to the number of system failures) makes it more difficult to collect meaningful data to learn from and impose corrective actions. In industries with higher risks of accidents with catastrophic consequences, this problem is all the more significant. In this light, it is essential for patient safety interventions to examine all of the human and systemic conditions that contribute to error.

Similarly, patient safety (as a movement) should be careful not to become distracted with the singular goal of preventing error.[9] Of course, any genuine approach towards improving

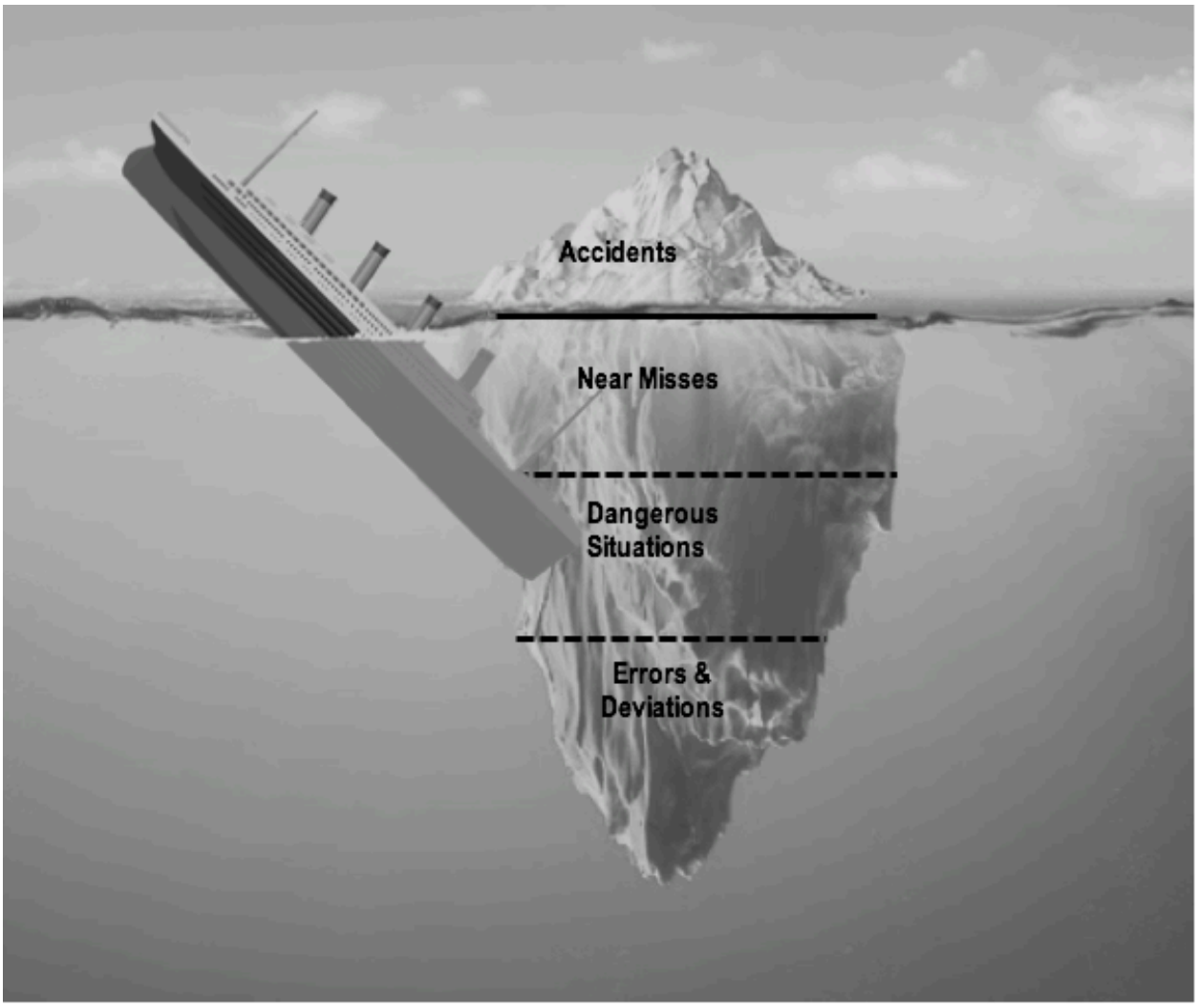

FIGURE 3.1. An Iceberg Concept of Errors

patient safety demands that institutions reduce errors of all kinds; yet, it is equally as important to pay adequate attention to the reduction of harms. Not only do a number of harms threaten patient safety regardless of error, there are also a number of minor errors that do not comprise patient safety.[10] Accordingly, while considering error is important in order to avoid, prevent, and ameliorate adverse outcomes, the overall aim of patient safety is to reduce harms.[11] After all, harm is what patients care most about. Errors only entered the conversation because, typically, preventable harm involves errors.[12]

1. Focusing on Preventable Harm

There is a debate, however, as to whether patient safety research should focus its attention on error or on harm. Indeed, a number of different paradigms have emerged for how to direct patient safety improvement efforts. Karsh *et al*. identify three broad categories:[13]

- Focus on reducing overall error rates
- Focus on reducing patient harm
- Focus on improving evidence-based medicine.

The first paradigm focuses wholly on reducing error.[14] It recognizes that errors can lead to patient harm, and, thus, concludes that preventing errors will eliminate harm. The IOM report, in proposing that a critical component for safety involved the design of safer systems, advocated for this paradigm. The Institute of Medicine reiterated this point in a later report, explaining that "a new delivery system must be built to achieve substantial improvements in patient safety—a system that is capable of preventing errors from occurring in the first place, while at the same time incorporating lessons learning from any errors that do occur."[15]

Conversely, the second paradigm prioritizes reducing patient harm itself because it recognizes that patient harm and errors are not always linked.[16] Indeed, the causal relationship between error and harm is a major challenge to understanding medical error. Not all errors cause harm. More serious errors that do not result in adverse events (or harm) are typically characterizes as near misses or close calls. Sometimes, these near hits occur simply because of luck. For instance, a patient might not suffer any adverse reactions to an incorrect medication. Other times, the error is not clinically significant enough to have any physiological effect. Lastly, the error could be caught before any harm results. Because there are many instances

when errors do not result in harm, advocates of this paradigm argue that it is not effective to devote resources to trying to eliminate those types of errors.

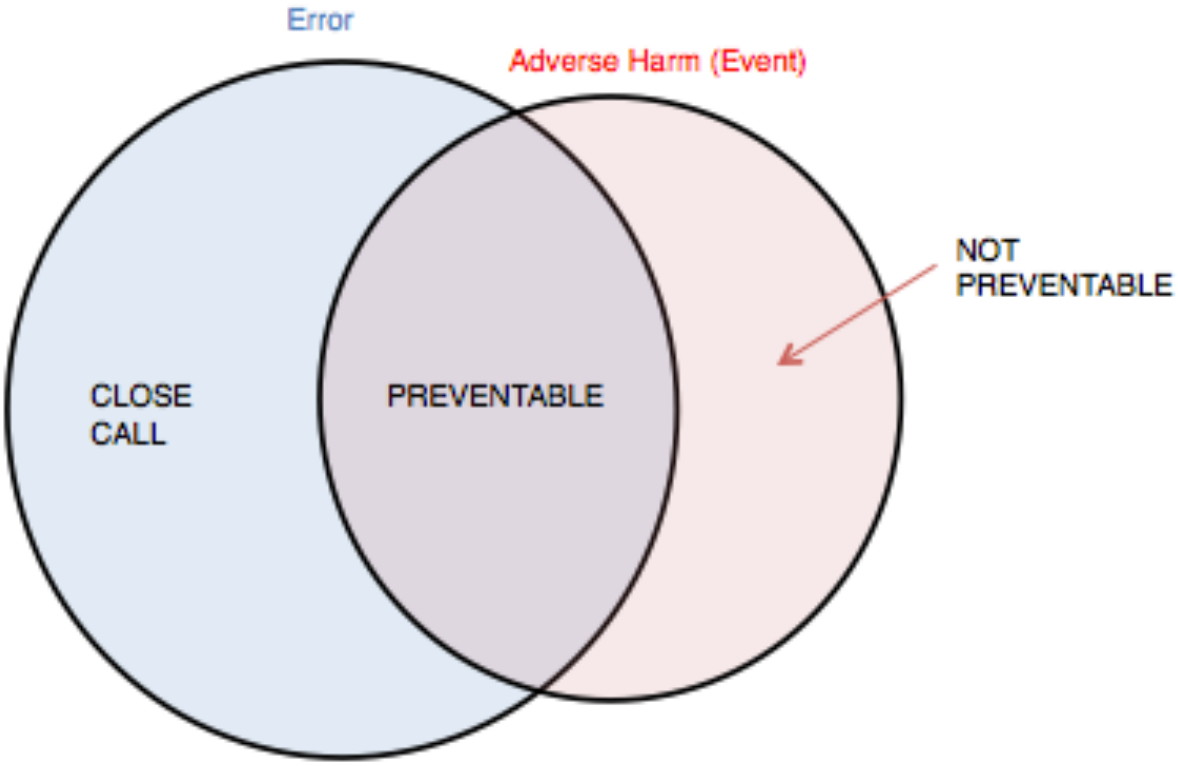

FIGURE 3.2. Comparing Error and Harm

In the same way that not all errors cause harm, not all harms are caused by error. As the safety movement grows, experts increasingly prefer to focus on preventable harm—or preventable adverse events.[17] An adverse event is an unintended and sufficiently serious injury that is caused by medical management rather than the disease process—it need not be caused by error.[18] Figure 3.2 depicts this relationship. As the figure shows, there are a great number of errors that do not cause a patient harm event (i.e., adverse harm) for the reasons listed above. Accordingly, proponents of this paradigm argue that efforts should focus on redesigning the system of care to eliminate factors that contribute to harm—which only partially overlaps with factors that cause error.

Likewise, it is important to clarify the distinction between preventable and non-preventable harm (i.e., adverse events).[19] A determination as to whether harm is preventable depends on a separate judgment concerning causation. However, given the complicated nature of patient injury and the subjectivity inherent in identifying errors, discovering the causes of harm can be problematic. As a moderately subjective assessment, determining the proximate cause of the injury to assess preventability is not entirely reliable and can lead to self-fulfilling analyses.

Not only is it sometimes impossible to make those determinations of causation, many safety experts also reject this distinction because of concerns that it is defeatist to accept that certain harms are not preventable. Remember, until fairly recently, all medical errors were regarded as the price that society must pay for medical progress.[20] As such, it may be difficult to identify which harms are not able to be prevented based solely on contemporary knowledge. A compelling example that captures this argument involves the prevention of central line infections.

Before the patient safety movement took hold, hospital epidemiologists and other infection control staff were responsible for preventing hospital-acquired infections. As catheter access to the central bloodstream became more common, so too did central line-associated bloodstream infections (CLABSI). Estimates find that as many as 20,000 patients die each year from CLABSI in the United States alone.[21] These infections occur when bacteria or other contaminants enter the bloodstream through the catheter, causing infection.[22] With the average cost of treatment for CLABSI hovering around $45,000, CLABSI cost up to $2.3 billion dollars each year.[23]

Though the CDC began studying CLABSI in the 1970s, their early efforts to reduce infections showed little success.[24] Clinicians largely believed CLABSI were simply inevitable. With a series of small-scale interventions, however, that attitude changed. Using evidence-based strategies, a handful of clinicians and researchers dedicated themselves to reducing their rates of CLABSI. Several hospitals participated in a CDC collaborative to help prove the concept that CLABSI were preventable, but it was the Keystone Project in Michigan that sealed the deal: more than 100 ICUs throughout the state reported a stunning 66% reduction of CLABSI within a mere 18 months.

Exceptional patient safety stories, such as the prevention of CLABSI really bolster the argument that it is not prudent to label some harms as being nonpreventable. Yet, at the same time, ignoring this already-present distinction carries its own risks. First, allowing or encouraging efforts to reduce harms that have proven to be difficult (if not, impossible) to prevent could contribute to burnout. Additionally, with the high rates of harm, overall, patient safety resources primarily be concerned with preventing harms that are already recognized as preventable. Further, blurring this distinction could imply to the general public that all harm results from error—which is demonstrably false.

In this light, the distinction regarding preventability (which is already widespread) does help reinforce the fact that not all injury results from errors.[25] Likewise, studies reviewing cases of harm in hospitalized patients have largely concluded that approximately half were preventable—a ratio that makes sense to pay attention to for now.[26] Acknowledging levels of preventability can also yield a number of other advantages. For instance, because the language focuses on outcomes rather than individuals, it may encourage disclosure and reduce individual

blame. For patients, who care most about their health care, more information is a welcomed compromise.

Focusing on this primary concern of providing quality patient care, the third proposed paradigm for patient safety is most devoted to implementing evidence-based practices to ensure patients receive more appropriate and higher quality care.[27] Advocates for this model argue that higher quality care is, by definition, safer care. Though these proponents acknowledge that safety science can offer meaningful contributions for how to design higher quality systems, they argue that determining causation is simply too subjective an undertaking. Not only does this make it difficult to measure and compare progress, they maintain, this preoccupation with accident prevention is also less effective. That is, according to these critics, few safety interventions (even those that appear to reduce errors) have demonstrated evidence of decreasing preventable harm.

Although the debate over terminology will continue because of its importance when attempting to prioritize efforts and measure progress towards improving safety,[28] the central aim must remain focused on finding ways to design safer care. Notably, though these paradigms disagree on the specific means of directing efforts to improve safety, all three paradigms agree on one essential theme: the importance of redesigning the healthcare system. Whether the focus is on reducing error, preventing harm, or providing higher quality care, the general consensus is that the changes must be made within the system. Disappointingly, the paradigms offer little insight into how system redesign will affect outcomes such as errors, harm, and quality. Karsh *et al.* suggests that these paradigms left unanswered the question, "what type of system design will lead to error / injury reduction or quality improvement?"[29]

In considering the type of system design that will produce a safer healthcare system, a fourth paradigm—one that seeks to integrate all three—may be most helpful. Indeed, the various elements and outcomes within any complex system are all interconnected. Accordingly, system inputs can affect multiple outcomes simultaneously—using a broader approach based on human factors engineering offers a mechanism to integrate the main paradigms. While it is critical to focus on system factors that influence patient outcomes, human factors science is better suited to redesign the system from a broader perspective of reducing hazards (as opposed to being preoccupied with reducing errors or injuries). This approach may also help to shift towards a more positive outlook (e.g., support performance with fewer hazards versus reduce bad outcomes). By not focusing on the errors or "bad" things that providers have done, this model can better communicate to providers that they are not the problem—the system is.

As an example, consider an incident wherein a nurse disregarded evidence-based treatment and administered an incorrect medication.[30] An error reduction strategy could focus on providing better information at the bedside, whereas the evidence-based medicine strategy might seek to ensure that providers have better training in order to follow appropriate guidelines. The fourth paradigm would attempt to identify the hazards within the human-machine system and apply methods from behavioral science from the perspective of focusing on the entire system. It would begin with the same goals as the other paradigms, but delve deeper into system design in an effort to improve performance and reduce hazards. For instance, it may more thoroughly investigate readability, interpretability, access, problem identification, and problem solving as it endeavors to redesign the entirety of the system to support the end user.

The major difference distinguishing these paradigms is a matter of perspective: rather than try to redirect the end user (i.e., the clinician) to behave differently (which is the approach

all three primary paradigms employ), human factors focuses on better engineering the system to support the end user. After all, it is this very shift from individual blame to systems thinking that characterized the rise of the patient safety movement.

2. Adopting Systems Thinking

Errors: Systemic and Inevitable

A key point for patient safety is that errors within our large, complex healthcare system are unavoidable. The healthcare field is immensely technical, and the environment is particularly complex even from a sociological standpoint.[31] Medical technologies and instruments themselves are complex and sometimes difficult to operate even under the best of circumstances. Similar types of medical equipment might operate differently within different floors or units, complicating practitioners' efforts to provide error-free care. Even with the most sophisticated cognitive enhancements to extend our human abilities and think better or faster, those in high-risk occupations will never be able to eliminate errors within these dynamic and changing environments.[32] In this light, Richard Cook observed:

> The potential for catastrophic outcome is a hallmark of complex systems. It is impossible to eliminate the potential for such catastrophic failure; the potential for such failure is always present by the system's own nature.[33]

This emphasis on the systemic nature of failure is central to understanding how to improve patient safety.

To better capture the systemic nature of harm-causing errors, consider the surgical horror story involving Willie King.[34] Willie King was a 51-year-old diabetic with severe peripheral vascular disease. In February 1995, King presented to Tampa University Community Hospital complaining of pain in his right leg. Upon examination, he had no pulse at the popliteal level in

either of his legs, which were both cold to the touch with gangrenous lesions. A radiologist later testified that the disease in each leg was so severe that it was hard to make a comparison between the two sides, but, ultimately, determined that the left leg seemed worse. Dr. Rolando Sanchez recommended vein bypass surgery in an attempt to save the leg, which might prolong amputation by another year or two. Though both of his legs would eventually require amputation, Mr. King was experiencing such horrendous pain in his right leg that his first priority was having it removed. In keeping with King's request, Dr. Sanchez asked the nurse to have Mr. King sign a consent form to amputate his right leg. Even still, Sanchez remarked that "it was clear to me, though, that the left leg would need to be amputated in the near future."[35] Indeed, the earlier examination revealed that the arteries in his left leg were almost totally occluded.

The series of events that followed are the archetype for understanding catastrophic error, which Cook eloquently captures:

> Because overt failure requires multiple faults, there is no isolated 'cause' of an accident. There are multiple contributors to accidents. Each of these is necessarily insufficient in itself to create an accident. Only jointly are these causes sufficient to create an accident. Indeed, it is the linking of these causes together that creates the circumstances required for the accident. Thus, no isolation of the 'root cause' of an accident is possible.[36]

Though the investigation never revealed why, the operating room schedule listed the procedure as a left below-the-knee amputation.[37] The day before the surgery, a floor nurse luckily caught the error and called the OR to notify them of the mistake. The floor nurse also told a surgery pool nurse, who made a handwritten correction to the surgical schedule and gave that corrected copy to another nurse at the end of her shift. In handing off the schedule, however, the nurse did not discuss the error or the handwritten correction. The corrected information also never made

its way back to the computer system. Because the computer's schedule was never corrected, all of the subsequent printed copies continued to mistakenly identify the wrong leg for the procedure. An uncorrected copy was distributed in the operating room, and the same information was noted on a blackboard there.

There was still another chance to correct the error: before being sedated, King identified the right leg as the correct limb for the surgery when discussing the procedure with circulating nurse Willie Mae Jones.[38] Jones noted this in the hospital records. Around this time, a technician arrived to set up the operating theatre. Seeing the operation listed as a left leg amputation on the official schedule and the blackboard, he sets up the leg holder on the left side of the operating table. Despite the nurse's recent conversation with Mr. King about which leg should be amputated, given the configuration of the operating table and the multiple incorrect surgical schedules and blackboard information, she prepped his left leg. Mr. King's medical chart with his signed consent form and medical record, including Jones' own notes that his procedure was scheduled for the right leg, were available in the operating room, but the effective standard of care did not require that anyone review that information before beginning the surgery.

Well after the procedure began, nurse Jones started reviewing Mr. King's records.[39] At once, she noticed the consent form clearly dictated that the amputation was for the right leg. A report notes, "Ms. Jones, who had been facing away from the operating area of the room, turned towards the area where the surgery was taking place. She looked under the draped blanket. She began to cry, and the surgical team then discovered that the wrong leg was being amputated."[40] Dr. Sanchez recalled that they were already three-quarters of the way through the procedure when he saw the nurse start shaking. The error was discovered too late, and Dr. Sanchez had no

choice but to finish the operation. Willie King was transferred to another hospital who amputated his remaining leg (the intended leg) about two weeks after the initial error—leaving King a double amputee several years or more before it would have otherwise been necessary.

As is common with most cases, multiple errors occurred throughout the entire system before resulting in the harm Willie King experienced. In essence, errors are the inescapable by-product of individuals operating within a system structure that allows errors to occur.[41] In fact, after studying the safety of complex systems, Charles Perrow argues that accidents within complex systems are simply inevitable.[42] In his book, *Normal Accidents,* Perrow attempts to capture one of the defining characteristics of complex systems: that accidents are normal events—an approach now referred to as normal accident theory (NAT). Perrow, who considers himself an organizational theorist, arrives at this conclusion after considering numerous examples of disastrous accidents. Through examining the events preceding each of these accidents, he demonstrates that not only were the accidents "unexpected, but [they were] incomprehensible" to the persons responsible for ensuring the safe operations of those systems. Accordingly, Perrow asserts that system accidents are normal.

As Perrow puts it, the "essence of the normal accident [is]: the interaction of multiple failures that are not in a direct operational sequence."[43] Most of these normal accidents will also possess a significant degree of incomprehensibility. The criterion of incomprehensibility is key. Though Perrow argues that accidents are normal, he does not posit that accidents are an inherent property of complex systems. Instead, the problem is that engineers and designers are helpless in preventing what Perrow terms normal accidents because they wholly fail to anticipate even their possibility. Here, complexity is the true enemy of safety.[44]

Safety, instead, depends on the ability to anticipate and resolve systemic flaws. This approach is similarly reflected in the latent failure model. As Reason articulated:

> Rather than being the main instigators of an accident, operators tend to be the inheritors of system defects created by poor design, incorrect installation, faulty maintenance and bad management decisions. Their part is usually that of added the final garnish to a lethal brew whose ingredients have already been long in the cooking.[45]

To understand this idea of *system* accidents, consider how systems become complex.

Fundamentally, a system is a group or set of interacting parts that (when assembled as a whole) work together for a specific, unified purpose.[46] As the IOM report stated, "a system is a set of interdependent elements interacting to achieve a common aim. The elements may be both human and non-human (equipment, technologies, etc.)." The critical component is that the parts are interdependent—without this level of dependency, the set would simply be a collection or grouping of parts. All systems share several defining characteristics:

- Systems have a discrete purpose, defining and unifying it;
- All parts of the system must be present for it to perform optimally;
- The ordering of the parts within the system affects its performance;
- Systems attempt to maintain stability through feedback.

The scope and coupling of a system will affect its risk—with accidents being virtually unavoidable in interactively complex and tightly coupled systems.[47]

Though complexity can be discussed relative to a number of different factors, Perrow isolated two important characteristics: the complexity of interaction and tightness of coupling.[48] Systems may be more or less linear.[49] Linear interactions unfold in expected and familiar sequences, even when unplanned. Non-linearity is a hallmark feature in complex systems.

Complex interactions progress in unfamiliar and unexpected sequences, which are either not visible or not immediately comprehensible. Unlike linear (or simple) systems, which allow decision-makers a vantage to observe and predict unplanned sequences, non-linear (e.g., complex) systems are characterized with near infinite variabilities—making it impossible to predict interactions and consequences.[50]

Sorting mail within a post office follows a linear (and, thereby, predictable) process. Manufacturers assembling automobiles use a production line process—a linear system. Even the process that a host at a neighborhood restaurant uses when managing new customers follows a linear process for seating and serving those customers; with each customer following the same projected path: request a table, wait for an available table, be seated, order drinks and appetizers, order the main course, possibly finish with dessert (a predicable variability), pay and tip your server, and, finally, depart. In this way, linear interactions follow an expected and familiar path. Conversely, providing care to an acutely ill patient is intensely complex. It does not follow any single path or order. There are so many variations and interactions that makes each patient's experience singularly unique. As a result, it is impossible to anticipate how the sequences will unfold. This level of non-linearity makes it incredibly difficult for decision-makers to avoid accidents.

The non-linearity of a process exponentially increases its complexity. Such systems will possess these general features:

- Components that are not linked together in a production sequence are in close proximity.
- Many common-mode connections (i.e., components whose failures can have multiple effects 'downstream') are present.

- There is only a limited possibility of isolating failed components.
- Due to the high degree of specialization, there is little chance of substituting or reassigning personnel. The same lack of interchangeability is also true for supplies and materials.
- There are unfamiliar or unintended feedback loops.
- There are many control parameters that could potentially interact.
- Certain information about the state of the system must be obtained indirectly, or inferred.
- There is only a limited understanding of some processes, particularly those involving transformations.[51]

Complex interactions follow unfamiliar sequences, with failures surging through the system in confounding ways that make them incredibly difficult to manage.

Systems also exhibit differing levels of coupling. Coupling is a way of conceptualizing the relationship between an action and its consequences.[52] Systems are tightly coupled when the relationship between act and consequence is intrinsically time dependent. Tight coupling dictates that, once a process has been set in motion, an established consequence will result every time. The relationship between placing your hand in a flame and being burned is tightly coupled—a burn will always result. In addition to not tolerating delay, tightly coupled interactions have invariant sequences and negligible slack. Loosely coupled systems, by contract, have slack and reserve their time and resources.[53] Parts can be isolated or sacrificed to protect the others.

To summarize a definition for normal accident theory, Perrow eloquently offers the following recap:

> Nothing is perfect, neither designs, equipment, procedures, operators, supplies, or the environment. Because we know this, we load our complex systems with safety devices in the form of buffers, redundancies, circuit breakers, alarm bells, and whistles. Small failures go on continuously in the system since nothing is perfect, but the safety devices and the cunning of designers, and the wit and experience of the operating personnel, cope with them. Occasionally, however, two or more failures, none of them devastating in themselves in isolation, come together in unexpected ways and defeat the safety devices—the definition of a "normal accident" or system accident. If the system is also tightly coupled, these failures can cascade faster than any safety device or operator can cope with them, or they can even by incomprehensible to those responsible for doing the coping. If the accident brings down a significant part of the system, and the system has catastrophic potential, we will have a catastrophe.[54]

As Perrow states, that is essentially the foundation for Normal Accident Theory. According to Perrow: for highly complex, tightly coupled systems, accidents cannot be prevented because they arise from the characteristics of the systems themselves. Operators fail to cope because they assume something else is happening—something they can understand—and are unable to intervene. Perrow suggests that this is the core of the common organizational problem.

As an example, Perrow offers the following scenario.[55] Your boss gives you an ambiguous order, which leaves you confused between doing A or doing B. You know that alternative A would be the right choice if something were terribly wrong or unusual. B is the correct alternative for a common situation that was not very serious. Given this, you decide your

boss wanted to you do B. After all, you have done B before, and it is easy to accomplish. You go about completing the various steps for option B and, as expected, all of the consequences that should occur at each stage in the process materialize in the right order. Feeling satisfied, you conclude that alternative B must have been the right choice because all of the expected outcomes were realized. In the face of uncertainty, you must, of course, make a judgment, even if only a temporary one—this act results in a "mental model" or expected universe. The downfall of this organizational problem is that is allows operators to confirm mental models that are congruent with their basic assumptions or interpretations without any actual relation to what is objectively true. This is precisely what happened with the operators leading to the accident at the Three Mile Island Unit 2 (TMI) nuclear plant near Harrisburg, Pennsylvania, on March 28, 1979.[56]

This accident at TMI was the most serious nuclear power plant accident to ever occur in the U.S. The accident began at around 4 a.m. in the cooling system. TMI had two cooling systems. The primary system circulates water through the core to remove heat from the reactor. The cooling water filling the reactor chamber, gets heated by the nuclear reaction. As the water temperatures rise, the pressure also continues to rise. The heated water rises to a steam generator, which heats the water in the secondary system. This transfer of heat from the primary to the secondary system keeps the nuclear reactor from overheating. The heat from the primary system also eventually converts the secondary system to steam, which spins the turbines to generate electricity. The steam is then cooled and reused to make more electricity.

Though the reason was unclear at the time, a seal within the secondary coolant system leaked. The moisture from the small leak interfered with the air pressure reading on two feedwater pump valves. This interruption stopped the feedwater pumps. This interruption of the cold water flow into the cooling system triggered an automatic shutdown, stopping the turbines.

Within seconds of the shutdown, an automatic safety device to relieve the pressure—a relief valve (PROV)—opened as intended. About ten second later it should have closed, because if too much water escapes the pressure drops too low. The PROV failed and did not automatically close. With the relief valve open, coolant from the reactor core was leaking at an increased rate. With too much coolant escaping, the pressure was rapidly dropping. This is dangerous if the water temperature is not also rapidly cooling because without pressure, the superheated water (over 2,000° F) will convert to steam which does not effectively cool the core. Steam also creates bubbles that block the flow of coolant, allowing certain spots to get much hotter than others and start fissioning again.

At the same time, another safety measure is designed to automatically start pumping fresh water to the steam generators. Even with the turbines off, the secondary coolant system still needs to function to remove heat from the reactor core. Perrow compares this to a teapot. Simply stopping the turbines is analogous to removing a whistling teapot from the stove with a plugged opening; even though it's no longer being actively heated, the already hot water in the metal pot will continue to produce steam. If that steam does not have a way to release, the pot may explode. Similar to how you would need to pour cold water over the tea kettle to keep it from exploding, the emergency feedwater pumps are supposed to come on to compensate for the boiling water until the reactor cools. The emergency feedwater turned on, as expected, but the operators did not realize that both pipes were blocked. A valve in each pipe was left closed after maintenance, leaving the water pumping into a closed pipe. With the steam generators not getting added water, they eventually boiled dry. This caused the reactor coolant (in the primary system) to heat up again because the secondary system stopped removing heat from the primary one.

Responding to the loss of cooling water, high-pressure injection pumps automatically pushed replacement water into the reactor system. As water and steam escaped through the open relief valve, the cooling water surged into the pressurizer, helping to compensate for the lost water. After the HPI came on, the operators were receiving conflicting information from two dials: one indicating that the pressure in the reactor was still falling, but one indicating that the pressure in the pressurizer was dangerously high—and rising. The pressurizer is supposed to control the pressure in the coolant system, and, as such, it should have the same pressure as the reactor. One could be wrong; but, which?

According to the control panel, the operators believed that the there was plenty of water going into the core through the coolant pumps (not knowing of the blockage) and through the HPI. With all of this water going into the core, it did not seem comprehensible that the pressure would fall; especially because the control panel also had a signal light confirming that the PROV was closed. A supervisor testified:

> I think we knew we were experiencing something different, but I think each time we made a decision it was based on something we knew about. For instance, pressure was low, but they had opened the feed valves quickly in the steam generator, and they though that might have been "shrink." There was logic at the time for most of the actions, even though today you can look back and say, well, that wasn't the cause of that, or, that shouldn't have been that long.[57]

Operators were faced with a dilemma between ambiguous readings. If they believed the core pressure indicator (alternative A) that would mean that the core was slowly being uncovered by water. This option was unheard of and had never happened at any large commercial light water reactors in all their years of operation. Trusting the pressurizer dial (alternative B), was more

aligned with their training and made sense with the information they had at the time. Afraid of letting the pressure rise much higher, and aligning with their strict training not to go solid (i.e., allowing the HPI to send too much water to the core, flooding the pressurizer with all solid water and no steam), the operators acted on alternative B and throttled back the HPI. As expected, the pressure dropped in the pressurizer after HPI was cut back. Unbeknownst to the operators, however, cutting back the HPI uncovered the core—melting the fuel rods and releasing radioactive material into the cooling water.

Having no framework to anticipate the unexpected or unlikely interactions, the operators at TMI made decisions and processed information to fit their expected world—finding reasons to exclude or rationalize any potentially contradictory information.[58] These limited constructs of reality made it impossible for the TMI operators to properly intervene. Given the impossibility of eliminating errors through human corrections, it is essential for industries (especially those that are high-risk) to employ other strategies to mitigate the consequences of errors. Indeed, this is the only sensible way to combat the human error problem. To achieve this goal, patient safety researchers have looked to other high-risk and complex industries (e.g., aviation, nuclear) to gain insights into how to better anticipate human factors in order to manage safety.[59]

Many of the important developments regarding the psychology of error (generally) originated after studying tragic accidents that occurred within complex industries. Researchers drew on this knowledge to approach error within the healthcare setting with a more sophisticated understanding of the nature of error. One of the first pioneers in this area, Jeffrey Cooper, was a bioengineer who worked for Massachusetts General Hospital.[60] Massachusetts General Hospital tasked Cooper with developing machines to assist anesthesiology researchers. In this role, Cooper noticed that the anesthetic machines were contributing to high rates of error because of

their poor design. For example, the machines were not standardized—whereas a clockwise turn of a dial on one machine would decrease the concentration of an anesthetic, it would increase that same concentration on a different machine. Not surprisingly, this was highly conducive to error.

In 1974 Cooper presented some of his concerns during a lecture at a NATO conference on Human Factors in Healthcare entitled, "The Anesthesia Machine: An Accident Waiting to Happen."[61] An attendee suggested to Cooper that he should consider using the critical incident technique that Flanagan pioneered to actually study errors, not merely observe them. This technique offers a set of procedures for collecting observations of human behavior.

As Flanagan notes, the critical incident technique was first used within of the United States Army Air Forces Aviation Psychology Program during World War II.[62] One of the first applications of this technique was used in the summer and early fall of 1941 to analyze why 1,000 expelled pilot candidates failed to learn to fly. This initial study examined the proceedings of the elimination boards, in which pilot instructors and check pilots reported their justifications for eliminating potential candidates. Though many of the reasons were subjective generalizations (e.g., lack of inherent flying ability, unsuitable temperament, insufficient progress), a number of specific behaviors were also reported. The results provided some helpful behavioral standards to use when selecting pilots. However, it also indicated the need to find better data regarding pilot performance.

Accordingly, the program carried out a second study during the winter of 1943-1944. This study emphasized the importance of collecting fact-based performance reports from competent observers. Despite the stress placed on recording precise facts, the official reports still failed to account for all of the factors and events.

In the summer of 1944, a third study investigating combat leadership endeavored to gather specific incidents of effective or ineffective behavior specific to an activity. The instructions asked combat veterans to report incidents that involved behavior that was either especially helpful or detrimental towards accomplishing the assigned mission. The instructions also explicitly directed the respondent to describe the officer's action. The several thousand of incidents collected from this study provided a rather factual and objective definition for effective combat leadership.

Towards the close of the war, the summary volume for the Aviation Psychology Program Research Reports provided a robust basis for understanding the technique and its procedures:

> The principle objective of job analysis procedures should be the determination of critical requirements. These requirements include those which have been demonstrated to have made the difference between success and failure in carrying out an important part of the job assigned in a significant number of instances. Too often, statements regarding job requirements are merely lists of all the desirable traits of human beings. These are practically no help in selecting, classifying, or training individuals for specific jobs. To obtain valid information regarding the truly critical requirements for success in a specific assignment, procedures were developed in the Aviation Psychology Program for making systematic analyses of causes of good and poor performance.
>
> Essentially, the procedure was to obtain first-hand reports, or reports from objective records, of satisfactory and unsatisfactory execution of the task assigned. The cooperating individual described a situation in which success or failure was determined by specific reported causes.

> This procedure was found very effective in obtaining information from individuals concerning their own efforts, from subordinates concerning errors of their superiors, from supervisors with respect to their subordinates, and also from participants with respect to co-participants.[63]

As the summary reflects, this approach relies heavily on collecting large samples of direct observations of human behavior.

After World War II ended, some of the psychologists who worked in the Aviation Psychology Program established the American Institute for Research, an organization devoted to the systematic study of human behavior. In some of its early studies, the American Institute for Research more formally developed the technique and gave this approach its present name. One of the Institute's first studies within an industrial situation sought to determine the critical job requirements for General Motors employees. First foremen collected 2,500 critical incidents by interviewing other foreman in the plants. Using that data, a form was developed (the Performance Record for Hourly Wage Employees) for foremen to collect incidents on a regular basis. Three groups of foremen (each split into groups of 24) were tasked with reporting incidents at regular intervals: with the first group recording daily, the second group reporting at the end of each week, and the final group submitting reports bi-monthly. Though each group was exposed to comparable work conditions, it became very apparent that daily recording provides the best results. The foremen who reported weekly (155 incidents) forgot nearly half of the incidents that they would have likely reported on a daily basis (315 incidents). Even worse, the foreman who reported bi-monthly only submitted 63 incidents—only 20% of the amount that the daily reporters observed.

From this discussion, it should be evident that the critical incident technique is a procedure to discern important facts about behavior for specific and defined situations. A hallmark of the technique—which is best understood as a flexible set of principles, rather than a single set of rules—is that it only requires observers to report simple observations. In fact, the critical incident technique is quite elegant in its simplicity.

After researching this technique, Jeffrey Cooper and his colleagues realized that they could benefit from learning from the perspectives and knowledge of the frontline workers.[64] Based on their findings, the team investigated various preventative strategies. They developed a prototype machine, "The Boston Anesthesia Machine," that was displayed during the 1976 Association Society of Anesthesiologists' annual meeting. This suggestion also pushed Cooper to publish a landmark study on anesthetist-reported incidents, which eventually led to the enactment of minimum monitoring standards.

As Cooper pointed out in his study (Preventable anesthesia mishaps: a study of human factors), prior studies examining human error contributing to anesthetic risk only concentrated on quantifying the overall risks. While useful, this information did not provide any insights into how to reduce that risk. Instead, using the critical incident technique, Cooper endeavored to identify the etiology of error. Unlike other studies, his study "focused on the process of error—its causes, the circumstances that surround it, or its association with specific procedures, devices, etc—regardless of final outcome."[65]

Cooper and his team used a modified critical incident analysis to examine 359 critical incidents, which staff anesthesiologists, residents, and nurse anesthetists self-identified during interviews.[66] A mishap was considered a critical incident when it was an occurrence that could have (if not discovered) or did lead to an undesirable outcome (e.g., anything from an increased

hospital stay to death). Each incident was also required to meet four additional criteria: (1) involve an error committed by a member of the anesthesia team, or an anesthetic equipment failure, (2) occur while the patient was under an anesthetist's direct care, (3) be described in clear detail by a direct observer, and (4) be clearly preventable. Acknowledging the difficulty of determining preventability, Cooper excluded incidents that left any doubt as to the likelihood of preventability.

Ultimately, Cooper realized that the scope of the problem was much larger than equipment-related errors. Cooper and his colleagues found that equipment error only accounted for 14% of incidents, with human error accounting for the remaining 82%. As Cooper tells it, though, another man was integral to translating his research into meaningful action.[67]

Ellison C. Pierce Jr., or "Jeep" as Cooper knew him, was the Chairman of the Anesthesia Department at the Deaconess Hospital and, in 1983, became the President of the American Society of Anesthesiologists. Partially motivated by his own experiences of loss after a friend's child died due to anesthetic error, Jeep was fiercely dedicated to improving anesthesia safety. In 1984, Jeep and Cooper (along with Dick Kitz) organized an international meeting to discuss how to prevent anesthetic catastrophes. The discuss led to disagreement, and Jeep suggested that they should create a foundation dedicated to examining these events and determining how to prevent them. Together, they formed The Anesthesia Patient Safety Foundation.

Because of an ongoing malpractice crisis that was dramatically impacting anesthesiologists' income, The Anesthesia Patient Safety Foundation was able to garner enough support to stay viable. Jeep was able to use the ongoing threats to the field to encourage anesthesiologists to support his goal of preventing the events that were leading to exorbitant

malpractice awards. In working towards this common goal, the focus on safety led to meaningful decreases in the risks to patients.

Cooper went on to co-author the landmark IOM Report, *To Err is Human*, and was integral to the formation of the National Patient Safety Foundation.[68] In many ways, his initial analysis of human factors in the safety of healthcare birthed the development of the patient safety movement. Indeed, unlike other practices, anesthesiology is the one specialty that identified a patient safety problem long before the 1999 IOM Report.

The critical incident technique—though used more frequently now—is still often neglected as a meaningful way to approach the etiology of error and system failures.[69] As applied in Cooper's original study, the technique collected direct reports of human errors and equipment failures that caused actual or potential patient harm. After Cooper published his landmark study, many anesthesiologists conducted their own studies. Interestingly, one of these studies employed same methods in Australia. The resulting paper was one of the major influences towards the development of the Australian Incident Monitoring System (AIMS); one of the first national reporting systems to collect data on patient safety incidents in an attempt to tackle the systemic nature of medical error. Though this type of reporting data can provide necessary and essential data for how to focus systemic defenses to improve patient safety, healthcare organizations must first adopt a systems-based approach.

Applying Systemic Defenses to Healthcare

When things go awry in health care (and elsewhere), the most common response is to attempt to identify and blame the culpable individual(s).[70] Interestingly, as James Reason explains, the desire to blame *people* for errors (as opposed to institutions or situations) developed in response to the predominantly Western concept of free will.[71] Psychologically, blaming

individuals is emotionally more satisfying than targeting institutions.[72] This is founded in the assumption that humans are capable of choosing between right and wrong. As such, humans perceive errors as voluntary and culpable actions. Although the study of human error and accident theory demonstrates that errors (by definition) are unintentional, society continues to hold the belief that individuals can somehow will themselves to be error-free. Not only does this belief encourage unnecessary guilt and shame, it also overlooks the most important factor for change. Focusing on who to blame distracts us from understanding the most critical issue when an error occurs: how can it be prevented. The systems approach to error challenges this model of individual blame.

Historically, however, the healthcare system (as a whole) tasked individual providers with the responsibility to ensure quality. Take, for instance, the American Medical Association's first code of ethics:

> A physician should not only be ever ready to obey the calls of the sick, but his mind out to be imbued with the greatness of his mission, and the responsibility he habitually incurs in its discharge. Those obligations are the more deep and enduring, because there is no tribunal, other than his own conscience, to adjudge penalties for carelessness or neglect.[73]

In other words, the nineteenth-century American doctor was solely accountable to himself. Though doctors are not quite so independent today, the assumption that physicians are uniquely qualified to safeguard quality is a lasting hallmark of the medical profession.[74]

In fact, most contracts describe physicians as independent contractors—not employees. This is an important legal distinction, which reflects the tradition role of the institution to maintain the building wherein private practitioners cared for their private patients.[75] Because

physicians were independent contractors, hospitals had no right to control the manner or provision of any treatment. However, this view of the relationship between physicians and organizations—which depicts hospitals as plain structures that added as shared workspace for medical providers—is outdated. Today, hospitals act as independent medical centers. Accordingly, institutions implement stringent control procedures and policies to regulate and manage the delivery of health care. As patient safety experts continue to assert, contemporary healthcare has become an incredibly complex institution with an even more complicated relationship between organizations and providers. Nevertheless, given the role organizations traditionally played, it made sense to attempt to identify and punish the culpable individual. This encouraged the proliferation of the person-based approach to medical error, which focuses on individual blame.[76]

The person approach focuses on specific errors and violations; blaming individual nurses, physicians, and pharmacists for forgetfulness, inattention, and recklessness.[77] It views unsafe acts as arising primarily (if not entirely) from individual errors—attributing the poor performance to the individual's personality or ability.[78] To address these failures, countermeasures focus on reducing the error-causing flaws in human behavior. The methods for intervention include launching poster campaigns to incite fear, writing additional protocols or procedures, levying disciplinary measures or punishments, threatening litigation, and other blaming and shaming tactics. People who support this approach commonly view errors as moral shortcomings, which is often fueled by a personal need to be able to believe that the world is orderly and just.[79]

Psychologist Melvin Learner first articulated this phenomenon, introducing it as the just-world hypothesis.[80] Learner proposed that individuals need to see themselves and others as

deserving of the rewards or punishments that they experience in order to give meaning to their actions:

> Individuals have a need to believe that they live in a world where people generally get what they deserve. The belief that the world is just enables the individual to confront his physical and social environment as though they were stable and orderly. Without such a belief it would be difficult for the individual to commit himself to the pursuit of long range goals or even to the socially regulated behavior of day to day life.[81]

Quite simply, this concept declares that good things happen to good people and bad things happen to bad people.[82] Even though this is patently false, this phenomenon helps to provide psychological defenses against a harsh and random world. In a sense, it preserves a sense of justice and helps insulate people from vulnerability.

Not only does the person approach encourage unnecessary guilt and shame, however, it also overlooks the most important factor for change: causality. The primary psychological flaw with the person-based approach is that it treats errors as moral failures. A person-based approach disregards the fact that well-trained, careful, and caring providers commit the majority of errors—which, by definition, are accidental.[83] Further, by focusing only on the individual sources for error, unsafe acts are isolated from their system context. Remember an important feature of errors is is that they are unintentional deviations.[84] In this light, it is impossible to avoid errors or otherwise increase patient safety simply by encouraging or cajoling individuals to try harder.

Perhaps more importantly, the person-based approach is also factually flawed. Even if errors were moral failures, this approach does not examine the incidence of error in the context of the broader healthcare system. Remember, human error is inevitable in complex systems.

Accidents result because of poor system design, not poorly trained healthcare providers. Because the institution, not providers, controls quality policies and procedures, it is unjust to hold individual providers responsible for system flaws. Ultimately, all of the various approaches towards patient safety agree on this one major tenant: that large system failures occur as the result of multiple seemingly minor faults. For this, and many of the aforementioned reasons, blame is especially counter-productive.

Pioneers in accident theory and organizational science were the first to suggest that the human is the system component that is most difficult to change. Thus, they advanced the argument that the main response to an accident should be system-based—not person-based. Rather than get distracted with who or whether an error occurred, this view directs its efforts towards improving the system function. After all, blameworthiness aside, the most critical issue when an error occurs is not who made the error, but how to avoid repeating the error. In this way, the system approach focuses its efforts on building system-level defenses to avoid or (at the very least) mitigate the effects of error.

The systems-based approach acknowledges that humans are fallible, focusing instead on improving system defenses, barriers, and safeguards to prevent errors.[85] Given the additional difficulty of classifying and identifying error, proponents of a systems approach also argue that (if nothing else) it is simply more effective to focus on improving the system. Psychologist James Reason first articulated a developed theory explaining this model. The latent theory model's main proposition is that disasters result, not from a single, large failure, but from a series of relatively minor failures. To illustrate this, Reason proposed the Swiss cheese model of system accidents (figure 3.2).[86]

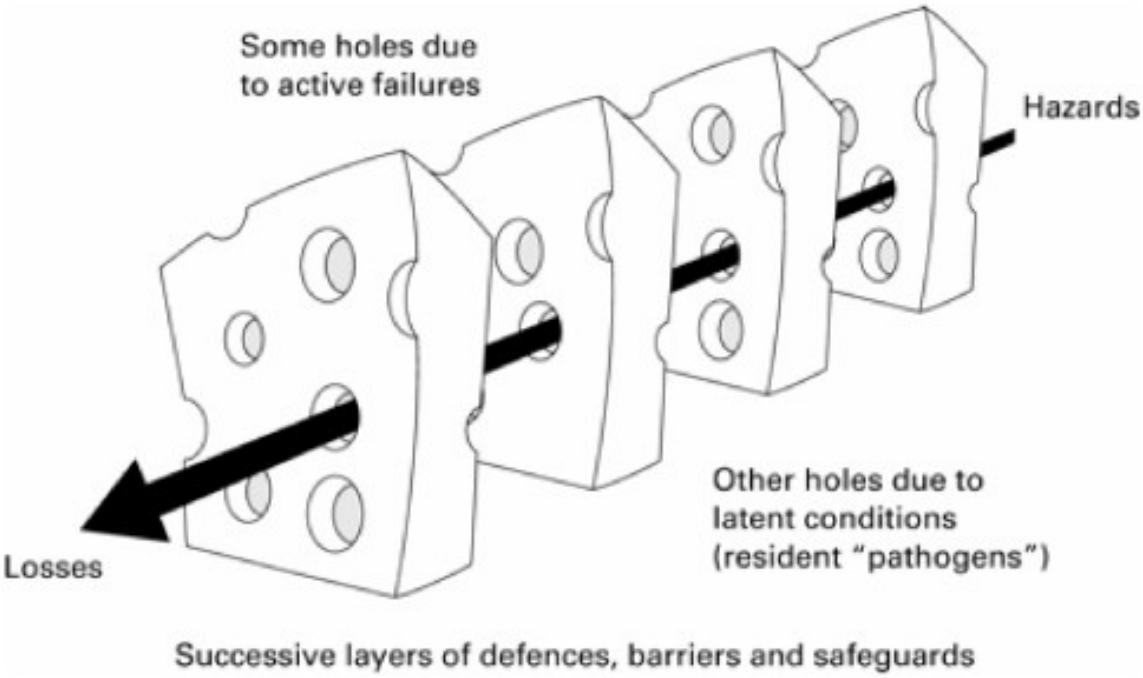

FIGURE 3.3. The "Swiss Cheese" Model of Accident Causation

Source: James Reason, J. Carthey, and MR deLeval "Diagnosing 'vulnerable system syndrome:' an essential prerequisite to effective risk management," *Quality in Health Care* 10, no. 2 (2001), ii21-ii25.

Reason's Swiss Cheese model emphasizes the fact that in complex systems (such as healthcare) a single error usually will not cause harm. Systems, especially high technology systems, have many defensive layers. Almost always, errors need to breach multiple defensive layers. Although each defensive layer should be intact, Reason explains that (in fact) the layers more closely resemble multiple slices of Swiss cheese. Unlike cheese, however, the many holes in the overlapping layers of protection are also continually shifting, opening, and shutting as the system adapts and changes.[87] Typically, holes in a single slice of cheese is not enough to cause a negative outcome. To result in a bad outcome, holes need to be aligned throughout successive layers of defense—allowing for a trajectory for harm.

These holes arise for two reasons: active failures or latent defects. Reason asserts that almost every loss involves a combination of both active failures and latent defects.[88] People at the sharp end (those in direct contact with the patient) such as surgeons, physicians, nurses, and pharmacists, represent active failures when they fumble or make mistakes. This is where the person-based approach investigation ends—with a direct cause to explain the occurrence of any unsafe acts, followers of the person approach have no reason to look any further. However, because an accident only occurs when the holes in the defenses align to allow a trajectory of harm to occur, Reason argues that accident theory must also consider latent conditions. Latent conditions are still casually connected to the adverse event, their connection is just earlier in time. Referring again to the figure, the holes in the overlapping layers of protections represent these latent errors. Latent conditions are the 'resident pathogens' within the system that arise from management decisions. These pathogens can lie dormant within the system for years, only revealing themselves when a unique set of circumstances align that breach the system's defenses. An adverse event (or, accident) occurs when the trajectory happens to line up with holes in all of the layers of protection (slices of cheese). Because it is impossible to change the human condition, this modern approach to error management focuses on changing the conditions within the system to anticipate and prevent errors.

Though it might initially seem as though this model merely shifts the blame from the clinicians at the "sharp end" to the system managers, its central theme is that both the clinicians operating at the sharp end and the managers further down the sequence are victims to a complex environment.[89] Each inherited, not necessarily instigated, the latent accident sequence. Indeed, managers operating within a non-linear, complex system face the same hurdles in attempting to anticipate the effects of their actions or policies. In this light, the best method for minimizing

accidents (and improving patient safety) is to learn how to uncover and understand the significance of latent failures before they produce disaster.[90]

In order to anticipate and prevent errors, the Swiss cheese model also acts as a framework to guide investigations of adverse events. Though the model serves as an incomplete framework when it comes to accident analysis, it nevertheless emphasizes the importance of considering the contributing factors for an adverse event—not just the single, active error (sometimes called the sharp-end because of the error's immediate effects).[91] Though Reason focuses more specifically on complex explanations and latent conditions, he also recognizes the importance of understanding the human factors that affect system performance. Those factors could materialize as either latent or active failures. This is similar in nature, but different from root cause analysis, which attempts to trace causation back to a single cause.[92]

Root cause analysis (RCA) is a tool that is used to systematically investigate an event in order to identify and correct the causal factors to prevent reoccurrence.[93] The goal of RCA to deliberately and comprehensively identify systems factors that contributed to the error and uncover ways to prevent recurrent errors.[94] Some underlying root causes could include an organizational culture of low expectation, production pressures, a lack of safety protocols, poor supervision of junior staff, and heavy workloads.[95]

There are a number of different techniques for RCA that healthcare organizations can adopt to investigate the occurrence of error.[96] The simplest method is to repeatedly ask why (apparently referred to as the 'ask why 5 times' technique). Another technique is to create a causal tree to diagram the root causes. Placing the event at the top of the tree, this method continues to stack causes—the causes for the top event are first, followed by the causes for those secondary causes, and so forth—until all of the endpoints are reached. In every technique, the

analysis focuses on what and why, not who. In this way, root cause analysis embodies the systems approach to error. Identifying the latent errors within the system makes it possible to decrease the likelihood that an error trajectory will pass through multiple layers of protection, thereby increasing safety. Therefore, a successful root cause analysis does not assign blame based on personal performance but rather determines how to improve the system.[97]

Within the framework of systems thinking, the swiss cheese model supports the goal of RCA, which is probably best described as a tool for quality improvement. In both cases, however, the concept works because individuals cannot be considered in isolation from the system. This is not only because health care is a human endeavor, but also because it occurs within a complex system.[98] Health care can be defined as a series of personal interactions between patients and clinicians.[99] While this definition seems relatively simple, health care also includes a number of additional component parts: support staff, infrastructure, technology, therapeutic agents, and so on. As such, complexity theory would hold that health care is a complex adaptive system that is marked with elements of unpredictability, codependency, and nonlinearity.[100] Indeed, a system is complex when the number of interactions makes long-term predictions impossible. This is because complex problems are too complicated to be reduced to a series of policies or rules. Accordingly, even though individual clinicians can implement their own strategies to optimize or reduce risk, deficiencies in the system will continue to frustrate their good intentions.[101] That said, efforts to improve safety must not neglect sharp-end errors. To truly foster a culture of safety, an institution must eliminate the dysfunctional aspects of the environment and organization that constrain individuals (systems error) and also establish strategies to prevent human errors.

In sum, healthcare organizations are more likely foster a safety culture and adopt a systems approach if they implement investigatory tools that focuses on accident causation globally (be it the swiss cheese model or root cause analysis) rather than a person-centered investigation, which is marked with blame.[102] To emphasize the systems thinking inherent within this approach, some critics, such as Charles Vincent, prefer using the notion of systems analysis rather than root cause analysis.[103] Vincent argues that root cause analysis is a misleading term that tends to imply that incidents occur from a single (or small number) of root cause(s). Additionally, Vincent contends that the term only reflects the purpose of the investigation—e.g., to determine what happened and what caused it. Instead, he argues that it is more appropriate to use a term that suggests that the purpose of the analysis is to prospectively create a safer healthcare system. Either way, however, this picture of harm and its causes helps to clarify the significance of organizational systems for patient safety. Regardless of terminology or investigative technique, most of the latent conditions or causes of serious accidents within complex systems are present long before an accident sequence occurs.[104]

Finally, human factors researchers have also been working to develop system-based tools for organizations to manage unsafe acts. Error management from this perspective has two components: reducing the occurrence of dangerous errors and creating systems that can better tolerate errors. As opposed to spending energy trying to improve individual performance, the systems approach targets the person, team, and organization collectively. To best understand how to develop a resilient system, safety scientists identified high reliability organizations. These organizations—systems operating in hazardous conditions that have far fewer adverse events—are prime examples of the system approach at work. Unlike traditional systems, that strive to eliminate human unreliability, high reliability organizations accept human variability.

These organizations realize that, due to human variability, they will never be immune to adverse events. Instead, high reliability organizations learn to use these setbacks to enhance and improve the system, making their ability to adapt to changing events one of their most important safeguards. Here, the pursuit of safety is characterized by an ever-constant vigilance to make the system as robust as possible in the face of its operational hazards. Though these organizations are fairly removed from healthcare, their defining cultural practices could be easily replicated to apply to clinical settings, which will be discussed at greater length in the upcoming section.

Through understanding the nature of harm within complex systems, it is apparent that the preoccupation with blame and personal accountability is largely irrelevant to the reduction of medical errors, which are often precipitated by external circumstances.[105] This context is essential in order to deliver safer health care. Moreover, focusing entirely on the concept of error is, in many ways, counterproductive to the ultimate goal of improving patient safety. Instead, creating a safe system of health care is an ongoing process that must constantly adapt to circumstances within the environment to maintain and improve safety. It is neither a static process, nor is it a linear process. Because it is impossible to change the human condition, this modern approach to error management focuses on changing the conditions within the system to anticipate and prevent errors. Not only is this a more practical approach, it better identifies the root cause of medical harm: poorly designed healthcare systems.

In sum, enhancing patient safety requires a far broader target than simply diminishing errors. It requires a total system redesign. Though the frameworks set out in this section help to clearly conceptualize and analyze accidents, they stop short of illustrating clear models for change and system design. The following section builds on this foundation to explore methods to re-design the healthcare system for patient safety.

B. Organizing a Patient Safety Program

> "Trying harder will not work. Changing systems of care will."[106]
>
> —Institute of Medicine, "Crossing the Quality Chasm

Understanding that system reform is part of the comprehensive solution to reducing preventable harm, this section more closely examines the various components of a successful system. One of the major pre-requisites for system-wide change of a systems-based approach is implementing safe practices at an organizational level. Although there are a number of different factors to consider for implementation, the obvious conclusion is that employing systems change requires a dramatic cultural shift within the institution.

1. Avoiding a Culture of Blame

The IOM argued that the biggest challenge to building a safer health system is shifting from a culture of blame to a culture that treats errors as opportunities to improve the system.[107] To fully appreciate this complexity, it is useful to first examine the concept of organizational culture.

Defining what we mean by culture is hotly debated. One of the most challenging is the debate between culture and climate. In 2013, the Healthcare Foundation organized a round table in an attempt to distinguish the terms:

> *Climate* emerges through a social process, where staff attach meaning to the policy and practice they experience and the behaviors they observe. *Culture* concerns the values, beliefs and assumptions that staff infer through story, myth and socialization, and the behaviors they observe that promote success. In other words, culture is more interpretative.[108]

Culture is a shared experience.[109] One that deeply intertwined with the history of a group, which is why it is often referred to as the collective memory. As a memory, there is the implication that culture must be learned. Because it is not clearly enumerated, group or organizational culture is always a bit fuzzy. Group members may not always agree about the set of attitudes or beliefs, but yet, these basic assumptions will influence and guide each member's behavior within the group. Regardless of the level of complexity, when humans interact to achieve something, they will develop a culture.

Some experts regard organizational culture as a phenomenon that goes well beyond the notion of practices.[110] Culture is related to everything we think and perceive, and it cannot easily be separated or changed because it is so deeply ingrained throughout the many subsystems within an organization. As a concept, organizational culture gained notoriety in the 1980s. Edgar Schein most clearly articulated this concept in his book, *Organizational Culture and Leadership*. Schein defines organizational culture as:

> as a pattern of shared basic assumptions learned by a group as it solved its problems of external adaptation and internal integration, which has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems.[111]

While there is no standard definition for organizational culture, Reason introduces a slightly simplified iteration, defining it as a set of shared values and beliefs that interact with the organization's structures and systems to produce behavioral norms.[112] There are at least two key elements within this definition: (1) the articulation of values, (2) which are accepted by the members of the collective as normative. Having a set of shared values is instrumental to shaping behavior in a way that cultivates a sense of culture.

Put simply, culture is the "way we do things around here."[113] As the phrasing suggests, the process of socialization is integral in transmitting that culture to new employees. Thus, the attitudes that manifest from an organization's culture are going to be closely and directly tied to employee behavior.

At a systemic level, a culture of blame is characterized by a set of norms and attitudes that typify an unwillingness to take risks or accept responsibility for any accidents because of fear of criticism or punishment from within the organization.[114] This type of culture cultivates fear and distrust, and encourages individuals within the system to quickly shift blame to someone else within the organization to avoid being personally reprimanded. This type of organizational culture also tends to stagnant, as individuals are too afraid of the consequences of being wrong to to suggest new ideas. Though toxic, an organization might not purposefully or even knowingly choose to implement a blame culture. Instead, such a culture tends to naturally evolve from a management style that is "highly rule-oriented, compliance-driven, and focused on assigning blame or accountability to individuals even for system-level failures."[115] Few environments are more demoralizing than a blame culture. Though individuals who are skilled at office politics usually thrive in these cultures, most hardworking employees are left feeling helpless and frustrated. Rather than leave ample time and energy for providers to focus on patient care and continuous improvement, a blame culture distracts employees by forcing them to protect themselves with mounds of paperwork and blame shifting (not unlike the concept of defensive medicine).

In response to insights of systems thinking, the term no-blame culture thrived during the 1990s. The basic premise behind the popular phrase was that, because a large proportion of unsafe acts were not blameworthy, systems should move away from punitive cultures entirely.

Proponents argued that establishing a no-blame culture encourages reporting of errors, near misses, and minor incidents.[116] Such a culture would allow individuals to freely discuss mistakes in order to embrace learning and improvement. Moreover, supporters point out that the creation of a blame-free culture would improve full participation in incident reporting—allowing ongoing quality improvement and safety initiatives to achieve greater success.

While it is important to cultivate a culture that allows for a frank examination of error, one of the recent concerns is that the push towards a blame-free culture is an overcompensation that could also diminish quality. Commentators worry that an entirely blame-free environment undermines individual accountability, which is equally as important as systems accountability.[117] Although the momentum behind the no-blame culture is frequently attributed to James Reason, the father of modern error theory also agrees that it is neither feasible nor desirable to design a culture with blanket immunity for all types of unsafe behavior.[118] Indeed, every safe industry still has firing offenses—and for good reason. Not only would a blame-free culture undermine individual accountability, it would hinder morale and lessen perceived credibility. Specifically, Reason warned that the no-blame concept has two serious weaknesses.[119] First, it often ignored (or, at the very least, failed to confront) individuals who willfully engaged in dangerous behaviors. Second, it did not address the issue of how to distinguish between culpable and non-culpable unsafe acts. From a practical standpoint, there must be some distinction between unacceptable behavior and blameless unsafe acts.

Thus, while it is important to avoid unnecessarily blame, a blame-free culture is both ill-advised and hard to sustain.[120] Taken literally, it would eliminate personal accountability and challenge any social, disciplinary, and legal restraints to promote safe clinical practice. A much better objective is to create a 'just culture' wherein blame is appropriately restricted.[121]

According to the Agency for Healthcare Research and Quality, a just culture is one that identifies and addresses systems issues that encourage individuals to participate in unsafe behavior while also maintaining accountability. Reason defines a just culture as an atmosphere of trust that encourages—and even rewards—people for being forthcoming with safety related information, while also appreciating the balance between acceptable and unacceptable behavior.[122]

Although the notion of just culture is an ideal (and, by definition, unachievable), determining whether an organization has succeeded to increase justice will depend on the perspective of its members.[123] If the majority of its members agree that the organization will act justly, particularly in response to human error, it is fair to assume that the organization supports a just culture.

A prerequisite for engineering a just culture is that the system fairly determines, and the staff clearly understands, what is considered culpable behavior.[124] For example, Reason suggests that reckless non-compliance and substance abuse deserve severe sanctions.[125] Drawing an *a priori* line for culpability, however, is difficult.[126] Culpability is socially constructed—it is not inherent within any single act or person. Instead, it depends on how people describe and perceive acts. In this way, whether an unwarranted act is culpable does not reflect a quality of the act itself, but rather the application of social rules and expectations to the act. As such, deciding culpability is a complex assessment that relies equally on factual and ethical determinations. The consequence is that it is impossible to be completely independent or objective when labeling culpability. This can be problematic. For instance, in a series of experiments, Alicke found that people are inclined to attribute responsibility to the most morally blameworthy factor—not necessarily causation.[127] He showed that people blame the driver who

caused an accident when that driver was on an immoral errand despite other plausible causes for the accident (e.g., blind spot, another driver, poor weather conditions).

Fairly discerning when unacceptable behavior justifies punishment has been an ongoing challenge within the legal system, as well. In considering whether punishment is appropriate, legal system theorists consider the philosophical justification for punishment.[128] Most often, the tension is resolved by distinguishing between retributive or restorative justice. These conceptions of justice generally aim to achieve one of two goals: (1) control behavior or (2) restore the balance of justice.[129] There are a number of ways to pursue either objective, which can be either punitive or constructive. The justice system can attempt to control behavior through deterrence (specific or general) or incapacitation—these are punitive responses. Alternatively, it could also pursue rehabilitation, which could be viewed as a constructive approach. When seeking to balance justice, the response ranges from pure retribution to restoration (generally through a modified conception of mediation). That is, to atone for a prior harm, the system could either unilaterally impose a punishment or the victim, offender, and community could attempt to resolve the imbalance and agree together on an acceptable resolution. The notion underlying the theory of retributive justice is that the punishment itself will restore justice. Curiously, the philosophical justification substantiating this approach (in any instance other than confinement or compensation) defies the ethical edict that 'two wrongs don't make a right.' Further, because retribution is applied unilaterally, the offender is not taught to accept responsibility or show contrition or remorse.[130] For these reasons, the retributive model is troublesome. The model risks imposing additional suffering or harm without any noticeable gain. Therefore, an organization should carefully consider blameworthiness and the goals of punishment before imposing disciplinary measures in order to build a safer health system.

2. Creating a Culture of Safety

As such, rather than simply increase funding for patient safety initiatives, healthcare organizations need to look more closely at their organizational culture. While it is important to move away from the 'blame and shame' model, building a safety culture requires more than engineering a just culture. Not surprisingly, fostering a safety culture takes time.

This is particularly true given the difficulty of actually knowing the characteristics that define a safety culture. The term first emerged after the 1986 explosion at the Chernobyl nuclear power plant. The International Nuclear Safety Advisory Group (INSAG) referenced the lack of safety culture in a report summarizing the findings of their investigation. The International Atomic Energy Agency defines safety culture as, "that assembly of characteristics and attitudes in organizations and individuals which establish that, as an overriding priority, safety issues receive the attention warranted by their significance."[131] One of the primary factors considers the employee's perception of the level of priority to assign to safety. Pinpointing the precise criteria necessary to foster a safety culture is difficult given the number of approaches that organizations can take. That said, studies have shown that there are six essential components:

- Caring and safe environment free of blame—leadership listens to and cares about patient safety concerns. The response to the problem focuses on improving system performance rather than on blaming individuals.
- Commitment and drive to be a safety-centered institution—the resources, incentives, and rewards are provided by the organization to allow this commitment to occur.
- Communication—action is taken on patient safety suggestions when communicated.

- Collegiality and openness about errors—colleagues encourage employees to report safety concerns, and there is an openness about errors and problems.
- Priority of Safety—patient safety is constantly reinforced as the primary priority.
- Safety—Management does knowingly compromise patient safety concerns for productivity.[132]

Other characteristics that are important to a culture of safety are an informed culture, reporting culture, flexible culture, and learning culture.[133] Many of these characteristics are interdependent: a safe culture is an informed culture, which, in turn, depends on creating an effective reporting culture, which must be supported by a just culture. This means that systems must create institute infrastructures to collect, analyze, and disseminate relevant safety information. Systems must also ensure that the information is available to managers and operators who understand organizational factors to effectively assess the system safety. To ensure that the system understands the hazards threatening safety, the systems must also encourage a reporting culture. Because the effectiveness of a reporting culture depends on the willingness of the members to report errors, the organization must instill a sense of trust within its staff that they will be treated fairly—it must be a just culture. Finally, the organization must be willing to learn and adapt.

An ideal safety culture will drive the system to maximizing safety regardless of leadership or commercial concerns.[134] However, this may be an elusive goal. Institutional support and commitment to safety is a prime component for safety culture. In fact, the role of leadership cannot be understated. Indeed, senior leaders need to convey the message that safety is a priority, creating a leadership-driven cultural shift. For instance, senior leaders can construct the necessary organizational culture by supporting and expecting learning and innovation,

valuing and empowering staff, focusing on patients, rewarding collaboration and teamwork, and remaining flexible.[135] After establishing a safety culture, the existing culture should ensure that incoming leaders share similar values; however, if a culture becomes dysfunctional, the ultimate responsibility falls to senior leadership.[136]

Transforming an entire healthcare organization to exemplify all of these necessary organizational factors, however, can seem a bit of an onerous task. While it is certainly a large undertaking, transformation only requires that all of the basic conditions be in place.[137] Transformational leadership theory distinguishes two types of leadership that are important for safety: transactional and transformational.[138] Transactional leadership describes an effective and efficient management style, whereas transformational leadership is concerned with conveying purpose and vision. While transactional leadership is useful and important to maintaining an efficient infrastructure, a growing body of literature suggests that transformational leadership is more closely related to safety climate. Indeed, senior leaders need to convey the message that safety is a priority, creating a leadership-driven cultural shift.

This is precisely the preoccupation with safety that is characteristic of other organizations that effectively addressed errors. Organizations such as airlines, nuclear power plants, and computer chip manufacturers all enjoy being known as high reliability organizations (HROs) for becoming relatively mistake-free.[139] High-reliability theory defines the level and degree of the effort that people, at every level within an organization, need to perform in order to ensure consistently safe operations.[140] HROs share four main characteristics: preoccupation with failure, commitment to resilience, sensitivity to operations, and a culture of safety. Organizations in these industries acknowledge the high risks associated with their activities and act accordingly. They are vigilant and attentive to issues facing their workforce and are

committed to developing capacities to detect unexpected threats before harm occurs. And, perhaps most importantly, they empower individuals to draw attention to potential or actual failures without fear of punishment or retribution. While the HRO literature will not offer specific examples of how to enhance safety in health care organizations, it does provide a structured way of conceptualizing what factors are important.

Given the multifaceted, systematic nature of safety, it is likely that sustained improvement can only be achieved by integrating all of the interacting components within a comprehensive strategy for safe health care.[141] This approach challenges the contemporary viewpoint that financial means and a highly skilled staff are the most important considerations for promoting safety. Instead, the major implication is that systems in health care must also assess other organizational factors, such as processes and culture. Five transforming concepts are informative towards accomplishing this goal: (1) transparency, (2) integrated care platforms, (3) consumer engagement, (4) purposeful work environment, and (5) education reform.[142]

Transparency is perhaps the single most important attribute. The uninhibited sharing of information is foundational for the development of a safety culture. In this sense, transparency is a precondition to safety. Unfortunately, healthcare leaders are timid when it comes to authentic transparency—especially with the public. Not only do organizations need to develop informational cultures that share information intra-organizationally, it is a moral imperative to keep patients informed about error and harm. However, until, as a nation, we can relinquish dependence on a punitive system of malpractice, this will be unattainable.

Together, these transforming concepts can help to direct an organization's efforts to foster a culture of safety. Without them, an organization will struggle to make progress. Indeed,

the nature and psychology of error demands a more robust approach wherein organizations radically change the way they think about health care.

C. Conclusion

To provide a basis for appreciating the ethical duty healthcare organizations owe to their patients, this chapter critically examines the history and evolution of the patient safety movement. More than just exploring the debate as to whether patient safety should be more concerned with reducing errors or preventing harm, this chapter helped to frame this dissertation's reference to patient safety. Patient safety is best characterized as a movement focused on transitioning from a person-based to a systems-based approach to safety and error management. At its core, this systems-focused approach, bolsters the argument that healthcare organizations must evolve to be safer organizational systems. Indeed, the patient safety movement makes clear that, because human error is unavoidable, the key to improving patient safety lies in redesigning the healthcare system. Because it is impossible to change the human condition, this modern approach to error management focuses on changing the conditions within the system to anticipate and prevent errors. Not only is this a more practical approach, it better identifies the root cause of medical harm: poorly designed healthcare systems.

Understanding that system reform is part of the comprehensive solution to reducing preventable harm, this chapter further explored how organizations can implement safe practices at an organizational level. Although there are a number of different factors to consider for implementation, the obvious conclusion is that employing systems change requires a dramatic cultural shift within the institution. Given the difficulties of moving away from the 'blame and shame' model, the Institute of Medicine argued that the biggest challenge to building a safer health system creating a culture that treats errors as opportunities to improve the system.[143]

Sadly, this discussion is only relevant in organizations or systems that have accepted the charge to genuinely tackle patient safety. In the United States, the biggest challenge is still a matter of accountability and incentive. Without incentive to seriously address medical error, healthcare providers are not fighting to be at the forefront of patient safety efforts. Too often, an organization's core values and mission statement is merely a flashy document that fails to cultivate ethical decision-making. In this light, it is painfully obvious that healthcare organizations must be held accountable for the epidemic of patient harm. Unfortunately, this has not occurred—which begs the question: why?

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CHAPTER FOUR: ORGANIZATIONAL MORAL AGENCY AND ACCOUNTABILITY

Armed with the recognition that healthcare organizations have an ethical responsibility to improve patient safety, this chapter ethically examines the philosophical foundation for the notion of organizational moral agency in order to analyze the application of organizational ethics to healthcare organizations. First, Section A defends the stance that a healthcare organization should be held accountable to improving quality and safety. Specifically, this subsection argues that, given the uniqueness of healthcare organizations as providers of human well-being, the healthcare industry should be considered an industry affected with the public interest—much like public utilities. Moreover, organizations should be held criminally responsible for breaching their ethical duty to the public. This approach, however, faces several obstacles. Most difficult, opponents argue that organizations are not moral entities capable of having ethics at all—positive or negative. Accordingly, Section B offers a normative framework to hold healthcare organization's morally accountable.

A. An Industry Affected with The Public Interest

If, as safety experts suggest, errors are caused by flaws in the system, rather than individual shortcomings, then organizational accountability is easily one of the most crucial elements at the heart of the patient safety reform. It is curious, then, why there is such little regulation in healthcare. Business leaders throughout America are held accountable for their earnings reports, and can even be imprisoned for misleading the public about their performance.[1] Yet, despite the fact that medical harm is deadly, the healthcare industry is not held accountable. Amazingly, there is no analogous law regulating American healthcare practices.

To fully unpack that reality, it is useful to first consider the origins of regulation within the business sector. To this end, subsection A(1) explores the definition and justifications

supporting government regulation. The following section delves deeper into this subject, examining the legal precedent for regulating businesses to protect the public interest. With a strong framework for understanding the legal issues involved, subsection A(3) begins to build a case for regulation. To appreciate the current regulatory state, and to also recognize the importance of applying the public utility concept to health care, it is critical to understand the historical origins of the American hospital system—as this greatly influenced the patchwork of regulations within the health care industry.

1. Defining Regulation

Though regulation is often discussed as a rather amorphous mode of governmental activity, it can be defined.[2] In establishing a central meaning, regulation can be thought of as the sustained and focused control that a public agency exercises over the activities that the community values. The word, however, is used in many different ways. Experts in law and economics—Robert Baldwin, Martin Cave, and Martin Lodge—explain that it is perhaps more useful to understand the ways that the term is predominantly used. They posit that regulation is used to refer to: (1) a specific set of commands, (2) a deliberate state influence, or (3) all forms of social or economic influence. In thinking of regulation as a specific set of commands, Baldwin et al. speak of the role of regulation in promulgating specific and binding rules. These rules are applied by a governing body founded for and devoted to the purpose of regulation. An example would be the occupational safety and health administration standards, enacted and enforced by the Occupational Safety and Health Administration to ensure healthful working conditions. Regulation can also refer to the larger series of state actions that are intended to influence either business or social behaviors, typically through the use of economic incentives (e.g., taxes and subsidies). Lastly, regulation can also be used to refer to all of the mechanisms

affecting behavior (including both state and private actors) that can broadly be deemed regulatory. In keeping with this expansive viewpoint, it is not even necessary for regulatory effects to be deliberate or intended.

Not only can the term be used in varying ways, there is also no single set of circumstances to adequately explain the rationale for every instance of regulation.[3] Governments, acting in pursuit of the public interest, advance several technical justifications for regulation. Three are most widely cited: the presence of concentrated economic power, the grant of public perquisites, and the potential for public harm.[4]

The most persistent and traditional justification to support regulation, involving concentrated economic power, can also be thought of as an instance of market failure.[5] The government justifies intervening in these cases based on the argument that the uncontrolled marketplace will, invariably, fail in a way that negatively impacts the public good. This is based on two assumptions:[6] first, this theory presumes that unhindered markets will fail because of market failures, such as monopolies. Additionally, the theory posits that the government—a benign entity—is able to correct for those failures through regulation.

The presence of monopoly is a prevalent market failure rationale.[7] Monopoly defines the situation wherein one seller produces all of the supply for the entire industry. The lack of natural competition facilities the market's failure. In most cases, the theory supposes that a company with a monopoly over the market will seek to maximize its profits by overcharging customers. Being the only supply source, the company can limit its output (to ensure sustained demand) and raise its prices above marginal cost. These same risks exist in a "natural" monopoly; however, in these cases it is less costly to society to allow a single firm to provide for the entire range of demand. For instance, in the case of railways and electric companies, it is most efficient to only

lay one set of tracks or cables rather than have a whole handful of competing firms install multiple, competing sets of tracks. In these circumstances, because it is costlier to society to allow competition, states will sanction their monopoly while simultaneously imposing other regulations to protect consumers from abuse.[8] In these cases, the regulator will attempt to set prices in a way that would simulate the output and pricing that would have been created under normal competitive conditions.

Another form of concentrated economic power occurs when a firm earns a windfall (i.e., excessive) profit by finding a supply source that it much cheaper than what is available within the marketplace.[9] This could result from a fortuitous discovery or sudden change in market structure that creates a supply shortage. For instance, a firm may happen to locate a large deposit of a valuable mineral; or, perhaps, it owns the only boat in a desert town that has been flooded. In every case, a windfall represents an unanticipated—and unearned—benefit that the recipient did not plan or cause to occur. Because these excess profits were not earned (in the sense that the profit resulted from the firm's useful and meaningful efforts), it makes sense that the government would intervene to ensure that the public is similarly allowed to benefit from the windfall. To ensure that the public is protected, regulation may be necessary to either share an allocation of the profits or to ensure that the public is not harmed.

Some argue, however, that the market failure rationale is insufficient.[10] Notably, Tony Prosser argues that this approach treats regulation as being second-best to market allocation.[11] In this light, regulation would only be necessary to correct market failures—even if true, this rationale fails to justify the scope of current regulatory practices. Instead Prosser posits that regulation should be viewed as a primary method to protect human rights and further social solidarity—two rationales for regulation that Prosser contends are equally, if not more, important

than market-centered regulation. Indeed, more recent definitions have expanded the concept of regulation to include social priorities beyond pure economics:

> Regulation is the sustained and focused attempt to alter the behavior of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behavior-modification.[12]

This approach, expanding the bounds of economic regulation, echoes the Court's holdings.

2. The Legal History of Business "Affected with the Public Interest"

> Only history can help us make sense of a health-care system that, from the perspective of its results, makes very little sense at all.[13]
>
> —Paul Starr, *Remedy and Reaction*

For about six decades, between 1877-1934, the Unites States Supreme Court adopted the position that there was a class of businesses (or industries) that were sufficiently affected with a public interest to justify legislative regulation despite the due process protection guaranteed by the Fourteenth Amendment.[14] Within this series of landmark decisions involving constitutional law, the court continued to hold that the Fourteenth Amendment prohibited regulating exclusively private industries—those that were not affected with the public interest. Cases sanctioned regulation of grain elevators, banks, fire insurance companies, and insurance agents. Over the vociferous dissents of several justices (e.g., Oliver Wendell Holmes, Louis D. Brandeis, and Harland Fiske Stone) the Supreme Court, however, ruled that the manufacture of food, clothes, and fuels, and the operation of employment agencies, gas stations, and ice plants were essentially private in nature—and, thus, beyond the reach of state regulation.

Munn v. Illinois, decided in 1877, was the first case to test the right of the government to regulate private business. *Munn*, in judicially approving economic regulation, did not predicate the authority to regulate on the monopolistic character of the industry. Instead, the Supreme Court held that the dispositive factor was the public interest. From a historical standpoint, the holding can be traced back to the common law contributions of Lord Chief Justice Hale.[15]

Around 1670, Sir Matthew Hale was the Lord Chief Justice of the King's Bench in England. Some hundred years later, Francis Hargrave published Lord Hale's private paper concerning the ports of the sea, *De Portibus Maris*. In his analysis, Lord Hale outlines the King's rights and powers with respect to regulating trade and commerce. He first acknowledges that ports are places with keys, wharves, cranes, and warehouses. The king is the *prima facie* owner of every public port, yet merchants may acquire property interests through charter or prescription. The public also has an interest in constructing and maintaining facilities for merchants and traders to utilize. This is the *jus privatum*, which is superimposed upon by the *jus publicum.* Lord Hale pointed out that when facilities (such as ferryboats or wharves) held themselves out to serve the public, they became affected with a public interest and ceased to be *juris privati* only. This treatise had important influence over the judiciary in both Britain and America.

The adaptation of Lord Hale's principle into American constitutional law opened with a misstep.[16] In *Munn*, the Supreme Court gave the first interpretation of public interest. At the time, the Fourteenth Amendment was only eight years old.[17] Regulation was not absolute—liberty of contract was the leading legal principle, which influenced the way the courts approached regulation. Though the government did regulate private activity in many cases, it was aggressively attacked for violating the Fifth and Fourteenth Amendments. *Munn* formulated

the first approach to reviewing these claims. It established that: (1) the principle of sovereignty granted government the inherent power to regulate, (2) the government had the authority to regulate activities vested with public interest, and (3) its exercise of regulation through the police powers was limited by the due process of law.[18]

Munn v. Illinois involved a state legislation regulating the prices of grain elevators.[19] Midwestern farmers, seeking to ship their grains to distant markets, would transport their grains to Chicago for distribution.[20] There, grain elevators would transfer grain brought to Chicago by railroads to boats that would transport the grains further east.[21] Thus, Chicago was a transfer point—shipping grain from western rail and lake traffic to Atlantic ports. This made the grain elevators a dominant feature in the grain trade.

The grain elevators—almost acting as adjuncts of the railroads—were contractually obligated to store all of the grain that their affiliate railroads tendered to them. In order to distribute from Chicago, farmers had no effective control over which of the fourteen grain elevators received and stored their grain—the railroads reserved the right to select the receiving grain elevator. In the fall of 1865, the Chicago elevators announced a unilateral rate increase—one they argued was necessary because the grain was in poor condition and would be difficult to store through the winter months. Farmers and grain dealers complained that the elevator owners had been gauging prices.

To help protect consumers, the state had recently passed the Illinois Regulate Public Warehouses and the Warehousing and Inspection of Grain acts of 1871. These regulations established maximum rates, limiting how much grain elevators in Class A cities could charge for storage.[22] The firm, Munn & Scott, operated a grain warehouse in Chicago, a Class A city.

Munn & Scott were fined for continuing to charge higher rates than the statue allowed. The firm then sued, alleging that the statute violated their Fourteenth Amendment rights to due process.[23]

Attorneys for Munn & Scott maintained that the Fourteenth Amendment guarantee that no law shall deprive any person of life, liberty, or property without due process of law also protected private business from arbitrary government interference.[24] The key to winning their argument was to convince the court that the rate regulations amounted to confiscation.[25]

Writing for the majority, Chief Justice Waite held that private property that is "affected with a public interest," is subject to regulatory control by the state. Though Waite did not explicitly deny the theory of substantive due process, the Chief Justice wrote that state regulation of private property does not automatically deprive the owner his property without due process: "under some circumstances they may, but not under all."[26] Though the state has an extremely limited ability to interfere in exclusively private property, Waite (reciting Lord Chief Justice Hale's treatise, *De Portibus Maris*) held that:

> when private property is "affected with a public interest, it ceases to be *juris privati* only."[27]

Waite continues, "this was said by Lord Chief Justice Hale more than two hundred years ago, in his treatise *De Portibus Maris*... and has been accepted without objection as an essential element in the law of property ever since."[28] Justice Waite explained that "when one devotes his property to a use in which the public has an interest, he, in effect, grants to the public an interest in that use, and must submit to be controlled by the public for the common good, to the extent of the interest he has thus created."[29]

Though there is a level of plausibility in applying Lord Hale's principle in the *Munn* case, Chief Justice Waite took it too far.[30] The grain elevators, as a type of tollway to access the

eastern ports, are analogous in many ways to the wharf or crane of the seventeenth century port. Lord Hale acknowledged that these and other conveniences were affected with a public interest because they were necessary to the public's access and use of the King's public port. In fact, in many cases the businesses even had to obtain a charter from the King to operate—strengthening the argument that they could be regulated. *Munn* dramatically expanded this somewhat narrow view to include *all* private property; not just businesses operating under a government grant. In citing Lord Hale, Chief Justice Waite used language that was so broad that it could be applied to any form of private property: "when private property is "affected with a public interest, it ceases to be *juris privati* only." However, that is not what Lord Hale concluded. Lord Hale stated that "now that the wharf and crane and other conveniences are affected with a publick interest, they cease to be *juris privati* only."[31] As a consequence, Waite enlarged Lord Hale's proposition, and transformed American law.

Not surprisingly, because *Munn* expanded the principle such that it would apply to any property, regardless of how private, it was met with strong dissent. Many argued that the Court blurred the line between impermissible and permissible regulation by holding that grain elevators were distinguishable from other exclusively private businesses such as shoemakers or tailors.[32] Justice Field, who penned the dissent in *Munn*, was clear in his belief that Waite's opinion was far too expansive:

> I do not doubt the justice of the encomiums passed upon Sir Matthew Hale as a learned jurist of his day; but I am unable to perceive the pertinency of his observations upon public ferries and public wharves… to the questions presented by the warehousing law of Illinois.[33]

Justice Field argued that Lord Hale's principle only applied to private property that was dedicated—in a strict legal sense—to public use. He cautioned that the majority opinion would grant the government a blanket power to regulate every type of property ("from a calico gown to a city mansion"[34]).

In subsequent cases, the Court began retreating from its holding in *Munn*—particularly with respect to its doctrine granting unfettered legislative power to control rates. Indeed, though *Munn* introduced the "public interest" principle, in upholding the Chicago regulations, the Court also held that the extent of government power should be controlled through local elections:

> We know that this is a power which may be abused; but that is not argument against its existence. For protection against abuses by legislatures the people must resort to the polls, not the courts.[35]

Breaking from this approach, the Supreme Court began using substantive due process to aggressively protect economic liberties from government interference.[36]

When the Court decided *Munn v. Illinois*, it judicially upheld the right of the government to regulate private business subject to the Fourteenth Amendment due process clause. At the time, however, this was interpreted to mean procedural due process. Yet, the dissenting opinion developed a corollary argument that became known as substantive due process. According to this legal theory, the Constitution not only requires that laws follow fair procedures before depriving a person of their interests (i.e., procedural due process), but it also demands that the government must demonstrate a compelling reason for such a deprivation.[37] Through this concept, a majority of justices reliably voted in support of business interest and repeatedly struck down state laws regulating private business—a significant reversal from the *Munn* precedent. In fact, almost 200 state laws were declared unconstitutional from 1905-1937.[38] With the onset of

the Great Depression, however, justices had a difficult time supporting substantive due process, as it prioritized business interests to the detriment of the general public.

Then, nearly at the moment of *Munn's* demise, the Supreme Court finally appeared to break with its past holdings.[39] In 1934, some 57 years after the Supreme Court first addressed the issue of regulation, it decided *Nebbia v. New York.*

Slightly before the Court would decide *Nebbia,* President Roosevelt was earnestly working to promote economic reactivation after the recent disastrous economic collapse (i.e., the Great Depression). One of the primary approaches President Roosevelt pursued was pledging to offer Americans a New Deal—one that used government regulation to protect the public welfare from marketplace corruption and greed. States followed suit and enacted their own New Deal-inspired regulations and economic reforms.

This was the state of the economy when New York shaped its own New Deal legislation to regulate the milk industry.[40] After a thorough investigation, New York found that the milk industry was suffering from unfair and destructive trade practices. Producers were too weak and unorganized to put pressure on their distributors to protect their own economic interests. As a consequence, providers were not receiving fair rates of return. To correct for those market failures, New York passed a law in 1933 establishing the New York Milk Control Board to better regulate the prices of milk—including setting state-wide minimums. The facts of the case were relatively straightforward:[41] the New York Milk Control Board set a fixed minimum price for milk, prohibiting dealers from selling milk for less than nine cents per quart. A grocer, Nebbia, sold a bottle of milk and a loaf of bread for the minimum price for the milk. Nebbia was indicted and convicted. He then appealed to the Supreme Court, arguing that the law deprived him of his right to due process.

In deciding *Nebbia v. New York*, the Supreme Court continued to struggle with how to apply the concept of a business 'affected with a public interest.' Prior cases had attempted to offer a clear test, but critics maintained that the phrase was too vague and illusory to pass muster.[42] The leading standard that developed in *Tyson, Ribnik,* and *Williams* for how to determine whether a business was 'affected with a public interest' required determining whether the business was (1) devoted to the public use, and (2) an interest in effect was (3) granted to the public in that use.[43] The drift from this holding became so great, the Supreme Court ultimately found that "it could no longer be deemed a controlling authority."[44] One such dissent succinctly expresses the views that ultimately prevailed in *Nebbia*:

> A regulation valid for one kind of business may, of course, be invalid for another; since the reasonableness of every regulation is dependent upon the relevant facts. But so far as concerns the power to regulate, there is no difference, in essence, between a business called private and one called a public utility or said to be 'affected with a public interest.' …The notion of a distinct category of business 'affected with a public interest,' employing property 'devoted to a public use,' rests upon historical error. …In my opinion, the true principle is that the state's power extends to every regulation of any business reasonably required and appropriate for public protection. I find in the due process clause no limitation upon the character or the scope of regulation permissible.[45]

In keeping with this view, the *Nebbia* Court sustained Nebbia's conviction; holding that "in the light of the facts the [regulation] appears not to be unreasonable or arbitrary, or without relation to the purpose to prevent ruthless competition from destroying the wholesale price structure on which the farmer depends for his livelihood, and the community for an assured supply of milk."[46]

The issue of the public interest still lingered. The defendant did not contend that the State lacked the authority to regulate the milk industry, generally. Instead, Nebbia argued that price-fixing was prohibited because the milk industry was not a business affected with the public interest—which, in his view, is the only subset of business that may be subject to price controls. Writing for the Court, Justice Roberts responded to this contention by holding that the phrase "affected with the public interest" did not refer to a fixed class of businesses. The Court explained:

> We may as well say at once that the dairy industry is not, in the accepted sense of the phrase, a public utility. …It goes without saying that those engaged in the business are in no way dependent upon public grants or franchises for the privilege of conducting their activities. But if, as must be conceded, the industry is subject to regulation in the public interest, what constitutional principle bars the state from correcting existing maladjustments by legislation touching prices? We think there is no such principle. The due process clause makes no mention of sales or of prices any more than it speaks of business or contracts or buildings or other incidents of property. The thought seems nevertheless to have persisted that there is something peculiarly sacrosanct about the price one may charge for what he makes or sells, and that, however able to regulate other elements of manufacture or trade, with incidental effect upon price, the state is incapable of directly controlling the price itself. This view was negatived many years ago [in *Munn*].[47]

Roberts continued to hold that the expression meant "no more than that an industry, for adequate reason, is subject to control for the public good."[48] The Court made clear that "there is no closed class or category of business affected with a public interest, and the function of the courts in the

application of the Fifth and Fourteenth Amendments is to determine in each case whether circumstances vindicate the challenged regulation as a reasonable exertion of governmental authority or condemn it as arbitrary or discriminatory."[49] Thus, *Nebbia* found that "'affected with the public interest' [was] the equivalent of 'subject to the exercise of police power.'"[50]

In this light, many scholars have argued that *Nebbia* overruled *Munn,* thereby discarding the concept of a 'business affected with the public interest.'[51] However, it is important to note that, while *Nebbia* signifies a radical turning point for the United States Supreme Court's interpretation of the due process clause, this reflects a nuanced aspect of Constitutional law that expands rather than eliminates this concept.[52]

Munn introduced the principle of "affected with a public interest," which the Court later used it to specifically broaden the scope of police power in price-fixing cases. Though *Munn* did not specifically limit its holding to price-fixing regulations, the justices continued to argue about the limits of the doctrine; leaving lower courts confused about the Supreme Court's opinion about which businesses were and were not immune to price regulation. The justices in *Nebbia* were faced with finding a compromise; continuing to treat businesses affected with a public interest as a closed category would limit the Court's ability to uphold state regulations. In finding an approach to uphold state regulations, the *Nebbia* court ultimately opted to free the scope of legislative power from the confines of businesses "affected with a public interest." In this way, the Court eliminated the standard in order to expand the governmental police power ("It is clear that there is no closed class or category of businesses affected with a public interest, and the function of the courts in the application of the Fifth and Fourteenth Amendments is to determine in each case whether circumstances vindicate the challenged regulation as a reasonable exertion of governmental authority or condemn it as arbitrary or discriminatory"[53]).

Thus, while contemporary scholars are correct to suggest that the Court discarded the tests developed in *Tyson, Ribnik,* and *Williams* for how to determine whether a business was 'affected with a public interest,' it is misleading to use that fact to imply that the Court no longer considers regulations based upon the public interest. To the contrary, the Court merely expanded the government's authority to "adopt whatever economic policy may reasonably be deemed to promote public welfare."[54] As such, the *Nebbia* case left it up to state legislatures to determine whether a business or industry is affected with the public interest.[55]

3. The Case for Regulation

With the legal hurdle removed, legislatures can look to the social sciences for insights when determining whether to enforce regulations. In every case, the government is justified in regulating private enterprises because they are unique in an important way—namely, that their business is of particular importance to the public welfare.[56]

The argument to apply this practice to health care is straightforward. Similar to other regulated industries, the healthcare field is profoundly affected with a public interest.[57] Moreover, hospitals are uniquely positioned to impose an unprecedented level of public harm—harm that rises to levels far more serious than other public utilities. Furthermore, as providers of life-saving medicine, hospitals also tend to exert monopoly power. After all, patients in dire health are not in any position (supposing that there even is another hospital in the region) to bargain for a better rate or transfer to a different hospital. To fully appreciate the relevance of this concept for the healthcare industry, however, a brief historical review is warranted.

The Rise of the Modern Hospital System

In America, the practice of regulation is as old as the precepts that underlie democracy.[58] The foundation for regulation can be traced back to medieval Europe, when the government first

asserted that the prices industries charged for "public" products (e.g., tollways and inns) must be fair and reasonable. In this way, public utility regulation has played a pivotal role in the development of the modern regulatory state—which has similarly shaped contemporary health law.[59] As detailed above, the Court embraced the common law practice of regulating private businesses affected with a public interest near the end of the nineteenth century. The category of businesses determined to be affected with the public interest were inconsistently referred to as public callings, public service corporations, or public utilities. In explaining the concept, legal historian James Hurst noted that:

> The public utility concept rests on recognition that some economic power is wielded at key points of intersection of human relations—for example in operating a railroad or an electric power generating plant. The men who stood at such a key point… had too much practical capacity to effect the lives of too many other people, to let them alone in market… So we brought the law more and more into play at these key points of intersection. Public policy insisted that these new forms of organized power, characterized by great aggregations of capital and capacity to affect life, should be legitimized by the criterion of utility and that this criterion should be enforced more and more by the law, and less and less by the market.[60]

Thus, any industry with sufficient market power to manipulate or abuse consumers (which did not necessarily need to rise to the level of monopoly) and served an important human need could be labeled a public utility. Nevertheless, during the early years, medicine was conspicuously missing from most lists. Why?

The original exclusion of medicine is less a statement about its positioning as a public utility and more a byproduct of its small and limited scale.[61] Though institutions devoted to

patient care have provided medical care for centuries (the first ones date as far back as the Roman empire), these wards were extremely rudimentary by today's standards.[62] During the early development of medical practice in America, medicine lacked any institutional structure or economic market.[63] There was no commercial nature to the practice of medicine. It was not a commodity. Insofar as the market for services were further limited by the conditions of rural life, practitioners who did enter the field made relatively little money. Given the high costs involved, most families simply did not have the means to spend on medical care. This encouraged most families to care for the sick a within the family and communal circle. These economic conditions also forced doctors to keep their costs affordable in order to drum up any business at all.

The few hospitals that did exist emerged as religious and charitable institutions built to care for the poor.[64] These institutions merely tended to the sick and destitute. They were a last resort for people who did not have family or friends to care for them. In this regard, hospitals did not exist to cure patients of their ailments. As a result, hospitals were dreaded places. Patients were just as likely to acquire new diseases than overcome the one that brought them to the hospital in the first place—it was far safer for the sick to stay home. This left little demand for the services of general hospitals. Nevertheless, these almshouses laid the foundation for the radical metamorphosis that would transform these dreaded places into citadels of science and order.

Public almshouses and similar institutions gradually transformed into the modern hospital by first becoming more specialized and then becoming more universal.[65] Almshouses, and other unspecialized wards, did not operate with any primary focus; mixing together the aged, the insane, the young, and the dying. In one sense, they were humanitarian. Indeed, the colonial

almshouse was often a religious house, which provided a substitute household for the poor or sick. These charitable hospitals were also communal, resembling a typical household. From there, general hospitals serving all classes of society began to appear. By 1800, however, there were only two facilities that could qualify as a hospital: Pennsylvania Hospital (established in Philadelphia in 1752) and New York Hospital (chartered in 1771, first received patients twenty years later). Massachusetts General Hospital followed in 1821. These early institutions were known as "voluntary" hospitals, as they were financed through voluntary donations.

The rise of these early hospitals did not mark the immediate decline in almshouses.[66] Urban workers were still most likely to visit an almshouse to seek care, rather than visit a hospital. While the colonial almshouse was largely intended to protect the general public from the feeble and poor, growing urbanization (particularly in seaport cities) dramatically increased the demand for care. Almshouses began to function as municipal hospitals, adding separate wards (isolated from the destitute, orphaned, and insane) to care for urban workers.

Additionally, around 1828 there was shift in public policy, and states began abolishing home relief (also known as outdoor relief).[67] Home relief was a practice of providing economic aid to the poor in cases of sudden necessity, generally in the form of a weekly or regular allowance.[68] With this form of aid eliminated, almshouses offered the only form of government assistance—which only served to increase demand. As a result, almshouses were often overcrowded and in disrepair. These conditions persisted until the Civil War.

The Civil War shaped the development of modern hospitals in important ways.[69] First, the war created an immense demand for medical facilities. To keep the armies supplied with healthy soldiers, American military hospitals evolved to operate as well-organized and sanitary models for health. The Union army alone built hundreds of hospitals with well over 130,000

beds. More importantly, the Civil War hospital was a triumph for scientific rationality,[70] with army hospitals boasting surprisingly low death rates.[71] During the last year of the war, the Union's vast network of military hospitals treated more than one million soldiers with an impressive eight percent mortality rate.

Second, the war helped to mobilize the professionalization of nursing. Prior to the Civil War (and for a short period after), nursing was not a trained profession. Hospital nursing had previously been a menial occupation for the lower class.[72] As Florence Nightingale described, "hospital nurses were generally those who were too old, too weak, too drunken, too dirty, too stolid, or too bad to do anything else."[73] In fact, many almshouse nurses had often arrived as inmates themselves—before gradually learning the trade. At the time, hospital nurses—who were regarded with slightly more respect than their public counterparts—even lived in the hospital, often in basements or odd spaces in the attics. The establishment of the first three nursing schools in 1973, however, marked a turning point for the profession. Nursing enjoyed a new prestige. At the same time, these graduates became the main labor force to support the growing hospital networks—particularly in the form of unpaid student nurses. With more consistent staffing, hospitals were better positioned to grow and expand.

The advancement of medical technology, namely the advent of antiseptic surgery also dramatically changed the scope of hospital care.[74] Before anesthesia, surgery was brutal and demanded that operations were quick and hasty. Anesthesia allowed for more careful and precise operations, which (when later paired with Joseph Lister's work on antisepsis) allowed for surgery to experience massive growth in volume and breadth.

Finally, the industrialization after the war increased the number of people living in urban centers. In 1800, America's total population numbered 5,308,483, with only six (6%) percent of

persons living in communities larger than twenty-five hundred (2500).[75] When the Civil War broke out (1861), America's population had increased to almost 32,000,000—an eight-fold increase. More importantly, not only had the population exploded throughout the country, American cities expanded at a particularly high rate. By the middle of the nineteenth century, nearly twenty (20%) of people were living in major cities.

As a consequence of these changes, it was no longer appropriate to care for the sick at home. As a 1913 analysis concluded: "Fewer families occupy a single dwelling, and the tiny flat or contracted apartment no longer is sufficient to accommodate sick members of the family… The sick are better cared for [in hospitals] with less waste of energy, and their presence in the home does not interrupt the occupation and exhaust the means of wage earners… The day of the general home care of the sick can never return."[76] The urban family lacked the physical space and labor power to attend to ill family members.

The effects of this change rippled outwards, and reform efforts focused on converting almshouses to public hospitals to respond to the newfound demand for hospital care.[77] The Philadelphia Almshouse evolved into Philadelphia General Hospital, Bellevue Hospital in Manhattan rose from the New York Almshouse, and the Baltimore County Almshouse joined the Baltimore City Hospitals. By 1910 the number of hospitals in the U.S. had surged to more than 4,000 (from less than 200 in 1872).

This rapid growth generally emerged in three parts: first was the foundation of private voluntary hospitals and the expansion of public almshouses, followed by the formation of religious and specialized hospitals in 1850, which finally gave rise to the for-profit model that developed in the early twentieth century.[78] The profit-generating hospitals, which exclusively

relied on fees for services, were primarily small surgical centers that physicians and private corporations operated.

Almost immediately, critics started lamenting the number of small, but uncoordinated hospitals.[79] These concerns were heightened after the Great Depression began. Simply stated, there were far too many hospitals. As a result, most hospitals were operating at or around 50% capacity. Many were experiencing great strain and financial pressure. Early reform efforts to address these deficiencies focused on standardization, which helped to create a paradox in the American hospital network: a vast system of hospitals with significant uniformity and minimal coordination. Without any integrated management, hospitals had increased needs for administrative support. Ironically, the proliferation of small hospitals and the lack of integration prompted the modern-day emphasis on business operations as a way to survive the intense competition. This was only further exacerbated by the American hospital system of attending physicians.

Insofar as hospitals allowed attending physicians to remain largely independent, they enjoyed great leverage over the hospitals.[80] These physicians were gatekeepers to patients (and, thus, financial stability)—giving them immense influence over hospital policy. Further, by not directly employing staff physicians, hospitals struggled to maintain control. Hospital administration became incredibly important. The field professionalized swiftly, leading these administrators to establish the American Hospital Association.[81] Physicians and administrators disagreed about the role of hospitals; with physicians regarding them as auxiliary workshops for their own private practices, and hospital administrators insisting that hospitals were independent medical centers. In any event, given the organizational complexity and demands for external

coordination, administrators all but gained sole authority of the domain of hospitals. A point that will become increasingly relevant as we examine the regulatory efforts that followed.

A Look at Hospital Regulation

There are essentially three forms of regulations or laws that govern hospital operations: common law principles,[82] non-governmental regulations, and governmental regulations.

Common law principles. In the United States, common law (also called stare decisis) is applied vertically (but not horizontally)—meaning that courts within one system (e.g., state, federal circuit) are not bound by decisions from lesser or lateral courts in the same system or courts in other systems, but they must follow precedent from higher courts within their own system.[83] Prior to 1940, there was very little case law specifically governing hospitals. The most relevant doctrine that existed during the early twentieth century regarded the duty to treat and aid others.[84] The traditional common law rule, which applied to everyone (including hospitals), made clear that there was no duty provide aid absent an existing physician-patient relationship. Without that contractual responsibility, neither physicians nor hospitals were held accountable or responsible for any harm to persons who had not entered a doctor-patient relationship.

Even when the hospital may have otherwise been liable for negligence, immunity protections also offered significant liability coverage. Throughout the early twentieth century, hospitals were immune from all liability due to charitable and governmental immunity.[85] Essentially, in both instances, public policy necessitated that the trust money should not be diverted away to pay for damages because it would undercut the charitable mission. Additionally, the doctrine contended, this policy would set a dangerous precedent that would discourage any public or private donations of funds. Because donors would not want to simply

fund lawsuits, anything short of absolute immunity would jeopardize the very existence of charitable institutions. Taken together, hospitals were essentially free to operate however they pleased.

Non-governmental regulations. As hospitals expanded, professional associations began to take a more active role in shaping hospital operations. In most states, as it still the case, hospitals faced more self-regulation than government regulation.[86] In the early 1900s, the American Medical Association's (AMA) Council of Medical Education worked to impose minimum standards for hospital internships.[87] Around the same time, the newly established American College of Surgeons (ACS) published the first minimum standard for hospitals in dedication to its mission of safeguarding and improving standards of care.[88] The ACS wanted to standardize not only surgical practice, but also the surgical workplace—the hospital.[89] This document, which represents the first regulation governing hospital standardization, was the product of nearly a decade of ongoing advocacy.

As early as 1910, Dr. Earnest Codman began criticizing the disgraceful condition of most hospitals.[90] Not long after, Dr. Codman advised that, in order to measure a hospital's efficiency, it was essential to have access to adequate records. To achieve these ends, Codman proposed an "end result system" that would allow hospitals to track every patient in order to assess outcomes and influence future recommendations regarding effective care. In plain terms, Dr. Codman explained:

> This system is perfectly simple, the only difficulty with it being its revolutionary simplicity. It requires straight forward truthful answers to these questions: What was the matter with the patient? What did the doctor do to him? What was the result? If the result was not good, what was the reason? Was it the fault of the doctor, the patient, the disease,

> or the hospital organization or equipment? Heretofore, in hospital organization there has never been a bona fide attempt systematically to fix the responsibility for the success or failure of each case treated. I claim our record system should enable us to fix responsibility, and that it should be used for this purpose.[91]

Though Dr. Codman failed to implement such an ambitious model of transparency and accountability, his urging did help set in motion the model for hospital standardization and regulatory framework that continues to guide accreditation to this day. In fact, one impetus for the foundation of the American College of Surgeons (in 1913) was to implement Codman's work on quality of care.[92]

The ACS recognizing that it lacked any authority to enforce its standard, respectfully asked hospitals to consider voluntarily accept their minimum standard based on the merit of its proposals.[93] After mailing a copy to all 697 hospitals with more than 100 beds in America and Canada, seven ACS staff members personally visited every hospital to present the standard and answer any questions. The 1918 Minimum Standard was a five-point program, requiring that hospitals: (1) establish an organized medical staff, (2) restrict membership to only licensed practitioners, (3) adopt and develop regulations and policies to govern hospital administration, (4) maintain standardized and accessible medical records, and (5) provide diagnostic and therapeutic facilities, including a clinical laboratory and X-ray department. Though participation was voluntary, it was difficult for hospitals to reject participation—not only were the standards extremely reasonable and rudimentary, many hospitals were cajoled into compliance in order to compete with nearby hospitals.

The ACS began inspecting hospitals for compliance, and soon learned just how poor hospital conditions had been—in 1918 (the first year it was offered), only 89 out of 692 hospitals

passed. At the October 1919 meeting, the ACS regents were so horrified with the dismal results that they burned every copy explaining these initial findings in the hotel furnace. Hospitals were given a stay of execution for the first year of participation. By 1919, the number of passing hospitals increased to 198 and continued to quickly improve in the coming years. By 1924, 831 (86.5%) of hospitals meet the standards.

The ACS continued to oversee the voluntary program until the creation of the Joint Commission on Accreditation of Hospitals (JCAH). Founded in 1951, the JCAH was established to coordinate the oversight of hospital accreditation to a single organization, thereby consolidating all of the similar programs conducted by the American College of Physicians, the American Hospital Association, and the Canadian Medical Association, as well as the ACS.[94] In 1952, the ACS officially transferred oversight of the Hospital Standardization Program to JCAH.[95]

Through a series of endorsements, state and federal authorities deferred hospital oversight to JCAH. Indeed, with the passage of the Social Security Amendments of 1965, Congress deemed that hospitals with JCAH accreditation comply with the Medicare conditions of participation and eligible to participate in the Medicare and Medicaid programs.[96] Even though few states made it illegal to operate without JCAH accreditation, because private and public insurers (including Medicare and Medicaid) require accreditation for reimbursement in most cases, JCAH accreditation is an operational necessity for most hospitals. As a result, accreditation became one of the primary regulatory tools policing hospital administration.

The Joint Commission (the shortened name JCAH adopted in 2007), a private non-profit organization, is a membership organization. Though its surveys and site visits are rigorous and thorough, critics argue that private accreditation fails to sufficiently protect public interest.[97]

Many argue that it is too gentle and lenient with its member hospitals to meaningfully regulate the industry.[98]

Governmental regulations. The majority of government hospital-based regulations falls into the broad category of reimbursement or cost-related regulation.[99] Nevertheless, there are three basic categories of regulations. The initial aim of hospital regulations focused on organizational matters, such as licensing. The following wave of regulations centered around the passage of large public programs, namely Medicare and Medicaid. Most recently, hospital regulations tend to be more varied, as most new regulations tend to be responses to specific problems.

Licensure is the most basic form of hospital regulations. These statutes and regulations outline the basic services and functions hospitals must provide to deliver an adequate quality of care. Unlike accreditation, licensure is a state-level governmental regulation. States bar hospitals from operating without a license, and these regulations are very difficult to challenge. Provided that the statutes are not prohibitively vague or arbitrary, courts will rarely intervene.[100] The scope of licensing regulations vary, but they typically address hospital organization, required services, nursing personnel, safety, sanitation, record retention, and occupancy.

Another major regulatory effort governing structural issues are certificate of need (CON) laws.[101] These laws were motivated to help control costs. The main inspiration for CON laws came from the American Hospital Association. The hospitals, anxious to avoid less desirable regulatory measures, encouraged states to contain costs by focusing on capital regulation. These laws required providers to obtain a certificate of need before undertaking any major capital expenditure of hospitals and nursing homes. Organizations were opposed to allowing outside agencies get involved in regulating medical services, but not only were hospitals willing to

accept capital regulation, they were also positioned to benefit from CON laws as a way to limit competition. The National Health Planning and Resources Development Act of 1974 mandated state CON laws as a condition of eligibility for certain federal health dollars. As to be expected, every state (except Louisiana) had enacted a CON law in the 1970s.[102] The federal government eventually repealed the requirement in 1987, prompting many states to repeal their own CON law. Currently, 35 states plus the District of Columbia and Puerto Rico maintain some form of CON program.

Unlike countries with a national health system, any remaining government regulation in the United States is fragmented throughout state and local legislation. There are few areas the federal government can regulate absent a centralized system, and when it does, it almost always imposes regulations through its ability to constrain federal funding.

Regulating Hospitals as a Public Utility

In the U.S., the debate over when and why the government should regulate business has dominated public policy. Few industries have as much influence and oversight over how they are regulated; hospitals are distinctly unique in this sense. This is likely because the historical association between hospital care and charity helped to insulate the industry from outside forces. Indeed, the government was incredibly slow to respond to the eventual evolution of hospitals from charitable institutions to market actors.[103] Even though municipalizes brought hundreds of cases challenging the tax-exempt status of voluntary hospitals (a common criticism when hospitals began billing patients for care), governments and municipalities still treated hospitals as entities beyond the purview of public utility regulation.

Traditionally, economists and jurists have defined businesses as public utilities when two basic considerations were met.[104] First, the business in question must provide an important

human need. Second, there must be a reason to belief that the market presented a risk for oppression. When these conditions were met, there were strong public policy justifications for requiring the industry to serve the public need in a reasonable and nondiscriminatory manner.

Even as hospitals proliferated, throughout the early twentieth century, the industry nevertheless lacked the market influence to warrant state intervention.[105] Furthermore, there was no need to subject charitable organizations to public utility regulation—the plain absence of any profit-driven motivation was believed to be sufficient. Indeed, the prevailing notion is that the government should only impose regulation when a feature of the market presents a substantial risk that the industry would exploit its consumers. Hospitals, as charitable intuitions, were unquestionably immune to these concerns.

However, as hospitals began to behave more like market actors, critics started to question this distinction. An increasing number of private, for-profit hospitals only further fueled this scrutiny. Even still, at that time, the cost of medical care was still extremely affordable. In 1910, the average cost of inpatient care per day was just $2—even after adjusting for inflation, that would amount to less than $50 today.[106] The lack of medical insurance also helped to keep costs in check. With patients paying out-of-pocket for all of their health care, natural cost constraints helped to restrain the medical economy.

However, as medicine became increasingly advanced and, thereby, costly, it gained the power to abuse its control over a public necessity.[107] Though *Nebbia* discarded the public interest standard as a test for reviewing constitutionality in 1934, the label ("affected with the public interest") still influenced regulatory efforts. It is no surprise, then, that courts began applying that label to hospitals in the 1940s and 1950s. This classification reflected an

increasing concern that hospitals had newly acquired substantial market power—power that positioned it to exploit consumers.

Efforts were soon underway to better manage hospital supply. Congress, in 1946, first embraced this goal on a national level by enacting the Hospital Survey and Construction Act (otherwise known as Hill-Burton).[108] The motivation to get involved reflected the understanding that access to hospitals was too important to the public welfare to leave it to market forces. The downfall of this approach is that Hill-Burton did not have any real regulatory force—it was only able to channel and direct public subsidies.[109] The IOM reported in 1980 that health planning was eventually viewed as inconsequential, and, often irrelevant. For these reasons (possibly) the planning movement was embraced as a less severe threat when compared to direct public regulation.

At the same time, medical spending was skyrocketing. With the early Medicare system lavishly reimbursed hospitals, it was increasingly difficult to defend Hill-Burton. It started to become evident that providing consumers with reasonably priced care would require more than facility construction. Health planners turned their attention to preventing duplicative institutions. The preferred technique to limit supply in this way was through certificate of need legislation—or, CON laws. These laws were clear examples of public utility regulation, and, perhaps, the closest the United States has come to a nationwide public-utility model.[110] Hospital interests were quick to support this model because it left ownership, management, and regulation intact.[111] Studies started to offer evidence that CON laws failed to meaningfully control medical inflation. Eventually, enthusiasm for CON faded. Even still, the majority of states continue to enforce a CON law.

More importantly, this illustration helps to show how deeply the public utility model shaped the medical industry.[112] Support its application or not, public utility regulation has dramatically influenced health law. Indeed, public utility regulation typically involves controlling profits and the number of firms within an industry. Though it does not embody a traditional conceptualization, the combination of CON laws and the economic conditions and rate limits imposed through public insurance programs like Medicare and Medicaid already function together to regulate medicine much like a utility—albeit using a much less organized and formal approach.

The problem is not that the government has not extended the public utility concept to hospital regulation; the problem is that the current situation in the hospital industry requires a tailored approach. Unlike other public utilities, hospitals are in a unique position to offer a service that is demonstrably different than electricity or telephone services. The greatest concern with typical utilities is that the firm with exploit their position of power to price gouge consumers. In the case of hospital care, however, the greatest concern extends far beyond the ability to pay. Of course, the issue of ability to pay (and the skyrocketing cost of health care) is a pertinent one. To this point, a recent news story offers a damning indictment: Leon Lederman, a 1988 Nobel Prize winner, reportedly sold his award for $765,000 in order to pay for his end-of-life medical expenses.[113] Yet, even still, the far serious threat is the patient safety risks that the hospital industry tolerates in order to generate a profit. The appropriate role of regulation is to ensure that firms providing key services are not permitted to sacrifice the general welfare to enrich their shareholders. This is precisely what is happening within the hospital industry—and the market power that these institutions hold, as consumers are faced with life-threatening conditions, is truly unparalleled.

Though hospital competition is monitored in most states through CON laws, and public (and sometimes private) payers help to police health care costs, few regulations consider the full magnitude of the harm hospitals inadvertently impose by not directing more recourses to improving patient safety. As it currently stands, hospitals are not legally required to report their complication rates, readmission rates, or other standardized performance metrics. Most hospital comparisons (such as Hospital Compare, www.hospitalcompare.hhs.gov) offer patient-safety metrics based on Medicare claims data—not medical chart review.[114] Rather than carefully consider the implication of their scores and implement patient-safety initiatives, this approach encourages hospitals to spend more money to improve the accuracy of their billing and claims data. For instance, one hospital, which was listed as having a high rate of accidental cuts in the new measures, found that most of the cuts were intentional, but had been erroneously billed under the code for an accidental cut.

The only minor exception is bundled within the Centers for Medicare and Medicaid Services (CMS) pay-for-reporting program, officially known as the Hospital Inpatient Quality Reporting Program. As of January 2011, CMS began requiring hospitals to report central line associated bloodstream infections (CLABSI) in intensive care units to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network system.[115] Any hospital that failed to submit information faced a 2% payment reduction. The Affordable Care Act also utilizes this information to calculate payment rates until the Hospital Value-Based Purchasing Program.

The Affordable Care Act also implemented a number of additional pay-for-performance initiatives. In an effort to link quality to payment and reduce overall healthcare costs, the Affordable Care Act (ACA) implemented three new programs. First, the Hospital Readmissions

Reduction Program authorizes Medicare to reduce payments by 1% to hospitals with excessively high rates of avoidable readmissions. The second program—the Hospital Value-Based Purchasing (VBP) Program—allows Medicare to adjust payments based on clinical process and patient experience of care. CMS compares hospital quality performance to national performance standards to determine an overall VBP score, which it will use to withhold payments from the worst performing hospitals (at or below the 50th percentile). In 2014, the penalty is 1.25%, but it will continue to increase until reaching 2% in 2017. Finally, the Hospital-Acquired Condition (HAC) Reduction Program requires the Secretary of the Department of HHS to withhold 1% of payments to the worst performing hospitals with respect to HACs.[116] The recent Affordable Care Act requires Centers for Medicare and Medicaid Services (CMS) to penalize hospitals with high rates of Hospital Acquired Conditions (HACs).

In spite of these programs, hospitals allocate sparse resources towards patient safety. Disturbingly, only few hospitals even devote resources to collecting patient-outcome statistics—a fatal threat—whereas almost every major company hires independent auditors to ensure the accuracy of their financial reports—a property threat. In part, this is explained through the history of the medical profession.

As far back at the New Deal, conservative ideology and the political strength of the medical profession has repeated thwarted any attempt at regulation. While physicians may view themselves as healthcare providers, the ongoing advancements in technology and medical inflation created a flood of managed care and hospital corporations that ideologically and financially reject any special responsibilities to the public. Remarkably, these corporations and special interests groups have protected enough of the public to make the system resistant to change. Though American values are not naturally opposed to healthcare reform, Americans

have developed a number of peculiar moral judgments where healthcare is concerned. For example, Americans do not demonize government involvement in the public-school system as "socialized education." Yet, the institutional legacies have greatly influenced how people apply their values to social spheres. Thus, the majority of Americans oppose the Affordable Care Act because in the early-twentieth century the organized medical profession successfully conflated public responsibility with a loss of freedom.[117] In this way (by encouraging public beliefs and ideologies to develop in reaction to its efforts, the healthcare industry has avoided virtually all regulation.

As a business affected with the public interest, it is time for healthcare organizations to begin to take corporate responsibility more seriously. Particularly given the nature of the health care, the industry should be considered an industry affected with the public interest.[118] From a modern perspective—one that demonstrates the way the *Munn* principle has adapted over time—microeconomic literature generally recognizes two competing theories of regulation: the public interest theory and the Chicago theory.[119] The public interest theory is an embodiment of the *Munn* holding—positing the fact that regulation should be enacted to protect the public interest.

Richard Posner first articulated the Public Interest Theory in 1974.[120] Posner suggested that the traditional rationale for regulation seeks to protect and benefit the public at large. The competing economic theory (the Chicago theory) assumes that regulations ultimately serve to protect the interest groups involved.[121] Regardless of the tension between the normative value of the two theories, a review of the concept of public interest throughout law, politics, and academia clearly reveals the notion being used time and time again to support regulation for the general welfare.

As is always the case, regulation is warranted when the magnitude of harm is too great for the general public to influence through the market. Indeed, the fact that a system causes public harm is especially important. Individuals are not situated to mitigate the effects of widespread, public harm through private enforcement. Only public enforcement is capable of remedying large-scale harm.[122] This is evident in the failed effort to monitor healthcare quality through malpractice claims and tort reform. The only untested solution left is to impose legislation to better control health care quality on a national level.

Though it is clear that the public is—quite literally—dying without public regulation, the U.S. government is unlikely to start regulating the healthcare industry in the immediate future without external pressure. Nevertheless, in order to advance an argument advocating for such action, it is critical to articulate a normative standard that supports holding health care organizations accountable in this way. One of the biggest barriers in this respect is the belief that corporations are ethically neutral.

B. The Complex Issue of Accountability

Whether organizations agree, each participant in the healthcare system has an ethical obligation to provide care without perpetuating public harm. Even more than in other industries, this dissertation argues that entities providing a basic necessity have a social responsibility to protect the public—not just their bottom line. However, many opponents strongly reject the notion that corporations, as moral agents, are able to be held morally responsible for an action (or inaction). Without any such moral responsibility, critics balk at the imposition of additional regulations.

1. Organizational Moral Agency

Moral agency refers to an actor's ability to behave morally, as opposed to immorally or amorally.[123] Social science reveals the prominence of amoral thinking among organizations, wherein organizations act self-interestedly—not because of intentional wrongdoing, but as a consequence of simply not considering their ethical responsibilities.[124] By contrast, the attribution of moral agency imposing moral obligations to consider normative responsibilities and translate those decisions into appropriate behavior.

Without moral agency, healthcare organizations cannot be held ethically accountable for their *institutional practices* or use of systems. This is an important distinction. Individuals within the healthcare organization have historically been held accountable to normative standards. A negligent clinician, for example, will encounter malpractice claims and professional penalties. Conversely, organizational ethics imposes normative standards for the institutional structures and ethical climate within an organization. Rather than hold an individual accountable, organizational ethics is grounded in the premise that organizations are subject to moral judgments.[125]

Peter French advances one of the principal arguments for attributing moral agency to corporations. He presumes that the necessary condition for moral agency is the notion of intentionality.[126] There must be a sense that the corporation in and of itself is an intentional agent; that it also has its own reasons for how it behaves as a collective, beyond the motivations of the people working within it. To clarify this distinction, French describes an important difference between an aggregate collectivity and a conglomerate collectivity.[127] An aggregate collectivity is nothing more than a collection of individuals all working together to accomplish a goal through the aggregation of their *individual* efforts. Conversely, a conglomerate collectivity

is an organized group of persons with an established internal organization to accomplish concerted action. Unlike an aggregate collectivity, French argues that a conglomerate collectivity has the ability to act independently (as a collective) and, therefore, as a moral agent. Concluding that corporations all have what he terms a CID (Corporation's Internal Decision) Structure, which delineates positions and levels of authority and corporate rules. This distinguishes corporations from aggregate collectives. Put another way, the CID Structure enables corporations to intend. As such, French argues that society can hold organizations responsible because an organization acts independently according to its own intentionality.

Admittedly, an organization is a fictional construct—it is not a person. Nevertheless, through analogy, it is clearly possible to attribute moral agency to organizations.[128] French's argument focuses on the fact that organizations "act" much like individuals. Although an organization acts through the collective decisions of its leadership and members, it functions as a unified system. It identifies goals and objectives that direct and shape individual and organization action. In this way, by identifying and delineating mission statements, institutional policies, and organizational processes, the organization functions as if it was a single person commanding the organization's business practices.[129] This is the same argument that the government adopts in order to treat businesses as separate entities under the law. While this does not provide a philosophical foundation for an organization's moral personhood, it does substantiate the notion that organizations have a separate identity. Of course, this sense of personhood is limited.

While an organization acts like an individual in many ways, it is still distinctly different.[130] Unlike full-fledged moral agents, an organization can only act through collective direction. It is important to hold the organization accountable as agents; however, this

organizational normative evaluation should not supplant the individual accountability of its members who are also liable for their individual choices. On the other hand, because organizations do act collectively, it would be insufficient to only consider individual actions. Thus, there must be a balance between organizational and individual accountability. Organizations are moral agents, in a sense, and should be held ethically accountable. At the same time, individuals, acting as agents for the organization, should be held morally accountable for their individual choices.

2. The Importance of Normative Authority

This position, that organizations can be normatively evaluated as moral agents, is controversial.[131] Some opponents argue that it is not necessary to confer moral agency on organizations in order to hold them to ethical standards of conduct, insisting that it is sufficient to judge organizations based solely upon their actions without imposing and moral rights or duties. While it is certainly possible to morally evaluate organizational actions without attributing moral agency on organizations, this position undervalues the importance of normative authority. For instance, while corporations are successfully evaluated and regulated under the law based solely upon organizational action, this approach is limited. The problem with adopting this approach is that it can only regulate behavior based upon external motivations or consequences. As an ethical approach, it is critical to maintain normative authority in order to proscribe and prescribe values, actions, and structures.

Without attributing moral agency, it would otherwise be impossible to hold the organization morally responsible for its actions. This approach to organizational ethics places the responsibility on the organization to develop its own sense of normative standards.[132] Rather than impose universal normative obligations, individual organizations are entrusted with the task

of defining their own core values and ethical climate based upon their own sense of ethics. Consequently, this approach allows for diversity in the normative content of organizational ethics. While this pragmatic approach still provides a basis to judge whether an organization is ethically admirable, it does not provide an argument to hold an organization morally responsible unless it violated a self-imposed normative standard.

Accepting organizational moral agency, of course, has implications for stakeholder theory. In the late twentieth century, business ethics scholars developed a number of conceptual frameworks to understand the ethics of business organizations.[133] Recently, that has coalesced into a framework for organizational ethics called stakeholder theory. Its main thesis is the normative claim that organizations must consider all of the interested parties (individual and collective) in order to behave ethically. As an industry, healthcare organizations interact with a number of different stakeholders (e.g., patients, families, healthcare providers, other professional staff, suppliers, third-party payers, the community). The critical question for stakeholder theory is which, if any, of the stakeholders enjoys priority when interests conflict? This is particularly relevant in the current context because truly committing to safety may expose healthcare organizations to certain levels of risk, in addition to financial expense.

It is not possible to resolve the issue simply by reviewing the interested parties. In this case, it is important to consider the organization's mission and core ideology. For all healthcare organizations this will revolve around the provision of health care. The significance of this guidance should not be overlooked. Without looking to the notion of stakeholder theory, any one healthcare organization could explore the notion of corporate moral agency themselves. In many instances, obligations to the organization and patients would conflict. However, by considering the application of stakeholder theory, it is clear that (regardless of how the

organization defines its own mission) organizational ethics supports the priority of patients. As such, healthcare organizations must be held accountable to discharge a set of moral obligations with regards to patient safety and the improvement of healthcare quality.

C. Conclusion

This chapter has critically examined the philosophical foundation and importance of conferring moral agency on healthcare organizations in order to build a case to hold healthcare organizations ethically and legally responsible for improving patient safety.

Specifically, this chapter examined the legal foundations supporting government regulation, particularly as applied to the hospital system. In this light, this chapter provided a framework to regulate private companies in order to protect the public interest. Some academics argue that this is an outdated justification, as the *Nebbia* case discarded the concept of a 'business affected with the public interest.' Yet, this chapter meticulously detailed the nuanced constitutional law developments, making clear that the Court used *Nebbia* to expand the government's authority to adopt policies to protect the public welfare. In practice, this has left the determination as to whether an industry or business is affected with the public interest to state legislatures. Through this lens and guided by the application of the public utility concept, this chapter developed a case supporting patient safety regulation.

Further, this chapter examined the extent of current hospital regulation. After examining the three forms of regulation, (common law, non-governmental, and governmental), it is clear that current regulatory efforts are failing. Though the government has extended the public utility concept to hospital regulation, it has not prioritized patient safety. Instead, nearly all examples of this type of intervention were economically motivated—focusing on the public's ability to pay for medical care. Hospitals are continuing to sacrifice the general welfare to enrich their

shareholders, however, they are not merely gauging prices. Moreover, consumers have even less market power, given insurance limitations and the immediate need inherent in life-saving medicine.

This chapter concludes that regulation is warranted when the magnitude of harm is too great for the general public to influence through the market. For the reasons explored in this chapter, the public unquestionably lacks this power. One of the primary tools at consumers disposal, malpractice, has failed to meaningfully influence medical practice. This is likely because of the inherent limitations that patients face in even learning of any safety breaches. Regulation is the only untried solution left.

Finally, from an ethical perspective, this chapter also defended the application of organizational moral agency to healthcare organizations—namely, hospitals. Indeed, even if the healthcare industry itself is failing patients, the typical approach has been to look to the direct-level providers. The concept of organizational moral agency, however, provides an ethical basis to support the plea to hold hospitals (corporate entities, and not individual providers) responsible for patient safety shortcomings. Indeed, in order to move beyond the traditional malpractice model, it is crucial to articulate a normative standard to hold healthcare organizations similarly accountable for patient safety incidents.

In this way, organizational ethics acts as a mechanism to develop normative methods to improve the quality and safety of healthcare. Without this basis, there is no normative authority to proscribe values, actions, and structures; organizational would only be morally accountable to maintain their own, self-imposed standards. At first glance, this may not seem particularly necessary. However, if the government is to impose regulations to hold hospitals accountable for patient harm in the same way that the law holds individuals accountable, it is imperative that the

hospital is viewed as an independent moral agent. Otherwise, investigations will not only continue to try to identify and blame individuals within the organization, but they will also fail to appropriately condemn the organization for its unethical behavior. Organizational systems must be held morally accountable. There is a tremendous opportunity to apply the concept of organizational ethics to impose those normative standards and demand that healthcare organizations assume responsibility for furthering patient safety.

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CHAPTER FIVE: THE DEBATE OVER ERROR REPORTING

Having determined that healthcare organizations have an ethical responsibility to improve patient safety; and, that said organizations can be held morally accountable, this chapter explores the significant, ongoing debate over how to best realize those goals. Specifically, this chapter analyzes the debate surrounding the healthcare system's primary obligation to the protect its patients: namely, the debate on centralized reporting of medical error.

Doctors and medical associations strongly oppose mandatory reporting, and have, historically, blocked all attempts at implementing a mandatory reporting system.[1] The prevailing argument is that mandatory reporting systems are unnecessary at best, and harmful at worst. Instead, the American Medical Association (AMA)—and organizations like it—favors voluntary reporting. AMA President Dr. James Rohack explained that "the AMA championed the passage of the patient-safety legislation to create a system where health care professionals can report errors in a voluntary and confidential manner so that future system errors can be avoided as we learn from past mistakes."[2]

After the release of the IOM report in 1999, President Clinton was eager to implement their recommendations and embraced mandatory reporting.[3] However, former AMA president, Dr. Nancy Dickey, clashed with Senators during a congressional hearing regarding the IOM recommendation to establish a mandatory federal reporting system, avowing:

> We are opposed to mandatory reporting. It may well drive underground the very information you need to improve safety. A number of states have mandatory reporting, and there's no evidence that they have greater safety or fewer errors.[4]

Richard Davidson, president of the American Hospital Association at the time, outright refused the White House's invitation to participate in the discussion. In a public statement, he echoed,

"The idea that a mandatory reporting system is going to change behavior is naïve at best. You need to focus on making a cultural change in hospitals, to promote open discussion of errors, and that's not possible if some plaintiff's attorney is climbing on your back."[5] Interestingly, Mr. Davidson's denouncement actually supports a call for a coordinated database. Any error data that a hospital reported to a nationwide (or even statewide) reporting system should be strictly and legally protected from disclosure—open discussion within the hospital, however, would not. Additionally, while there certainly may be other methods that would successfully change hospital culture, it is difficult to comprehend how evidence and data regarding common pitfalls and errors would hurt that effort. His statements seem to plainly evidence a general opposition to greater transparency (from any source), which appears to be motivated (at least in part) by a fear of litigation.

In any event, these statements highlight much of the controversy surrounding the debate about reporting systems. Logically, the opposition to mandatory reporting tends to embrace one of two arguments for why such a system will fail: (1) empirical evidence demonstrates that even mandatory reporting does not solve the problem of underreporting,[6] and (2) mandatory systems discourage participation.[7] To best appreciate these arguments, it is useful to review the IOM's recommendations.

A. The Call for Error-Reporting Systems

The IOM report envisioned a collaborative approach to reporting that would include two separate systems: a nationwide, mandatory system, as well as non-regulatory, voluntary reporting systems.[8] According to the IOM, these reporting systems would serve two essential functions: increased accountability and improved safety.

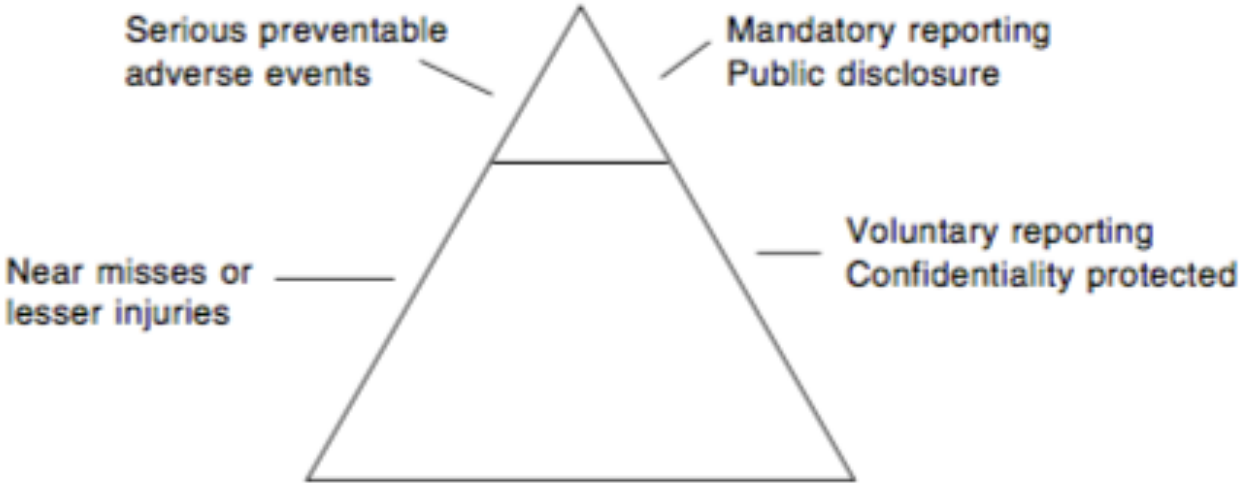

FIGURE 5.1. IOM Hierarchy of Reporting

The IOM report argued that the primary purpose of a mandatory reporting system is to hold providers accountable. As such, the IOM intended for mandatory systems to only collect data concerning the most severe errors—those that were associated with serious injuries or death. The committee depicted this relationship between mandatory and voluntary reporting in figure 5.1.[9] As portrayed in the figure, the committee strongly believed that the public has the right to be informed about unsafe conditions—particularly those associated with serious injuries, and even death. This tactic emphasizing accountability, they contended, served three important purposes. First, mandatory systems help to restore public trust by providing a baseline level of protection against the most egregious errors. Second, they leverage the threat of public exposure and penalties to pressure health care organizations to take greater steps to improve safety. Finally, they force all health care organizations to invest in patient safety. Analyzing this data to better understand the causes of such serious errors seems to be almost an afterthought.

Conversely, the IOM report explicitly tasked voluntary systems with the goal of actually improving safety. Unlike mandatory reports, these submissions should be protected from

discoverability. Because these reports would be submitted in confidence, the IOM report reasoned that voluntary systems are particularly well-suited to collect data about all errors—even those resulting in minimal or no patient harm (otherwise known as a near miss).

As likely expected, the IOM's recommendation for mandatory reporting systems drew such fierce opposition because of its insistence on holding health care providers accountable. At the time of the IOM report, the committee found that at least one-third of states had some form of reporting system.[10] In developing their recommendations, the committee interviewed thirteen (13) of those states to learn about the scale and scope of the systems. Most, the committee learned, focused on patient injuries or facility issues. All of the states reported that they protected the confidentiality of certain data, but the extent of protections varied. Most states cited a lack of recourses and limited data in explaining why they do not aggregate the data to publish information about general trends and best practices. Rather than focus on this level of feedback and intervention, the state health departments used the information to follow up with institutions on a case-by-case determination (depending on the severity of the incident).

After the IOM publication, critics quickly turned to the failings of the existing mandatory state systems. Most officials and experts (including spokespeople representing professional associations and hospital systems) generally agreed that the first step in improving safety is collecting information in order to better understand the scope of the problem. They further generally agreed that error reporting systems could present a means to gather the necessary data. They took issue, however, with the characterization that providers should be forced to submit mandatory reports. Instead, they argued that obligatory reporting would not offer a surefire

solution to underreporting. The solution, according to the industry representatives, is to simply remove all legal disincentives:

> We have to create an environment in which we learn from failure. This cannot be achieved in an environment of punishment or fear of legal prosecution for doctors, nurses and other caregivers who step forward after an unfortunate mistake is made.[11]

With these barriers removed, everything would work itself out. Look at Pennsylvania, they argued. At the time of the IOM report, Pennsylvania required reports for events that seriously compromised patient safety, such as death or gross injury (e.g., rape, infant abduction, fire, patient abuse). Though the Pennsylvania statute legislated a mandatory system, the Department of Health only received a single report for the entire year ending in June of 1999.[12] This alone, critics contended, proves that mandatory reporting is misguided.

Additionally, opponents also took issue with the contradicting recommendations. Though the IOM report emphasized the importance of abandoning the blame and shame model, its preoccupation with public accountability and punitive measures contravened its own edict. As one expert lamented:

> [T]he 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.[13]

Indeed, the IOM cannot have it both ways—public shaming is either beneficial or detrimental. Now, perhaps the IOM intended to shift accountability from the individual provider to the hospital system, but surely the committee must have recognized that, practically, practitioners—not organizations would bear the ultimate responsibility to submit reports. Organizations, faced with the threat of public disclosure and punitive action, are likely to (either explicitly or

implicitly) discourage individual providers from admitting their mistakes. Furthermore, given mounting malpractice litigation concerns, individual providers are also likely to be wary to report errors that caused serious harm with the knowledge that the information contained in the report will be released to the public.

From an ethical perspective it is obvious why the IOM report declared that "requests by providers for confidentiality and protection from liability seems inappropriate" in face of the public's right to be informed about safety hazards, particularly when patients are dying.[14] Additionally, the IOM's comprehensive approach to improving patient safety relied on public outcry. By threatening health care organizations with public exposure, the IOM intended to force organizations to invest in patient safety. In this light, the IOM was attempting to replicate the same public outcry that prompted progress in all of the high profile, but singular cases of harm that the media exposes.

From a public policy viewpoint, however, it is immediately apparent that this approach will fail. The theory that a punitive, public mandatory system will improve quality depends on five key assumptions: (1) providers will report, (2) the mandatory nature of the system can be enforced, (3) consumers will have access to usable information within a timely fashion, (4) consumers will actually use that information, and (5) health care organizations will respond by improving patient safety.[15] While past cases tends to support the fact that consumers will care about these risks and health care organizations will take steps to improve safety in response to their newly public shortcomings, there is no evidence that providers will report to a system against their own interests. Further, in an industry where harm is so easily concealed, it is nearly impossible to envision how the government could enforce the mandatory nature of the reporting. The only plausible suggestion even mentioned within relevant articles notes that the United

States could adopt a Japanese approach and utilize the legal system to criminally prosecute hospitals and providers for adverse events. While this constant worry and fear of police investigation and criminal prosecution has helped Japan realize substantial patient safety improvements, even the article's author recognized that it would not be beneficial for the U.S. to adopt a similar approach. Thus, the government will continue to struggle to enforce self-reporting in a punitive-oriented system.

In this light, the IOM report greatly weakened its own call for widespread error reporting; and, in doing so, it opened itself up to harsh (and legitimate) criticism. This bolstered opponents, and offered ample ammunition to condemn mandatory reporting outright. Indeed, this is why former AMA president, Dr. Nancy Dickey, was able to so easily contest the IOM recommendation to establish a mandatory federal reporting system. The IOM report did attempt to include a counterargument to this line of attack, asserting that:

> All reporting programs, whether mandatory or voluntary, are perceived to suffer from underreporting. Indeed, some experts assert that all reporting is fundamentally voluntary since even mandated reporting can be avoided. However, some mandatory programs receive many reports and some voluntary programs receive fewer reports. New York's mandatory program receives an average of 20,000 reports annually, while a leading voluntary program, the MER Program, has received approximately 3,000 reports since 1993.[16]

This counterargument, however, falls flat. First, the proffered counter-example (that New York, a mandatory system receives more reports than a voluntary system) is a logical fallacy. Suggesting that these two specific systems are representative of the group is a classic false dichotomy. More damning, however, is the fact that New York law protects the confidentiality

of incident reports.[17] That is, New York is a confidential, mandatory system. As such, the IOM cannot point to New York to counter the primary opposition to its recommendation (i.e., that a punitive system will stifle the discussion and reporting of errors). By purporting to make the debate about the voluntariness of the system, the IOM is conflating confidentiality with compulsion. New York's alleged success does not help the IOM defend a mandatory, nonconfidential reporting system. A punitive-focused reporting system, as described in the IOM report would, in fact, seem to drive information underground. Though it may be intuitive, studies further comparing different mandatory reporting systems conclude the same.

In 2005, Weissman *et al.* published a study comparing the perceptions and opinions of hospital leadership with respect to error reporting systems.[18] The authors point out that critics not only fear that mandatory systems have a chilling effect on reporting, but also that public disclosure could unnecessarily frighten or alarm the public (to their own detriment). To help test these concerns, the study sought to uncover how hospital executives regarded mandatory reporting systems. Weissman *et al*. surveyed the chief executive and operating officers in more than 200 randomly selected hospitals within six states. At the time of the study, 2002-2003, two states had mandatory, confidential reporting systems (Pennsylvania and Florida), two states had mandatory reporting coupled with public disclosure (Massachusetts and Colorado), and two states lacked any mandatory reporting (Georgia and Texas).

During that period, Massachusetts required facilities to submit incident reports to the Department of Public Health for incidents involving serious injury or death "resulting from an accident or other unknown cause," along with any other "serious incidents that seriously affect the health and safety of patients." Approximately 640 reports were filed in the year preceding the study. Upon request, any information that the Department of Public Health learned during an

investigation would be provided to the public—though, patient names and identifiers were redacted.

Similarly, Colorado law required facilities to submit reports to the Department of Public Health and Environment concerning specific serious injuries. The state would then release a summary report to the public. In addition to protecting the patient, Colorado reports redacted and maintained the confidentiality of the specific health care provider(s) involved—thereby only exposing the institution.

Conversely, Pennsylvania and Florida had mandatory, confidential systems. Pennsylvania required hospitals to report to the Department of Health any "situation or … occurrence of an event at the facility which could seriously compromise quality assurance or patient safety." The information contained in the report is strictly confidential, except by court subpoena.

At that time, Florida required hospitals to report adverse events to the Agency for Health Care Administration. A state statute defined adverse events as "an event over which [a] health care professional could exercise control and which is associated in whole or in part with medical intervention, rather than the condition from which such intervention occurred." Finally, Georgia and Texas did not have any mandatory patient safety reporting (although both have since enacted one).

The study utilized a questionnaire to elicit opinions about mandatory patient safety reporting systems, particularly as it relates to the impact of public disclosure. The first question sought to ascertain whether non-confidential systems discouraged reporting. Similarly, the questionnaire sought to learn more about the opinions of executive leadership had regarding the effect of those systems on malpractice litigation. Next, Weissman *et al.* asked leadership which

system would best reduce hospital errors (a confidential or non-confidential one). Finally, the questionnaire presented the respondents with a series of three vignettes detailed hypothetical errors. After each, the survey asked respondents how likely or often this kind of error would be reported to a government or external organization (using a scale of always, usually, sometimes, rarely, or never).

Throughout the responses, only 8% of respondents thought that a mandatory, non-confidential reporting system would encourage internal reporting; and, 79% believed that this type of system would encourage lawsuits. However, the results did suggest that respondents were more likely to overestimate this fact, as hospital leaders from states with nonconfidential systems were more likely to approve publicly disclosing information (22% as compared to only 4%-6% from other states). In this way, familiarity seemed to cultivate a moderate level of acceptance.

Nevertheless, 73% thought that mandatory systems would have neutral or even negative effects on patient safety. Additionally, respondents from states with mandatory, confidential reporting systems had the most optimistic perspective on the effects of reporting systems on patient safety. While every other group (including those from non-mandatory reporting states) believed that the negative effect of mandatory systems would vary between 30% and 43%, only 17% of leaders from mandatory, confidential states believed that such systems would produce negative effects. If experts are to be believed in asserting that, ultimately, every system is voluntary, then this study is a glowing endorsement of a mandatory, confidential system; as buy-in is bound to be an important factor in maintaining reporting compliance.

Interestingly, respondents from mandatory, nonconfidential states were also far less likely to report incidents with less severe injury (3% to 7% as compared to 20% to 34% of leaders from

confidential states). This also corresponds with the perspective that the executives had when asked about the level of discretion their hospital had in reporting incidents: only 6% thought that they had no discretion. As administrators and executives perceive mandatory reporting as a threat, it is expected that they might find ways to creatively interpret reporting requirements to circumvent the law.[19]

These findings highlight Charles Billings' contention that all reporting is voluntary. Billings argues that:

> in some form, in one way or another, all incident reporting becomes voluntary. It either becomes voluntary because of inertia on the part of reporters, or it becomes voluntary because of constraints within the establishment and the environment, or it becomes voluntary because hospitals… decide that they are not required to report this particular event because of the fine print in that particular incident reporting regulation or statute.[20]

With such a malleable outlook even in mandatory systems, it should come as no surprise that underreporting is a rampant problem.

With that, the next section examines the first major contention in the debate over reporting systems: that mandatory systems do not remedy the problem of underreporting.[21]

B. Common Arguments Against Mandatory Reporting Systems

1. The Problem of Underreporting

Despite the proliferation of multiple reporting systems, underreporting is an extensive problem that is plaguing all reporting systems.[22] In fact, as many as 50%-96% of all adverse events go unreported.[23] In one 2007 study examining rates of reporting, case note review detected 110 admissions with patient safety incidents.[24] Of these, only six (a rate of just 5%)

were reported to the system. There is no question, in this sense, that underreporting is rampant. This begs the question: why?

The opponents of mandatory reporting systems would argue that forced reporting—especially in nonconfidential systems—is to blame. However, it is misleading (at best) to suggest that the empirical evidence does not support a mandatory reporting system. As of January 2015, at least twenty-eight states and the District of Columbia have implemented some form of adverse event reporting system.[25] Of these, only one state system (Oregon) is voluntary. See Appendix 1 for a survey of the state reporting laws. Given widespread underreporting throughout these state systems, critics argue that the problem is mandatory systems—that mandatory reporting systems simply do not work. This contention has several main flaws.

First, the majority of these laws were not specifically designed to improve patient safety. As such, it is unclear that voluminous reporting was a design goal. That is not to say that the current underreporting data is not useful; but, it does undermine targeted attacks on mandatory systems as a whole. It is, in fact, possible for the current mandatory systems to be failing, not because they are mandatory, but because they were poorly designed for the task of improving patient safety.

Indeed, the mandatory reporting requirements are often surprisingly lax. Moreover, most states only use the information to trigger investigations and issue correction plans for a specific and defined list of incidents.[26] In this way, the state statutes are self-limiting. This narrow scope of incidents subject to mandatory reporting could be a contributing to low rates of incident reports. At least one state, Alabama, appears to only require individual practitioners to report errors to the medical board in an attempt to police the field.[27] In Texas, hospitals are only required to submit an aggregated annual report for certain specified types of medical errors.[28]

Additionally, mandatory reporting critics overstate the occurrence of public disclosure within current mandatory systems. Most hospital leaders argue in favor of voluntary programs, as if only voluntary systems offer non-punitive and confidential reporting. Though the majority of the state systems are mandatory, only six states report public data with facility-specific information. This means that, similar to voluntary systems, twenty-two (or, 44% of) states protect the identity of health care organizations. Of the remaining states, five do not report any data at all, and sixteen only report aggregate data. Most of the states that do report public data—whether in aggregate or facility-specific—publish their findings on an annual basis. Only four states publicly report data more frequently. For example, Colorado publishes a monthly report that identifies both the types of facilities and the types of events that occurred, while also posting an online summary report of every occurrence on a weekly basis. In keeping with concerns about lag time (to be discussed in further detail below), however, the most recent data comparison report Colorado has published online (as of 2018) is three years behind. The impact of data that is so delayed is certain to be dulled and pose far less threats to health care organizations. Further, as a ten-year comparison reveals through the following reporting data,[29] Colorado has continued to improve its reporting rates over time; a fact that tends to suggest that hospitals may have realized they originally overestimated the negative impact of reporting.

TABLE 5.1. All Facility-Reported Incidents by Date Entered

Occurrence Type	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Abuse / Physical	855	910	942	880	914	1043	1013	965	1044	1656
Abuse / Sexual	152	177	170	175	197	189	198	222	208	288
Abuse / Verbal	160	155	177	156	142	199	164	184	153	300

Anesthesia Complication	4	9	6	5	5	6	13	17	18	31
Brain Injury	105	120	136	114	144	157	146	161	184	191
Burns	0	0	0	0	1	2	1	0	0	0
Death	42	60	68	56	90	68	86	84	81	79
Diverted Drugs	179	188	205	226	219	221	210	278	301	335
Equip Malfunction / Misuse	49	64	77	89	131	186	201	339	254	279
Property Misappropriation	184	212	229	268	351	396	403	442	516	666
Missing Person	371	431	377	351	340	400	400	359	407	505
Neglect	93	119	177	178	295	407	440	241	249	304
Spinal Cord Injury	2	8	8	5	9	7	5	7	7	10
Transfusion	2	2	4	2	3	3	8	7	3	5
TOTALS	**2198**	**2455**	**2576**	**2505**	**2841**	**3284**	**3288**	**3306**	**3425**	**4649**

Sources: Adapted from Colorado Department of Public Health & Environment, "Acute Hospital Occurrences Submitted—Ten Year History," April 4, 2016, https://drive.google.com/drive/u/0/folders/0ByqZDBabyNVSbFdKYWVfdWRWcmM.

In cases where the state statutes do impose strict requirements, many reporting programs lack the funding or power to enforce the mandates. Instead, empirical evidence tends to show that the current mandatory reporting systems in place are underfunded and poorly executed. In Pennsylvania, for instance, a spokeswoman for the Department of Health explained that the law "doesn't provide for us to go out and see what's taking place."[30] As such, even where the legislature intended to promote patient safety, the resulting state systems are frequently

underfunded and unsophisticated. These shortcomings have rendered them ineffective, which again points to a flaw with the current systems rather than the entire scope of mandatory reporting systems. Moreover, given prevalent ambiguity with reporting requirements (coupled with the lack of state enforcement power), it is often easy for facilities to argue that the incident did not constitute a reportable error—dodging regulations. Consider the case of Gary William Clezie.[31]

Gary scheduled an outpatient arthroscopic shoulder surgery at a facility in Yakima, WA. According to state investigation records, after a successful surgery, nurses administered a continuous intravenous infusion of Dilaudid—a powerful narcotic that is commonly prescribed to treat pain after surgery. While IV Dilaudid (hydromorphone) is a highly effective pain management drug, it also carries a high mortality risk due to respiratory depression. To minimize accidental overdose and narcotic-related respiratory depression, pulse oximetry monitors should be utilized to continuously monitor all patients receiving opioids during the postoperative period.[32] Unfortunately, for reasons that are unclear, the nursing staff failed to attach a pulse-oximeter to Clezie. As a result, the medical staff did not notice when Gary's blood oxygen level became dangerously low. Shortly afterwards, Clezie suffered a respiratory arrest and was found unresponsive. He was resuscitated, but due to prolonged oxygen deprivation, he suffered degeneration of brain function—in effect, Gary was brain dead.

Washington requires facilities to report adverse events, as they are defined by the National Quality Forum (NFQ). The NFQ publishes a 28-item list of serious reportable events (SREs), which is shown in figure 5.2 below. Even though patient safety experts have applauded the NFQ list for helping to standardize and clarify reporting requirements, this case perfectly demonstrates the way that specific, contextual variations thwart these efforts.

1) SURGICAL OR INVASIVE PROCEDURAL EVENTS
- 1A. Surgery performed on the wrong site,
- 1B. Surgery performed on the wrong patient,
- 1C. Wrong procedure performed on the patient,
- 1D. Unintended foreign object left in the patient,
- 1E. Intraoperative or immediately postoperative death, in a healthy patient

2) PRODUCT OR DEVICE EVENTS: any patient death or serious injury associated with
- 2A. The use of contaminated drugs,
- 2B. The use or function of a device in patient care, in which the device is used or functions other than intended
- 2C. Intravascular air embolism that occurs while being cared for in a healthcare setting

3) PATIENT PROTECTION EVENTS
- 3A. Discharge or release of a patient, who is unable to make decisions, to other than an authorized person
- 3B. Patient death or serious injury associated with elopement (patient disappearance)
- 3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting

4) CARE MANAGEMENT EVENTS
- 4A. Patient death or serious injury associated with a medication error
- 4B. Patient death or serious injury associated with unsafe administration of blood products
- 4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy
- 4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- 4E. Patient death or serious injury associated with a fall
- 4F. Any stage 3, stage 4, and unstageable pressure ulcers acquired after admission
- 4G. Artificial insemination with the wrong donor sperm / egg
- 4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
- 4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

5) ENVIRONMENTAL EVENTS
- 5A. Patient or staff death or serious injury associated with an electric shock
- 5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated
- 5C. Patient or staff death or serious injury associated with a burn
- 5D. Patient death or serious injury associated with the use of physical restraints or bedrails

6) RADIOLOGIC EVENTS
- 6A. Death or serious injury of patient or staff with the introduction of a metallic object into the MRI area

7) POTENTIAL CRIMINAL EVENTS
- 7A. Any instance of care ordered by or provided by someone impersonating a healthcare provider
- 7B. Abduction of a patient/resident of any age
- 7C. Sexual abuse/assault on a patient/staff member within or on the grounds of the facility
- 7D. Death or serious injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of the facility

FIGURE 5.2. NFQ List of Serious Reportable Events

As a result of several nursing errors, including a misadministration of narcotics, Gary died within two days of a simple outpatient shoulder surgery. Clearly a reportable error, right? Though Gary plainly died because of medical error, the Department of Health eventually agreed with the facility that the errors were (shockingly) not reportable events. The incident was not reportable within 1E because Gary did not die within 24 hours of surgery—the maximum time frame the state considered to be qualifying as an "immediate" postoperative death. Though Gary was determined to be brain dead within that time period, the state did not recognize the concept of brain death as human death. Gary did not meet the definition of clinical death (or, cardiac death) until his family removed life support two days later.

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Similarly, the Washington Department of Health determined that 4A did not apply because the error was not associated with the medication itself. Instead, a blood-oxygen monitoring device was never attached to monitor Gary's respiratory function while hydromorphone (Dilaudid) was being administrated through a continuous intravenous infusion. It is confusing that, even though proper monitoring could have prevented the respiratory arrest

that killed Gary, such a costly error is not reportable. It is even more confusing to try to understand how respiratory failure from a medication overdose would not fall within the scope of medication error. To this point, the assistant health department secretary explained that Gary's official cause of death was improper oxygen saturation. Even though the improper oxygen saturation likely resulted from an overdose, there was no evidence to that fact—only evidence that the nursing staff did not appropriately monitor the patient's vitals. Amazingly, that is not a reportable care management event.

When it is so easy to circumvent the intent of the regulation it is no surprise that underreporting is problematic. Further, it is questionable to cite examples of underfunded and unsophisticated systems to argue that mandatory systems are ineffective. The more accurate interpretation is that poorly funded and executed—not necessarily mandatory—systems are ineffective. Not surprisingly, these systems are unable to foster buy-in and help stimulate meaningful change. After all, providers will not report to either voluntary *or* mandatory systems if it is not in their best interest—which could depend on a number of factors. In many of these cases, the most common reason is likely that providers are unwilling to devote time (which they do not have) to submitting information through a process they do not trust to yield positive results. Far from an argument against mandatory reporting, this ongoing problem, instead, highlights the importance of garnering greater administrative support.

Common barriers can be classified in two ways: one that views barriers from a systems perspective and one that considers the viewpoints of individual providers.[33] A preferred integrative model (particularly when assessing factors that correlate with improvements to health care quality) is the *Donabedian* outcome model.[34] Donabedian asserted that assessing improvement requires a three-part analysis, examining the interrelated and co-dependent

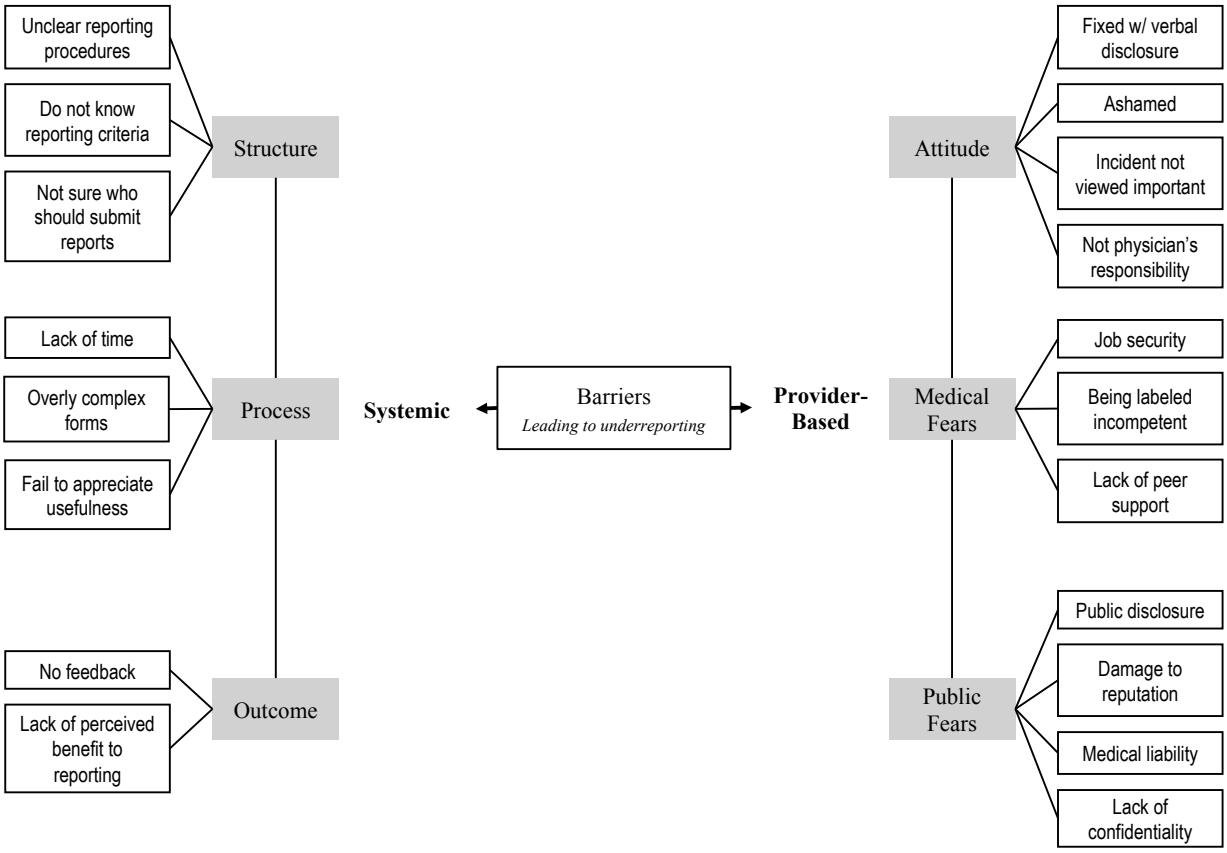

FIGURE 5.3. Common Barriers to Incident Reporting

measures of structure, process, and outcome. According to the model, each measure impacts and affects the others. Douglas Nobel and Peter Pronovost grouped provider-oriented barriers into three categories: attitudes, medical fears, and public fears.[35] These barriers are depicted in figure 5.3 above.

According to the *Donebedian* model, reporting systems are plagued by systemic, organizational problems. Overall, unclear procedures contribute to significant underreporting. Even absent their own biases, providers are often unsure who or how to complete reports. Worse yet, even when they set out to submit a report, poor design makes it difficult for providers to find the time to devote to completing reports that are often far too complex. Additionally,

exceptionally long lag times, as well as insufficient feedback discourages providers from submitting new reports.

Indeed, studies suggest that timely and worthwhile feedback (often called, closing the safety feedback loop) is essential to the success of any reporting system.[36] In fact, as many as 62% of providers agree that the lack of feedback is a primary barrier to incident reporting.[37] Not only is such feedback a critical step towards actually improving safety (as opposed to simply counting errors), it is needed in order to demonstrate to reporters that their time submitting incident reports is well spent. Absent this, reporters are quickly discouraged. A system must find a satisfactory way to close the feedback loop in a way that results in positive organizational changes for clinicians to believe in the importance of reporting.[38] The importance of feedback in motivating reporting cannot be overstated.[39] Indeed, when clinicians believe that management fails to act in response to incident reports, it leads to apathy and a reluctance to report incidents.[40]

To appropriately close this loop, it is not enough to simply provide feedback. The proffered feedback must include potential corrective actions and explain the specific systemic vulnerabilities that permitted the incident.[41] To best understand the characteristics of effective feedback systems, researchers interviewed nineteen experts from sectors in civil aviation, maritime, energy, rail, offshore production, and international healthcare. Through their analysis, Benn *et al.* identified fifteen requirements for the design of effective safety-feedback systems (see table 5.2) concerning the role of leadership, credibility, dissemination, and timeliness.

TABLE 5.2. Fifteen Requirements for Effective Safety-Feedback Design

Requirement	Description
Feedback at Multiple Levels of the Organization	Feedback should operation at multiple organizational levels; across individual teams, units, or sub-departments. This allows for learning to be broadly applied across various contexts.
Appropriate Modes for Delivering Feedback	Feedback should be disseminated through a variety of modes, channels, and formats to

	increase awareness. Email bulletins, workplace leaflets, bulletin board postings, team briefings, and safety newsletters can all be used to provide feedback. The more modes, the better.
Provide Relevant Content within Local Systems	The content of information should be targeted to individual work system contexts so that operators are not inundated with irrelevant information.
Integrate Feedback within System Design	Feedback functions should be embedded within the design of risk-management IT systems and incident databases so that the reporting community can access or generate custom reports
Control Feedback to Information Requirements of Different User Groups	Careful consideration should be given to how to disseminate information, especially regarding safety incidents. This is particularly relevant when considering external audiences.
Empower Front-Line Staff to Take Responsibility for Improving Safety	Effective feedback should support front-line staff, while offering examples for how they can take responsibility for improving safety in their direct working environment.
Capability for Rapid Feedback Cycles	The feedback loop, or a rapid response process, should quickly complete for incidents involving immediate threats to safety; even if the initial response is incomplete and only offers a temporary solution until a more thorough investigation can be completed.
Direct Feedback to Reporters and Key Issue Stakeholders	Feedback should be provided to reporters and key stakeholders at various stages throughout the reporting loop. Feedback and dialogue with the original reporters helps to keep them engaged and help to foster a reporting culture by communicating that reports are valued and acted upon.
Feedback Processes are Established, Continuous, Defined, and Understood	The clear definition of process steps, roles, and responsible parties will ensure that the safety improvement process is embraced and accepted. This will also contribute to a more proactive (versus reactive) approach to patient safety.
Integrate Safety Feedback Within Working Routines	A formal requirement for front-line staff should be to be aware of up-to-date safety information. It is important to allocate sufficient time to staff for these safety awareness activities; however, it is also important to design these practices to be minimally disruptive.
Visible Improvements Should be Made within the Local Work System	To encourage future reporting, it is necessary to demonstrate the impact of reporting. This allows busy professionals to justify the efforts they make in reporting their errors, near misses, and incidents. It also challenges the view that reports disappear into a “black hole.”
Front-Line Personnel Should View Feedback as Credible	Front-line staff must be able to trust in the commitment of org. leadership in order to accept

	that the changes and safety initiatives that are fed back from their incident reports.
Feedback Should Preserve Confidentiality and Foster Trust	Reporters must be able to trust that there will not be any negative personal consequences from reporting. There should be clear policies and guidelines to assure them of an appropriate level of confidentiality.
Visible Senior-Level Support for Systems Improvement and Safety Initiatives	Safety actions should be visibility supported by senior level management and executives.
Double-Loop Learning to Improve the Organization's Safety-Feedback Process	The safety improvement process should itself be subject to monitoring and evaluation to continue to better detect and mitigate system vulnerabilities.

Sources: Adapted from Jacqueline Benn et al., "Feedback From Incident Reporting: Information and Action to Improve Patient Safety," *Quality and Safety in Health Care* 18, no. 11 (2009): 17.

As their findings conclude, the safety feedback loop must represent an ongoing, cyclical, and credible process of receiving, analyzing, and responding to incident reports.

In addition, numerous individual barriers are responsible for low reporting rates. When asked why they do not reliably report or discuss errors, providers overwhelmingly report that they fear damaging their personal reputations. In one study, 182 intensive care staff elaborated on those reasons, listing the following barriers: threat to personal reputation (76%), malpractice (71%), societal and patient expectations (68%), fear of disciplinary actions (64%), concern over job security (63%), and personal ego or pressure from colleagues (60% and 61%).[42] Even absent fears regarding external repudiation, medical professionals are acutely aware of how easily a good doctor can be labeled incompetent with just a single mistake.[43] These concerns are all encompassed in figure 5.3 as common forms of barriers that affect individual providers.

Finally, incident reporting is troubled with three serious epidemiological problems.[44] Foremost, simply establishing a reporting system creates a false impression that there are increasing levels of error—a phenomenon known as the reporting paradox. This concept acknowledges the fact that, as providers become more comfortable with the reporting process

and structure, they will use it more readily. This leads to an increased number of reports, but does not necessarily evidence any change in the underlying error rates.

Second, because of underreporting, aggregate reports and data analysis will be systematically biased. For instance, a high percentage of incident reports from nurses involve falls. While every opportunity to improve patient safety is worthwhile, the frequency of error from nurses in this scenario are likely to create the false impression that falls are more prevalent or important that other incidents. Until reporting is equally distributed throughout an interdisciplinary sampling of health care professionals, it will be difficult to correctly prioritize safety efforts.

Lastly, physicians are poor reporters. In one study at the University of Virginia, while approximately 72 (of 120) physicians admitted to having observed three or more incidents, 78 of those same physicians never submitted a single report.[45] As a consequence, reporting ownership is strongly skewed towards nursing staff. Indeed, the Australian Incident Monitoring System reported that physicians only contributed to 2% of their reports, as compared to the 88% nurses submitted.[46] Not only does this further exacerbate systematic biases and limit the generalizability of data, it leads to a participation bias. More than unfairly burdening nurses with the responsibility of improving patient safety, low physician reporting is problematic because it excludes an entire subset of risks and hazards. For instance, despite his best efforts, a nurse is never likely to identify as many risks or errors affecting chemotherapy as an oncologist might. The exclusion of major stakeholders within the hospital system will frustrate and hinder patient safety efforts.

To recap, the most prevalent reasons for underreporting are: unawareness, failure to perceive that an incident occurred, lack of clear definitions identifying incidents, time pressures,

fear of punitive measures, lack of feedback, and the lack of belief that reporting will contribute to positive changes in patient safety.[47] Many of these barriers apply equally to both voluntary and mandatory programs. In this light, while underreporting is a serious issue that any successful program will need to address, empirical evidence does not suggest that mandatory reporting systems are uniquely afflicted with these concerns. Indeed, a recent retrospective case review concluded that only approximately 7% of all adverse events were reported to the National Patient Safety Agency—the national voluntary error reporting system in the United Kingdom.[48]

Having rebuffed the argument that mandatory systems either exacerbate the occurrence or will otherwise fail because of the problem of underreporting (in ways that voluntary systems are immune), the following section addresses the broader argument that mandatory systems discourage participation.[49] One of the primary contentions in this respect directly attacks the punitive nature of some mandatory systems.

2. Fear of Malpractice Litigation

Opponents argue that mandatory systems encourage individual blame and boost malpractice litigation. However, this too, conflates a number of different factors. Most importantly, (as is also true with the problem of underreporting) these are design-specific criticisms. Indeed, a voluntary system could be just as susceptible to these criticisms based on the extent the system protects confidentiality. In the same way that a confidential voluntary reporting system would eliminate worry over potential litigation, so too would a confidential mandatory reporting system.

In one critique about the punitive risks inherent within a mandatory system, Dr. Michelle Chiang clarifies that the problem is less logical:

[I]ncreased reporting will not be achieved through a mandatory reporting system because

whether practitioners report does not turn on the mandatory or voluntary nature of the system, but rather on whether reporters feel comfortable reporting.

Dr. Chiang goes on to argue that, while mandatory systems understandably attempted to ensure accountability by holding providers responsible for lapses in patient safety, evidence does not support that approach because providers do not report to punitive systems. Given this, Dr. Chiang purposes that the solution is to create a "well-planned, thoughtfully-designed reporting system" to encourage reporting. The key, she argues, it to identify the information that the system needs to collect and remove the disincentives to reporting that information. A primary disincentive to reporting, according to Dr. Chiang, is fear of litigation.

Dr. Chiang contends that there are two elements that must be addressed in order to adequately eliminate this barrier: (1) protect confidentiality, and (2) educate providers about the law. The rub, she argues, is that physicians do not fully understand the law and are overwhelmingly skittish about malpractice. Partly because of repeated horror stories, physicians tend to grossly overestimate their risk of being sued and are generally very fearful about the extent of legal protections in place to protect them.[50] In fact, in an internet survey, 85% of respondents (purporting to be healthcare professionals) did not trust that the government could deliver in truly protecting confidentiality in states with confidential, mandatory reporting systems.[51]

In truth, malpractice litigation is not nearly as problematic as tort reformers suggest. Though it is common to hear that frivolous malpractice lawsuits are plaguing the U.S. healthcare system, evidence suggests that far too few malpractice claims are filed. While more than 400,000 patients die every year from preventable harm, most expert agree that only 85,000 cases end in litigation.[52] Of these, about 46% (or, nearly 40,000) are settled before trial. Yet, even that

small number is enough to unnerve most physicians. Because they do not often distinguish between their personal and professional competency, most physicians react strongly to lawsuits. As Marshall Kapp notes, "A lawsuit is particularly and uniquely offensive to physicians, and the vehemence of their negative reaction to the experience far exceeds that of any other kind of professional defendant."[53] In part, this reaction stems from not understanding the law. However, to an extent, it also reflects the haphazard application of privilege in malpractice cases.

Indeed, the indiscriminate application of privilege to protect the confidentiality of incident reports has made it difficult for doctors to anticipate whether plaintiffs' attorneys will be able to later use those reports to sue them. Take, for instance, the case of *Chicago Trust Co. v. Cook County Hospital*.[54] *Chicago Trust* involved a malpractice case that proceeded to trial after a patient was accidentally disconnected from a ventilator. The defendant argued that incident and situation reports were protected from disclosure through the peer-review privilege. The court disagreed, clarifying that documents prepared before a peer review committee was formally initiated were not protected by privilege. Additionally, the court explained that the act of providing these previously prepared documents to the peer review committee once an investigation began would still not extend peer review privilege to the prior documents. The court justified its holding by explaining that to allow the peer review privilege to protect all existing information at the initiation of a peer review committee "would make everything confidential, except for the patient's own medical records."

While this seems sensible, it nevertheless fails to recognize that the peer review privilege was embraced as a way to encourage providers to candidly investigate and evaluate case in order to improve hospital conditions. Undermining those protections, regardless of the reason, makes it less likely that providers will act in good faith. As such, a crucial element in the success of the

peer review process is the willingness of providers to discuss mistakes.[55] Widespread uncertainty about the extent of confidentiality protections, discourages physicians from filing incident reports.

Throughout the years, most states have passed statutes granting a peer review privilege to remedy this problem.[56] While this was a productive step forward, starting in the mid-1990s, court holdings and state statutes have been slowly eroding the extent of the protections.[57] For example, Florida used to have one of the most comprehensive peer review privilege statutes. In 2004, however—goaded by the plaintiffs bar—state voters approved a state amendment ("The Patient's Right to Know") that gutted the peer review privilege. Though no administrator or provider would officially go on record, many confessed that since the amendment took effect in 2008, peer review investigations halted. While, officially, these conferences are still scheduled—as federal and state law require—the process is essentially a farce.

The key issue with respect to determining the appropriate extent for peer review privileges turns on how to balance the competing interests. Initiated in the early 1900s, the peer review process was created to "decrease instances of medical malpractice and improve the condition of health care by allowing practicing physicians to recognize inadequacies in their peers' performance and discipline accordingly."[58] Consider the following example of a typical scenario.[59]

Six-year-old Hannah is scheduled for a tonsillectomy. Hannah's parents are nervous but Hannah's surgeon, Dr. Gwande, reassures them that the procedure is routine; they do hundreds of them without incident. Feeling calmed, Hannah's parents wave as she is wheeled away towards the operating room. Dr. Stevens administers anesthesia. The operation proceeds

without incident, and her tonsils are skillfully removed. But yet, Hannah never wakes up. Her parents are devastated and confused.

The hospital launches a peer review investigation to examine what went wrong. During the course of the investigation, Drs. Stevens and Gwande openly reveal that a medical error killed Hannah. They discovered that someone incorrectly mixed the anesthesia dosage, leading to a 100-fold overdose. As a result of this conference, the hospital immediately implemented new procedures to ensure that a similar mistake does not occur in the future. Had Drs. Stevens and Gwande covered up the error, the hospital would still be unaware of the latent procedural defect that allowed for the medication error—more patients would die.

A year later, Hannah's parents sue the hospital and doctors. During discovery, they demand access to the information, admissions, and documents from the peer review investigation. The conflict is obvious. On the one hand, Hannah and her parents suffered a real and tragic loss—a wrongful harm that tort law typically compensates. At the same time, however, fear of adverse litigation creates a perverse enticement for providers to hide their mistakes.[60] When providers do not disclose, or worse, actively cover up mistakes, health care is less safe for everyone. Given these competing interests, how should the court decide?

First, it is important to note that protecting the confidentiality of peer review materials does not inhibit Hannah's parents' ability to advance their wrongful death lawsuit. It does not provide hospitals or physicians with immunity. It simply requires that the family build their case through other evidence. In this light, protecting confidentiality is no different from the evidentiary protections that prohibit disclosure in other relationships (e.g., clergy, spousal, attorney-client).

Secondly, the extension of confidentiality in these instances is a practical necessity. For example, eroding the confidentiality protections protecting statements individuals reveal to their attorneys or psychologists would stand as a permanent obstacle undermining the entire undertaking. Put another way: without confidentiality protections, people would not trust the fiduciary relationship. Psychology cannot treat mental disorders if patients are not honest. Attorneys cannot advise and defend clients, if those defendants refuse to talk with their attorneys to provide any information about the circumstances of the case for fear of that information being revealed on the witness stand. Similarly, peer review will not exist without confidentiality protections. Had Drs. Stevens and Gwande known that their admissions during the investigation would be introduced into evidence in a malpractice lawsuit, they would be far more reluctant to participate in good faith. Thus, the liability protections extended to Drs. Stevens and Gwande (as well as the hospital) are not intended to protect them. Rather, the privilege is necessary to protect the public welfare by providing a practical mechanism for the health care industry to prevent future deaths. The negative impact to the families affected by relevant losses or errors is an unintended harm that is nevertheless necessary to ensure a greater good—it is an ethically justified double effect.

Interestingly, efforts are currently underway to use Patient Safety Organizations (as established by the 2005 Patient Safety and Quality Improvement Act) as a federal mechanism to conducting morbidity and mortality investigations.[61] The Patient Safety and Quality Improvement Act (PSQIA) provides peer review protection to all information reported to a PSO—termed "Patient Safety Work Product." Congress intended that hospitals would join a PSO. As incidents occur, providers meet to investigate the errors through the hospital's Patient Safety Evaluation System (PSES)—taking the place of peer review conferences. The providers

can openly and candidly discuss the case. The hospital makes its own system and policy changes to prevent future occurrences, while also submitting the data to the Network of Patient Safety Database. The database will also analyze the PSWP and promulgate regional or national recommendations to all of the hospitals it serves, allowing for better shared learning nationwide. Though the actual implementation of these protections is still questionable, the existing framework provides a mechanism to help alleviate physician fears of malpractice. Though the current system is voluntary, making it mandatory would not undercut its protections.

More importantly, even if mandatory reporting does encourage more lawsuits, this alone is not a compelling enough reason to allow the healthcare system to continue to evade accountability and harm patients. There are plenty of protections in the legal system to prevent frivolous lawsuits; it is hardly convincing to argue that it would be unjust if litigation increases because patients are more informed about the occurrence of error. Though, this is not a likely result. While there are a number of factors at issue, part of the disconnect is that private individuals generally lack the resources to seek civil remedies from large healthcare corporations. Additionally, research consistently shows that the decision to sue depended more on insensitive handling and poor communication than the injury itself. In one study, 91.4% of respondents sued because they wanted the hospital to assume accountability and prevent similar incidents in the future.[62] As such, full disclosure and greater accountability is proven to contribute to decreased litigation.

Finally, even if these studies were inaccurate, there are better (more responsible) ways to discourage malpractice litigation—namely, taking proactive steps to reduce the incidence of harm. Interestingly, one medical specialty did just this.[63] From the 1950's through the 80's anesthesiologists were paying some of the highest medical malpractice premiums in the field.

Mortality was as high as 2 for every 10,000 administrations of anesthesia. Undergoing anesthesia was one of the most notoriously dangerous procedures in medicine. Frustrated with frequently losing lawsuits and paying high insurance premiums, the American Society of Anesthesiologists (ASA) established a Safety and Risk Management committee. In the mid-1980's, the ASA initiated a comprehensive claims study, which concluded that human errors contributed to a majority of anesthesia-related injuries. This led to the first standards of practice to introduce 'safety monitoring' as a method to prevent accidents. The ASA implemented protocols, established monitoring standards, improved training and education, redesigned equipment, and limited how many hours anesthesiologists could work. Within ten years, the mortality rate plummeted to only 1 in 200,000 administrations. The field has enjoyed unparalleled success in terms of patient safety—spurred, in part, by record numbers of malpractice cases.

3. Psychological Processes

Much of the debate and controversy surrounding the utilization of error reporting systems relates to institutional or individual fears—usually over liability.[64] Supposing that a system is able to thoughtfully assuage those fears, there are other obstacles that would thwart the implementation of a successful reporting system. In addition to the many external barriers that providers face, there are internal psychological barriers that impact reporting. As with many ethical decisions, individual providers will likely turn to risk-benefit analysis to determine whether to report any errors.[65]

When asked, most physicians participating in a focus group agreed (in principle) that doctors have an ethical imperative to disclose instances of medical error.[66] However, the physicians often qualified their belief based on contextual variations. For instance, some

explained that the duty would be suspended if the patient only experienced trivial harm. Others felt that there was likewise no need to disclose if the patient was unaware of the error. Curiously, this scenario is the exact reason for why physicians owe their patients full disclosure. Nevertheless, this sort of ethical rationalization comports with ongoing research studying the influence of cognitive development and self-interest in moral decision-making.

An individual's cognitive processing and sense of moral duty influences their moral decision-making. The Theory of Planned Behavior posits that actual behavior is driven by intentions, which are developed through beliefs (both personal and social). When faced with an error, the intention to disclose the error would only develop if the physician believes that he or she would derive some positive outcome. Generally, this includes a two-pronged determination that factors for who approves or wants the disclosure and ranks the importance of each opinion. While the Theory of Planned Behavior concentrates on the correlation between belief and intent and intent and behavior, Kohlberg's theory of Cognitive Moral Development delves even further into the cognitive processes underling belief and intention.

Based on empirical research, Kohlberg presented six identifiable stages of moral reasoning.[67] Using Kohlberg's theory, moral reasoning researchers have noted that individuals employ higher levels of cognitive moral reasoning when responding to hypothetical ethical dilemmas than when justifying real behavior.[68] For instance, in a convenience sample of 370 corporate managers, James Weber and Janet Gillespie found that the mean score response for participants who responded that cheating should be reporting (3.24) was higher than those who would report (3.06) and still higher than those who did report (2.73).[69] Stage three moral reasoning focuses on a sense of duty due to how the individual will perceived, whereas stage two considers the sense of duty to oneself. While stage three also includes a concern for personal

integrity and personal relationships, stage two primarily factors for the consequences of personal reward and concern for personal satisfaction. Those who did not report the cheating used an even lower level of moral development to justify why they did not report (2.3). In fact, far fewer participants actually reported instances of observed cheating (127) as compared with those who believed that cheating *should* be reported (296). Interestingly, 67 of the participants who felt that cheating should be reported (belief) also responded that they would not report cheating themselves (intention). There are two conclusions that can be drawn here: (1) individuals provide higher-level rationales when considering the ideal response than when making real decisions, and (2) most persons make ethical decisions based on stage 2 moral reasoning. Thus, in the case of medical error, physicians are not likely to report incidents or errors without a perceived reward.

Without a compelling personal reward or sense of duty to oneself, providers justify creating caveats to their ethical duty to disclose medical error. Moral justification is the process of re-interpreting immoral behavior in terms of a higher purpose. Generally, individuals use the following justifications:

- Displacement of responsibility – *blaming others.* "I was only following orders."
- Diffusion of responsibility – *deflecting the unethical behavior by attributing it to a group, and not one particular individual*. "We all do it. It's the standard of practice."
- Advantageous comparison – *comparing one's behavior to other's worse behavior*. "We are better about taking responsibility than most hospitals."
- Disregard or distortion of consequences – *minimizing the harm.* "If I don't report near misses, no one will be hurt."

- Attribution of blame – *blaming someone else for causing the behavior.* "I don't tell patients because they don't want to know. It's not my decision. I have to respect their wishes."[70]

Individuals are able to behave self-interestedly through these processes for psychological self-deception.[71] Although the concept of self-deception seems paradoxical, it is essential in unethical decision-making. Very few individuals would consciously violate ethical principles. These psychological processes help to eliminate negative ethical characterizations, or even distort them into position ones.

Given this reality, it is even more important to model the appropriate ethical response by requiring mandatory reporting—while also realizing that any reporting system (including a mandatory system) will fail if it does not successfully provide a perceived reward.

4. Withholding Information to Prevent Public Panic and Mistrust

Though, related, there is also concern that full transparency would truly harm the public. Some opponents fear that disclosure may incite panic or irreparably harm patient trust. For instance, one physician remarked:

> You don't want to be accused of scaring people. I've had patients tell people I was scaring them when I thought I was simply being informative and, you know, not being dramatic or anything. But clearly in those cases, I was telling people more than they wanted to know.[72]

Another echoed that sentiment, explaining:

> My job is to relieve anxiety, not to create it. And to a certain extent when an error occurs that doesn't get to the patient. It's not their problem. It's my problem.

Indeed, trust is not only important for medicine; it holds society together. Interestingly, while the public feels that nurses are significantly more trustworthy than medical doctors,[73] one study found that 96% of nurses and 90% of all other healthcare providers felt that nurses were primarily responsible for ensuring patient safety.[74] In fact, nurses remain the most trusted profession in the United States for the 13th time in 14 years.[75] Yet, nurses report medical errors more frequently than doctors.[76] During the congressional Senate hearings, vice president Barbara Blakeney, even relayed the American Nurses Association's unconditional endorsement for mandatory reporting.[77] This alone rebuffs the notion that offering more transparency fosters mistrust. In fact, it is quite the opposite—withholding information denigrates trust. The era of blind trust and paternalistic medicine is gone; trust is more conditional now. Patient trust is encouraged and sustained through forthcoming communication, respect for patient views, the provision of information, and reasoned and inclusive decision-making.[78]

B. Ethical Implications of Reporting

1. Non-Disclosure as a Cause of Medical Error

Despite enduring changes in interpretation, the Hippocratic Oath has persisted as the paradigm of medical ethics in Western medicine.[79] Some argue that the Hippocratic ethic can be reduced to the fundamental maxim, *Primum non nocere*: "Above all [or first] do no harm."[80] Though nonmaleficence (the contemporary articulation of the obligation to avoid harm) is an important ethical imperative, it is dangerous to ignore the fact that beneficence is the first moral principle of the code (and the whole Hippocratic tradition).[81] Nonmaleficence merely imposes an obligation to avoid harming patients; and, while this does include accidental harm, it is incomplete without the complimentary obligation to take positive action to act for the benefit of others. Taken together, these principles require that healthcare providers must not only refrain

from harming patients, but that they must also contribute to their welfare when harm does occur.[82]

Although this seems relatively obvious, the scope of the duty to disclose medical error remains controversial. Providers are particularly less inclined to disclose the occurrence of "nonharmful" errors.[83] This is problematic. While harm may have been averted for the particular patient, given the systemic nature of error within the healthcare industry, the close call still exposes a latent defect that will likely threaten future patients. In this light, non-disclosure allows for future errors—these are simply mistakes waiting to happen. Even if disclosure will not make any impact on the patient involved in the incident, it will protect against future harm—and is required by the ethical duty to act for the welfare of all patients within the healthcare system (i.e., beneficence).

2. Fiduciary Duty to Disclose

As if that is not enough justification, the special nature of the physician-patient relationship also creates legal obligations for doctors. As a legal concept, the notion relies on the common law concept of a trust. In legal systems, a trust is a fiduciary relationship in which one or more persons hold property for the benefit of another (known as the beneficiary). Over time, this doctrine expanded to include similar special relationships wherein one party (the fiduciary) is entrusted with the welfare of another (the beneficiary).[84] Because of this inherent imbalance of power and expertise, the law imposes duties to ensure that the fiduciary does not take advantage of the vulnerable beneficiary. Generally, the duty requires that the fiduciary exercises undivided loyalty in promoting the best interests of the beneficiary. One court described the duty as one of "'most abundant good faith,' requiring absolute and perfect candor, openness and honesty, and the absence of any concealment or deception."[85]

Moreover, there is a growing body of case law that is specifically finding that this fiduciary relationship "prohibit[s]… [physicians] from misrepresenting the nature of the patient's medical condition."[86] This longstanding principle was evoked in a recent California case involving a woman who was told she had a particularly aggressive form of breast cancer.[87] After she underwent four months of unnecessary intensive chemotherapy and a radical mastectomy, her surgeon discovered that the lab misread her initial biopsy slides. In fact, they never showed any signs of cancer. The surgeon conveyed this information to her oncologists, but they concealed the error. As a result, the woman spent another two years believing that she had a terminal illness. On appeal, the court rejected the doctor's argument that they were only liable if they *knew* that the patient was not informed of the results, implying that a fiduciary has a duty to disclose material facts regardless of the beneficiary's actual knowledge.

It is worth noting that this duty also tends to extend beyond the end of the physician-patient relationship.[88] For example, after researchers studying the effects of diethylstilbestrol (DES) learned that prenatal exposure was linked to cancer and other health problems, several court cases held that the fact that the risk was not known until after the patient was treated does not affect the obligation; a defendant breaches her fiduciary duty if she fails to notify the patient (including past patients) when the risk becomes known.[89]

3. Counting Mistakes v. Improving Safety

There is some concern, however, that the focus on disclosing errors may eclipse the more important goal of improving safety.[90] While it is important to disclose and study errors (and all other forms of adverse harm), it is crucial that experts also have access to the information and are advising willing providers and hospital systems as to how to promptly make the necessary changes to improve patient safety.

Dr. Carl Macrae explained this problem using the symbol of the orange wire.[91] As Dr. Macrae describes, the original goal of incident reporting within healthcare was quite simple. It sought to recreate the success of incident reporting in other safety-critical industries—especially from aviation. The analogy theorizes that Boeing 757 engines contain an orange wire that is essential to their safe and proper function. Suppose that during a pre-flight inspection, an engineer noticed that the orange wire in a single aircraft was damaged in a way that suggested that there was a systemic default within the engine. Because the problem is far more invasive than simple wear and tear, the orange wire hypothesis posits that the aviation industry would immediately inspect every Boeing 757 and replace any faulty orange wires.

This example of efficient and system-wide action is held up as a benchmark for how incident reporting systems should function. In this way, the orange wire test asks whether the healthcare industry responds in a way that mimics the same level of rapid and system-wide safety improvements. Dr. Macrae concludes that it does not. He explains:

> [In] translating incident reporting into healthcare from aviation, what was largely missed was that, in airlines and other industries, the rapid detection and resolution of safety issues depends on a deeply embedded and widely distributed social infrastructure of inquiry, investigation and improvement.[92]

Within the aviation industry, incident reporting represented the natural progression from decades of regularly conducting thorough and systematic investigations of incidents and accidents. The healthcare did not have any comparable history. As a result, Dr. Macrae argues that the healthcare industry has failed to replicate the same safety gains. He rationalizes that, without the coordinated organizational infrastructure to conduct systematic investigations, the healthcare

industry reporting systems supplanted a different image: the filing cabinet. As such, healthcare has singularly focused on collecting large quantities of incident data, rather than devoting itself to the quality of the resulting safety investigation. Dr. Macrea states that this focus of the number of reports rather than the actual task of improving safety has contributed to a number of problems (see table 5.3).

Most relevant, the ever-constant goal of increasing reporting presents several complications. Paradoxically, collecting too many reports can ultimately lead to an overall reduction in the frequency of future reports. As discussed earlier, slow and insufficient feedback acts as a strong deterrent to reporting; soliciting more reports than the system can effectively investigate and address will cause the system to fail.

Additionally, focusing on quantity over quality cultivates a poor culture of learning. For instance, patient falls account for 20% of all of the incidents reported to the National Health Service in the UK. Dr. Macrae argues that there must be more efficient ways to record the incidence of highly common events, thereby allowing the reporting system to focus on more serious events.

With the preoccupation with underreporting in the health care industry, it is interesting to note that aviation safety investigators are more concerned with over-reporting.[93] With much of investigators' work concerned with determining which incidents are most important, aviation experts recognize that too many reports can overwhelm the system and complicate efforts to identify and prioritize new or emerging risks.

In this light, critics concern over underreporting (while still problematic) is not nearly as devastating to a reporting system as their loud objections might imply. While, it is certainly important for incident reporting systems to collect enough data to detect emerging risks, it is not

TABLE 5.3. Problems Relating to the Mismatch Between Principles and Practices of Incident Reporting

Key Principles in Other Safety-Critical Industries	Common Practices within the Healthcare Industry
Focus on reporting that provides serious, specific insights	Encourages broad reporting of any and all incidents, regardless of relation to safety goals
Avoid overwhelming the reporting system to ensure that reported incidents can be thoroughly reviewed	Celebrate higher numbers of incident reports; goal is increasing reporting rates
Use incident reports to identify and prioritize significant or emerging risks	Quantify, count, and chart different categories of incident reports to monitor performance trends
Harness the social processes of reporting to increase awareness and reporting of current risks	Aim to increase reporting to address perceived epidemiological or statistical biases in reported data
Expect reports to be inaccurate and incomplete; focus on investigation as primary means of obtaining complete picture	Improve accuracy of incident reports through more comprehensive data collection process
Apply pragmatic incident taxonomies that support basic analysis, improvement action and retrospective search	Expect incident taxonomies to accurately explain and map complex realities
Ensure incident reporting systems are managed and coordinated by an operationally independent group	Incidents reported to direct supervisors or other operational managers within organization
Reporting constitutes one component of broad range of conversations and activities focuses on safety and risk	Incident reporting represents the most visible safety activity for many organizations
Use incident reports to identify and prioritize significant or emerging risks	Quantify, count, and chart different categories of incident reports to monitor performance trends

Source: Adapted from Carl Macrae, "The Problem with Incident Reporting," *BMJ Quality and Safety,* September 7, 2015, http://dx.doi.org/10.1136/bmjqs-2015-004405.

necessary (or, possibly, even prudent) to become too distracted with overall reporting rates. Instead, patient safety improvements will be realized by improving the infrastructures for investigation, learning, and sharing.

Unfortunately, the majority of states and experts alike measure the success of current mandatory reporting systems based on how many reports those systems receive. Charles Billings, the architect of the oft-cited Aviation Safety Reporting System points to three factors as being crucial for the system's success: reporting must be safe, simple, and worthwhile.[94] With this guiding framework, the following section examines the existing reporting systems.

D. A Review of Existing Reporting Systems

After President Clinton failed to prompt the federal government to establish a nationwide, mandatory public error reporting system, he called on the states to implement mandatory reporting systems within three years (by 2003).[95] If not all 50 states adopted a mandatory reporting system, federal officials were supposed to offer recommendations to ensure full participation. Yet, more than a decade later, only twenty-six states and the District of Columbia operate some version of a mandatory error reporting systems to collect adverse event data.[96] Oregon has an event reporting system in place (making it the 28th system, overall), but it is a voluntary system. Further, it is important to note that, due to Hurricane Harvey (as of June 1, 2016), Texas facilities have been required to report any preventable adverse harm data. Section 418.016 of the Texas Government Code suspended all regulatory statutes that would prevent or hinder any necessary relief efforts.[97] Accordingly, there is very little data available—the reporting requirements were only in effect for 18 months before Texas declared a state of disaster. Thus, in effect, only 26 states and the District of Columbia are currently enforcing a mandatory reporting requirement.

Following the publication of the IOM Report and President Clinton's urging, the number of states with adverse event reporting systems has only marginally increased. For comparison, there were 15 state adverse event reporting systems in 2000. Worse, this number has barely risen since 2007. In 2007, 27 states had incident reporting systems. Between 2007 and 2015, one state allowed their system to lapse due to a sunset clause (Wyoming) and two implemented systems (New Hampshire and Texas). With a decade of heightened focus on patient safety, the United States only saw a net gain of one state adding a reporting system. To date, the federal government still has not stepped in to provide a mechanism to require reporting in the twenty-two states that have no system.

On an encouraging note, the participating states have made great process in standardizing reports, improving follow-up, and expanding the scope of facilities. The National Quality Forum (NQF) was instrumental in standardizing reporting. Fifteen (15) states have either adopted or adapted the NFQ's list of serious reportable events. Additionally, advancements in reporting mechanisms has allowed state systems to streamline and simplify the reporting process. Indeed, in 2000, only one state was cable of accepting electronic reports. As of 2014, however, at least twenty-two (2) systems could receive data electronically.[98] With evidence that electronic reporting improves the accuracy and frequency of error reports,[99] this is certainly good news. Finally, as the IOM intended, most state systems have expanded to gather data from a number of different health care facilities. Of the 28 existing state reporting systems, all include hospitals as reporting institutions.[100] Few, however, only require reports from hospitals (California, Georgia, Maryland, Ohio, Rhode Island, and Vermont)—with other states choosing to also solicit reports from one or more other facilities (e.g., surgical centers, long-term care centers, home care providers, abortion clinics, birthing centers, substance abuse facilities, and pharmacies).

Modest progress aside, however, there is still much left to be accomplished. Though the existing reporting systems vary considerably, none have demonstrated marked gains in improving patient safety. On one hand, it is difficult to measure the impact of a reporting system—there is no obvious or reliable way to quantify errors or incidents that have been prevented. Lacking a reliable way to defend their programs, states instead point to the ways that the systems have increased open communication about patient safety, enabled some level of internal trending, and guided training to bring about heightened awareness to patient safety issues.[101] To this end, generally, experts agree that there are seven critical characteristics for a successful reporting system, which are listed in table 5.4.

TABLE 5.4. Characteristics of Successful Reporting Systems

Characteristic	Explanation
Nonpunitive	Reporters do not need to fear retaliation or punishment
Confidential	All information regarding the patient, reporter, and institution are kept private
Independent	The program is organizationally external and independent
Expert Analysis	Experts who can understand the circumstances and underlying system causes evaluate the reports
Timely	Reports are analyzed within a reasonable timeframe; and feedback is rapidly disseminated to key stakeholders
Systems-Oriented	Recommendations focus on changes to systems and processes—not individual performance
Responsive	The agency managing the reporting system has the capacity to disseminate recommendation; which participating institutions will readily implement

Source: Adapted from Lucian Leape, "Reporting of Adverse Events," *New England Journal of Medicine* 347, no. 20 (2002) 1634-1636.

In the states that have implemented a mandatory reporting system, the information is often protected from public disclosure. While it is important to maintain patient confidentiality

and legal protections for individual providers (see table 5.4), this does not help to realize the IOM's intended aim of accountability.[102] Despite the IOM call, however, accountability does not require public disclosure. At the same time, it does demand reasonable oversight.[103] To foster public trust, some amount of data (even minimal) would need to be publicly reported as evidence demonstrating that actions are being taken to improve patient safety. Unfortunately, when reporting does occur, most state statutes seem to utilize reporting as a means to investigate infractions and regulate the practice of medicine—much to the chagrin of providers and hospitals alike. Even in states that intended for the information to be used to improve safety and contribute to the development of 'best practices,' overworked and underfunded receiving agencies are rarely able to provide much support. These limitations raise concerns with respect to the goals of reporting.

To increase transparency, the IOM called for public reporting. Theoretically, this data can be used to encourage institutions to devote more resources to patient safety (as a means of avoiding public exposure). It can also promote learning, depending on the availability and breath of data available. Generally, states will report either facility-specific data, aggregate data, both, or none. As of 2015, the distribution was as follows:[104]

- Fifteen states and the District of Columbia only release public reports with aggregate data:
    - California, the District of Columbia, Florida, Kansas, Maine, Maryland, Nevada, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, and Washington
- Three states release reports with facility-specific data:
    - Connecticut, Indiana, Massachusetts

- Four states issue both aggregate and facility-specific reports:
    - Colorado, Minnesota, New Hampshire, and Texas[105]
- Five states do not report any data to the public:
    - Georgia, Illinois, South Carolina, South Dakota, and Tennessee

Additionally, three of the five states that do not publicly report data (Georgia, South Carolina, and South Dakota) will provide incident-specific information upon request. In almost all cases, however, the publicly reported facility-specific and aggregate data is far too limited to yield significant research. Indeed, most often, the data simply identifies the number of incidents throughout the state (with or without specifying the facility).

Take, Oregon, for instance—arguably the state with the greatest emphasis on a primary goal of improving patient safety (as opposed to accountability). In 2004, the legislature created the Oregon Patient Safety Commission (OPSC)—a semi-independent state agency to advance and support patient safety.[106] In establishing the OPSC, Oregon sought to create a non-punitive haven for the collection of patient safety data in order to identify and share best practices to change the climate of patient safety.[107] The OPSC manages and oversees the operation of the Patient Safety Reporting Program (PSRP), a voluntary reporting system that provides facilities with complete confidentiality. The system is designed for organizations to voluntarily submit incident reports to PSRP, along with any strategies it developed for mitigating similar harm in the future. The OPSC then analyzes and disseminates that information. In 2017, the system received 453 adverse event reports.[108] The OPSC then publishes an annual report with aggregate data about these events. Though the OPSC states that it is committed to sharing what it learns to make healthcare safer, there is no indication that it will share actual data—de-identified or not. Instead, this promise appears to be alluding to its own work in analyzing and sharing its findings

through the publication of an annual report. It is unclear how effectively hospitals could implement improvements based on the level of detail available.

For example, in addressing fall events, the 2017 Annual Report provides information about the statistics, the leading risk factors, pre-fall activities, patient goals (i.e., the reason the patient got up), and physical environments.[109] To that end, in 2017 there were 45 reports of fall events. Thirty-four falls (76%) resulted in physical injury. Presumably, these injuries could have been prevented. Yet, in thirty instances (83%) the patient was already identified as being at risk for falling, and nine falls occurred while the patient was assisted. Most of these falls occurred while the patient was performing or attempting to perform a routine activity: toilet-related (24%), transferring to or from bed, wheelchair, etc. without assistance (13%), dressing or undressing (11%), and walking (9%). Loss of balance or footing was the most common physical cause, accounting for nineteen cases (42%). This information clearly seems to point to deficiencies within the system, however, it does little to guide improvement efforts. At no point in the fifty-six-page annual report does the OPSC offer any insight into how to reduce or limit patient falls. The only obvious recommendation directs organizations to prevent patient harm by focusing on identifying root causes and system-level contributing factors in order to develop system-level action plans. This same advice is echoed on the OPSC website.[110] In a news update, the OPSC acknowledges that healthcare organizations are struggling to prevent falls. OPSC Patient Safety consultant Lynn Guiducci theorizes that part of the problem is that organizations are stopping short of determining the actual cause of falls. Rather than look past the initial finding (e.g., patient did not wait for assistance), organizations need to investigate the system-level factors. The OPSC does not identify these factors, but rather advises organizations (again) to conduct a more thorough root cause analysis.

TABLE 5.5. Overview of State Reporting Systems

	Agency Receiving Reports			Purpose of Receiving Reports			
	Dept. of Health	Other Sate Dept.	State agency for Pt. Safety	Regulate Field	Investigate & publicize	Analyze & develop best practices	Aggregate data for research
California	•				•		
Colorado	•				•		
Connecticut	•				•		
D.C.							
Florida		•			•		
Georgia		•					
Illinois	•						
Indiana	•				•		
Kansas	•				•		
Maine	•						
Maryland	•				•		
Massachusetts	•					•	
Minnesota	•				•	•	
Nevada	•					•	
New Hampshire	•			•		•	
New Jersey	•						
New York	•					•	•†
Ohio	•						
Oregon			•				
Pennsylvania			•		•	•	
Rhode Island	•			•			
South Carolina	•			•			
South Dakota							
Tennessee	•					•	
Texas	•			•			
Utah	•						
Vermont	•						
Washington	•			•			
~~Wyoming~~§	•				•		

† New York data is only available upon request to facilities, not the general public.
§ Wyoming system had a sunset clause and has expired.

In this light, while Oregon has seemingly collected useful data to monitor rates of error, it is not utilizing that data to improve patient safety. This is a common problem. In fact, as detailed in table 5.5, only New York aggregates the data into a database to encourage research. Not surprisingly, many healthcare providers complain about the lack of perceived benefit.

Pennsylvania is unique. It was the first state to pass legislation, and it is the first and only state to require mandatory reporting of both serious adverse events and near misses.[111] It established the Patient Safety Authority (a semi-independent agency) to receive, evaluate, and recommend solutions to facilities for improving safety practices. More than perhaps any other state, Pennsylvania is committed to sharing feedback to improve safety. It publishes a peer-reviewed quarterly journal, the Patient Safety Advisory, to offer clinical guidance to improve patient safety using de-identified information about actual events that occurred across the state.[112] Not only does Pennsylvania also offer statewide training to thousands of providers annually, it takes seriously its own obligation to ensure the quality its reporting system and improvement efforts. It is one of only three states that conducts formal evaluations, surveying facilities every year. In addition to seeking feedback about the ease of using its reporting system, Pennsylvania also solicits information about how often and to what extent facilities have implemented the suggestions it published in the Patient Safety Advisory. And, to a certain degree, Pennsylvania has achieved noteworthy success.[113] In responding to a survey, patient safety officers reported that their health care organization had implemented more than 500 changes in response to published Patient Safety Advisories. These initiatives ranged from utilizing color-coded wristbands to note important patient information, forming a skin integrity task force, restricting the use of Propofol to the anesthesia department, and limiting the use of verbal orders.

However, even the robust Pennsylvania Patient Reporting System PA-PSRS (pronounced PAY-sirs), with its annual $5 million budget, struggles to realize marked improvements in safety. For instance, in 2012, the Authority offered 21 recommendations to reduce or eliminate wrong-site surgery (data shows that WSS events are reported at a rate of one event for week). The Authority also sought out individual facilities that were having continued problems to develop and implement programs to provide education, tools, technical assistance, resources and interactive forums. Unfortunately, the numbers at the close of the first two quarters (July to September and October to December) of the 2013-2014 academic year are already higher than the previous year (20 WWS reports as compared with 17 in 2012-2013).[114]

In part, these shortcomings can be attributed to two primary obstacles: limited data sets and insufficient organizational participation (due to lack of investment or motivation). One major benefit to a nationwide (or even a smaller, but still large-scale) collaborative system is that it allows for organizations to learn from patient safety events that cause significant harm, but happen relatively infrequently at any single institution. The incidence of such a tragic event at one hospital is too limited for organizations to glean meaningful insights and implement successful patient safety improvements. By collaborating as a group invested in a common goal, however, organizations can share their findings to identify important systemic causes and promulgate best practices to avoid similar harms.

In examining hospitals' use of state-mandated reporting systems, one study confirmed that providers only gather mandatory reporting data to satisfy their legal obligation—they do not view the time as an opportunity to investigate or reduce patient safety risks.[115] In their view, the reporting system offered no additional value. Additionally, many hospital respondents complained about the way that reporting requirements can drain resources.[116] Due to

requirements, this is exacerbated by needing to submit duplicitous reports regarding the same events to both the state agency and JCAHO. By comparison, more health care personnel find value in JCAHO Sentinel Event Alerts:

> JCAHO alerts are valuable because they put together a panel of experts who ask hospitals for risk reduction strategies and review the literature for other strategies and then distribute this information to hospitals. This is very helpful and I believe this was the original intent of NYPORTS but I haven't seen anything like this yet. You read about best practices in the paper before you hear about them from NYPORTS. There would certainly be more of a benefit of this system if the state shared best practices from the repository of information available to them.[117]

Though respondents acknowledge that NYPORTS does publish newsletters with the same purported goal as the JCAHO sentinel alerts, the state delayed so long in disseminating the information that it lost all value:

> When the state gets information on a serious case they should immediately sent out a prevention strategy to all hospitals in the state. The newsletter alerts are not as good as they can be and are often slow to be released. In the case of a chemotherapy overdose that happened in 1995, the state did not issue an alert until 2001. That is pathetic.[118]

This is an astounding confirmation that the current reporting systems are failing the orange wire test.

E. Conclusion

As the IOM acknowledged, an error-reporting program that does not foster accountability will be ineffectual. Though Pennsylvania's regulation has successfully tackled the issue of funding and support, it still fails to demonstrate substantial gains. Why? This

dissertation argues that it has failed because without an incentive to seriously intervene to reduce preventable harm, facilities and providers do not take the problem seriously. Although the rise of safety culture will likely encourage more frequent reporting, even the most proficient state statutes have only built-in incentives (or disincentives) to discourage underreporting.[119] While underreporting is a serious problem for legislatures to address, it is not the only obstacle that states must overcome in order to demonstrate marked gains towards improving patient safety. More than healthy reporting numbers, states must develop systems that are adequately funded and organized to incentivize and demand that hospitals act to reduce future incidents. Most programs attempt to achieve these results by requiring hospitals to conduct RCA and develop action plans. Though RCA and action plans are likely to produce safer systems, these efforts fail to capitalize on the greatest resource states have available: data about the most prevalent and common safety incidents. Hospitals need to be held accountable to implementing system-level remedies to common problems, but these organizations cannot fix what they are uninformed about. Feedback needs to be a clear and driving priority. In addition, the government must enact more broad sweeping legislation that incentivizes health care organizations to assume greater accountability in meeting patient safety improvement goals.

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CHAPTER SIX: AN ETHICAL MODEL FOR CENTRALIZED MEDICAL ERROR REPORTING

> We have to create an environment in which we learn from failure. This cannot be achieved in an environment of punishment or fear of legal prosecution for doctors, nurses and other caregivers who step forward after an unfortunate mistake is made.[1]
>
> —statement of Stanton Smullens, AHA spokesman

A. The Structure for Centralized Reporting

In the preceding chapters, this dissertation has revealed the many ways that the current efforts to improve patient safety—a formidable and serious epidemic claiming the lives of hundreds of thousands of patients—are failing. Regrettably, this is the same conclusion that the Institute of Medicine published in 1999. It is tragic that the many attempts to address this problem have been so badly floundered. Though the healthcare industry is astounding complex, it is inexcusable that hospitals have, nevertheless, been permitted to skirt their ethical responsibility to protect patients from harm. The level of complexity, as formidable it may be, does not justify the lack of progress. Ironically, the Institute of Medicine report, *To Err is Human*, is at least partially to blame.

In an attempt to prioritize transparency and accountability, the Institute of Medicine advanced a principled recommendation to implement a two-tiered reporting structure. In an attempt to recreate the successes of the error-reduction in the aviation industry, the IOM report called for a national, mandatory reporting system designed to threaten healthcare organizations into making greater investments in patient safety. Despite the IOM's best intentions, such a hostile and punitive approach is simply not pragmatic. Perhaps with the appropriate enforcement means, the United States could have succeeded in developing such a system (indeed, similar to

the Japanese approach discussed in chapter five). Yet, as it currently stands, a reporting system cannot succeed without robust and voluntary reporting. Even if Congress had managed to pass legislation to create the mandatory system recommended by the IOM report, it would have failed—not only because providers will not report to a system that stands to harm them, but also because the complexity of the healthcare system requires meaningful participation from hospitals and providers. Indeed, harm is so easily concealed given the complexities and uncertainties involved in patient care. Without disclosure, most families never consider the possibility of iatrogenic harm.

In this way, the IOM report was right in understanding that the system would need to mandate that hospitals participate; however, it was wrong to believe that the way to entice that participation was to threaten hospitals to embarrass them by publicly exposing their shortcomings. In the same was that organizational ethics helps to establish moral agency to hold institutions accountable, it similarly recognizes that there are distinctions separating individual and organizational responsibility. More importantly, if the patient safety movement is to be respected, its central messaging regarding the importance of understanding organizational attributes must be heeded. Blame offers no solutions, and it is not productive to simply transfer the same policy of aggressive litigation and blame that harm individual providers to the organizations in which those providers work.

Accountability is of paramount importance, yes. But, at the same time, it is crucial to recognize that complex organizations do not operate with the same clarity of direction as individuals. These organizations must be held accountable, but in the same way that the legal system imposes varying degrees of punishments, the consequences healthcare organizations face for patient safety incidents should be applied proportionately. Our nation's understanding of

justice treats accidental crimes as lesser offenses when compared to reckless or intentional wrongdoing—culpability is not fixed. In this light, unrestrained blame will not create a safer healthcare system.

Even if its inadvertent, organizations will discourage providers from reporting to a system that carries the threat of public shaming and punitive actions. Absent overt pressure, providers, as contractors who are dependent on the continued operation and profitability of hospitals, will recognize that their job security is more closely tied to the reputation and financial standing of hospital than to the incidence of patient safety events.

From an ethical perspective, it is more important to protect potential patients than it is to enforce moral absolutism. As tempting as it is to want to vilify hospital leaders, overhauling the system to improve patient safety will require a collaborative effort. To accomplish this goal, this dissertation has identified five main criteria for a successful system:

1) Incentivize safety efforts
2) Protect providers and institutions from unfair punitive measures
3) Integrate the reporting mechanism within existing systems to streamline reporting
4) Ensure reporting mandates are clear and easy to interpret
5) Provide meaningful feedback to encourage continued reporting

In other words, as Charles Billings contended, the system must be safe, simple, and worthwhile.[2]

1. Incentivizing Safety

A successful mandatory error reporting system must provide a comprehensive solution that is both practical and effective. Without incentive to seriously address medical error, healthcare providers are not fighting to be at the forefront of patient safety efforts. The fact that

patient safety initiatives must compete for resources with other priorities makes the need to build a business case even more important. As JCAHO President Dennis O'Leary explains:

> With operational resources already strained in many organizations, potential investments in patient safety compete every day against other basic needs such as staff recruitment, maintenance of the physical plant, clinical technology upgrades simply to meet the standard of care and other investments to respond to community needs. Further, investments in patient safety—while a moral obligation—usually provide financial benefits to payors and purchasers rather than to the organization [a point not lost on stressed organization leaders].[3]

Interestingly, this problem is compounded by the failure to hold hospital chief executive officers (CEOs) accountable for performance metrics. It is obvious that CEOs shape the priorities and performance of their organizations. For instance, senior leaders can construct the necessary organizational culture by supporting and expecting learning and innovation, valuing and empowering staff, focusing on patients, rewarding collaboration and teamwork, and remaining flexible.[4] Given this incredibly important role, it is disturbing that a 2014 study could not find any connection between hospital quality and CEO compensation.[5] Despite earning an average salary of $595,781 (in 2009), researchers could not find any link between CEO pay and hospitals' financial performance, quality of care, patient outcomes (such as risk-adjusted mortality rates and readmission rates), or community benefit. In fact, hospitals with better mortality rates actually paid their CEOs $4667 less than poor performers. Oddly enough, patient satisfaction scores—the most subjective quality measures—were the only quality metric that had any association to compensation. Hospitals with higher satisfaction scores compensated CEOs $51,706 more than hospitals with lower scores (95% CI, 15,166 to 88,247). This disconnect

clearly indicates that it is critical to encourage systems improvements by persuading hospital leadership that investing in patient safety is good business.

Three general mechanisms can stimulate hospitals to improve patient safety: professionalism (e.g., values, norms, and educational activities), regulation, and markets. Of these potential influences, research shows that hospitals have primarily designed patient-safety initiatives in response to quasi-regulatory requirements, namely the Joint Commission on Accreditation of Healthcare Organizations[6]—now simply called, The Joint Commission.[7]

The Joint Commission is a private-sector, non-profit organization that operates accreditation programs for healthcare organizations.[8] Although The Joint Commission accreditation is not an absolute requirement in order to operate a hospital, the standard is recognized nationwide as a symbol of quality and safety in health care.[9] Additionally, healthcare organizations can utilize The Joint Commission accreditation as a method to efficiently demonstrate compliance with federal regulations. In order for a healthcare organization to be eligible to receive federal funds from the Medicare and Medicaid programs, it must satisfy certain Conditions of Participation (CoPs).[10] Typically, the certification is granted based upon a survey by a state agency. However, hospitals and other healthcare organizations with The Joint Commission accreditation are deemed to meet the CoPs. Indeed, as soon as Medicare was founded, the Centers for Medicare & Medicaid Services (CMS) granted the Joint Commission a deeming authority for compliance with the CMS Conditions of Participation. In this way, the governmental public programs leverages federal funding eligibility to give the Joint Commission inspections their force. Consequently, approximately 77% of hospitals within the United States are currently accredited through The Joint Commission.[11] Therefore, it is not surprising that

when The Joint Commission began enforcing patient safety policies and requirements, hospitals responded.

While this is a noteworthy achievement, it has helped to dramatically increase the amount of patient-safety initiatives without providing meaningful guidance—or evidence, for that matter—for systemic improvement. Even worse, because The Joint Commission requirements do not recommend specific initiatives and there are no superseding federal regulations, some experts speculate that the majority of hospitals fumble to implement ineffective safety initiatives simply to meet accreditation standards.[12]

Normally, The Joint Commission policies mandate certain organizational outcomes (e.g., improve patient identification) without always identifying the specific structures and processes that hospitals should use to achieve them. Prior to the development of the National Patient Safety Goals (NPSG) The Joint Commission developed two major patient safety requirements. In 1996, The Joint Commission implemented a Sentinel Events Policy, which required accredited organizations to identify and respond to any patient safety event that results in death, permanent harm, or severe temporary harm.[13] The Joint Commission referred to these as sentinel events because of the way that these incidents signal the need for immediate investigation and response. The Joint Commission Sentinel Events Policy has four stated goals: to positively impact patient care by preventing unintended harm, to focus on understanding the factors that contributed to a sentinel event in order to prevent similar events from recurring in the future, to increase general knowledge about patient safety events, and to maintain and earn public confidence that patient safety is a major priority within healthcare institutions.[14]

Following the publication of the IOM report, The Joint Commission also implemented an entire new set of Patient Safety Standards. The original set of standards required hospitals to

implement patient-safety programs, prevent medical error through analysis, and inform patients of healthcare outcomes, including errors.[15] Responding to criticism that the patient safety standards were not substantial enough to bring about fundamental change in institutional practice, The Joint Commission formed an advisory group to develop a set of National Patient Safety Goals. The first set of goals, as detailed in table 6.1, became effective January 1, 2003.[16]

TABLE 6.1. Joint Commission Patient-Safety Goals, 2003-2019

	Joint Commission National Patient Safety Goals	**Disposition**
1	Improve accuracy of patient identification	2003
2	Improve effectiveness of communication among caregivers	2003
3	Improve the safety of using medications	2003
~~4~~	~~Eliminate wrong-site, wrong-patient, and wrong-procedure surgery~~	2003, Retired 2004
~~5~~	~~Improve the safety of infusion pumps~~	2003, Retired 2006
6	~~Improve the effectiveness of clinical alarm systems~~ Reduce the harm associated with clinical alarm systems	2003, Retired 2005, Revived 2014
7	Reduce the risk of healthcare-associated infections	2004
~~8~~	~~Accurately and complete reconcile medications across the continuum of care~~	2005, Moved to Goal 3 in 2011
~~9~~	~~Reduce the risk of patient harm resulting from falls~~	2005, MTS 2010
~~10~~	~~Reduce the risk of influenza and pneumococcal disease in older adults~~	2006, NA

~~11~~	~~Reduce the risk of surgical fires~~	2006, NA Retired 2010
~~12~~	~~Implementation of applicable NPSG and associated requirements~~	2006, NA
~~13~~	~~Encourage the active involvement of patients and their families in the patient's care as a patient safety strategy~~	2006; 2007 MTS 2010
~~14~~	~~Prevent health care-associated pressure ulcers~~	2006, NA
15	The organization identifies safety risks inherent in its patient population	2007
~~16~~	~~Boost response time when a patient's condition is worsening.~~	2008, MTS 2010
UP	Conduct a pre-procedure verification process Mark the procedure site Perform a time-out immediately prior to the procedure	2009

MTS = Moved to Standards

NA = Not a goal that applied to hospitals

In 2004, The Joint Commission added a seventh goal: reduce the risk of healthcare-acquired infections. National Patient Safety Goal four (4) was superseded by the mandatory enforcement of The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery in July 2004.[17] Compliance with universal protocol is required for hospitals to maintain their accreditation. Additionally, National Patient Safety Goal six (6) was incorporated into The Joint Commission Environment of Care Standards. The Joint Commission also added two new requirements: accurately and complete reconcile medications across the continuum of care and reduce the risk of patient harm resulting from falls. To accomplish NPSG eight (8), The Joint Commission directed hospitals to develop a process for documenting a complete list of patient medications when the patient is admitted and ensure that the list is

satisfactorily communicated to all providers involved in the patient's care. NPSG nine (9) tasks organizations with monitoring and assessing each patient's risk for failing in order to attempt to take necessary precautions to prevent falls. The 2006 National Patient Safety Goals retired goal five (5), which was incorporated into The Joint Commission Environment of Care Standards. In 2007, The Joint Commission added one relevant NPSG: the organization identifies safety risks inherent in its patient population.[18] The NPSG also added one new goal in 2008, requiring hospitals to respond more quickly to changes in a patient's condition.[19] In 2010, the Joint Commission started to streamline and shorten its list of NPSG.[20] Ultimately, as of its 2019 revision, the NPSG have been consolidated into seven primary goals: (#1) identify patients correctly, (#2) improve staff communication, (#3) use medicines safely, (#6) use alarms safely, (#7) prevent infection, (#15) identify patient safety risks, and (UP) prevent mistakes in surgery.

While implementing The Joint Commission-related-patient-safety initiatives were a major focal point for hospitals, hospital respondents noted the challenge of maintaining progress in these areas.[21] Overall, non-hospital respondents were skeptical that hospitals had made any major progress toward improving safety—a concern that seems to be confirmed by recent research regarding the sustained incidence of medical harm.

Additionally, despite this strong incentive to allocate finances towards fulfilling The Joint Commission requirements, in a 2004 study, 92% of hospitals reported that they did not have a budget line item for patient safety.[22] On average, hospitals reported a $1.9 million budget (with ranges from $50,000 to $15 million), with only 58% of hospitals expecting an increase. Furthermore, while the risk of not complying with The Joint Commission's patient safety policies provides a clear incentive and enforcement mechanism for accountability (i.e., loss of accreditation status) The Joint Commission does not require demonstrable progress, only that

hospitals implement initiatives. Thus, even when hospitals do devote money to implement the required initiatives, there is no guarantee that The Joint Commission compliance translates into safer health care.[23] While The Joint Commission requirements are motivating spending (and attention), the results are insufficient.

Given the lack of regulation and societal pressures, it is also painfully evident that, in order to realize progress, it is important to provide organizations with a more compelling business case for patient safety. This challenge moving forward will be providing a better basis for such a case. While legal reforms are not likely to be the only solution, regulation can be an integral part of the resolution—should the public succeed in applying political pressure within their local or federal government. This means that the system must carefully balance competing stakeholders: it must be capable of evoking change through public outcry (when necessary), while still providing some sort of institutional reward.

The difficulty is identifying ways to develop a better basis for healthcare organizations to appreciate the value of patient safety. The most obvious starting point is to focus on market forces. Consumers have a surprisingly persuasive voice in this regard—remember that patient satisfaction is the *only* quality metric that influences CEO pay. The obstacle is persuading consumers to take advantage of their collective voice. One of the most promising incentives is to continue to make the public aware of the problem. To this end, it is critical for reform efforts to not to lose sight of transparency and accountability. At the same time, the threat of public shame must be appropriately scaled.

A promising compromise would only use public reporting as a secondary measure to penalize non-compliance. First, the central agency would provide hospitals with time statutes to implement new programs and demonstrate compliance. These programs and initiatives would be

guided and informed by the collected reporting data. The incentive extended to hospitals for their prompt and earnest compliance is anonymity—comply in good faith within a reasonable time-frame and there is no benefit to publicizing any investigatory findings. The moral foundation for this approach recognizes that many in hospital leadership and administration are not intentionally allowing patient harm to proliferate. Instead, given the complexities of the system, most are baffled at what steps to take to prevent patient safety incidents.

Though it would be preferable to hospitals to prioritize efforts on their own, part of the usefulness of a nationwide system is that it allows analysts to access data concerning exceptional, but rare instances of severe harm. Independently, a single hospital would be hard-pressed to institute proactive measures for these sorts of instances—instead, improvements would be mostly reactionary to prevent similar harm after an accident occurred. Thus, the reporting mechanism offers patient safety insights that hospitals would otherwise not uncover until after harm already occurred.

Indeed, some of the most useful lessons from reporting systems are uncovered by aggregating uncommon cases across a large sample of hospitals. For instance, through aggregate data spanning 132 events, Colorado learned that 100% of wrong-site surgical events involved a communication failure, and 72% did not perform a time-out before the procedure.[24] Because of the irregularity of these more uncommon events, it took six (6) years and 5,927 physicians to identify these vulnerabilities. A single hospital would never be able to collect enough data to replicate that learning. Viewing the situation in this way, it is clear that it is ethically appropriate to allow hospitals the opportunity to utilize new knowledge to improve before penalizing them for their negligence.

With this in mind, it is useful to review incentive recommendations. This dissertation recommends two primary incentives: economic leverage given the massive amount of federal monies hospitals rely on to survive, and confidentiality protections for healthcare organizations that are satisfactorily discharging their ethical obligation to fix system defects and improve patient safety.

First, because evidence has continually demonstrated that The Joint Commission remains a primary driver in influencing hospitals' approach to patient safety, it is fair to conclude that safeguarding accreditation status with The Joint Commission is an extremely effective incentive. This leaves the federal government with two options: collaborate with The Joint Commission to incentivize participation or circumvent The Joint Commission (but risk possibly lessening the influence and authority The Joint Commission currently wields). Remember, hospitals are so highly motivated to maintain their accreditation status because accreditation with The Joint Commission is an eligibility requirement to receive federal monies. In fact, Medicare funds account for approximately 40% of hospitals' revenue.[25] This gives the federal government the opportunity to exert massive influence over hospital budgets and priorities.

Second, the government needs to shore up confidentiality and peer review privileges applicable to any federal reporting system in order to credibly offer anonymity as an incentive for the hospitals and other healthcare organizations that are striving to improve patient safety in good faith. Offering confidentiality is, admittedly, not a novel approach. Plenty of mandatory state reporting systems already incorporate these protections and are not evidencing great successes. The important distinction is that this recommendation attempts to combine the benefits of both types of systems (public and confidential; punitive and non-punitive) that are currently in use.

2. Protect Providers (and Hospitals) from Unfair Punitive Measures

In order to preserve incentives, the system must have protections in place to protect providers. Though the Institute of Medicine argued that "requests by providers for confidentiality and protection from liability seems inappropriate" in face of the public's right to be informed about unsafe conditions,[26] this contention fails to recognize how difficult it is for providers to improve safety—and how infrequently individuals are responsible for harm.

Even efforts to prepare clinicians to offer more ethical care (a much less ambitious goal than creating safer healthcare) fall flat. Consider the approach that Albert Jonsen, Mark Siegler, and William J. Winslade applied in publishing *Clinical Ethics: A Practical Approach to Ethical Decision Making in Clinical Medicine*. The authors aspired to address the ethical issues that clinicians encounter in order to help clinicians practice improved clinical care. According to the authors, this comprehension is necessary because ethical issues (e.g., informed consent, candor, and end-of-life decision-making) are pervasive throughout research and clinical care. In an attempt to parallel the normal diagnosis and treatment process that clinicians learn during their training, the authors offer a methodology to identify and analyze ethical questions that directly corresponds to the typical structure of a clinical case. Specifically, their approach includes four components: medical indications, patient preferences, quality of life, and contextual features. Medical indications refer to diagnostic and therapeutic interventions, patient preferences consider the express choices of the patient or surrogate, quality of life examines the relative features of a patient's life before and after possible interventions, and contextual features leaves space to reflect on broader settings, e.g., the family social, institutional, and financial considerations.

Unfortunately, like much of the (limited) formal training that clinicians receive, this book offers conclusory statements regarding ethical issues without offering comprehensive justifications. Although the book aspires to equip providers to tackle ethical issues, it is a long-winded—yet insufficient—summary of otherwise obvious ethical dilemmas. It is not necessarily a bad book; it simply fails to accomplish its objective. It seems that, perhaps, the authors did not choose an objective that was narrow enough to be managed in a single book. With its incomplete analyses and perfunctory approach, the book did not fully address the range of ethical issues that clinicians face in practice. In what may have been an attempt to incorporate too much information, the authors published a book that seems fragmented and inaccessible. While the authors managed to succinctly review many topics and issues that will influence ethical decision-making, it is unlikely to actually help clinicians practice improved care.

Furthermore, the book did not offer many suggestions for how to address complex questions—which is truly when most practitioners will begin to struggle. By not acknowledging this complexity and/or referring clinicians to discuss these cases with their ethics committee or consultants, the book enforces the notion that specific training or competencies are not necessary to address ethical issues in healthcare. Indeed, the tone of the book may do a disservice when paired with the information if it sends the message that the introductory information offered within the pages provide all of the necessary competencies to ensure ethical decision-making in clinical practice.

This attitude also pervades throughout the general medical community. As a result, many individuals provide ethics consultations without any training. This is precisely why the American Society of Bioethics and Humanities (ASBH) assumed responsibility for the task of representing clinical ethicists, which includes the promulgation of guidelines to ensure quality of

care.[27] The ASBH adopted and distributed the contribute of its final Task Force as its first edition of *Core Competencies for Healthcare Ethics Consultation*, which it published in 1998.[28] One of the report's four objectives was to define the nature and goals of HCEC, which included a determination of the most appropriate approach to HCEC.

In addition to explaining the role of an ethics consultant, the ASBH report also developed a set of minimum competencies to respond to concerns that individuals participating in ethics consultations lacked the skills, knowledge, and attributes to perform competently.[29] Indeed, many have expressed concern about the level of training and qualifications that the individuals providing ethics consults possess.[30] Accordingly, the ASBH task force attempted to describe the requisite knowledge and skills to analyze the nature of the uncertainty and facilitate a consensus—the core features within the ethics facilitation model. Essentially, the revised edition of the ASBH *Core Competences* separates the competencies into three sections: core skills, core knowledge, and personal traits. Many believe that these core competencies are instrumental in professionalizing the field of health care ethics consultation, and that the cluster of competencies (specific skills, particular knowledge, and personal traits) combine to enhance the quality of the practice.[31]

However, the response to the ASBH's efforts is mixed. Engelhardt harshly criticizes the *Core Competencies* for failing to recognize that ethics consultation is a social-historical construction, which follows a legal normativity.[32] As such, Engelhardt questions the ASBH's authority to even author the competencies. As he points out, fewer than 10% of those providing ethic consultation—approximately 30,000 individuals—are ASBH members.[33] Additionally, less than 4% of existing members offered feedback on the proposed document. Thus, not only do the *Core Competencies* seem to represent an underwhelming minority of the membership of

ASBH itself, it is questionable whether the competencies are widely regarded outside of the organization. Without credentialing or licensing requirements, ASBH publications are merely suggestions; and, given the remarkably low membership percentages, it is not even apparent that ASBH's suggestions are strongly considered among individuals within the field. Even worse, some argue that the *Core Competencies* report failed to address the central challenge in the ongoing debate about ethics consultation—characterize the role of an ethics consultant in a manner that would limit the practice to only those individuals with the requisite skills and knowledge.[34]

It is clearly important to appropriately address all of these ethical questions that impact clinical care and practice. In this respect, the ongoing efforts are beneficial. If nothing else, encouraging clinicians to at least think about ethical concerns is a positive step in the right direction. Unfortunately, many physicians treat mention of ethics as a potential threat and/or challenge to their own morality and professional stature.

In this respect, the persistence of many of these ethical questions (ones with decades of scholarship and general consensus in terms of ethical resolutions) demonstrates that targeting individuals is not working. This is why the Veteran Administration's IntegratedEthics model is so innovative. It is the first widely known attempt to consider ethics quality from a broader, comprehensive perspective; utilizing principles for organizational change that have proven success in other fields. The effectiveness and efficiency of this type of systems approach, however, depends on an affirmation of moral duty and accountability. The effort must move past traditional approaches to corporate ethics, which focus entirely on adherence to statutes and regulations (i.e., compliance).

For instance, central line-associated bloodstream infection (CLABSI) is one of the most deadly and costly hospital-acquired infections in the United States. Pennsylvania has mandatory hospital-acquired infection (HAI) reporting regulations and was one of the first states to withhold hospital payments for HAI. The intention was to reduce HAI, however, conversation during rounds tends to suggest that it created disincentives to aggressively pursue and report all infections. It was clear from personal observations during rounds that the attending physicians were incredibly cognizant of the number of line infections. At one point, after realizing that another patient had a line infection, the attending noted that infection would push the hospital above a certain number and would result in punitive measures. Rather than improve safety, Pennsylvania inadvertently encouraged ICU staff not to check for line infections. Specifically, residents were being taught not to run tests to check for line infections because they usually are not serious, and the hospital gets dinged for them. In this way, efforts to enforce compliance continue to fail. This is a perfect example of how incentives are remarkably unpredictable.

Extrinsic incentives routinely conflict with other motivations.[35] Benabou and Tirole advance a model that posits that individuals have a utility function that advances three main tenants. The model contends that incentives will succeed to varying levels depending on individual preferences with respect to (1) the value of extrinsic rewards; (2) the extent to which they enjoy participating in a given activity; and (3) how greatly they care about the way that others view them. In this way, incentives can have two effects: they either make the incentivized behavior seem more attractive, or they will accidentally trigger an indirect psychological effect. For instance, offering incentives for higher academic performance may inadvertently signal to the agent that the goal is particularly difficult or not worthwhile.

This is particularly relevant when considering pro-social behavior. Gneezy and Rustichini conducted a study in 2000 that concluded that students who collected door-to-door donations for charity invested more effort when they were not compensated. When offered a small compensation, the students exerted less effort. Once compensation was introduced, the level of effort corresponded directly the amount of compensation. In this light, extrinsic incentives crowd-out image motivation (e.g., wanting to be viewed as moral and altruistic). This desire for social approval is a strong motivator.

The same inadvertent consequences result from efforts at disincentives. In another study by Gneezy and Rustichini, a fine that intended to discourage parents from picking their children up late from daycare accidentally resulted in an increase in the number of late pick-ups.[36] Prior to the institution of the fine, parents knew that the contract required them to pick up their child by a certain time but did not specify the penalty. The fine that the daycare imposed was minimal: it only amounted to about $3.00. The small amount inadvertently signaled to parents that arriving late was not that serious. Even after removing the fine, the parents were more likely to arrive late to pick up their child. Once the message is sent that being on time is only as important as a few dollars, removing the fine would not undo the effects.

Rather than rely on punitive incentives, the system needs to encourage accountability (both organizational and individual) by candidly discussing ethical obligations. The reporting system must harness the collective desire to garner social approval by encouraging providers (and the institutions they represent) to meaningfully engage in patient safety efforts. This requires protecting those providers from a potential negative image as a consequence of participating. Additionally, the corollary mandate is that 'good' work is publicly rewarded, yielding a positive image.

From a logistical standpoint, this requires addressing the patient safety work privilege. As briefly discussed in chapter five, the Patient Safety and Quality Improvement Act (PSQIA) endeavored to provide peer review protection to all patient safety information reported to a Patient Safety Organization.[37] Congress intended for all hospitals to join a PSO. The hospital would collect and analyze information related to any patient safety incidents as port of its Patient Safety Evaluation System. That information would then be shared to a Network of Patient Safety Databases (NPSD)—a national, non-identifiable, aggregated patient safety event database. In this way, Congress attempted to provide a tool to resuscitate the peer review privilege.[38]

Indeed, the Senate unanimously approved the PSQIA (the House proffered three dissenting votes) to address inadequate state peer review protections (among other reasons). Senate report 109-544 clearly stated: "State peer review protections are inadequate to allow the sharing of information to promote patient safety." With such a clear mandate, it is curious that the PSQIA has not succeeded in protecting patient safety work product (the PSQIA's term for confidential peer review information concerning medical errors).

The PSQIA defines "patient safety work product" (PWSP) as:

> Except as provided in subparagraph (B), …data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—
>
> (i) which—
>
> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
>
> (II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.[39]

To date, dozens of defendants have sought to avail themselves of these protections—nevertheless, no court has ruled that (in the context of a medical malpractice action) the PSQIA operates to protect peer review documents or statements.[40] *Tibbs v. Bunnell* is possibly the most glaring example of the problem.[41] The *Tibbs* court held 4-2 that the PSQIA created a narrow privilege that was circumvented by state law.[42] According to their logic, because Kentucky law required hospitals to establish and maintain administrative reports (including incident reports) the PSES investigation and report were not privileged under the PSQIA.

Tibbs involved a malpractice lawsuit resulting from the death of Luvetta Goff.[43] Goff had died as the result of complications she suffered during an elective spine surgery while being treated at the University of Kentucky Hospital. The *Tibbs* majority acknowledged Congress's intent in enacting the PSQIA to encourage healthcare providers to share patient safety work product through PSO's in an attempt to create an "enduring national system capable of studying, analyzing, disseminating and acting on events, solutions, and recommendations for the betterment of national patient safety."[44] The court even included the full purpose statement for the PSQIA as set out in the House of Representatives report:

The IOM report offered several recommendations to improve patient safety and reduce medical error, including that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement that are developed and analyzed by health care organizations for internal use or shared with others solely for the purpose

> of improving safety and quality. This bill's intended purpose is to encourage the reporting and analysis of medical errors and health care systems by providing peer review protection of information reported to patient safety organizations for the purposes of quality improvement and patient safety. These protections will facilitate an environment in which health care providers are able to discuss errors openly and learn from them. The protections apply to certain categories of documents and communications termed "patient safety work product" that are developed in connection with newly created patient safety organizations. This patient safety work product is considered privileged and, therefore, cannot be subject to disclosure....[45]

Despite this, the majority determined that the plain language of the act itself excluded from protection as patient safety work product any information that meets the following exceptions:

> (B) Clarification:
>
> (i) Information described in subparagraph (A) *does not include* a patient's medical record, billing and discharge information, or any other patient or provider record.
>
> (ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.
>
> (iii) Nothing in this part shall be construed to limit—
>
> > (I) the discovery or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

42 U.S.C.A. § 299b-21(7)(B) (emphasis added).[46]

Based on that language, the *Tibbs* court held that because the PSQIA intended to establish an entirely separate system, "to the extent that information normally contained in such state-mandated incident reports is intermingled with other material property privileged under the Act" the information is not protected.[47] A scathing dissent argued that the majority holding clearly frustrates the Act's purpose, while simultaneously taking issue with the implication that strictly protecting patient safety work product requires denying Kentucky information required pursuant to its regulatory duties.[48] The dissent points out that the Senate Report even addressed this conflict, explaining:

> '[P]rotecting data in a reporting system… does not mean that the plaintiff in a lawsuit could not try to obtain such information through other avenues if it is important in securing redress for harm, it just means that the plaintiff would not be assisted by the present of a reporting system designed specifically for other purposes beneficial to society.' Importantly, the bill does not alter existing rights or remedies available to injured patients. Laws that provide greater confidentiality or privilege protections are also not affected by this legislation.[49]

The dissent explains that the reporting system should have no bearing on a medical malpractice claim. In an effort to ensure that submitting data to a patient safety evaluation system (e.g., to a

PSO) does not shield that information from state or other mandated reporting obligations, the majority failed to appreciate that it was allowing the patient safety information to be exposed to state law liabilities—it was circumventing the normal procedural channels and allowing the plaintiff to invade the patient safety system to search for information that, if require by law, should have been duplicated in a discoverable incident form.

As *Tibbs* evidences, the major flaw in the PSQIA is that it provides that nothing in the Act shall be construed to preempt or otherwise affect any state reporting requirement.[50] Congress indicated that it intended to preempt state law with respect to the admissibility of PSWP, but it is silent on the issue of information generated as a result of a state reporting requirement. Though the *Tibbs* dissent argued the opposite, sending the same information to a PSO that the hospital also sent to the state reporting system does not automatically immunize that information. Indeed, because state mandates require that patient safety information exists separately, the PSQIA will not protect it when it is copied to the PSO. By definition, the PSQIA only protects original documents—it will not protect any information that exists separately from the patient safety evaluation system. This is an exceptionally narrow scope of protection.

Congress, as the most suited branch, needs to reform the statute to clearly recognize the PSWP privilege.[51] Though it is not at issue, Congress was acting well within the scope of its power to regulate interstate commerce when it enacted the PSQIA. Courts have affirmatively held that there is "no doubt concerning the power of Congress to regulate a peer review process."[52] To this end, Congress must amend the Patient Safety and Quality Improvement Act to unambiguously protect PSWP, making clear that this information may be accessed by state regulators without waiving federal privilege.[53] As Congress itself pointed out in the House

Report, it can freely and vigorously protect all patient safety data submitted pursuant to the Act without depriving the plaintiff bar of other avenues for discovery.

3. An Integrated and Effective Design

> [Charles] Billings stated that counting incidents is largely a waste of time, that reporting systems capture a fraction of the true number of incidents, and that the underlying population from which the reports are drawn is seldom known.[54]
>
> —Charles Vincent, "*Incident Reporting and Patient Safety"*

Even with the requisite incentives and protections in place, the reporting system design must ameliorate and remove the many barriers that are currently preventing more frequent and detailed reporting. Many barriers will be addressed through the recommended approach to incentives and patient safety information protections. One major remaining barrier is more practical than philosophical—lack of time. This one barrier intersects with a number of different co-factors, e.g., the report asks for too much information, the reporting system is too complex, difficult to access or use. Though it seems obvious, the system must be designed to be easier and less burdensome to use.[55] Experts typically advance two shared suggestions: (1) integrate reporting for quick and easy access in the electronic environment providers use, and (2) ensure the systems are incredibly easy to use with minimal or no training.[56]

One major area ripe for development is natural language processing.[57] With this approach, (assuming that the reporting system is electronically integrated with the electronic medical record system) natural language processing would be running in the background as providers enter important data into the medical record. That processing would be programed to respond to key words or phrases that would trigger a prompt to the provider suggesting that it might be information they would want to submit in a patient safety incident report. Innovations

like these that will help to automate and streamline reporting will go a long way towards improving reporting systems. The future of patient safety incident reporting must take advantage of these and other health information technology developments.

4. Clear and Standardized Reporting Requirements

On a similar note, President Obama reportedly opposed mandatory reporting because he feared that it would be too impractical:

> [t]he best way to… [reduce medical errors] is to make sure not only that they're reporting these preventable errors, but that they're also available to consumers—the American people—so if you've got too many of them, after a while it starts getting embarrassing.[58]

While President Obama agreed that preventable harm is a serious problem, he only supported mandatory reporting for infections—the administration argued that this is because infections are easier to document.[59] While this reflects the important goal of transparency, it seems to provide too great of an allowance to hospitals to withhold this information. Not surprisingly, this will make it very difficult for his concept, which he implemented to a degree within the Affordable Care Act, to succeed.

Though the Obama administration's argument could have merely been masking their pragmatic decision to avoid a fight over error reporting (in order to retain the support of the American Medical Association and the American Hospital Association in order to pass the Affordable Care Act), their premise is still valid. It is incredibly important that reporting requirements are standardized nationwide. One of the main reasons that doctors fail to submit reports is that the form takes too long to complete.[60] Given the fact that thirty-two states and the District of Colombia track at least one Hospital Acquired Condition,[61] it is critical that the process is standardized in every region. Providers simply will not engage if there are conflicting

systems and reports to complete. The Joint Commission and other quasi-regulatory organizations collecting this data should consider integrating with the national model rather than operating as a duplicitous reporting system that will only contribute to reporting fatigue. For instance, a useful design might allow reporters to click a toggle box to indicate that the report should also be sent to The Joint Commission. With a proper drafting of the PSWP by Congress, and adoption of that same standard by The Joint Commission, sharing the incident reports in this way would not void the PSWP.

Moreover, evidence shows that reporting systems are more effective when reportable incidents are clearly and narrowly defined.[62] The criterion for what constitutes a patient safety incident needs to be explicit. Similarly, the report needs to be limited in scope. Consider the lessons learning through John Flanagan's critical incident technique.[63] Initial applications of this technique failed to provide sufficient data regarding pilot performance. A second attempt, despite emphasizing the importance of fact-based reports from competent observers, still failed to collect information accounting for all of the factors and events. The third study, however, did manage to provide factual and objective information—it appeared to succeed where prior studies had failed by explicitly directing the respondent to describe the officer's actions. Indeed, a hallmark of this technique is that it only requires observers to report simple observations. In the same way, a patient safety reporting system will function best when it limited in scope and only requires for reporters to objectively describe the actions involved in the incident.

This is bolstered when you consider how frequently providers make mistakes when the reporting forms expect providers to encode and classify variables. In fact, one study found that providers misclassified the event category in as many as 25% of all reports.[64] Similarly, 20% of those reports miscoded the level of impact. This contributes to significant waste and

inefficiencies within current methods that expect providers to not only report the incident, but also begin analyzing and classifying it. To the extent that the PSQIA has already made progress in implemented a standard reporting format, it should incorporate the lessons expounded in this section.

A simple and standardized reporting form will also help provide better feedback about needed system changes.[65] Currently, the lack of standardization makes it difficult for reviewers to compare and aggregate data—in turn, this makes it more difficult to prevent future errors.

5. Closing the Feedback Loop

There are a number of different factors that will determine whether a reporting system will successfully close the feedback loop.[66] As chapter five determined, timely and meaningful feedback (a process that is referred to as 'closing the safety feedback loop') is critical to a successful reporting system.[67] Indeed, in one study, 86% of nurses and 81% of physicians agreed that they would be more likely to submit a report if the reporting system provided feedback about what steps were being taken to correct the system defects that allowed for the error incident.[68] As such, the importance of this step is too great to be overstated.[69]

An important aspect to understand is that closing the feedback loop requires more than proforma feedback. The feedback undertaken in response to reported information must both identify and explain the systemic vulnerabilities that allowed for the incident, and also offer credible correction plans.[70] Ultimately, the safety feedback loop must represent an ongoing, cyclical, and credible process of receiving, analyzing, and responding to incident reports.

One critical point in that cycle calls for rapid feedback cycles: this alludes to the capability to quickly provide an initial response, even if that initial response is incomplete and only offers a temporary solution while an investigation is ongoing.[71] In addition to the design

advantages discussed above, another major benefit of web-based reporting systems is that it could enable providers to access timely information on their own, comparing indicators and other trends with a peer group or past reports.[72] Allowing providers to access this information in real time would help to counter concerns that reporting is wasted time. Ideally, the de-identified reports could be tagged with certain markers based on their topic and primary system defects involved. The reporting system could then use these markers to add updates to the applicable incident reports; while this would not absolve the reporting system and hospital leaders of acting in response to the most recent incident report, it would offer evidence that could build confidence that feedback is prioritized and offered. Not only would this approach give providers instant access to potential solutions (helping to provide value to reporting), it would go a long way to combating apathy.[73]

B. Codifying the Model

1. Model Legislation

The Patient Safety and Quality Improvement Act already provides a mechanism to develop a centralized, mandatory, non-punitive reporting system that can collect and disseminate adverse event information to a national audience. Given the existing infrastructure, Congress is in a unique position to more easily fix this problem by amending an existing Act. This is a major benefit. It already took Congress five years to pass The Patient Safety and Quality Improvement Act, and another four for it to become effective in 2009. It would be imprudent to discard those years of progress and start with a new statute. Instead, Congress should commit to a bi-partisan effort to amend and improve upon the existing legislation.

2. Roadblocks to Achieving Regulation

Each congressional session since the 105th Congress has produced some variation of patient safety legislation; however, passage is often thwarted. Unfortunately, healthcare lobbying plays a vital role in the development and passage of healthcare legislation. These powerful interest groups will represent one of the most powerful barriers in the push towards amending the existing nationwide regulation. Fearing retribution, the healthcare industry has been aggressively lobbing against mandatory error reporting for decades. Though legislation can be drafted to attempt to allay some of these concerns, and proponents can push the business case, the voice of the American public will be the most influential force in passing this sort of reform. Voters will need consider this issue when heading to the ballots and continue to stress the importance of this issue when their representatives are considering relevant bills.

This will require cohesive messaging and a major public campaign. Indeed, Americans notoriously struggle to understand their own interests—especially within the healthcare field—because polarized politics make it difficult to comprehend the reforms clearly and with historical perspective. Given the peculiar moral judgments that Americans have developed—although it is only one factor in an incredibly complex trap—the social consequences of human behavior might be the most powerful obstacle. Indeed, as Paul Starr explains, American values are not naturally opposed to healthcare reform (in any capacity). Starr notes, for example, that Americans do not demonize government involvement in the public school system as "socialized education."[74] Starr reconciles this contradiction by explaining that institutional legacies influence how people apply their values to social spheres. In this way, moral values are inexplicably complicated. Rather than engage in self-reflection, the public beliefs and ideologies develop in reaction to interest group's efforts to mobilize shared values on behalf of their positions.

The extent of this public ignorance and misinformation proves to be a formidable foe for advancing public policy. Especially given the broader pattern of increased polarization in American politics, it is easy to appreciate how greater social cohesion would contribute to better public policies. To participate in constructive dialogue, therefore, it is critical to understand how health care became such treacherous terrain in American politics. It is perhaps more crucial to monitor the interplay between the mass media and the political market. Without this understanding and influence, advisors will struggle to implement effective policies for social change.

C. Conclusion

This chapter unequivocally posits that unrestrained blame will not create a safer healthcare system. The United States must mandate participation in a national, nonpunitive reporting system, while simultaneously ensuring participation through thoughtful and effective system design. While organizational ethics offers an avenue and normative foundation to hold institutions morally accountable, the success or failure of error reporting will ultimately depend on how well the structure for centralized reporting functions.

From an ethical perspective, the most important issue is protecting patients. This will always be more pressing and take priority over enforcing moral absolutism. Further, this dissertation has evidenced that genuine reform will require a unified and collaborative approach—one that must include hospital leadership. To accomplish this goal, this dissertation has identified five main criteria for a successful system: (1) incentivize safety efforts, (2) protect providers and institutions from unfair punitive measures, (3) integrate the reporting mechanism within existing systems to streamline reporting, (4) ensure reporting mandates are clear and easy to interpret, and (5) provide meaningful feedback to encourage continued reporting.

Incentivizing safety will require providing a compelling business case for participation. The greatest tool at the federal government's disposal is its allocation of federal monies through Medicare and Medicaid—accounting for nearly half of hospitals' revenue.[75] The most promising approach for implementing this would mandate reporting as a condition of participation, while coordinating with The Joint Commission to enforce this mandate. Ideally, this might have the added benefit of encouraging hospital and healthcare institutions to consider patient safety metrics when determining CEO and senior leadership compensation.

As a necessary step in protecting those incentives, the government must reform the Patient Safety Quality Improvement Act to needs to clearly recognize the PSWP privilege.[76] To protect against judicial intrusion, the amended statute must make clear that patient safety work product is unambiguously protected, regardless of whether state mandated reporting requires its own duplicitous reports. Congress is more than capable of vigorously protecting all patient safety data submitted pursuant to the PSQIA without depriving plaintiffs' access to that information through other means.

With those barriers removed, the system itself must also be improved to better integrate within the normal workflow. Evidence points to electronic databases—particularly ones that directly integrate with the hospital's electronic medical record system—as being influential in increasing both the number and accuracy of reports. This approach easily meets the two primary criteria for overcoming these barriers: quick and easy access to reporting that is incredibly easy to use with little training.

To both ensure that reporting stays simple, while also safeguarding the ability of reviewers to aggregate and compare incoming data, it is imperative that reporting requirements are clear, and the reporting forms are standardized. The goal of reporting systems should be to

improve safety, not to simply collect as much data as possible. Recall the wisdom of the orange wire test—the reporting system must not be allowed to exemplify the filing cabinet instead of the orange wire.

Lastly, to that point, the reporting system must close the feedback loop. This is, after all, the entire purpose for the reporting mechanism—to utilize the incident data to create a safer healthcare system.

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CHAPTER SEVEN: CONCLUSION

Patients are dying—as many as 400,000 every year. Guilt-stricken providers are persecuted for these mistakes—accidents that they are powerless to stop. Hospitals are not being held accountable. Despite ongoing awareness of the epidemic, the country is stuck in a cycle of inaction.

While there are already countless efforts and programs in place (at state, institutional, and quasi-regulatory levels) to collect information about patient safety incidents, these efforts have been falling flat. Too often, the patient safety efforts that are being implemented do not build from basic cause and effect. To be fair, it usually is not possible—the United States does not have a comprehensive database with information on adverse events in order for organizations to learn from experience.[1] As a result, even though the IOM report generated widespread awareness that medical errors continue to occur throughout health care, there is still an overwhelming ignorance as to the nature of the problem.[2] Even when one program or system is able to collect enough data to reveal a defect or factor that contributes to harm, the lack of coordination between the various programs is inhibiting and stunting our learning.

Complicating efforts is our innate human desire to want to find someone to blame when errors arise. Psychologically, blaming individuals is emotionally more satisfying than targeting institutions because society believes that individuals are able to choose between right and wrong in ways that organizations cannot.[3] Although the study of human error and accident theory demonstrates that errors (by definition) are unintentional, society continues to hold the belief that individuals can choose to be error-free. Not only does this belief encourage unnecessary guilt and shame, it also disregards contemporary knowledge about what actually causes harm (i.e., system defects).

Not surprisingly, according to the IOM, the biggest challenge to building a safer health system is shifting from a culture of blame to a culture that treats errors as opportunities to improve the system.[4] This oversimplifies the problem. Rather than focus entirely on how we treat individuals (including, how we can structure systems to adjust for human fallibility), as a society, we must reform notions of accountability to include organizational duty. Social science reveals the prominence of amoral thinking among organizations, wherein organizations act self-interestedly—not because of intentional wrongdoing, but as a consequence of simply not considering their ethical responsibilities.[5] By attributing collective moral agency to the organization, society can impose a moral obligation to consider normative responsibilities and translate those decisions into appropriate behavior. There is a tremendous opportunity to apply the concept of organizational ethics to impose those normative standards.

To successfully improve patient safety, it is critical to shift to a more comprehensive and integrated approach to ethics and quality improvement, which is captured in the transition to organizational ethics. The purpose of this analysis is to approach the problem of medical error from the perspective of organizational ethics in healthcare. In this respect, this dissertation explored the ethical justification for developing a centralized, mandatory, non-punitive reporting system that can collect and disseminate adverse event information to a national audience. This argument relies on two foundational concepts:

1. that a systems-based approach to patient safety recognizes that healthcare organizations are best suited to intervene to improve patient safety, and
2. that organizational ethics provides a normative foundation to force government actors to hold healthcare organizations morally accountable for defects and failures within the system design that allow for these mistakes to occur.

Together, these concepts have provided an ethical framework to call for greater transparency and a nationwide implementation of a mandatory reporting system for preventable harm. The argument builds by first acknowledging the widely accepted understanding of error management (i.e., that poorly designed complex systems are the primary, or root, cause for accidents). This foundation provides a mechanism to adopt a similar organizational approach to call for a nationally mandated reporting system to address the problem of medical errors. This is the first dissertation to use a bioethics analysis, grounded in organizational ethics to argue that healthcare organizations are ethically required to invest in patient safety.

The dissertation first explored the extent of the problem within healthcare. Chapter two critically examined the complex arena of medical error, exploring how the history of medicine and rise of technology harm helped to create a system that facilities error. After describing the magnitude of the current crisis, this chapter further analyzed the current taxonomies and definitions that laypersons and researchers employ when discussing medical error. Consequently, this dissertation defines *medical error* as an act or omission during planning or execution that contributes (or could contribute) to an unintentional and unreasonable deviation.

To provide a context for understanding the responsibility that healthcare organizations owe, chapter three considers the history and evolution of the patient safety movement. This analysis studied the terminology and methods that guide modern approach to patient safety and reviewed how the application of a systems-based approach to error will develop a safer healthcare system. The key teaching in this sense is that, given the complexity of organizational systems, the prevailing culture of blame is primarily responsible for the current rates of error. Indeed, because of the unavoidability of errors within complex systems, safety depends on the ability to resolve systemic flaws. As such, errors are *system* accidents—not human weaknesses.

Chapter four, then, sought to understand why hospitals and healthcare organizations have not traditionally been held accountable for this harm. After first examining the historical application of government regulation—particularly as applied to hospitals—this chapter unpacked the legal precedent for regulating businesses to protect the public interest. As it explained the historical origins of the American hospital system contributed to a patchwork of regulations within the healthcare industry. Though many scholars have argued that *Nebbia* discarded the concept of a business affected with the public interest, this chapter makes clear that the *Nebbia* court ultimately freed the scope of legislative power from the confines of businesses "affected with a public interest." Ultimately, this case expanded the state police power—leaving it up to individual state legislatures to determine whether a business or industry is should be regulated as being affected with the public interest.

Of particular significance to this dissertation's central argument, this legal history paved the way for hospitals to be regulated as public utilities. As demonstrated, regulation is warranted when the magnitude of harm is too great for the general public to influence through normal market forces—accordingly, the U.S. government is justified in regulating healthcare organizations to improve patient safety.

Lastly, this chapter critically examined the ethical obligation within the industry to develop patient safety systems. Through this analysis, it is clear that healthcare organizations need to assume greater responsibility in the patient safety movement. Specifically, as moral agents, organizations have a robust moral and ethical obligation to develop patient safety systems and reduce public harm. In this way, this dissertation uses organizational ethics as a mechanism to advance normative methods to improve the quality and safety of healthcare.

Armed with the legal authority to regulate, chapter five reviewed the ethical and legal debate surrounding voluntary and mandatory reporting systems. The prevailing argument is that mandatory reporting systems are unnecessary at best, and harmful at worst. There are a number of co-factors, but ultimately, there are two reasons why doctors and medical associations strongly oppose mandatory reporting, and have, historically, blocked all attempts at implementing a mandatory reporting system. Opponents argue that:

(1) empirical evidence demonstrates that even mandatory reporting does not solve the problem of underreporting,[6] and

(2) mandatory systems discourage participation.

Chapter five effortlessly countered these arguments. Indeed, it is misleading to suggest that because the current punitive-focused mandatory reporting systems are failing, all mandatory systems will fail. The critics have admittedly raised important flaws that plague many systems, however, these are merely issues that need to be addressed when designing the system—not reasons why a well-designed system cannot succeed.

However, given the lack of regulation and societal pressures, it is also painfully evident that, in order to realize progress, it is important to provide organizations with a compelling business case for patient safety. This challenge moving forward will be providing a better basis for such a case. While legal reforms are not likely to be the only solution, regulation can be an integral part of the resolution—should the public succeed in applying political pressure within their local or federal government.

People are dying, and we have the power (and responsibility) to intervene. This epidemic will persist until we, as a nation, demand change. We must demand greater accountability within the healthcare system. To facilitate this change, this dissertation provides the framework to

develop a centralized, mandatory non-punitive reporting system to collect and disseminate feedback to improve patient safety. While confidentiality is a central component, it is also critical that negligent or reckless patient safety failings (that identify organizations, not providers) are appropriately reported to the public. In this sense, the model depends on a two-prong approach relying on both positive incentives and public scrutiny to hold the healthcare system accountable. Accordingly, chapter 6 offers recommendations for how to codify and implement this approach. To accomplish this goal, this dissertation has identified five main criteria for a successful system: (1) incentivize safety efforts, (2) protect providers and institutions from unfair punitive measures, (3) integrate the reporting mechanism within existing systems to streamline reporting, (4) ensure reporting mandates are clear and easy to interpret, and (5) provide meaningful feedback to encourage continued reporting.

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[1] Lucian Leape, "Reporting of Adverse Events," 1633-1638.
[2] Vincent, *Patient Safety*, 3-25.
[3] Reason, *Human Error*, 768-770.
[4] Institute of Medicine, *Crossing the Quality Chasm*.
[5] Gary Weaver, "Virtue in Organizations," 350.
[6] Kohn et al., *To Err is Human*, 48.

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APPENDIX. NATIONAL SURVEY OF LAWS

Alabama	Ala. Admin. Code §§ 540-X-10-.11(1) (requires outpatient surgery physicians to report adverse events to board of medical examiners)
Alaska	No error reporting laws.
Arizona	No error reporting laws.
Arkansas	No error reporting laws.
California	Cal. Health & Safety Code §1279-1280 (2008)
Colorado	Colo. Rev. Stat. § 25-1-124 (2008), Colo. Rev. Stat. § 25-3-601 to -607 (2008).
Connecticut	Conn. Gen. Stat. § 19a-127n (2007), Conn. Gen. Stat. § 19a-494 (2007), Conn. Agencies Regs. § 19a-127n-2 (2008).
Delaware	No error reporting laws.
DC	D.C. Code § 7-161 (2008), 17-40 D.C. Code Mun. Regs § 4017.40 (Weil 2008).
Florida	Fla. Stat. § 381.0271 (2006), §381.028 (2006), 395.0197 (2006), 458.351 (2006), 459.026 (2006)
Georgia	Mandatory reporting of patient incidents, O.C.G.A. §§. 31-2-4, 31-2-6, 31-5-5, 31-7-2.1, 31-7-15, 31-7-133, 31-7-140, and 50-18-70.
Hawaii	No error reporting laws.
Idaho	No error reporting laws.
Illinois	Adverse Health Care Reporting Act of 2005, 410 Ill. Comp. Stat 522/10-5 to 522/10-50 (2005), Hospital Report Care Act, 86/25(a)(2) (2008), Ill. Admin. Code §255, §§250, 280 (2008).
Indiana	Ind. Code § 16-40-5-4 to § 16-40-5-6 (Supp. 2008), 410 Ind. Admin Code 15-1.2-1 (2008), " 15.1-4-2 (2008), and " 2.2.
Iowa	No error reporting laws.
Kansas	Kan. Stat. Ann. § 65-4921 to -4929 (2007), Kan. Admin Regs. § 28-52-1 to -4 (2008).
Kentucky	No error reporting laws.

Louisiana	No error reporting laws.
Maine	Me. Rev. Stat. Ann. tit. 22 §§ 8751-8756 (2008), 10-144-112 ME. Code R. § VI (Weil 2008), 10-144-118 ME. Code R. § 5.C.7 (Weil 2008), 10-144-125 ME. Code R. § 4.B. (Weil 2008), 10-144-126 ME. Code R. § 4.F. (Weil 2008).
Maryland	MD. Code Ann., Health-Gen. § 19-304 (2005), MD. Code Regs. 10.07.06.01-16 (2008) (Hospital Patient Safety Program)
Massachusetts	Mass Gen. Laws ch. 111, §§ 203-205 (West 2003 & Supp. 2008); Mass. Gen. Laws ch. 112, § 5 (Supp. 2008); 243 Mass. Code. Regs. 3.07-3.08 (2008).
Michigan	No error reporting laws.
Minnesota	Minnesota Adverse Health Care Events Reporting Act of 2003, Minn Stat. §§ 144.7063-144.7069 (Supp. 2008), Minn. Stat. § 145.64 (Supp. 2008)
Mississippi	No error reporting laws.
Missouri	No error reporting laws.
Montana	No error reporting laws.
Nebraska	Patient Safety Improvement Act, which allows for **voluntary** reporting. Neb. Rev. Stat. §§ 71-8701-02 (Supp. 2007).
Nevada	Nev. Rev. Stat. §§ 439.800-890 (2005 & Supp. 2008), Nev. Rev. Stat. §§ 630.293.96, 630.505.07 (LEXIS 2008), Nev. Admin. Code §§ 439.900-915 (2008)
New Hampshire	No error reporting laws.
New Jersey	Patient Safety Act, N.J. Stat. Ann. §§ 26:2H-12.23 to -12.25a (West 2007), N.J. Admin. Code §§ 8:43E-10.1 to 10.11 (2008)
New Mexico	No error reporting laws.
New York	N.Y. Pub. Health Law § 2819 (HAI reporting), N.Y. Comp. Codes R. & Regs. tit. 10, § 405.11 (2008) (HAI reporting), N.Y. Pub. Health Law § 2805-1 (2008) (incident reporting), N.Y. Comp. Codes R. & Regs. tit. 10, § 405.8 (2008) (incident reporting), N.Y. Pub. Health law §§ 2995-2998 (initiative to create statewide health information system)
North Carolina	No error reporting laws. Only exception was a law governing reporting of medication-related errors in nursing homes, which was repealed in 2013.
North Dakota	No error reporting laws.
Ohio	Ohio Rev. Code Ann. § 3727.33 (LexisNexis 2008)
Oklahoma	No error reporting laws.
Oregon	Only mandatory for HAI, Admin. Rules 409-023-0000 *et seq.* (2008)
Pennsylvania	§ 1303.407 (quality improvement payment to facilities that achieve a 10%

	reduction in HAI) 40 Pa. Con. Stat §§ 1303.103 to .407 (2008 & Supp. 2008).
Rhode Island	R.I. Gen. Laws § 23-17-40 (2001)
South Carolina	S.C. Code Ann. Regs. 61-16 (2008)
South Dakota	No error reporting laws.
Tennessee	Tenn. Comp. R. & Regs. 1200-8-1.11 (2007), Tenn. Comp. R. & Regs. 1200-8-6.11 (2007)
Texas	Annual report, 25 Tex. Admin Code §133.48 (2008)
Utah	Sentinel event, Utah Code Ann. §26-33-103 (2007)
Vermont	NQF events, Vt. Stat. Ann. tit. 18, §§ 1912-1919 (Supp. 2007)
Virginia	No error reporting laws.
Washington	NFQ events, Wash. Rev. Code § 43.70.056 (Supp. 2008)
West Virginia	No error reporting laws.
Wisconsin	No error reporting laws.
Wyoming	Wyo. Stat. Ann. § 35-2-912 (2007), 35-2-912 Wyo. Code R. §§ 1 to 14 (Supp. 2008)