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Enterprise Dispute Resolution: Full Disclosure and Early Offer Policies in the Event of an Indisputable Medical Error

Do the Economic and Ethical Benefits Outweigh the Potential Financial Exposure?

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INTRODUCTION

The 1999 release of "To Err is Human: Building a Safer Health System" by the Institute of Medicine (IOM) rocked the healthcare arena, uncovering the massive amounts of medical errors prevalent in our healthcare system.[1] Attributing as many as 98,000 deaths each year to "preventable medical errors,"[2] the IOM report forced providers to confront their roles in causing patient harm.[3] If the Center for Disease Control were to list "preventable medical error" as a cause of death, these staggering numbers would make it the sixth leading cause of death in the United States, before Diabetes or Alzheimer's disease.[4] The medical community was on notice. Lack of patient safety was its own cancer, a scourge on the providers' oath to "do no harm." The ethical mandate to champion patient safety was clear, and ensuring transparency in healthcare delivery during all stages of care was the only way to achieve the goal. The more progressive entities quickly realized that, in the aftermath of medical error, they would have to work with patients, rather than against them, to minimize harm. The movement toward full disclosure and transparency gained momentum.

Despite the spotlight the IOM report shined on this dark side of medicine, the efforts to reduce preventable errors and increase patient safety are failing. In 1999, the number of deaths attributable to medical error was equivalent to the number of deaths if a commercial jetliner crashed on American soil every day.[5] Paul Levy, former CEO of Boston's Beth Israel Deaconess Medical Center, contextualized by stating, "I don't think that crashing a 727 jet every day and killing everybody aboard is a good standard of care in U.S. hospitals. If that happened in aviation, they would shut the airlines down."[6]

Today, over a decade after the perilous report, patients continue to suffer lethal medication errors and erroneous care leading to avoidable medical harm.[7] A 2010 study by the Department of Health and Human Services – Office of Inspector General revealed that in the course of one year, one in seven Medicare beneficiaries, at least 134,000 people, suffered at least one adverse event upon admission, with many of these events

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[1] Comm. on Quality of Health Care in Am. & Inst. of Med., *To Err Is Human: Building a Safer Health Care System.* (Linda T. Kohn, Janet M. Corrrigan & Molla S. Donaldson eds., Nat'l Academies Press 2000).

[2] *Id.*

[3] *Id.*

[4] National Center for Health Care Statistics at the Centers for Disease Control, *Deaths/Mortality, 2010,* available at http://www.cdc.gov/nchs/fastats/deaths.htm.

[5] Steve Sternberg, *Medical Errors Harm Huge Number of Patients,* U.S. News (Aug. 28, 2012), at http://health.usnews.com/health-news/articles/2012/08/28/medical-errors-harm-huge-number-of-patients_print.html.

[6] *Id.*

[7] *Id.*

considered "clearly or likely preventable."[8] In November 2010, the New England Journal of Medicine followed suit and published the disturbing results of a five-year study of North Carolina hospitals which revealed that, between 2002 and 2007, efforts to make hospitals safer in response to the IOM report had failed.[9] One of the most comprehensive efforts to collect patient safety data since the 1999 IOM report, this study exposed the staggering truth that 25.1 incidences of harm occurred for every 100 hospital admissions, translating to 25% of all admitted patients suffering a preventable harm.[10] 2.9 percent of these cases resulted in permanent injury, such as brain damage; slightly more than 8 percent resulted in life-threatening illnesses; and, 2.4 percent resulted in patient death.[11]

The basic "fight or flight" instinct is not only expected, but usually, an acceptable human response to adverse circumstances. However, in the instance of a provider-caused medical error, the analogous "deny or defend" response employed by most medical entities forces patients to file suit, leading to prolonged litigation, often for the simple purpose of obtaining information as to how and why the error occurred.[12] As set forth more fully below, litigation also causes unnecessary suffering for survivors as well as the providers. Even more dangerous, the "deny and defend" approach discourages providers from disclosing the cause or source of the error, essentially precluding the ability to implement policies and procedures to prevent recurrence of the error.

This paper argues the economic and ethical benefits of full disclosure, early offer, and apology in the event of a medical error indisputably caused by a provider. While formal implementation of full disclosure and early offer programs methodically vary by facility, the overall advantages of increasing transparency in medical care and its attendant communication are irrefutable. Section I summarizes the protections of the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and how they provide a basis for many of the successful full disclosure and early offer programs currently employed by healthcare systems. Section II describes the practical application of full disclosure as a method of avoiding malpractice litigation in cases of indisputable error. It details the devastating story of Mary White, a mother of two who, although a victim of egregious medical error, opted not to file suit after providers were forthcoming and apologetic for their errors. Section III examines the root of malpractice litigation, including why patients sue, as well as the ineffectiveness of the "deny and defend" approach usually invoked by the providers who defend malpractice from behind a shield fortified by a "culture of silence." Section IV discusses the importance of transparency and full disclosure throughout the course of medical care beginning with informed consent, and not just after the occurrence of an adverse event. This section also

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[8] DHHS - Office of the Inspector General, Daniel R. Levinson, Inspector General, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, at https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf (November 2010).

9 Christopher P. Landrigan, *et al.*, *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, N. Engl J Med 363:2124-2134 (Nov. 25, 2010) at http://www.nejm.org/doi/full/10.1056/NEJMsa1004404.

[10] *Id.*

[11] *Id.*

[12] Charles Vincent *et al., Why do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 Lancet 1609-13 (1994).

illustrates the benefits a full disclosure policy lends to providers, enabling them to exchange crucial information without the fear of negative professional or personal backlash. Section V reveals a deterrent to apologize that is common to the vast majority of providers. It is contrasted with the positive effect of a sincere apology, both on the provider as well as the victim of medical negligence. Section VI provides a synopsis of highly successful full disclosure and early offer programs currently utilized at the University of Michigan, University of Illinois, and Stanford University medical centers. Section VII describes the recent law enacted in Massachusetts, the first of its kind, which legally mandates the "Disclosure, Apology, and Offer' approach as the primary method of resolving medical malpractice claims. This paper concludes with the determination that a well-designed and well-managed full disclosure, apology, and early offer program results in economical and ethical benefits to providers, patients, and the healthcare landscape as a whole.

I. THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

To demonstrate its own commitment to a culture of patient safety, the United States government enacted sweeping patient safety legislation in the form of The Patient Safety and Quality Improvement Act of 2005 (PSQIA).[13] In relevant part to the matter of full disclosure, the PSQIA "established a voluntary reporting system designed to enhance the data available to assess and resolve patient safety and health care quality issues. To encourage the reporting and analysis of medical errors, PSQIA provides Federal privilege and confidentiality protections for patient safety information, called patient safety work product. PSQIA authorizes HHS to impose civil money penalties for violations of patient safety confidentiality. PSQIA also authorizes the Agency for Healthcare Research and Quality (AHRQ) to list patient safety organizations (PSOs). PSOs are the external experts that collect and review patient safety information."[14] By providing formal legal protection for those reporting issues of patient safety and healthcare quality, critical information is exchanged and utilized in an effort to prevent the errors from recurring. PSQIA's legal protections provided a catalyst for the patient-principled disclosure and early offer models adopted by several highly-regarded institutions such as the University of Michigan, University of Illinois Medical Center, and Stanford University. At the University of Michigan, for example, providers have implemented full disclosure and early offer programs which have resulted in a marked increase in patient and physician satisfaction, reduced litigation, and provided protected opportunities to design safety regimens to preclude future recurrence of the adverse event.[15] The PSQIA protections initiated the dismantling of the "culture of silence," which often pre-empts most post-injury communication between providers and patients.

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[13] Patient Safety and Quality Improvement Act of 2005, Pub.L. 109–41, 42 U.S.C. ch. 6A subch. VII part C (2005).

[14] *Id.*

[15] Richard C. Boothman, *et al*., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, J. Health & Life Sci., Vol. 2, No. 2, 125-159 (2009).

II. THE SUCCESS OF FULL DISCLOSURE – THE MARY WHITE STORY

We are so accustomed to stories of vicious litigation in the news and similar anecdotes in Hollywood films, that a scenario in which a victim of medical negligence working alongside the healthcare provider who committed the error to resolve the matter and avoid filing suit seems unimaginable. Though certainly unusual enough to be newsworthy, it happened, and successfully so, to Mary White of Boston. Following a routine polyp removal, Mary White received an urgent call from her gynecologist informing her that the polyp was a malignant form of uterine cancer.[16] A 45 year old mother of two teenage girls, Mary immediately underwent a radical operation to remove her uterus, ovaries, fallopian tubes, cervix, and lymph nodes.[17] As she nervously awaited her prognosis, wondering if she would be able to see her daughters into adulthood, she received another shocking call from her gynecologist.[18] The original pathology report was wrong, and Mary never had cancer. Due to an erroneous transcription of the pathologist's findings, Mary's diagnosis was misread, mishandled, and egregiously miscommunicated.[19] The error had already sent Mary hurtling into highly invasive surgery and painful recovery; and, would bring about the inevitable aftermath of early menopause and nerve damage.[20] Despite the incongruous feelings of elation and raging anger, Mary opted not to sue Brigham and Women's Hospital, or her doctors.[21] "She reached her decision largely because the hospital, caregivers, and the insurer swiftly apologized, disclosed details about what went awry, improved hospital procedures, and offered financial settlement for her pain and suffering."[22]

Mary's decision not to file a formal malpractice action was a direct result of her providers' respectful treatment of her shocking misfortune, as well as the frank and candid disclosure of their catastrophic medical errors. Immediately following the initial call to inform Mary about the error, the surgeon called her to let her know that top level administrators "felt terrible about the mistake."[23] She referred Mary to a patient advocate, who started the informal resolution process by directing Mary through the proper support channels.[24] Just two months later, Mary received a letter from the Head of Pathology detailing the clerical error which led to her radical surgery.[25] In short, her polyp biopsy results were handwritten by the pathologist and identified as "adenomyoma

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[16] Liz Kowalczyk, *Mass. Hospitals urged to apologize, settle*, Boston Globe, (May 27, 2012), available at http://bostonglobe.com/lifestyle/health-wellness/2012/05/26/mass-hospitals-urged-apologize-settle/wY4Sf6N3Zka6JyXfnqSG1N/story.html.
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] *Id.*

submucous" (a noncancerous mass).[26] However, when the secretary finalized the report, she transcribed the polyp as "adenosarcoma submucous," which is malignant.[27] Subsequent system failures occurred, including her physician's failure to review the final report, which ultimately avalanched into communication of a spurious diagnosis that changed Mary White's life and body forever.[28] Yet, despite clear error and lasting damages, Mary did not sue. She admits the "pathologist's apology was a factor in me not wanting to go after more . . . . It softens the rage."[29]

While many potential error situations are not as clear as Mary's, her tempered reaction to the providers' conciliatory approach is instructional on many levels. Most importantly, it suggests with regard to the notion of the "deny and defend" approach that it, along with its "culture of silence" canopy, ought to be replaced by a transparent and principled approach to patient care, risk management, and dispute resolution.

III. MEDICAL MALPRACTICE – AN OVERVIEW

Over the last thirty years, "medical malpractice" has become a turf war between attorneys and healthcare providers. The conservative right claims attorneys are "ambulance chasers," constantly attempting to empty the insurers' deep pockets. The liberal left claims insurers and healthcare entities are only interested in raising the bottom line, even if it means further harming the victim of error. Regardless of the true origin, malpractice insurance rates have skyrocketed, and insurers blame the increases on litigation.[30] As such, creating transparent processes to reduce unnecessary litigation would benefit all involved in healthcare – insurers, practitioners, and most importantly, patients. Moreover, curbing superfluous litigation would be significantly beneficial to today's clogged dockets and overall judicial economy.

The Disturbing Statistics and Resulting Efforts

According to a comprehensive study by the Congressional Budget Office (CBO) in 2003, 181,000 severe injuries incurred by hospital patients were attributable to medical negligence.[31] The staggering findings supported the results of a study by the Institute for Healthcare Improvement (IHI). Based upon IHI's extensive experience studying injury rates in hospitals, IHI estimates that between 40 and 50 incidents of harm occur for every 100 hospital admissions.[32] Citing the American Hospital Association National Hospital Survey findings that 37 million hospitalizations occur annually, a medical error rate of

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[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] Boothman, *supra* note 15 at 129.
[31] *See* Congressional Budget Office, *Key Issues*, (Dec. 2008), 150-54.
[32] Patient Safety & Quality Healthcare, *IHI Launches National Campaign to Reduce Medical Harm*, (Jan/Feb 2007) at http://www.psqh.com/janfeb07/5million.html (citing findings of extensive studies by the Institute of Healthcare Improvement).

this magnitude translates into 15 million harm events per year, with 40,000 harm events occurring each day.[33]

These findings were endorsed by preeminent pioneers in the field of transparency and patient safety, including Lucian Leape, MD, adjunct professor of Health Policy at the Harvard School of Public Health; Brent James, MD, executive director of Intermountain Healthcare's Institute for Healthcare Delivery Research; Ross Baker, PhD, professor of Health Policy, Management and Evaluation at the University of Toronto; and David Bates, MD, medical director of Clinical and Quality Analysis, Information Systems at Partners HealthCare System.[34] The alarming statistics also galvanized the IHI's "5 Million Lives" campaign.[35] With the support of such respected authorities, IHI launched the campaign to "dramatically reduce incidents of medical harm in U. S. hospitals" by asking them to rapidly improve their care in a manner designed to prevent five million incidents of medical harm over a 24-month period.[36] Partners in IHI's efforts include: leaders of the Blue Cross and Blue Shield health plans, the American Hospital Association (AHA), the American Nurses Association (ANA), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[37] Each pledged that their organization will act as national champions and clinical advisors for the critical work involved in increasing patient safety.[38] A subsequent survey by the Harvard School of Medicine revealed complementary findings, showing at least 25 percent of patients in hospitals suffer preventable injury during the course of their care.[39] Consequently, efforts to reduce and eliminate preventable injuries are imperative to provide safe healthcare to the masses.

The numbers are astounding. The lack of awareness of the problem is even more alarming. One in three Americans report they or a family member has experienced a medical error, and one in five say that a medical error has caused serious health problems or death.[40] Yet, about half of the respondents to the survey believe the annual death toll from medical errors is 5,000 or less – nearly 20 times lower than the findings of the IOM.[41] At a time when crushing medical costs are blamed on "frivolous" lawsuits, it is critical to note that the vast majority of patients who suffer a medical injury as a result of

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[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] Christopher P. Landrigan, et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, N. Engl J Med 363:2124-2134, 2129 (Nov. 25, 2010) at http://www.nejm.org/doi/full/10.1056/NEJMsa1004404.
[40] Kaiser Family Foundation, *National Survey on Consumers' Experiences With Patient Safety and Quality Information*, Nov. 17, 2004, available at http://www.kff.org/kaiserpolls/pomr111704pkg.cfm.
[41] *Id.*

provider negligence do not file suit.[42] In fact, today's tort system is considered difficult for patients to navigate, demanding a burdensome amount of time and effort to deliver highly variable results.[43] Recent studies report "only 2 to 3% of patients injured by negligence file claims, only about half of claimants recover money, and litigation is resolved discordantly with the merit of the claim . . . about a quarter of the time.[44] As such, for the tort reformists who argue there are hundreds of thousands of meritless malpractice suits for only a handful of genuine medical errors, the reverse is actually true.[45] University of Pennsylvania law professor Tom Baker claims there is "an epidemic of medical malpractice, not of malpractice lawsuits."[46] Yet, medical malpractice litigation shoulders the lion's share of blame for rising medical costs. In actuality, the key to reducing healthcare costs is by reducing preventable malpractice litigation.

Defensive Medicine and its Toll on Healthcare Costs

Several factors contribute to the rising healthcare costs. Litigation overhead costs are estimated to consume 55% of every malpractice premium.[47] Malpractice premiums themselves can exceed $250,000 per year.[48] The most concerning factor, however, is the rampant practice of defensive medicine. Physicians today perceive patients to be overly litigious and legally aggressive, and design their care protocol with the intention of avoiding any potential liability.[49] As a result, providers are practicing "defensive medicine," where high-risk patients are turned away and an overabundance of tests, referrals, and services are ordered to reduce liability risk.[50] This fear-based practice of medicine costs the healthcare industry upwards of $45 billion dollars annually in superfluous and unnecessary medical care.[51]

A common-sense antidote to the defensive medicine cost factor is to transform the practice of defensive medicine into transparent medicine. Dr. Lucian Leape, chairman of the Lucian Leape Institute of the National Patient Safety Foundation, analogized the

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[42] David M. Studdert, *et al*., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, N. Eng J Med 354:2024-2033, 2024 (May 11, 2006) available at http://www.nejm.org/doi/full/10.1056/NEJMsa054479 (citing Localio AR, Lawthers AG, Brennan TA, *et al. Relation between malpractice claims and adverse events due to negligence; results of the Harvard Medical Practice Study III*. N. Engl J Med 325:245-51 (1991)).

[43] Allen Kachalia M.D., J.D., and Michelle M. Mello, J.D., Ph.D., *New Directions in Medical Liability Reform*, N. Eng. J. Med 364:1564-1572, (Apr. 21, 2011) at http://www.nejm.org/doi/full/10.1056/NEJMhpr1012821.

[44] *Id.* at 1565

[45] *Preventable Medical Errors – The Sixth Biggest Killer in America*, American Assn for Justice, at http://www.justice.org/cps/rde/justice/hs.xsl/8677.htm.

[46] *Id.* (citing Tom Baker, *The Medical Malpractice Myth*, 2005).

[47] Kachalia, *supra* note 43, at 1565.

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] *Id.*

practice of medicine to air travel, stating "[t]ransparency is one of the reasons that commercial aviation in America has such an impressive safety record. When an airplane crashes, the National Transportation Safety Board swoops in and launches a full investigation: entire planes are re-assembled; press conferences are held to update the public; a report is issued on the investigation's findings; the entire industry is informed, and corrective measures are required of all similar aircraft."[52] Similarly, Dr. Leape considers the ability to study violations of safety measures and resulting adverse events to be critical to improving the delivery of future medical care.[53] Without understanding what went wrong and why, a faulty system cannot be improved.[54] "By acknowledging errors and investigating them, we can avoid them in the future."[55] The analogy, though not perfect, does beg the question of why the aviation industry is required to publicly acknowledge and explain fatal errors, while medical providers, who also serve and impact a large population, are permitted to passively hide behind the "wall of silence" when error occurs.

Beginning with informed consent, transparency proscribes the abuse of defensive medicine by encouraging physicians and patients to participate in full disclosure and the exchange of crucial information throughout the provision of care. By reviewing and understanding the purpose of each test, procedure, and service, the physician and patient can work in concert to ensure only the necessary tests and procedures are performed. And more importantly, by providing an open forum to discuss treatment strategies as well as missteps, the abundance of information available for review during and after the care will optimize patient safety.

The True Source of Rising Costs

The debate over medical malpractice litigation rages on as politicians, attorneys, physicians, and insurers blame each other for the precipitous rise in healthcare costs. Tort-reform advocates cite "frivolous" malpractice suits as the source of rising costs. Plaintiffs' attorneys, confined by statutorily-limited contingency fees, claim the prevalence of medical errors deem meritless suits "bad business and unnecessary."[56]

Simply put, a properly executed disclosure and early offer program can preempt unnecessary malpractice suits often blamed for skyrocketing malpractice insurance costs. As corroborated by the Innovations Exchange of the Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ), an effective full

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[52] Lucian L. Leape, *A Blueprint on Patient Safety*, Boston Globe (Nov. 15, 2011) at http://www.boston.com/bostonglobe/editorial_opinion/blogs/the_podium/2011/11/_by_lucian_l_leape.html.

[53] *Id.*

[54] *Id.*

[55] *Id.*

[56] David M. Studdert, *et al*., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, N. Eng J Med 354:2024-2033, 2024 (May 11, 2006) available at http://www.nejm.org/doi/full/10.1056/NEJMsa054479.

disclosure program actually reduces malpractice claims and claim costs.[57] Referencing the University of Michigan Health System full disclosure program, described in specific detail in Section VI, AHRQ not only recognized the patient-centered principle of the program, but also how it successfully "reduced malpractice claims and costs per claim, hastened the claims resolution process, reduced insurance reserve requirements, and . . . resulted in significant savings to the health system."[58]

The Economics of Never Paying for Never Events

Although much of the discussion around medical malpractice focuses on costs, for patients to access care as well as for physicians to practice medicine, the prospective savings from eradicating unnecessary litigation is noteworthy. The Center for Medicare & Medicaid Services, (CMS), the agency which provides healthcare coverage for 100 million people, echoes this sentiment.[59] In 2002, in response to the 1999 IOM report, the National Quality Forum (NQF) established a list of 27 "Never Events," with an additional one added in 2006.[60] The NQF defines Never Events as, "errors in medical care that are clearly identifiable, preventable and serious in their consequences for patients."[61] Examples include wrong-site surgery or unintended retention of a foreign object in a patient after surgery.[62] In 2008, CMS issued a ground-breaking directive prohibiting reimbursements to hospitals for these "never events," as well as for remediation of provider or hospital errors.[63] By refusing to subsidize the costs of care associated with provider error, CMS created a financial incentive for hospitals to incorporate procedures optimizing patient safety, and saved taxpayers millions. One federal paper estimates CMS's policy on withholding payment for provider and hospital errors saves taxpayers $21 million dollars annually.[64]

In 2008, CMS issued a virtual directive urging State Medicaid Directors to follow suit and eliminate payment to hospitals for care associated with the 28 "never events" identified by the National Quality Forum.[65] Citing a study by the Center for Disease Control (CDC) which found that common medical errors were responsible for an average annual expenditure of $4.8 billion in additional medical costs, CMS advised States to "align payment and quality" and follow the lead of 20 states considering adoption of the CMS policy to refuse payment for the occurrence and ensuing care of never events.[66]

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[57] AHRQ, *Full Disclosure of Medical Errors Reduces Malpractice Claims and Claims Cost for Health System*, at http://www.innovations.ahrq.gov/content.aspx?id=2673#7.
[58] *Id.*
[59] Centers for Medicare and Medicaid Services (CMS), at http://www.cms.gov/.
[60] Herb B. Kuhn, CMS Correspondence to State Medicaid Directors, July 31, 2008, available at http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD073108.pdf.
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] 72 F. R. 47201
[65] Kuhn, *supra* note 64
[66] *Id.*

In August 2009, New Jersey enacted Bill S2500/2471 into law, which requires hospitals to publicly report 14 serious medical errors and prohibits hospitals from charging for certain medical errors.[67] One of the first state laws of its kind in the United States, the New Jersey legislation barred hospitals and providers from seeking payment for follow-up care and costs related to "never events" for which Medicare disallows payment, and the federal government deems preventable.[68] New Jersey essentially heeded the CMS advisory and adopted its payment methods, presumably to realize the financial savings of doing so while encouraging optimum quality of care. In fact, since the National Quality Forum issued its original list of "Never Events" in 2002, 11 states have mandated reporting of these incidents whenever they occur, and an additional 16 states mandate reporting of serious adverse events, including those listed by the NQF.[69]

The natural step forward in the process is to obligate the hospitals and practitioners responsible for medical errors to fully disclose the circumstances behind patient harm, and, where warranted, offer to resolve the ensuing claim in a fair and expeditious manner. Doing so would only serve to benefit the patient and provider community as a whole, and ultimately, save millions in resources expended to defend defenseless claims.

Deny & Defend Does Not Work

When faced with an unanticipated patient injury and resulting claim, providers instinctively resort to the "deny and defend" mentality. Aptly described by William Sage, "deny and defend" is a philosophy adopted by insurers and defense counsel to "urge secrecy, dispute fault, deflect responsibility, and make it as slow and expensive as possible for plaintiffs to continue the fight."[70] As a result, patients' claims can take upwards of five years to resolve, while the information about the cause of the harm, compensation for subsequent care, and feedback to prevent its recurrence remains cloaked in litigious secrecy. Moreover, the protracted litigation causes "volatility in premiums by increasing legal uncertainty and making malpractice insurers more dependent on investment income for profitability."[71] Though human instinct is to retreat when threatened, in the arena of preventable medical errors, doing so seems to exacerbate the harm. Though physicians may be understandably hesitant to openly discuss or disclose errors rather than deny them, they are ethically bound to disclose, and ought to

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[67] N.J. Bill S-2471, available at http://www.njleg.state.nj.us/2008/Bills/S2500/2471_I1.PDF, (adopted Aug. 31, 2009) (Requires DHSS to report certain patient safety indicators on a hospital by hospital basis and prohibits hospitals from charging for certain medical errors.)

[68] *Id.*

[69] AHRQ, *Patient Safety Primer - Never Events*, available at http://psnet.ahrq.gov/primer.aspx?primerID=3

[70] Richard C. Boothman, *et al*., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, J. Health & Life Sci., Vol. 2, No. 2, 125-159, 128 (2009) (*citing* William M. Sage, *The Forgotten Third: Liability Insurance and the Medical Malpractice Crisis*, 23 Health Affairs 11-12 (2004)).

[71] *Id.*

follow a principled protocol to ensure the information is promptly disclosed to the aggrieved parties.

Why Patients Sue

In a large-scale study reported in the Lancet almost 20 years ago, Charles Vincent and his team surveyed hundreds of patients or representatives on their incentive to file legal action. His findings supported the theory that the "deny and defend" stance taken by offending providers literally drove the claimants to seek counsel.[72] While compensation is also a driving force, most of the patients and relatives reported that they sought counsel to act as an advocate for their interests.[73] Someone to procure the elusive answers and information about the trauma, and, to ensure the harm does not recur.[74] In fact, 37% of the study participants reported that an apology would have "made the difference" in deciding whether to file suit.[75]

Vincent's study uncovered the true basis of malpractice suits. He found "70% of the 227 patients and relatives interviewed were seriously affected by incidents that gave rise to litigation, with long-term effects on work, social life, and family relationships. Intense emotions were aroused and continued to be felt for a long time. The decision to take legal action was determined not only by the original injury, but also by insensitive handling and poor communication after the original incident."[76] Accordingly, taking a sensitive and informative approach following a medical error is critical to avoiding suit.

The study also spoke to the patients' ultimate purpose in pursuing legal action. Four major factors were prevalent in the decision to sue: 1) to prevent similar incidents in the future; 2) to obtain an explanation – to know how the injury happened and why; 3) to obtain compensation – for actual losses, pain, and suffering or to provide care in the future for an injured person; and, 4) to see accountability – a belief that the staff or organization should have to account for their actions.[77]

The overriding motivation driving patients to sue seems to be the fundamental need to understand what caused their harm, and, to hold the providers accountable to ensure it does not recur, if determined to be actually preventable. Not money. Therefore, where a provider undeniably causes harm as a result of inappropriate care, fighting back defensively to avoid fiscal liability is an act of futility, if not an act of provocation. It is not money as much as it is information and acknowledgment that the patients want. At the end of the day, "patients taking legal action wanted greater honesty, an appreciation for the severity of trauma they suffered, and assurances that lessons would be learned from experiences."[78] Full disclosure programs fulfill these needs. No amount of tort reform measures designed to cap damages and hinder filings will discourage lawsuits

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[72] Charles Vincent *et al*., *Why do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 Lancet 1609-13 (1994).
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *Id.*

seeking causal information. Malpractice claims initiated for answers will persist until a better process of answering the needs of an aggrieved patient, such as a full disclosure program, is adopted and implemented in hospitals across the country.

IV. FULL DISCLOSURE STARTS AT THE BEGINNING

"Disclosure" in the context of patient injury refers to a process defined as, "a prompt, truthful, and compassionate explanation of how the injury occurred, its short and long term effects, remedies available to the patient, and steps developed, following an analysis of the root cause of the error, that will be taken to prevent its recurrence."[79] Full disclosure begins when the relationship begins.

Disclosure is vital to the informed consent process. Patients have a right to know all information as it relates to their past, present, and future medical treatment. In terms of preventing medical errors, an evolving discussion of the risks and benefits of all treatment plans, actual and projected, is essential for the patient, as well as his providers, to continuously make informed decision which will ultimately reduce errors.

Disclosure is especially necessary in a situation involving a preventable injury caused by the physician or his/her staff while providing medical services. In that instance, it is important for the physician to expressly disclose the circumstances giving rise to the preventable injury. In addition to being legally required to disclose the details surrounding the injury, a provider fulfills his or her fiduciary and ethical duty to the patient by being forthcoming and truthful about the treatment.[80] Finally, full disclosure sets the groundwork for the provider and the patient/family to begin the healing process of forgiveness. The provider and the patient both reap the rewards of learning from the error and doing their individual parts to ensure history will not repeat itself.

The Content of Disclosure and Why it Matters

While the method and specificity of disclosure in a medical setting can vary greatly, the content is extremely important. In her 2003 study, Jennifer Robbenolt found that "a poorly executed disclosure will impact an early-offer process negatively. The study found that the more full and transparent the disclosure and apology, the more likely a patient/family will be inclined to accept an offer of compensation and settle the matter with the organization without litigation. 73% of the study participants stated that, if properly addressed, they would be inclined to settle the event with the organization directly; less than 15% were either inclined to reject the offer or remained unsure as to what they would do."[81]

The significance of full disclosure is evident in cases such as Mary White's erroneous cancer diagnosis and subsequent surgery. Because her providers were upfront,

[79] Barbara Youngberg, *Principles of Risk Management and Patient Safety*, Ch. 17 – *Full Disclosure as a Risk Management Imperative*, 216 (2011).
[80] *Id.*
[81] *Id.*

honest, and forthcoming with information, Ms. White opted not to sue.[82] In fact, she was impressed with the letter she received from the pathologist, which went beyond disclosure and apology, and outlined four system improvements the hospital made to ensure the error never occurred again.[83] Although Ms. White's life was "turned upside down," the hospital's steadfast efforts to keep her informed, make internal changes, and compensate fairly were received by a reasonable claimant willing to put the matter behind her and move forward.[84] By cooperating, both parties averted the daunting process of a costly, multi-year litigation. In the end, even Ms. White's attorney regarded the settlement as "very fair and within the range a jury would award."[85]

Failure to Disclose Leads to Litigation

Full disclosure is imperative to open the channels of communication and to preserve the integrity of a physician-patient relationship. A significant number of patient-plaintiffs report that they file suit to compel providers to disclose information about how and why harm occurred.[86] Patients are ethically and legally entitled to know what transpired in their case. Yet, even in instances of patently avoidable harm, the prevailing culture of "deny and defend" behind the "wall of silence" forces physicians and hospital administrators to cease productive communication on the matter.[87] The silence or denial is an affront to the injured patient's sense of dignity, and often spurs them to sue to "right" the wrong.[88]

When patients are not given the respect of truthful information, including their providers' acknowledgement of harm, they often feel they have no choice but to sue to get their answers.[89] M.S. Woods, an expert in the field, states that, "[t]here is no evidence that reporting or disclosing medical errors actually leads to lawsuits."[90] Moreover, Robbenolt's study confirms patients who experience medical error 1) sue if they are not given sufficient information about the event; 2) desire communication that the organization is taking responsibility for what has occurred; and, 3) tend not to sue when their expectations are met.[91] In greater detail below, this paper enumerates quantifiable evidence that proper disclosure has consistently decreased malpractice claims and suits, as well as insurance premiums in the industry.[92]

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[82] Liz Kowalczyk, *Mass. Hospitals urged to apologize, settle*, Boston Globe, (May 27, 2012), available at http://bostonglobe.com/lifestyle/health-wellness/2012/05/26/mass-hospitals-urged-apologize-settle/wY4Sf6N3Zka6JyXfnqSG1N/story.html.
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] Youngberg, *supra* note 82, at 217.
[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] *Id.* (*citing* M.S. Woods, *Healing Words: The power of apology in medicine*. Oak Park, IL: Doctors in Touch (2007)).
[91] *Id.* at 256.
[92] *Id.* at 217.

Disclosure Benefits the Healthcare Provider

Full disclosure of the circumstances which led up to an avoidable injury also benefits the healthcare provider. The vast learning opportunities inherent to dissecting the cause and circumstances behind a preventable medical error ought not be squandered under the veil of "deny and defend." When the providers and patients are contemporaneously available to provide insight into the events as they transpired, everyone wins. The healthcare organization can respond by altering its systems and procedures to ensure the harm does not recur, and, the patient can take solace in knowing he did his part to protect future patients. By promoting a culture of immediate and methodical disclosure and open communication, the provider improves his care and will likely see a decrease in malpractice claims, as well as insurance premiums.[93]

V. THE POWER OF APOLOGY

An apology is a "written or spoken expression of one's regret, remorse, or sorrow for having insulted, failed, injured, or wronged another. . . an acknowledgement expressing regret or asking pardon for a fault or offense."[94] Where disclosure ought to be mandated in all facets of patient care, an apology should be a mandate when patient care has resulted in avoidable injury. A patient who has suffered a medical error at the hands of a negligent provider is entitled to an apology as a show of respect to his dignity. To Mary White, the pathologist's written apology was powerful enough to convince her to "not be angry at him" when she could have "developed an image of him as an arrogant doctor too rushed to read reports."[95] Taking responsibility for a medical error restores the emotional balance within the patient, as well as the provider. Providers often report obtaining a sense of relief from the guilt and personal anger rooted in causing a preventable injury. Research supports Mary White's tempered reaction, mellowed by apology, is not an aberration.

Why Not Apologize? The Culture of Perfectionism

In 2006, researchers from the University of Washington surveyed 1,404 surgeons and general practitioners in Canada, a sovereign which drastically limits medical liability and discourages malpractice suits, caps damages for pain and suffering, and forces the patient who loses the case to pay the doctor's legal bills.[96] Surveys were also sent to 1233 surgeons and general practitioners in Washington and Missouri, two states on the front line of the medical malpractice insurance crisis due the lack of affordable liability

[93] *Id.*
[94] *Id.* at 216.
[95] Liz Kowalczyk, *Mass. Hospitals urged to apologize, settle*, Boston Globe, (May 27, 2012),
[96] Carol M. Ostrom, *Lawsuit Fears aren't Reason for Doc's Silence on Errors*, Seattle Times, (Aug. 17, 2006).

insurance available to their physicians.[97] The subjects responded to specific hypothetical scenarios in which they had committed medical errors.[98] The results showed doctors in both the U.S. and Canada were significantly less likely to inform patients about serious medical errors where patients were unlikely to uncover the mistakes on their own.[99] Over half of the respondents stated they would apprise patients about adverse events, but would not inform them that the adverse events resulted from medical errors.[100] Only one-third of the physicians said they would apologize following a medical error.[101] As such, given the large variance in malpractice laws between the U.S. and Canada, the results strongly suggested that potential medical malpractice litigation was not the prime deterrent of disclosing errors.[102]

If not for the fear of ensuing malpractice litigation, what deterred the physicians from apologizing? Study authors Eric Larson, former medical director at University of Washington Medical Center, and Thomas Gallagher, an Internal Medicine physician at the University of Washington Medical Center theorized that physicians hail from a "culture of perfectionism" in medical school, which does not train doctors on how to start the conversation about mistakes, and therefore, discourages the disclosure of medical errors.[103] Larson surmised, "[t]his code of silence, this conspiracy of silence does not work for reducing errors," adding, "[w]hat we know now is it does nobody any good to bury a mistake or cover up a mistake; you can't correct what led to the mistake unless you deal with it explicitly."[104]

Debates over the U.S. medical malpractice landscape continue to fuel providers' contentions that an overly litigious system discourages doctors from being forthcoming about medical errors.[105] Ironically, these physicians even invoke the Canadian malpractice system as exemplary of how well a system which limits malpractice liability and discourages lawsuits would work to encourage disclosure.[106] However, the findings of the 2006 study indicate that safeguarding personal reputation, perhaps more than potential malpractice liability, drives physicians behind the "wall of silence" when an error occurs. However, the retreat to self-preservation is exceedingly unproductive

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[97] Kaiser Health News, *'Culture of Medicine,' Not Fear of Malpractice, Prompts Physicians To Withhold Information About Medical Errors From Patients, Study Says,* available at http://www.kaiserhealthnews.org/dailyreports/2006/august/18/dr00039290.aspx?referrer=search (Aug. 18, 2006) (*citing* Thomas H. Gallagher, M.D., et al., Choosing your Words Carefully, JAMA Internal Medicine, Vol. 166, No. 15, available at http://archinte.jamanetwork.com/article.aspx?articleid=410785 (Aug. 14, 2006)

[98] *Id.*

[99] *Id.*

[100] *Id.*

[101] *Id.*

[102] *Id.*

[103] *Id.*

[104] *Id.*

[105] Carol M. Ostrom, *Lawsuit Fears aren't Reason for Doc's Silence on Errors*, Seattle Times, (Aug. 17, 2006).

[106] *Id.*

because disclosure of errors is crucial to advancing patient safety and ensuring mistakes do not recur. As such, a full disclosure program fortified with personal and professional safeguards for physicians offering an apology or statement of remorse can evolve the practice of medicine out of the culture of silence and into the open forum of transparency where patients and physicians can work together to avoid recurrence of preventable errors.

Apologizing Benefits the Patient as well as the Provider

The Vincent study findings reflect the fundamentals of human nature. When someone is wronged, they want a sincere apology. In the study, patient claimants were asked if anything could have been done to prevent the litigation they commenced after suffering the medical error.[107] Over 41% of respondents answered "yes."[108] Of the actions that might have prevented litigation, receiving an "explanation and apology" was at the top of the list, with 39% of respondents confirming that it would have prevented their litigation action.[109] Patients who were treated as neurotic, or deprived of explanations, apologies, or honesty felt they had no option but to sue.[110] Where patients were provided explanations and treated with respect, they felt they received the information and empathy to which they were entitled, and ultimately, were more likely to engage in meaningful discussions with their providers.[111]

Apology Laws Protect Providers and Encourage Empathy

In 1986, Massachusetts enacted the first legislation protecting providers who acknowledge responsibility for a medical error or offer condolences for an unanticipated outcome.[112] Over 30 states have followed and enacted "apology laws" with a variable level of protection.[113] Within certain parameters, the providers' statements of sorrow or remorse toward patients or survivors are protected communications.[114] Without fear of having the statements used against them in ensuing litigation, providers are empowered and more willing to elicit an expression of grief, apology, explanation, or sorrow.[115] In cases of medical error, expressions of sincere apology from providers are reported to comfort the distressed human psyche, as well as support the effort to reduce soaring malpractice fees. With these protections in place, providers can freely show human empathy and remorse.

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[107] Charles Vincent *et al., Why do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 Lancet 1609-13 (1994).
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] Youngberg, *Principles of Risk Management and Patient Safety*, at 220.
[113] *Id.*
[114] *Id.*
[115] *Id.*

The Indisputable Success of Full Disclosure and Apology

Several entities have successfully implemented the use of disclosure and sincere apology in their post-harm procedures. As detailed more fully below, the University of Michigan is a trailblazer of the full disclosure/early offer theory.[116] Since its implementation, the number of pre-suit claims and lawsuits has decreased from 260 pending in July 2001 to fewer than 100 in January 2007.[117] Moreover, the average amount spent on legal fees for each case has fallen more than 50 percent.[118] In all, litigation costs fell from an average of $65,000 per case to $35,000 per case, which resulted in a total average annual savings of $2,000,000 to the hospital.[119] And perhaps most beneficial to all parties involved, the average time to resolve a case dropped from 20.7 months to 9.5 months.[120]

Similarly, COPIC, the largest malpractice insurer in Colorado, enrolled 1800 physicians in a program requiring them to express remorse to patients for medical care gone wrong and give full disclosure as to the sequence of events.[121] Malpractice claims against the selected physicians dropped by 50 percent from 2000 to 2005, and the cost of settling claims dropped by 23 percent.[122]

According to Richard Boothman, Chief Risk Officer at University of Michigan, "[m]any doctors really want to be open and apologize to the patients, but are led to believe it can end up in financial disaster, when the truth is quite the opposite."[123] When providers are afforded proper protections, the lines of communication open up and the parties are seemingly willing to listen. In the tense time following preventable medical error, nothing seems to be more conducive to resolving the issue than having parties prepared and willing to exchange information.

VI. DISCLOSURE AND EARLY OFFER PROGRAMS IN ACTION

The University of Michigan Health System, University of Illinois Medical Center, and Stanford Medical Center are leaders in the nation's movement toward a full disclosure/early offer approach to resolving claims of medical error. By implementing innovative, patient-centered, and principled approaches, these institutions have enjoyed extensive success in the areas of fiscal savings, hospital procedures, and patient and provider satisfaction.

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[116] *The Full Disclosure/Early Offer Movement: What it could Mean for You if You Ever Suffer a Medical Mistake*, 07/09/12, available at www.sixwise.com.
[117] *Id.*
[118] *Id.*
[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *Id.*

The University of Michigan Health System – A Principle-Driven Approach

Richard Boothman, Chief Risk Officer at the University of Michigan Health System (UMHS), devised a full disclosure/early offer risk management program in 2001.[124] The program is centered on three basic principles:

1. **Compensate quickly and fairly when unreasonable medical care causes injury;**

2. **Defend medically reasonable care vigorously; and,**

3. **Reduce patient injuries (and claims) by learning from patients' experiences.[125]**

In this model, distinguishing between reasonable and unreasonable medical care is critical. As such, the UMHS risk management department was overhauled to include licensed medical caregivers to evaluate the potential malpractice claims and care provided.[126] Once the situation is reviewed, the risk management team schedules a meeting with the patient and patient's family, if appropriate.[127] Following a meeting of open communication between all parties involved, the risk manager continues the investigation, prioritizing the patient's needs throughout the process.[128] The next stage of review involves a committee appointed to review the Risk Management department's findings – to ensure proper checks and balances.[129] To "perfect" the process of full disclosure, the UMHS puts the onus on the attending physician to begin the disclosure process at the early stages of Informed Consent, and continue it throughout the treatment, especially after an unanticipated outcome is reported.[130] With guidance from the Risk Management team, the physician is supported and encouraged to be forthcoming with any and all information he or she can share.[131]

Since eliminating "deny and defend" and implementing the Full Disclosure-Early Offer approach, the UMHS has seen its claim numbers plummet from 262 open claims in August 2001 to less than 100 in late 2005.[132] Moreover, the UMHS process is thought to "have achieved the unthinkable: it pleases doctors and trial lawyers."[133] 98% of the

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[124] Richard C. Boothman, *et al*., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, J. Health & Life Sci., Vol. 2, No. 2, 125-159 (2009).
[125] *Id.*
[126] *Id.* at 139.
[127] *Id.*
[128] *Id.*
[129] *Id.* at 140.
[130] Youngberg, *supra* note 82 at 228.
[131] *Id.*
[132] Testimony of Richard C. Boothman, Chief Risk Officer, University of Michigan Health System, before the U.S. Senate – Committee on Health, Education, Labor, and Pensions, Thursday, June 22, 2006.
[133] *Id.* at 4.

faculty physicians surveyed in 2006 reported that they fully approved of the UMHS approach; and, 55% stated the approach was a significant factor in their decision to stay at the University of Michigan.[134] Members of the Plaintiff's bar in Southeastern Michigan expressed a similar sentiment.[135] 100% of the attorneys rated the UMHS "the best" and "among the best" health systems for transparency; 81% said they changed their approach to the UMHS in response, which also lowered their costs; 71% admitted when they settled cases with the UMHS, the settlement amount was less than anticipated; 86% agreed that the UMHS transparency allowed them to make better decisions about the claims they chose to pursue; and, 57% admitted that they declined cases after the 2001 implementation of the program that they would have likely taken prior to 2001.[136]

The most compelling evidence of the efficacy of the UMHS full disclosure program in lowering medical malpractice litigation costs is the dramatic reduction in pending litigation against UMHS from 262 open claims in 2001 to 83 pending in August 2009.[137] In 2001, prior to full implementation of the program, approximately two-thirds of the malpractice claims were engaged in formal litigation.[138] However, by September 2009, only 17 percent of malpractice claims were in litigation.[139] Finally, the overall annual filings reduced from 121 in 2001 to only 61 in 2006, and that number remained steady through 2009, despite an approximately 30% annual increase in patients over the studied period.[140]

The UMHS approach is a thriving and successful program in the field of healthcare liability and dispute resolution. Following its implementation, the UHMS has amassed millions of dollars in savings while prioritizing the needs of patients.[141] Therefore, the answer to the universal dilemma of lowering medical malpractice costs, and, the ensuing insurance ramifications, may be to follow the trail the University of Michigan has successfully blazed.

University of Illinois Medical Center at Chicago – The Seven Pillars

In 2004, under the leadership of Timothy B. McDonald, Chief Safety and Risk Officer, the University of Illinois Medical Center at Chicago (UIMCC) pioneered the implementation of a "comprehensive process for responding to patient safety incidents resulting in patient harm."[142] The UIMCC defines "patient safety incident" as "an event or circumstance which could have resulted, or did result, in unnecessary harm to the

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[134] *Id.*
[135] *Id.*
[136] *Id.* at 5.
[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] *Id.*
[141] *Id.*; *The Full Disclosure/Early Offer Movement: What it could Mean for You if You Ever Suffer a Medical Mistake*, 07/09/12, available at www.sixwise.com.
[142] Timothy McDonald, *et al*., *Responding to Patient Safety Incidents: The Seven Pillars*, available at http://onlinemj.luc.edu/documents/McDonaldDoc1.pdf (2009)

patient." [143] The UIMCC process is grounded in principles consistent with the UMHS approach, and also includes additional tenets promoting a "just culture."[144] Generally speaking, the UIMCC process discourages blame of providers involved in system-induced errors, but promotes remedial measures for individuals who engaged in "reckless disregard for patient safety."[145]

Dr. McDonald and his team developed a "**Seven Pillars**" approach to guide investigations into patient safety incidents at UIMCC as follows:[146]

1. Patient Safety Incident Reporting

The first pillar encourages practitioners and patients to immediately report the prospect of an incident to the Risk Management team.[147] Systems are set up so reporting, anonymously if desired, can occur by telephone, hand-written note, or online.[148] A Risk Manager is available on-site 24 hours a day to receive and respond to the incidents.[149] Further, a "robust reporting culture" is achieved by rewarding those who speak up about incidents, and punishing those who fail to report incidents.[150] Since the implementation of this program, the number of patient safety reports has doubled at UIMCC.[151]

2. Investigation

The investigatory pillar charges the Risk Manager to conduct a preliminary review of an incident to determine if a harm as occurred.[152] Once the presence of harm, or lack thereof, is determined, the incident is referred to the Chair of the Medical Staff Review Board (MSRB), or categorized as a "near-miss" to be further studied.[153] The MSRB convenes a "rapid investigation team" to perform a root cause analysis of the incident within 72 hours of the incident to determine whether the care provided was reasonable.[154] The results are presented to the MSRB for determination about the standard of care, accountability, and quality improvement recommendations.[155] To promote a "fair and just culture," the MSRB measures the error against "Reason's algorithm of unsafe acts" to objectively determine personal culpability versus system failure.[156]

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[143] *Id.* at 6.
[144] *Id.* at 7.
[145] *Id.*
[146] *Id.* at 8.
[147] *Id.*
[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] *Id.*
[153] *Id.*
[154] *Id.* at 9
[155] *Id.*
[156] *Id.*

3. Communication and Disclosure

UIMCC regards the communication and disclosure pillar as central to the process.[157] By maintaining ongoing communication with the patients throughout the investigation, including the reasonableness of the care provided, the process optimizes full disclosure to the patient.[158] If the care is deemed unreasonable, the team provides full disclosure to the patient and an explanation of how the harm occurred.[159]

4. Apology and Remediation

The fourth pillar involves an apology, if warranted, and an appropriate remedy.[160] When an unreasonable or avoidable harm has occurred, the UIMCC process promotes rapid remediation and an early offer of compensation, if required.[161]

Rapid remediation in the form of holding and waiving hospital bills for injuries sustained as a result of the harm is an important factor in easing the patients' worry about paying hospital bills. By removing the burden of payment, the patient-claimant is likely more open to participate in a reasonable discussion. With the lines of communication and trust open, the UIMCC rapid settlement team works with the patient and his representatives to arrive at a prompt resolution of monetary claims.[162]

5. System Improvement

The fifth pillar of system improvement provides a far-reaching benefit to the healthcare organization. System improvements implemented to prevent recurrence of the patient incidents are critical to the overall patient safety efforts at UIMCC. Proper reporting and processing of patient safety incidents decrease the chance of future recurrence, and therefore decrease the amount of claims against the providers.

6. Data Tracking and Performance Evaluation

The sixth pillar of data tracking and analysis provides UIMCC with hard statistics to utilize for "internal quality assurance, research, public outreach, and dissemination."[163] The Risk Management department maintains the database and makes quarterly reports to the UIMCC administration to ensure providers are kept abreast of recent incidents and outcomes.[164]

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[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] *Id.* at 10.
[161] *Id.*
[162] *Id.* at 11.
[163] *Id.*
[164] *Id.*

7. Education and Training

The seventh pillar is arguably the most important - to ensure the incidents do not recur. Caregivers are required to obtain continued education, participate in annual competency assessments, monthly patient-safety programs, unit-specific patient safety and disclosure training, and "train-the-trainer" programs.[165]

These programs also include peer-to-peer support, and where caregivers are involved in patient safety incidents, the chance to participate in patient communication and disclosure as part of their own personal healing process.[166] The provider is often the overlooked "second patient" in patient safety issues, who also benefits from peer support, forgiveness, and education from the incident.[167]

Success of the Seven Pillars at UIMCC and Beyond

In February 2013, preliminary data from the $3 million AHRQ-funded demonstration project in which the "Seven Pillars" program was expanded to 10 other hospitals decisively showed the full disclosure, apology, and remediation approach reduced legal costs at the participating institutions.[168] Where the typical malpractice case in the area took five years to resolve, for UIMCC and the 10 grant hospitals, the time to settle claims decreased 80%.[169] Further, while the costs of defending a typical malpractice suit averaged $300,000-$350,000 prior to trial, UIMCC and the grant hospitals reduced their litigation costs at least 70% by implementing and utilizing the Seven Pillars approach.[170]

Hospitals were not the only beneficiaries of savings. Pursuant to the fourth pillar mandating remediation, participating hospitals waived all hospital and professional fees resulting from unreasonable or substandard care, resulting in a $6 million dollar savings for payers within the first two years of the grant.[171] Seven Pillars has also exhibited a chilling effect on the practice of defensive medicine.[172] Preliminary findings show superfluous laboratory and radiology tests were prescribed less, resulting in a minimum savings of 20%.[173]

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[165] *Id.* at 12.
[166] *Id.*
[167] *Id.*; Albert Wu, *Medical Error: the second victim*, BMJ Vol. 320 (Mar. 18, 2000)
[168] Andis Robeznieks, *Full Disclosure First – Alternative Med-Mal Approaches Show Promise*, Modern Healthcare.com, available at http://www.modernhealthcare.com/article/20130202/MAGAZINE/302029954?AllowView=VW8xUmo5Q21TcWJOb1gzb0tNN3RLZ0h0MWg5SVgra3NZRzROR3l0WWRMWGJWdjBERWxYOU9qTENvK25lK0g4UkxyeWplMDVxa3c9PQ==#, (Feb. 2, 2013).
[169] *Id.*
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] *Id.*

Since implementation of this patient-centered, ethically-driven program, the UIMCC has seen no increase in malpractice claims or payouts as a result of full disclosure and early offer.[174] Two years into its implementation at UIMCC, the Seven Pillars process activated over 2,000 incident reports submitted annually; over 100 investigations requiring root cause analysis; and, 200 system improvements through lessons learned from errors.[175] The process also prompted 106 disclosure conversations, and 20 full disclosures of "inappropriate or unreasonable care" which caused harm to UIMCC patients.[176]

The success of the Seven Pillars model at UIMCC proves there is a demand for transparency in the delivery of medical care. The pillars represent and inspire a "culture of safety, transparency, inquiry, and medical error disclosure."[177] While the program requires years to fully implement and a substantial investment to position an experienced management and round-the-clock risk management team, the Seven Pillars procedure promotes ample opportunities to evaluate medical errors, respond to the errors in a legally and ethically appropriate manner, and modify delivery of future care to ensure the error does not recur.[178] According to the principles of the Seven Pillars approach, transparency is the foundation for safe and high quality patient care.[179]

Stanford University PEARL: Process for Early Assessment and Resolution of Loss

In 2007, Stanford University Medical Center's captive insurer, Stanford University Medical Indemnity and Trust (SUMIT), established the Process for the Early Assessment and Resolution of Loss (PEARL) to effectuate "early assessment of 'concerning outcomes,' open disclosure of preventable unanticipated outcomes, compensation when warranted, and turning the . . . lessons of these concerning outcomes into performance-improvement opportunities."[180] Jeffrey Driver, Director of Risk Management for Stanford Health Center declared PEARL to be a "principle-based policy" and "one that promotes transparency, integrity, fairness, and healing."[181] Echoing the tenets of the Transparency in Medicine movement pioneered by Dr. Leape, Stanford's dedication to transparency and fairness not only reinforces the fundamental promise in the practice of medicine to "do no harm," but also the notion that such

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[174] McDonald, *Seven Pillars*, at 12.
[175] T. B. McDonald, L.A. Helmchen, *et al. Responding to patient safety incidents: the "seven pillars."* BMJ Quality & Safety, Vol. 19, Issue 6, available at http://qualitysafety.bmj.com/content/19/6/e11.full (Mar. 1, 2010).
[176] *Id.*
[177] *Id.*
[178] *Id.*
[179] *Id.*
[180] Barbara Youngberg, *Principles of Risk Management and Patient Safety*, at 258 (*citing* Stanford University Medical Indemnity & Trust Insurance Company, *et al.* (2007) Process for Early Assessment and Resolution of Loss (PEARL)).
[181] Stanford Hospital Medical Staff Update, *Informational Tools Available For Coping with Unanticipated Medical Outcome*, available at http://med.stanford.edu/shs/update/archives/JUNE2009/pearl.htm (June 2009).

idealism is a realistic expectation capable of being achieved through an economical and ethically sound system of healthcare delivery.

PEARL is designed to encourage immediate action from all parties involved in a potential medical error.[182] Stanford promotes the program as one which "allows for early analysis, appropriate immediate and long-term interventions, and [one that] helps physicians and their patients recover from and manage unexpected outcomes proactively."[183] PEARL's focus on the well-being of the patient and the provider is an integral component to its success, and further supports the principle that a well-managed full disclosure and early offer program is both economically and ethically appropriate.

Success of PEARL

The success of PEARL in action is irrefutable. SUMIT, Stanford's Risk Management Office, is usually notified of a PEARL case following a "concerning outcome" in a medical case.[184] In cases where the PEARL process is not activated, it could take up to 11 months for SUMIT to receive notification of the adverse event, and that is usually through a written claim or lawsuit.[185] However, where PEARL is involved, SUMIT can be engaged within hours or days, encouraging contemporaneous, in-depth review of the circumstances surrounding the incident.[186] Most important, however, is that the immediate involvement of insurers and decision-makers delivers assistance and care to the aggrieved patient and medical staff at a "critical time of care."[187]

The preservation of time and resources following Stanford's implementation of PEARL is incontrovertible. Prior to PEARL, the industry standard from the date of file open to file close was roughly 5 years.[188] However, a review of a number of PEARL files by experts in the field found that a PEARL case could be opened and closed within a span of 6 months.[189] The PEARL matters were often closed without involving the litigation process, which not only resulted in economic benefits, but also protected patients and providers from the emotional trauma of re-living the medical error through a lengthy legal process.[190]

Stanford also reports the PEARL outcomes resulted in direct financial savings when the "concerned outcome" was "addressed with an early-off-and-disclosure process."[191] When the patient and/or his family were notified of the outcome and apprised of the circumstances and treatment plans to mitigate the preventable harm, the

[182] *Id.*
[183] *Id.*
[184] Youngberg, at 258.
[185] *Id.*
[186] *Id.*
[187] *Id.*
[188] *Id.*
[189] *Id.*
[190] *Id.*
[191] *Id.* at 258

aggrieved parties were less likely to retain legal counsel.[192] The forthcoming approach invoked by Stanford obviated the need to secure counsel in order to obtain information usually hidden behind the "wall of silence." The PEARL cases demonstrated a "marked decrease in overall claim costs when compared with litigated cases," and, "the expenses involved in a PEARL review can be as low as 5% of the average cost of a litigated case."[193]

How PEARL Works

PEARL operates in a series of steps to ensure the interests of the hospital, providers, and patients are protected. Prior to engaging the services of the PEARL team, practitioners are advised to stabilize the patient and take all necessary measures to maximize patient safety.[194]

a. Notify Risk Management within 4 hours of Concerning Outcome using the 24 hour Consultation Service.

Upon the occurrence or suspected occurrence of a "concerning outcome," practitioners are required to notify the PEARL Risk Management Team available to them via telephone around the clock.[195]

b. PEARL Risk & Claims Advisors Dispatched

Following notification of a "concerning outcome," trained PEARL Risk & Claims Advisors provide consultation to the facility and practitioner in a manner consistent with the SUMIT protocol.[196] Following the consultation with the PEARL Advisor, the provider is to proceed with providing and documenting the patient's care.[197]

c. PEARL Embraces and Builds Upon any Hospital Disclosure Policy

Given the positive economic and emotional effect following detailed disclosure, PEARL relies on open and honest lines of communication to ensure a constructive exchange of information between provider and patient.[198]

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[192] *Id.*
[193] *Id.*
[194] *Id.* at 12
[195] Stanford SUMIT, *Disclosure and Risk Management in HSCT*, http://bmt.stanford.edu/documents/symposium2008/driver.pdf
[196] *Id.*
[197] *Id.*
[198] *Id.*

d. PEARL Utilizes "Just-In-Time" Expert Coaching[199]

Acting as a partner in providing optimum care to its hospital, its practitioners, and the patients, SUMIT's PEARL program employs the services of expert Risk Management advisors to ensure the legally and medically proper measures are taken to rectify the concerning outcome and address the ensuing issues.

e. PEARL Always Focuses on Assessment[200]

A preventable unanticipated outcome is the primary component of any successful early offer program. It is imperative that the outcome is one that was a result of indisputable medical error and could have been prevented. As such, the initial assessment to determine that the concerning outcome was preventable is necessary to moving on to the next step of offering remediation to motivate resolution of the loss. Only the Preventable Unanticipated Outcomes (PUO) will be subject to the early offer.

f. Once PUO is Established, PEARL Advisors Assist in Presentation to the Patient[201]

The highly-trained PEARL Risk and Claims Advisor counsels the hospital or practitioner, or the respective spokespeople, on how to communicate with the harmed patient and/or his family. The hospital representatives are briefed on Stanford's full disclosure policy; on communicating the lessons learned from the unfortunate experience; on approaching needs assessment to expedite recovery; and, perhaps most important, to listen to the patient and/or his survivors.[202] PEARL fully endorses disclosure to maximize Stanford's allegiance to the ethical practice of medicine; patient self-determination; and, ongoing informed consent practices.[203]

Stanford's PEARL program is not a "sorry" initiative. In fact, it is quite the opposite. It vigorously defends its staff when the immediate expert review finds medical negligence did not cause the harm.[204] However, when a human error does occur, PEARL opens up the lines of communication, usually diffusing the patient and his family's reflexive need to mount an adversarial approach, and ultimately, line the pockets of attorneys in order to find the answers to which they are entitled.

g. Early Offer is Authorized Following Needs Assessment

Soon after the patient or family's needs assessment is completed, the PEARL Risk & Claims Advisor authorizes an early offer for discussion with the patient and/or

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[199] *Id.*
[200] *Id.*
[201] *Id.*
[202] *Id.*
[203] *Id.*
[204] *Id.*

family.[205] Although the offer is based upon the results of the needs assessment, the offer is up to full indemnity reserve valuation; and, it can only be effectuated through a formal settlement agreement.[206] The patient and/or family are advised to retain counsel for the purposes of reviewing the agreement and advising in a legal capacity.[207]

h. PEARL Outcome Measures

Upon completion of a PEARL matter, Stanford utilizes a 16-step review to determine whether the case resulted in an Overall Positive Outcome.[208] These measures include: Expenses Paid; Indemnity Paid; Case Reserves; Comparison of Paid v. Reserved; Pending Lawsuits; Case Open Time; Physician Well-Being; Patient Satisfaction/Distress; Physician Satisfaction/Distress; SUMIT Staff Satisfaction; Patient Forgiveness; Time of Report/Recognition; Corporate Morale/Culture; and, Resolution Method.[209]

VII. "DISCLOSURE, APOLOGY, OFFER" BECOMES LAW IN MASSACHUSETTS

On August 6, 2012, Massachusetts became the first state in the nation to enact a Healthcare Cost Control Bill, a comprehensive law projected to save the state $200 billion over the course of 15 years by controlling annual health increases and implementing several cost-effective provisions such as increasing transparency, implementing health information technology, and promoting wellness.[210] The most revolutionary aspect of the law is the provision making Massachusetts the first state in the nation to formally implement the Disclosure, Apology, Offer (DA&O) approach to help resolve medical malpractice cases.[211] Pursuant to the DA&O model, healthcare professionals, institutions, providers, and insurers are required to disclose to the patient or his survivor of an unanticipated adverse outcome; investigate and determine the cause of the occurrence; establish systems to improve patient safety and prevent the recurrence of such incidents; and, where appropriate, apologize and offer fair financial compensation without forcing the patient to file a formal legal action.[212] The legislation also institutes a six-month pre-litigation resolution "cooling-off" period, during which time the DA&O

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[205] *Id.*
[206] *Id.*
[207] *Id.*
[208] *Id.*
[209] *Id.*
[210] *Governor Patrick Signs 'Next Big Step Forward' on Health Care Reform, Massachusetts Poised to Lead the Nation on Cost Control*, available at http://www.mass.gov/governor/pressoffice/pressreleases/2012/2012806-governor-patrick-signs-health-care-reform.html (Aug.6, 2012)
[211] *Id.*
[212] *Mass. Embraces 'Disclosure, Apology, Offer' Approach for Med Mal Cases*, http://www.insurancejournal.com/news/east/2012/08/07/258509.htm?print (Aug. 7, 2012)

process is executed.[213] Within this timeframe, all pertinent medical records are shared; each providing entity fully discloses the care provided; and, any expression of remorse or apology by a provider is inadmissible in court. As the first state to formally endorse DA&O as a cost-effective method of malpractice resolution, Massachusetts will be a model state as it tests the program in various practice environments involving differing insurance processes.[214]

The legislation was the result of a "historic and unprecedented partnership" between the Massachusetts Medical Society; the Massachusetts Bar Association; and, the Massachusetts Academy of Trial Attorneys.[215] The alliance of these influential Massachusetts professional organizations echoed the sentiment of doctors who described the DA&O as "an improvement to the current tort system."[216] The previous "deny and defend" defense mounted by providers in response to a claim created a "culture of silence" in the medical community; impeded improvements in patient safety efforts, and, motivated physicians to practice defensive medicine which ultimately led to higher healthcare costs.[217]

Attorneys and Physicians both hail this legislation as an "extraordinary accomplishment."[218] It is expected to encourage greater transparency in the delivery of medical care, protect the rights of aggrieved patients and families, improve overall patient safety, reduce litigation, and ultimately lower healthcare costs and fees.[219] Attorneys agree that "fairness is the child of transparency," and that a transparent approach will bring immediate care to victims to ameliorate damage should an error have occurred.[220] While the inherent learning opportunities from prior errors are a valuable component to this law, the bill is lauded for its recognition by doctors and lawyers that disclosure of mistakes fosters healing for both the patient and the physician.

As the Healthcare Cost Control bill is fully implemented and its function tested, Massachusetts' medical liability system will be watched as the prototype for other states to follow. Already considered a trailblazer in the healthcare industry by virtue of its 2006 legislations which expanded coverage to 98% of residents and 99.8% of children, Massachusetts maintains its position as a progressive healthcare leader by embracing an alternative to expensive and protracted litigation.

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[213] *Id.*
[214] *Id.*
[215] *Id.*
[216] *Id.*
[217] *Id.*
[218] *Id.*
[219] *Id.*
[220] *Id.*

CONCLUSION

Critics of the full disclosure-early offer programs predicted "financial Armageddon"[221] for healthcare organizations and providers as perceived "deep pockets" admitted guilt and voluntarily opened their pocketbooks. They were wrong.

University of Michigan's Mr. Boothman aptly described the aftermath of preventable medical error, underscoring that the pre-suit interests of patients and providers involved in medical errors are "aligned: both sides seek honest answers to questions raised by the patient's adverse outcome."[222] Without a cooperative process in place, both sides are likely facing years of expensive litigation, drawn out to ultimately benefit only the attorneys. The healthcare organizations involved lose valuable opportunities to learn from the errors, and, to correct system failures. The patient endures the unavoidable sentence of continuously reliving the calamity through protracted litigation and cannot move forward. Without question, the vast expense and time spent in defending an indefensible error is a waste of critical hospital resources. On the flip side of the same coin, neither the patient nor his attorney wants to pursue an unmerited case, and, be responsible for the attendant legal fees for both sides in the event of a loss. Therefore, a well-managed full disclosure, early offer, and apology program supervised by experienced professionals providing guidance at each step of the process optimizes the interests of both sides, restores trust in the healthcare delivery system, and permits all aggrieved parties, patients and providers alike, to move forward with their personal and professional lives.

[221] Timothy McDonald, *et al*., *Responding to Patient Safety Incidents: The Seven Pillars*, at 12, available at http://onlinemj.luc.edu/documents/McDonaldDoc1.pdf (2009)
[222] Richard C. Boothman, *et al*., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, J. Health & Life Sci., Vol. 2, No. 2, 125-159 (2009).