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ABSTRACT

The medical and legal fields increasingly endorse transparency and disclosure as a better way to handle unexpected medical outcomes which result in harm to patients. Patients and doctors both say, at least in the abstract, that they want honest interactions. Yet, in the aftermath of a medical mistake, these conversations between doctors and patients rarely occur. The legal protections offered by apology and disclosure statutes are incomplete and do not offer adequate assurances to a physician who wants to be forthcoming with a patient about a medical error. Yet, incomplete disclosures may anger a patient and increase the risk of legal action. Despite these obstacles, disclosure programs do exist which demonstrate that it is possible to implement a process which reduces litigation and associated expenses, increases patient satisfaction, and encourages the transparency around systemic errors, and which allows for improved patient safety measures to be implemented. This paper proposes that a model for a disclosure program must provide adequate context and additional legal protections for physicians in order to accomplish the shared safety goals of patients, health care providers, and the general public.

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INTRODUCTION

The Institute of Medicine (IOM) ignited a firestorm of controversy in 1999 when it published a report that shocked the medical community. The IOM reported that medical errors are the eighth leading cause of mortality in the country, responsible for as many as 98,000 deaths per year.[1] The report found that the majority of these medical errors could be prevented by improved systems,[2] but unless doctors and hospitals acknowledged and disclosed these errors and near-misses, there would be no opportunity to implement safer systems and policies.[3] A national debate ensued about the proper response to this crisis in health care and patient safety.

Following the report, a new era of patient safety efforts was launched, and in 2001, the Joint Commission on Accreditation of Healthcare Organizations instituted a disclosure requirement[4]—this requirement was simply a statement that patients should be informed about all outcomes of care, including "unanticipated outcomes."[5] Although the disclosure requirement did not specify the level of detail of disclosure or require that patients be informed when a mistake had occurred, the professional ethos of secrecy around harmful errors began to shift. Over the next decade, it became increasingly difficult for health care providers to "delay, deny, and defend," which had been the traditional way of dealing with medical errors with the potential to lead to litigation.[6] Although the organized medical profession has acknowledged that providers have an ethical duty to disclose harmful errors, this ethical obligation is not legally enforceable and has been expressed in very general, even vague, ways.[7] Since the 2001 report,

1. INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1 (Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 2000) [hereinafter TO ERR IS HUMAN].

2. *Id.* at 6.

3. *See generally id.*

4. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, IMPROVING CARE IN THE ICU 19 (2004); JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK RI-13 (2007) (requiring that patients and, when appropriate, families are informed of all outcomes of care, treatment, and services under standard RI.2.90).

5. *Id.*

6. *See* ROSEMARY GIBSON & JANARDAN PRASAD SINGH, WALL OF SILENCE: THE UNTOLD STORY OF THE MEDICAL MISTAKES THAT KILL AND INJURE MILLIONS OF AMERICANS 9–10 (2003).

7. *See generally* Thomas H. Gallagher et al., *Disclosing Harmful Medical Errors to Patients*, 356 NEW ENG. J. MED. 2713 (2007) [hereinafter *Disclosing Harmful Medical Errors*].

efforts to increase patient safety have been increasingly directed at encouraging disclosure of errors and near-misses in order to understand why the errors occurred and to design safer systems to prevent the reoccurrence of errors.[8] Safety improvements depend on the ability to learn from errors and near-misses, which means they must first be acknowledged with specificity.[9]

In addition to allowing patient safety measures to be implemented in response to medical errors, disclosure has other tangible benefits to the injured patient. The information allows a patient "to obtain timely and appropriate treatment to correct problems" and to gather the "necessary information to make informed decisions."[10] The IOM report and its aftermath made clear that not only was there a crisis in patient safety but also that patients who were injured by medical mistakes were not being adequately informed, treated, or compensated.[11]

Although rates of medical error are high, only 2–3% of patients injured by medical mistakes file lawsuits, and of those, only half ever receive compensation.[12] When a patient does receive compensation, it is on average five years after the incident, often at a cost of well over $100,000, and patients typically receive only half of the eventual award—with the other half covering attorney's fees and costs.[13] Litigation in the health care arena is an inefficient and time-consuming process that leaves most patients who have experienced a poor outcome uncompensated.[14] Yet when patients are faced with health care providers who do not provide acknowledgement or explanations for unexpected medical outcomes, litigation is often the only path open to patients who are trying to get information about what happened to them.[15] There is an exorbitant

8. INSTITUTE OF MEDICINE, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 78–82 (2001).

9. *See generally* Richard C. Boothman et al., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, 2 J. HEALTH & LIFE SCI. L. 125 (2009).

10. Elaine O'Connor et al., *Disclosure of Patient Safety Incidents: A Comprehensive Review*, 22 INT'L J. FOR QUALITY HEALTH CARE 371, 373 (2010).

11. *See generally* TO ERR IS HUMAN, *supra* note 1.

12. Michelle M. Mello et al., *Who Pays for Medical Errors? An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives for Patient Safety Improvement*, 4 J. EMPIRICAL LEGAL STUD. 835, 838 (2007).

13. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2026–27 (2006).

14. *Id.* at 2026–27, 2031.

15. *See generally id.*

overhead associated with this information-gathering process. For every dollar in compensation, fifty-four cents goes to administrative expenses, lawyers, experts, and costs, and 37% of claims eventually turn out not to involve errors—which, of course, injured patients have no way of knowing until someone with the necessary information talks to them.[16]

The driving force behind doctors' unwillingness to communicate with patients about medical errors is presumably a concern about the confidentiality and legal discoverability of the information they convey. Doctors fear litigation and tend to overestimate the rate of medical malpractice claims brought in response to errors.[17] Despite the low per-incident rate of litigation, given the high frequency of medical errors, 75–99% of physicians are sued at some point in their careers.[18] Fear of liability has been cited as the primary barrier to the development of patient safety initiatives in hospitals.[19] Fear of litigation creates a culture of secrecy and mistrust, and lack of disclosure creates frustrated and angry patients who are more likely to engage in litigation.[20] The anticipation of a lawsuit creates a low tolerance for uncertainly about medical outcomes, resulting in the practice of defensive medicine and driving up the costs of health care for society in general.[21] The effect of the process of litigation on physicians is to encourage them not to acknowledge mistakes and to avoid talking to an injured patient at all.[22]

While the effects of medical errors can be devastating for patients and their families, the effects of lawsuits on physicians is devastating as well. Doctors are named individually in lawsuits under our current tort system and are affected emotionally, financially, and professionally.[23] Symptomatic reactions are common among physicians who have been sued

16. *Id.* at 2024.

17. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE, OTA-H-602 27 (1994).

18. Anupam B. Jena et al., *Malpractice Risk According to Physician Specialty*, 365 NEW ENG. J. MED. 629, 629 (2011).

19. Boothman et al., *supra* note 9, at 131.

20. *See* Anna C. Mastroianni et al., *The Flaws in State "Apology" and "Disclosure" Laws Dilute Their Intended Impact on Malpractice Suits*, 29 HEALTH AFFAIRS 1611, 1616 (2010).

21. *See, e.g.*, Boothman et al., *supra* note 9, at 151–56 (examining the costs of litigation from the plaintiff's and defendant's perspectives).

22. TO ERR IS HUMAN, *supra* note 1, at 43.

23. Thomas H. Gallagher et al., *Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors*, 289 J. AM. MED. ASS'N 1001, 1005–06 (2003) [hereinafter *Patients' and Physicians' Attitudes*].

for malpractice, with 97% experiencing physical or emotional reactions.[24] Doctors who have made an error experience diminished quality of life and higher burnout.[25] In addition, they may develop symptoms of depression and decreased empathy with patients.[26]

Taken together, these findings suggest a system that does not work well for either the patients, whose questions are not answered and whose injuries are usually not addressed, or the health care providers, who feel threatened and victimized by the litigation system. The current tort system of medical malpractice claims has proven to be inefficient, expensive, and contrary to the ultimate goal of better health care. The Joint Commission on the Accreditation of Healthcare Organizations noted in 2005 that there is a "fundamental dissonance between the medical liability system and the patient safety movement."[27]

While the health care system has traditionally discouraged disclosures, there is, nonetheless, a steady momentum toward programs that promote transparency and full disclosure of medical errors in the United States and in other western countries.[28] A system that encourages medical disclosure and transparency through a safe, supportive, and highly effective process that addresses both the needs of the patients and the needs of the physician can also serve the broader goals of increased patient safety. Concerns that increased transparency around medical errors might result in increased litigation have been argued vigorously,[29] but the data do not necessarily

24. Sara C. Charles, Charlene E. Pyskoty & Amy Nelson, *Physician on Trial—Self-Reported Reactions to Malpractice Trials*, 148 W. J. MED. 358, 358 (1988).

25. *See generally* Collin P. West et al., *Association of Perceived Medical Errors with Resident Distress and Empathy: A Prospective Longitudinal Study*, 296 J. AM. MED. ASS'N 1071 (2006).

26. *Id.* at 1071–72.

27. JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., HEALTHCARE AT A CROSSROADS: STRATEGIES FOR IMPROVING THE MEDICAL LIABILITY SYSTEM AND PREVENTING PATIENT INJURY 4 (2005).

28. *See, e.g.*, *Canadian Disclosure Guidelines: Being Open with Patients and Families*, CANADIAN PATIENT SAFETY INSTITUTE (2011), *available at* http://www.patientsafetyinstitute.ca/English/toolsResources/disclosure/Documents/CPSI%20Canadian%20Disclosure%20Guidelines.pdf; *Guidance on Open Disclosure Policies*, HEALTH AND DISABILITY COMMISSIONER (2009), *available at* http://www.hdc.org.nz/media/18328/guidance%20on%20open%20disclosure%20policies%20dec%2009.pdf; *Being Open: Communicating Patients Safety Incidents with Patients, Their Families and Careers*, NATIONAL PATIENT SAFETY AGENCY (2009), *available at* http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=65170&type=full&servicetype=Attachment.

29. *See generally* David M. Studdert et al., *Disclosure Of Medical Injury To Patients: An Improbable Risk Management Strategy*, 26 HEALTH AFFAIRS 215 (2007).

support this fear. Research suggests that a provider's lack of transparency may actually increase the likelihood that patients will seek legal retribution, especially when they have not received adequate answers to questions, they sense an absence of accountability, or they worry that the same mistake will recur in the future.[30] Thirty-seven percent of patients who sought legal action said that an explanation and apology would have influenced their decision to sue their doctor.[31] Another study found that 24% of patients filed suit only after discovering that the physician was not honest about what had happened or that the patient had been intentionally misled.[32] Even more to the point, programs that have implemented a disclosure policy and published their findings demonstrate that it is possible for such programs to operate without increasing liability claims and costs.[33]

Research shows that the three things patients want most in the face of medical error are: (1) information about what happened; (2) a sincere apology; and (3) the assurance that measures to prevent the error from happening to someone else have been implemented.[34] Notably absent from this list of patient's concerns is either the desire to punish health care providers or to collect large sums of money, although those factors certainly can become issues, especially if a patient becomes angry and frustrated with the process of unsuccessfully trying to get answers to questions.

Studies point to the importance of physician-patient communications and suggest that communication failures can result in lawsuits.[35] When professionals behave in an emotionally distant, brusque, or uninformative

30. Charles Vincent, Magi Young & Angela Phillips, *Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 LANCET 1609, 1609 (1994).

31. *Id.* at 1612 tbl.5.

32. Jennifer K. Robbennolt, *Apologies and Medical Error,* 467 CLINICAL ORTHOPAEDICS & REL. RES. 376, 377 (2009) (citing Gerald B. Hickson et al., *Patient Complaints and Malpractice Risk*, 287 J. AM. MED. ASS'N 2951 (2002)).

33. Allen Kachalia et al., *Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program*, 153 ANNALS INTERNAL MED. 213, 213 (2010); *see* Randolf Peto et al., *One System's Journey in Creating a Disclosure and Apology Program*, 35 JOINT COMM'N J. QUALITY & PATIENT SAFETY 487 (2009) (discussing the implementation of a disclosure policy in the Baystate Health integrated health care system).

34. *Patients' and Physicians' Attitudes*, *supra* note 23, at 1001, 1006; Lucian L. Leape, *Understanding the Power of Apology: How Saying "I'm Sorry" Helps Heal Patients and Caregivers*, 8 FOCUS ON PATIENT SAFETY 1 (Nat'l Patient Safety Found., North Adams, M.A.), 2005, at 1.

35. *See generally* John D. Banja, *Does Medical Error Disclosure Violate the Medical Malpractice Insurance Cooperation Clause?*, *in* 3 ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION 371, 377 (Kerm Henriksen et al. eds., 2005).

manner, that tone can be a primary factor in encouraging malpractice actions.[36] Persons harmed by error are more likely to consider litigation if deprived of the truth when they ask for it or if they feel the physician was not honest in addressing the incident.[37] Research has not indicated that patients are primarily motivated, at least initially, by the prospect of a large settlement, punishing the physician, or revenge.[38]

WHAT HAPPENS WHEN DOCTORS DISCLOSE?

Health care providers have begun to implement disclosure programs to inform patients about medical errors and unexpected outcomes. Early evidence suggests that disclosure and apologies may be effective both in decreasing the cost of civil actions[39] and in improving efforts to prevent medical errors from recurring.[40]

By 2005, sixty-nine percent of health care institutions had error disclosure policies.[41] Yet even where these reporting mandates are in place, there is generally no guidance for when and how the disclosure is to be achieved or what information is to be disclosed.[42] A handful of programs have implemented their own very high standards for transparency and disclosure.

Four landmark programs that have implemented disclosure policies are considered, briefly, here:

Lexington, Kentucky VA

In 1987, over a decade before the Institute of Medicine report, the Veterans Affairs Medical Center (VA) in Lexington, Kentucky

36. Gerald B. Hickson et al., *Patient Complaints And Malpractice Risk*, 287 J. AM. MED. ASS'N 2951, 2955 (2002).

37. Carol B. Liebman & Chris Stern Hyman, *A Mediation Skills Model To Manage Disclosure Of Errors And Adverse Events To Patients*, 23 HEALTH AFFAIRS 22, 23–24 (2004).

38. *But see id.*

39. Benjamin Ho & Elaine Liu, *What's An Apology Worth? Decomposing the Effect of Apologies on Medical Malpractice Payments Using State Apology Laws*, 8 J. EMPIRICAL LEGAL STUD. (ISSUE SUPPLEMENT S1) 179, 179 (2011).

40. Matthew Pillsbury, *Say Sorry and Save: A Practical Argument for a Greater Role for Apologies in Medical Malpractice Law*, 1 TRENDS & ISSUES SCI. EVIDENCE 171, 185 (2006).

41. *Disclosing Harmful Medical Errors*, *supra* note 7, at 2714.

42. *See* B.A. Liang, *A System of Medical Error Disclosure*, 11 QUALITY & SAFETY HEALTH CARE 64, 64–65 (2002).

implemented a radical new policy designed to reduce medical errors, consisting of "extreme honesty," which was directly contrary to the entrenched strategy of "deny and defend;" their policy was instead to disclose, apologize, and compensate.[43] They were spurred by having lost two malpractice claims totaling more than $1.5 million and wanted a more proactive approach to deal with medical errors.[44] Under the new policy, patients who experienced a harmful error were told about the error and informed about their rights to file a claim.[45] Researchers tracked the medical malpractice claims against the VA from 1990 to 1996 and compared them to other VA hospitals.[46] Results indicated that total payouts to settle or resolve claims were in the bottom 25% of hospitals, even though the number of claims was in the top 25%.[47] The authors concluded that an "honest and forthright risk management policy that puts the patient's interests first" saves money by avoiding "lawsuit preparation, litigation, court judgments, and settlements at trial."[48]

The COPIC Program

A Colorado medical malpractice insurance carrier (COPIC) adopted a disclosure program in conjunction with early offers of compensation, following three principles: (1) recognize unanticipated events; (2) respond soon after the event occurs; and (3) resolve any related issues.[49] While the program had strict criteria for the type of events that it encompassed, malpractice claims by physicians covered by COPIC dropped by 50% and settlement costs dropped 23%.[50]

43. Steve S. Kraman & Ginny Hamm, *Risk Management: Extreme Honesty May Be The Best Policy*, 131 ANNALS INTERNAL MED. 963, 964 (1999).

44. *Id.*

45. *Id.*

46. *Id.*

47. *Id.* at 965 fig.

48. *Id.* at 966.

49. Richert E. Quinn & Mary C. Eichler, *The 3Rs Program: The Colorado Experience*, 51 CLINICAL OBSTETRICS & GYNECOLOGY 709, 709 (2008).

50. Boothman et al., *supra* note 9, at 147–48.

Seven Pillars Program

The "Seven Pillars" disclosure program implemented at UIMMC in Chicago resulted in 106 disclosure conversations in the first two years and prompted almost 200 system improvements related to patient safety.[51]

University of Michigan Program

Perhaps the most successful disclosure-and-offer model is exemplified by the University of Michigan, where a program was instituted with three goals: (1) "[c]ompensate quickly and fairly when unreasonable medical care causes injury;" (2) "[d]efend medically reasonable care vigorously;" and (3) "[r]educe patient injuries (and therefore claims) by learning from patients' experiences."[52]

The experience at the University of Michigan Health System (UMHS) suggests that open and honest disclosure need not lead to increased litigation. Since the implementation of the transparency and disclosure program, the number of new claims fell over the course of seven years from 136 in 1999 to 61 in 2006, despite corresponding increases in clinical activity during this period.[53] In addition to the overall reduction in claims, claims were resolved more quickly with processing time dropping from an average of 20.3 months to 8 months and litigation costs being cut in half.[54] Physician satisfaction with the program was astoundingly high: 98% of the UMHS faculty physicians who responded to a survey perceived a difference to the approach to malpractice and 98% approved of the approach.[55] Fifty-five percent said that the approach influenced their decision to remain employed at the University of Michigan.[56]

Taken together, these programs demonstrate that a medical center can successfully implement a disclosure program without increasing malpractice costs. Disclosure programs may also alleviate some of the major shortcomings of our current liability system, such as the long delays for patient compensation and the high administrative costs of defending medical malpractice claims. Evidence also suggests that disclosure may

51. Timothy B. McDonald et al., *Responding to Patient Safety Incidents: The "Seven Pillars"*, 19 QUALITY & SAFETY HEALTH CARE e11 (2010).

52. Boothman et al., *supra* note 9, at 139.

53. *Id.* at 143.

54. *Id.* at 144.

55. *Id.* at 146.

56. *Id.*

help keep non-meritorious claims—claims where there was either no harm or no medical error—from becoming lawsuits, while meritorious claims may be settled earlier and for less money.[57] Institutional policies of openness, which result in increased patient safety efforts, may satisfy patients for whom litigation was formerly their only alternative for getting information and an understanding regarding their medical outcome.[58]

Since the IOM's 1999 report sparked the national conversation about patient safety, the importance of disclosure has become a frequent topic in the medical literature.[59] Even though the available data support that disclosure programs can successfully accomplish not only patient safety goals but also lower costs and improve patient satisfaction, progress has been "frustratingly slow," according to two of the authors of that initial report.[60] Given that disclosure is increasingly expected and desired by both patients and physicians and given the evidence that disclosure is effective in reducing lawsuits and costs, why are providers slow to change their responses to medical errors?

A number of barriers to disclosure have been identified.[61] Some physicians assert that patients would prefer not to know about an error because it diminishes their trust in physicians.[62] Some physicians are reluctant to disclose in cases in which they believe that the patient would not understand what the physician was telling them, and some physicians are not inclined to disclose adverse events if the patient would not know about the event without being told.[63] In addition, there are psychological reasons for non-disclosure.[64] Admission of guilt may damage a physician's confidence and self-esteem rendering them less effective, damaging reputations and perceived authority, and lessening potential for advancement.[65] And, of course, it is human nature to avoid difficult

57. *See id.* at 146, 151–56.

58. *See* Kachalia et al., *supra* note 33, at 213 (noting the decrease in the monthly rate of lawsuits within disclosure programs).

59. *See, e.g., id.*

60. Lucian L. Leape & Donald M. Berwick, *Five Years After* To Err Is Human*: What Have We Learned?*, 293 J. AM. MED. ASS'N 2384, 2385 (2005).

61. O'Connor et al., *supra* note 11, at 372 tbl.1; Rick Iedema et al., *What Prevents Incident Disclosure, and What Can Be Done To Promote It?*, 37 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 409, 410 tbl.1 (2011).

62. *Id.* at 410.

63. *Id.* at 412.

64. *Id.* at 410 tbl.1.

65. *Id.*

conversations.[66] The fear of increased insurance premiums and the potential loss of malpractice coverage are also real concerns.[67] Insurance companies have customarily included "cooperation" clauses requiring health care providers to cooperate with the insurer's efforts to defend against a legal claim, and these clauses typically include provisions prohibiting the insured from admitting fault to a patient.[68]

In 2007, Studdert and his colleagues published a study calling the disclosure strategy "improbable" and asserting that while the disclosure of medical errors might ethically be the "right" thing to do, in the long run, it would increase litigation volume and costs.[69] Because the vast majority of patients injured by medical error never sue and may not even know that an error occurred, there is a large pool of potential lawsuits which could be spurred by disclosure.[70] The authors of the Lexington study criticized Studdert for being "irresponsible" and for "promoting bad science,"[71] and in 2009, Richard Boothman published an analysis of the University of Michigan program, which concluded that not only is disclosure and transparency the ethical approach, but it also makes financial sense, resulting in decreased claims, shortening processing times, and reducing litigation costs—exactly the opposite of what Studdert feared would happen.[72] Other researchers have similarly concluded that both utilitarian arguments and duty-based frameworks provide support for the disclosure of adverse events.[73] Health care providers may not need to choose between the financially smart approach and the ethically responsible approach—they may be the same.

LEGAL PROTECTIONS FOR THE HEALTH CARE PROVIDER

Patients are more likely to feel the need to seek out an advocate when they cannot get adequate answers to questions, when they sense an absence

66. *Id.* at 410.

67. Boothman et al., *supra* note 9, at 128.

68. Banja, *supra* note 35, at 371.

69. Studdert et al., *supra* note 29, at 225.

70. *Id.* at 222–23.

71. Steve S. Kraman & Ginny Hamm, Letter To The Editor, *Bad Modeling?*, 26 HEALTH AFFAIRS 903, 903 (2007).

72. Boothman et al., *supra* note 9, at 143–46.

73. Denise M. Dudzinski et al., *The Disclosure Dilemma—Large-Scale Adverse Events*, 363 NEW ENG. J. MED. 978, 979 (2010).

of accountability, or when they worry that other patients might experience the same mistake.[74]

Despite the trend in the consciousness of the medical community that disclosure is the right approach, there is still reluctance on the part of providers to embrace full disclosure programs. Research shows that physicians are primarily concerned about the legal consequences of disclosing errors, including the discoverability and admissibility in court of their disclosures.[75] Physicians lack awareness about what legal protections are in place, are concerned that the protections are too weak, and believe that the laws have limited applicability.[76]

Apologies

Injured patients view apologies as an appropriate ethical response in the case of medical error.[77] Apologies can facilitate healing and provide closure. An apology can promote the early resolution of a dispute and result in significant savings in legal bills, as well as a reduced settlement amount for the physician or insurance provider.[78]

Patients want to hear apologies and explanations, and physicians claim to want to give them.[79] Although physicians report they are committed to being truthful with patients, fear of litigation limits what they tell patients about mistakes that have resulted in harm.[80] To encourage this desire for communication, thirty-four states and the District of Columbia have adopted "apology" laws and nine states have adopted "disclosure" laws to provide protection for those conversations.[81] Thirteen states have neither apology laws nor disclosure laws.[82]

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74. *See* Vincent, Young & Phillips, *supra* note 30, at 1612.

75. Jane Garbut et al., *Lost Opportunities: How Physicians Communicate About Medical Errors*, 27 HEALTH AFFAIRS 246, 252 (2008).

76. David M. Studdert, Donella Piper & Rick Iedema, *Legal Aspects of Open Disclosure II: Attitudes of Health Professionals—Findings from a National Survey*, 193 MED. J. AUSTL. 351, 353 (2010).

77. Kathleen M. Mazor et al., *Health Plan Members' Views about Disclosure of Medical Errors*, 140 ANNALS INTERNAL MED. 409, 416 (2004).

78. Benjamin Ho & Elaine Liu, *Does Sorry Work? The Impact of Apology Laws on Medical Malpractice* 3, 24 (Johnson Sch. of Mgmt., Working Paper No. 04-2011, 2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1744225.

79. *Patients' And Physicians' Attitudes*, *supra* note 23, at 1003.

80. *Id.* at 1006.

81. Mastroianni et al., *supra* note 20, at 1612.

82. *Id.*

In 2010, a survey of state apology and disclosure statutes found that, while they vary widely between states, these laws did not provide overall adequate protection for full disclosure.[83] An expression of regret is only one aspect of a comprehensive disclosure. Other important parts of disclosure are details about what happened, the possibility of remediation, and overall process and systems changes. Even when apology statutes apply, they will sometimes not apply to accompanying statements explaining the event or its causes.[84] These remain potentially discoverable and admissible in legal proceedings.[85]

Apology Statutes

Patients see apologies as a necessary part of the resolution process, but lawyers and insurance carriers have typically discouraged expressions of sympathy out of concern that these could be used in litigation.[86] Yet apologies rank in the top three things that patients want in the event of a harmful medical error.[87] Research is overwhelmingly favorable toward the use of apologies,[88] which can increase the likelihood that a settlement offer will be accepted and decrease the costs of litigation.[89] Even in the face of such evidence, health care providers may be hesitant to apologize for a medical error in the belief that an apology may be regarded as an admission of liability, thus making it more likely that a patient will sue. In fact, this concern is valid; at common law, an apology that admits fault is admissible to prove liability.[90] The Federal Rules of Evidence, adopted by most states, do allow overt admissions to be admissible in court to prove negligence, even if the apology itself is inadmissible.[91]

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83. *Id.* at 1613.

84. *Id.* ("These laws suggest that portions of a statement that explain or acknowledge responsibility—such as, "I'm sorry *I hurt you*," or, "I'm sorry *I made a mistake when I administered the wrong medication*"—could be used in litigation.").

85. *Id.*

86. *See* JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., *supra* note 27, at 27–28 ("Insurers, too, are increasingly urging apologies.").

87. *Patients' and Physicians' Attitudes*, *supra* note 23, at 1006.

88. *See, e.g.*, *id.*

89. Jennifer K. Robbennolt, *Apologies and Settlement Levers*, 3 J. EMPIRICAL LEGAL STUD. 333, 337 n.18 (2006).

90. *See generally* AM. COLL. LEGAL MED., MEDICAL MALPRACTICE SURVIVAL HANDBOOK (S. Sandy Sandbar et al. eds., 1st ed. 2007).

91. FED. R. EVID. 801(d)(2).

To address this concern, over two-thirds of states have enacted apology laws, which make all apologies inadmissible in civil actions.[92] Apology statutes differ by state but can generally be categorized by what type of communication is protected. Some states (e.g., Florida, Hawaii, Indiana, Louisiana, Maine, Maryland, Missouri, Nebraska, New Hampshire, South Dakota, Tennessee, Texas, Virginia, and Washington) specify that a statement of fault is "not inadmissible" as evidence—these states block only the admission of statements of sympathy and regret but not any acknowledgement of fault.[93] Under such a statute, "I'm sorry you got hurt" is protected, but "I'm sorry that I hurt you" is not, and "this is how you got hurt" is definitely not. However, patients are unlikely to consider "I'm sorry you got hurt" to be a full apology, and hearing an incomplete sentiment may do more to anger than to assuage the patient because explanations perceived as incomplete or evasive can create additional distress.[94]

The second type of apology statute protects the specific information related to the cause of the incident or fault, as well as the expression of regret.[95] For example, Colorado's law specifically applies to and protects statements of fault that are offered as part of an apology.[96]

The North Carolina apology statute is an example of an intermediate level of protection.[97] The statute offers protection for statements made by a health care provider apologizing for an adverse outcome and, additionally, applies to offers to provide corrective or remedial treatment, as well as gratuitous acts to help affected persons.[98] It does not, however, protect any admissions of fault or acknowledgement of responsibility. The statute reads as follows:

> Statements by a health care provider apologizing for an adverse outcome in medical treatment, offers to undertake corrective or remedial treatment or actions, and gratuitous acts to assist affected persons shall not be admissible to prove negligence or culpable conduct by the health care provider in an action brought under Article 1B of Chapter 90 of the General Statutes.[99]

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92. Mastroianni et al., *supra* note 20, at 1612.

93. *Id.* at 1612–13, 1619 n.39.

94. *Patients' and Physicians' Attitudes*, *supra* note 23, at 1005; *see generally* Leape, *supra* note 34.

95. Mastroianni et al., *supra* note 20, at 1613.

96. Boothman et al., *supra* note 9, at 132.

97. *See* N.C. GEN. STAT. § 8C-413 (2011).

98. *Id.*

99. *Id.*

Because the majority of states' apology laws only protect the expression of regret and do not cover any accompanying explanation or admission of fault,[100] apology laws by themselves provide incomplete protection for a physician to reasonably feel safe enough to engage in full disclosure of an error which results in harm.

Disclosure Laws

What about laws mandating disclosure? As of 2010, seven states passed mandatory disclosure laws, and two passed discretionary disclosure statutes.[101] The mandatory disclosure laws require health care facilities, but not individual providers, to notify patients of unanticipated outcomes of medical care.[102] One example of a mandatory disclosure law is New Jersey's "Patient Safety Act," which creates a legal duty to immediately disclose medical errors to patients who are harmed by them.[103] This mandated communication between health care providers and patients requires that when a patient is a victim of a "serious preventable adverse event[]"—defined as one that results in death, loss of a body part, disability, or loss of bodily function lasting more than seven days, or still present at the time of discharge—the medical providers have twenty-four hours after the discovery to notify the patient that a mistake has occurred or the provider is subject to a fine of $1,000 or $5,000.[104]

Out of the nine states with disclosure statutes, only six also provide legal protection regarding subsequent use of the statements during litigation.[105] Some studies have concluded that the disclosure laws have overall "structural weaknesses" that may actually discourage comprehensive disclosures and apologies and weaken the law's impact on malpractice suits; "[d]isclosure laws do not require, and most apology laws do not protect, the key information that patients want communicated to them following an unanticipated outcome."[106] Doctors tend to concur. In 2010, Studdert and Richardson published a survey of health professionals discussing the legal aspects of open disclosure in jurisdictions that have

100. Mastroianni et al., *supra* note 20, at 1612–13.

101. *Id.* at 1614.

102. *Id.*

103. N.J. STAT. ANN. §§ 26:2H-12.23 to -12.25 (2004).

104. *Id.* §§ 26:2H-12.25(a), (d); N.J. ADMIN. CODE §§ 8:43E-3.4(a)(15), 8:43E-10.7(b) (2013).

105. Mastroianni et al., *supra* note 20, at 1614.

106. *Id.*

apology laws and found that doctors perceive the current protections to be inadequate in the medical malpractice arena.[107]

Disclosure laws require only a minimum statement that an unanticipated outcome occurred, and the apology statutes mostly protect only an expression of sympathy.[108] These are minimal standards and not likely to meet patient expectations about disclosure and transparency. Where legal protections are unclear or inadequate, health care providers who are uncertain about their legal protections may engage in vague, general expressions of sympathy and very brief indications that an unexpected event occurred—without full explanations or disclosure. These laws may not adequately offer either patients or health care providers the opportunity for frank and open conversations that both claim to want. Worse, they may be encouraging, rather than discouraging, litigation.[109] If apology and disclosure statutes are inadequate to provide health care providers with the protection they need, what accounts for the fact that some disclosure programs appear to be successful in the eyes of both patients and physicians while others are not?

Patients typically say they want to know about all errors that occur, how and why the event occurred, and what is being done to prevent mistakes from recurring.[110] Yet when disclosure is done poorly or incompletely, the result is not what anyone wants—the patient is not satisfied and the health care provider may have put himself at increased risk of litigation.[111] Physicians also increasingly claim that, at least in principle, they want to be open with patients because it is the right thing to do.[112] Yet these conversations are still the exception and not the rule. Despite the success of disclosure programs at the University of Michigan, at the Lexington VA, at the University of Chicago, and at the COPIC program—all of which indicate that it is *possible* to develop a disclosure program which satisfies both patients and providers—it is not sufficient to merely mandate disclosure. Fear of litigation, discomfort with having the difficult conversation, insecurity about the most effective way to disclose,

107. David M. Studdert & Mark W. Richardson, *Legal Aspects of Open Disclosure: A Review of Australian Law*, 193 MED. J. AUSTL. 273, 275 (2010).

108. Mastroianni et al., *supra* note 20, at 1615.

109. *Id.* at 1616.

110. *Patients' and Physicians' Attitudes*, *supra* note 23, at 1001.

111. *See* Lola Butcher, *Lawyers Say "Sorry" May Sink You in Court*, 32 PHYSICIAN EXECUTIVE 20, 22–23 (2006).

112. *Patients' and Physicians' Attitudes*, *supra* note 23, at 1003.

and fear of embarrassment that patients will not respond well all remain obstacles.[113]

Abroad, Australia has implemented a national Open Disclosure Standard, which has been in place since 2003.[114] All states within Australia have apology statutes to protect health care providers.[115] Yet surveys of physicians indicate continuing uncertainty and lack of awareness about the legal protections in place,[116] and surveys of patients indicate that the disclosure process frequently does not meet their needs.[117] Surveys of patients find that:

> [M]ost patients and family members felt that the health service incident disclosure rarely met their needs and expectations. They expected better preparation for incident disclosure, more shared dialogue about what went wrong, more follow-up support, input into when the time was ripe for closure, and more information about subsequent improvement in process.[118]

A procedure that consists of informing a patient that an error occurred, without any accompanying support or follow-up, may meet the minimal disclosure requirements of the statute but is not an adequate disclosure program.

In 2007, Gallagher speculated that within a decade, "full and frank disclosure" of medical errors would be the norm.[119] The article acknowledged the need for provider education about legal protections and hypothesized that organizations would do one of two things: either provide disclosure training and coaches to support health care providers when a disclosure was warranted or, in contrast, avoid the risks of conducting poor disclosures altogether by removing the clinical provider from the equation and using surrogates, like risk managers, to interact with patients.[120] The problem with this latter model is that it does not address the needs of the

113. *See Disclosing Harmful Medical Errors*, *supra* note 7, at 2713, 2716.

114. *Id.* at 2714.

115. Studdert, Piper & Iedema, *supra* note 76, 352.

116. *Id.* at 352–54.

117. Rick Iedema et al., *Patients' and Family Members' Experiences of Open Disclosure Following Adverse Events*, 20 INT'L J. FOR QUALITY HEALTH CARE 421, 430 (2008).

118. Rick Iedema et al., *Patients' and Family Members' Views on How Clinicians Enact and How They Should Enact Incident Disclosure: The "100 Patient Stories" Qualitative Study* 1 (BMJ, Paper No. 343:d4423, 2011), *available at* http://www.bmj.com/highwire/filestream/388298/field_highwire_article_pdf/0/bmj.d4423.

119. *Disclosing Harmful Medical Errors*, *supra* note 7, at 2718.

120. *Id.* at 2717.

physician to gain closure over an incident, and it does nothing to heal the relationship between the physician and the injured patient.

What kind of context makes the difference between a successful and a problematic disclosure? One type of program that is designed to more fully meet the needs of both patients is the collaborative law model. For the patients, it provides complete disclosure, apology, and the opportunity to ask questions, emotional support, and legal representation; for physicians, it provides legal protections against liability, a context for initiating a difficult conversation, and emotional support for putting the physician's professional reputation at risk. The model includes lawyers and mental health coaches for patients and health care providers, as well as mediators, for a collaborative conference where all the parties meet to share information and ask questions.[121]

THE COLLABORATIVE LAW MODEL

Collaborative law is a structured, voluntary, cooperative dispute resolution process which involves a series of meetings with parties and attorneys to work toward a resolution uniquely tailored to the facts of the individual case and not limited by legal remedies.[122] Collaborative law has primarily been used in the context of family law, in which it has been judged to be highly effective.[123] Research shows that "[p]arties to a problem-solving approach are . . . more likely to be satisfied with the outcome because of their involvement in fashioning it."[124] A problem-solving process such as collaborative law can often effectively be used in difficult cases in which there is a relationship to be preserved or transformed. Research conducted by the International Academy of Collaborative Professionals from October 16, 2006 through August 24, 2009 showed that 86% of 793 reported collaborative law cases settled with an agreement on all issues; an additional 3% of cases reconciled.[125] As of

121. *See generally* Kathleen Clark, *The Use of Collaborative Law in Medical Error Situations*, THE HEALTH LAWYER, June 2007, at 19.

122. *Id.* at 19.

123. J. Herbie DiFonzo, *A Vision for Collaborative Practice: The Final Report of the Hofstra Collaborative Law Conference*, 38 HOFSTRA L. REV. 569, 571, 600 (2009) (recognizing the origins of collaborative law practice in the context of family law and its expansion into other areas of civil law).

124. Linda K. Wray, *Collaborative Practice: Lawyer as Negotiator and Problem-Solver*, FAM. L. F., (Minn. State Bar Ass'n, Minneapolis, Minn.) Spring/Summer 2011, at 19, 22.

125. *Id.*

May 19, 2010, there have been no ethical complaints or lawsuits filed against collaborative attorneys.[126]

The application of the principles of collaborative law to health care disputes has the potential to be tremendously advantageous to patients who might otherwise go unrepresented, uncompensated, and uninformed about what happened to them. It provides emotional and legal support to both patients and physicians in the form of coaches and collaborative law attorneys, as well as a supportive context in which to have a potentially difficult conversation.[127] In addition, the collaborative law approach provides a context in which a number of additional legal protections are put in place for the health care provider.

Under the IACT program,[128] North Carolina's only collaborative law program for health care disputes, the legal protections for the health care providers can be identified as follows: the participation agreement's confidentiality clause; the agreement of all parties not to be involved in future proceedings; the stipulation that parties mutually and voluntarily agree to be governed by certain applicable statutes; the health care settlement agreement; the North Carolina statute applicable to mediation negotiations; rules of evidence which exclude compromise and offers to compromise; and the collaborative law statute.[129]

The Collaborative Law Statute

North Carolina is one of four states to adopt a statute that applies to communications that occur during collaborative law conferences.[130] The statute applies to cases of separation and divorce and does not specifically apply to health care disputes.[131] However, by signing a participation agreement, the parties in a health care collaborative conference mutually agree to be governed by the collaborative law statute.[132] The statute states, in part:

126. *Id.* at 32.

127. *Id.* at 25.

128. JESSICA SCOTT, IACT PROGRAM: A MEDICAL DISCLOSURE AND TRANSPARENCY PROGRAM 3–4 (2011), *available at* http://www.iactprogram.com/wp-content/uploads/2011/08/Copyrighted-IACT-White-Paper5.pdf.

129. *See generally id.*

130. Rachel M. Zahorsky, *ABA Rejects Proposed Measure for Collaborative Law Guidelines*, A.B.A. J. (Aug. 9, 2011, 1:28 PM), http://www.abajournal.com/news/article/the_aba_house_of_delegates_rejected_resolution_110b/.

131. *See* N.C. GEN. STAT. § 50-77 (2011) (arising in the section concerning divorce, alimony, and child support).

132. *Id.*

> All statements, communications, and work product made or arising from a collaborative law procedure are confidential and are inadmissible in any court proceeding.... All communications and work product of any attorney or third-party expert hired for purposes of participating in a collaborative law procedure shall be privileged and inadmissible in any court proceeding, except by agreement of the parties.[133]

Collaborative law requires the parties and their attorneys to sign a participation agreement, which is a prerequisite to participation in the process and provides for confidentiality among all parties. One clause of the IACT Program's Participation Agreement reads as follows:

> Participants agree to... [f]ull, open and honest disclosure, and in exchange, agree that all statements, communications, and work product during the Collaborative Law Process, whether made by Participants, neutral experts, and IACT Program administrators, are to be kept confidential and used only to facilitate resolution during this Process.[134]

A collaborative lawyer agrees to withdraw from representation of a client if the client commences litigation on the matter or if a client refuses to comply with the disclosure requirements.[135] Barring the lawyers from pursuing litigation ensures that parties adhere to interest-based negotiations rather than positional bargaining. Because the litigation pathway is not available to them, lawyers are encouraged to act more collaboratively and work cooperatively to help both parties obtain a satisfactory settlement and some measure of closure. Clients are advised that, in the event that either party pursues litigation, the attorneys for both parties are disqualified.[136] Because clients must retain new counsel if they decide to pursue litigation, the new attorney is not aware of any disclosure that occurred during the collaborative process, and the confidentiality of the process precludes him from finding out what was discussed.

Another provision of the IACT program's participation agreement states that all non-party participants together with their work product are prohibited from involvement in future proceedings.[137] This provision allows information, including the opinion of a neutral medical expert, to be shared freely during the collaborative discussions without the fear that the information gained will then be used as the basis for litigation.

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133. *Id.*

134. IACT Program Collaborative Process Participation Agreement 1 (on file with author).

135. DiFonzo, *supra* note 123, at 579.

136. *Id.*

137. IACT Program Collaborative Process Participation Agreement 2 (on file with author).

In addition to the adoption of the collaborative law statute, the participation agreement signed by the parties contains a clause through which the parties agree to be governed by certain additional statutes, one of these being the mediation negotiation statute.[138] The privilege accorded to conversations that happen during mediations is relatively new. An increasing number of states have adopted the Uniform Mediation Act,[139] and all states have enacted statutes or rules to protect communications made during mediation from disclosure in legal proceedings.[140] Confidentiality is necessary to the success of mediation because, otherwise, parties would be hesitant to speak freely if statements could be used against them in trial. The mediation privilege encourages open discussions. In addition, the mediator is protected from being subpoenaed, which protects the mediator's neutrality.[141]

Under the North Carolina statute, statements made during mediation are not subject to discovery and are not admissible in any proceeding in the action.[142] In addition, the mediator may not be compelled to testify regarding statements made during the mediation.[143]

While a collaborative conference is not a mediation *per se*, if a mediator presides over the conference, the process falls under the umbrella of mediation.[144] Under the North Carolina statutes, mediation is defined as "an informal process conducted by a mediator with the objective of helping parties voluntarily settle their dispute."[145]

North Carolina's Rule of Evidence 408 is virtually identical to Rule 408 in the Federal Rules of Evidence, which every state has adopted.[146] It provides that if, during a settlement negotiation, a party either makes an offer to compromise or accepts a compromise, the offer cannot be later used in court as evidence to prove negligence.[147] The adoption of Rule 408

138. N.C. GEN. STAT. § 8-110 (2011).

139. Matt Brown, *Legislation: Where the Uniform Mediation Act Stands in the States (Web)*, INT'L INST. FOR CONFLICT PREVENTION & RESOL., http://www.cpradr.org/Resources/ALLCPRArticles/tabid/265/ID/239/Legislation-Where-the-Uniform-Mediation-Act-Stands-in-the-States-Web.aspx (last visited Sept. 30, 2013).

140. Jay M. Zitter, Annotation, *Construction and Application of State Mediation Privilege*, 32 A.L.R.6TH 285, 301 (2008).

141. *Id.*

142. N.C. GEN. STAT. § 8-110(a).

143. *Id.* § 8-110(b).

144. N.C. GEN. STAT. § 115C-106.3(12).

145. *Id.*

146. *Compare id.* § 8C-408 *with* FED. R. EVID. 408.

147. N.C. GEN. STAT. § 8C-408.

changed the North Carolina practice that allowed a "distinct admission of an independent fact" made during compromise negotiations to be offered as evidence.[148] However, the rule is clear that just because a statement is made during settlement discussions does not disqualify the information itself from being used in a subsequent lawsuit if that information was "otherwise discoverable."[149] In addition, the information may be used for a purpose other than to show liability, such as to show bias or prejudice.[150] This limitation on confidentiality must be carefully explained to clients by their attorneys—just because information arises in a protected setting does not preclude it from being pursued in another legal setting.

Finally, at the end of the collaborative conference, parties sign a health care settlement agreement which is a mutual release as to all claims relating to the matter at issue in the collaborative conference(s).[151] Once the parties have created an acceptable settlement, the matter is resolved, and the option to pursue litigation is waived.[152]

CONCLUSION

A culture change is underway. Transparency and disclosure programs are increasingly a part of the medical landscape, and the early results of those programs tell us that the context of the conversations is critical to their success or failure. Patients increasingly report that they want and expect to be told about mistakes. This includes receiving both a disclosure and an apology when an adverse event occurs. An effective disclosure program such as a collaborative law program has mechanisms for providing information, acknowledgement, apology, and appropriate compensation. The additional legal protections that can be incorporated into a collaborative law program make it possible to change the focus of how we address medical errors by removing the punitive aspect of a lawsuit and replacing it with a sense of shared responsibility for improving patient outcomes. Because doctors and patients both need support after a medical error has occurred, and because hospitals desire safer processes, everyone benefits from a paradigm shift in which openness, compassion, and transparency are the ultimate focus.

148. Dean P. Loven, Walker J. Blakey, & Glen Weissenberger, NORTH CAROLINA EVIDENCE: 2012 COURTROOM MANUAL, ch. no. 408 (Matthew Bender & Co. 2012).

149. N.C. GEN. STAT. § 8C-408.

150. *Id.*

151. IACT Program Collaborative Process Participation Agreement 1 (on file with author).

152. *Id.*