Why Medical Error is Killing You (And Everyone Else)

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ABSTRACT

In 2000, the infamous report To Err is Human *rocked society with its focus on the pervasive danger of medical error. More than two decades later, medical error rates remain high and pose a consistent danger to patients. Today, medical error ranks as the fourth leading cause of death behind heart disease, cancer, and COVID-19. Medical error reflects the vulnerabilities of the healthcare process and may be diagnostic in nature. A large concern in responding to medical error is an overemphasis on blame and the idea that good physicians do not make mistakes. Our perspective on how to address medical error is flawed. The successful reduction of error will require rethinking how we respond to error and creating a culture of openness and transparency. Changing how we address error benefits all patients but is particularly important for racial and ethnic minorities, women, and the LGBTQ+ population, whose healthcare needs have historically been overlooked.*

This Article reviews what we know about medical error and the disproportionate effects of harm it can cause. I consider issues leading to the persistence of medical error and emphasize the need to improve patient safety, address harm to vulnerable communities, and decrease medical malpractice litigation. Successfully addressing error requires a multi-pronged approach that embraces different disciplines. First, the healthcare industry should emphasize restorative justice strategies and institute legal safeguards, such as increased protections for apologies and information disclosure from healthcare institutions. Second, communication theory and high reliability organizations offer model methodologies to both address and prevent harm from medical error. Third, error response should shift away from a culture of blame and instead emphasize developing a Just Culture that encourages the acceptance of responsibility under collective accountability. Finally, the healthcare field should work to be more patient focused, with patients at the center of care and decision-making. Medical error presents a real and deep concern for patients and their families. Reducing the widespread effects of medical error will require a multidisciplinary approach extending to fields far beyond medicine, and even the law, to see real change.

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Introduction

   This Article focuses on the dangers of medical error, the risks it poses to vulnerable communities, and why it is killing you and everyone else. This piece explores patient safety and the persistence of medical error and offers a critique of the adversarial nature of our medical malpractice system while emphasizing the need to reimagine our conversations and response to medical error. In changing the culture of how we talk about

error and how we address it, we can create safer systems overall for patients.

This Article also advocates for a culture shift and highlights the need to move away from blame as the primary response to medical error. Without sufficient legal protections in place, healthcare professionals are unlikely to do this on their own. The expansion of legal protections such as apology laws and use of restorative justice techniques can help change how we perceive and address error. Healthcare professionals are often reluctant to disclose an error out of fear, embarrassment, and the threat of medical malpractice litigation.

But research shows that in the aftermath of a medical error, patients want to know what happened.[1] Patients also want an apology for the harm they experienced.[2] To an extent, apology laws protect healthcare providers' apologies and expressions of sympathy to the patient from being used against them in court.[3] While some apology laws are more limited in their protection (in terms of the level of disclosure by medical professionals after an error occurs),[4] the apology itself still holds particular significance to harmed patients.[5] However, apology laws must be more expansive. Apology laws should encompass protection for the disclosure of the error, an explanation as to why the error occurred, how the error's effects will be minimized, and steps the healthcare institution will take to prevent recurrence.

Another avenue for addressing harm is restorative justice, which provides a space for harmed patients to air their grievances, discuss resources they need to recover, and communicate with those

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1.   *See* John Hicks & Courtney McCray, *When and Where to Say "I'm Sorry,"* CLAIMS LITIG. MGMT. MAG. (Feb. 16, 2021), https://www.theclm.org/Magazine/articles/apology-laws-medical-malpractice /2172 [https://perma.cc/TX7T-V4ES]; *see also* Bruce L. Lambert, Nichola M. Centomani, Kelly M. Smith, Lorens A. Helmchen, Dulal K. Bhaumik, Yash J. Jalundhwala, & Timothy B. McDonald, *The "Seven Pillars" Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes*, 51 HEALTH SERVS. RSCH. 2491 (2016); Michelle M. Mello, Richard C Boothman, Timothy McDonald, Jeffrey Driver, Alan Lembitz, Darren Bouwmeester, Benjamin Dunlap, & Thomas Gallagher, *Communication-and-Resolution Programs: The Challenges and Lessons Learned From Six Early Adopters*, 33 HEALTH AFFS. 20 (2014); David M. Studdert, Michelle M. Mello, Atul A. Gawande, Troyen A. Brennan, & Y Claire Wang, *Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 HEALTH AFFS. 215 (2007); Phoebe Jean-Pierre, *Medical Error and Vulnerable Communities*, 102 B.U. L. REV. 327 (2022).

2.   *See* Lorens A. Helmchen, Michael R. Richards, & Timothy B. McDonald, *Successful Remediation of Patient Safety Incidents: A Tale of Two Medication Errors*, 36 HEALTH CARE MGMT. REV. 114, 114–15 (2011) (discussing rise of patient safety culture); Daniel Rocke & Walter T Lee, *Medical Errors: Teachable Moments in Doing the Right Thing*, 5 J. GRADUATE MED. EDUC. 550, 550–52 (2013).

3.   *Id.*

4.   Hicks & McCray, *supra* note 1 (explaining function of apology laws).

5.   *See* Helmchen et al., *supra* note 2; *see also* Rocke & Lee, *supra* note 2.

responsible.[6] Patients' harm often stems from common types of medical errors such as adverse drug events, burns, equipment failures, misdiagnosis, mistaken identities, wrong site surgeries, and surgical injuries.[7] When a medical error occurs, it can cause physical, emotional,[8] mental, or psychological harm.[9] Patients, their families, and healthcare professionals need space to process the error's impact. Creating opportunities for open conversations in the aftermath of an error leads to safer systems for all patients[10] and allows healthcare institutions to introduce safeguards to identify error and prevent reoccurrence. Such opportunities are beneficial for vulnerable populations who have historically been overlooked in their medical care.[11]

Medicine should also look to other fields to learn how to both respond to harm and prevent it. Extensive research exists within the field of communication studies around the power of apology, the importance of openness and transparency, and how to communicate in the aftermath of a medical error.[12] Despite this large body of literature, medical malpractice litigation persists—and these suits depend on an adversarial system,[13] one that often fails to address the actual harm suffered by patients.

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6.   *See Restorative Justice*, CAN. DEP'T OF JUST., (Dec. 10, 2021), https://www.justice.gc.ca/eng/cj-jp/rj-jr/index.html [https://perma.cc/BBE2-HHT4]; *About Restorative Justice*, U. WIS. MADISON L. SCH., https://law.wisc.edu/fjr/rjp/justice.html [https://perma.cc/M4NV-Q2RM] (last visited Sep. 15, 2023).

7.   *See* Kevin A. Schulman, et al., *The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization*, 340 NEW. ENG. J. OF MED. 618 (1999).

8.   *See* MILOS JENICEK, MEDICAL ERROR AND HARM: UNDERSTANDING, PREVENTION, AND CONTROL (CRC Press 2011); *Open Communication Can Help Patients and Families Who Experience Harm*, BETSY LEHMAN CTR. FOR PATIENT SAFETY (June 20, 2019), https://betsylehmancenterma.gov/news/open-communication-can-help-patients-and-families-who-experience-harm [https://perma.cc/69G2-TZF8]; Andrew A. White & Thomas H. Gallagher, *Medical Error and Disclosure, in* 118 HANDBOOK OF CLINICAL NEUROLOGY 107, 115 (L. Bernat James & H. Richard Beresford eds., 2013).

9.   *See* JENICEK, *supra* note 8.

10.   *See* BETSY LEHMAN CTR. FOR PATIENT SAFETY, THE FINANCIAL AND HUMAN COST OF MEDICAL ERROR . . . AND HOW MASSACHUSETTS CAN LEAD THE WAY ON PATIENT SAFETY 15 (2019), https://psnet.ahrq.gov/issue/financial-and-human-cost-medical-error-and-how-massachusetts-can-lead-way-patient-safety [https://perma.cc/BZ7V-HTEX].

11.   *See* David B. Waisel. *Vulnerable Populations in Healthcare*, 26 CURRENT OP. ANESTHESIOLOGY 186, 186–92 (2013).

12.   *See, e.g.,* Anashua Rani Elwy, Barbara G. Bokhour, Elizabeth M. Maguire, Todd H. Wagner, Steven M. Asch, Allen L. Gifford, Thomas H. Gallagher, Janet M. Durfee, Richard A. Martinello, Susan Schiffner, & Robert L. Jesse, *Improving Healthcare Systems' Disclosures of Large-Scale Adverse Events: A Department of Veterans Affairs Leadership, Policymaker, Research and Stakeholder Partnership*, 29 J. GEN. INT. MED. 895 (2014); Thomas. H. Gallagher, Sigall K. Bell, Kelly M. Smith, Michelle M. Mello, & Timothy B. McDonald, *Disclosing Harmful Medical Errors to Patients: Tackling Three Tough Cases*, 136 CHEST 897 (2009); Bruce L. Lambert et al., *supra* note 1; Bryan S. Lee & Thomas H. Gallagher, *Saying "I'm Sorry": Error Disclosure for Ophthalmologists*, 158 AM. J. OPHTHALMOLOGY 1108 (2014); Lauren E. Lipira & Thomas H. Gallagher, *Disclosure of Adverse Events and Errors in Surgical Care: Challenges and Strategies for Improvement*, 38 WORLD J. OF SURGERY 1614 (2014); Mello, et al., *supra* note 1.

13.   *See* Rocke & Lee, *supra* note 2; *see also* Jennifer K. Robbennolt, *Apologies and Legal Settlement: An Empirical Examination*, 102 MICH. L. REV 460 (2003).

High reliability organizations (HROs) provide another alternative to medical malpractice and provide a better model to protect patients and create safer systems.[14] HROs refer to industries, like the aviation or nuclear power industries, that function under complex and high-hazard conditions for extended periods of time without serious accidents or catastrophic failures.[15] As medicine also faces high pressure and the potential for catastrophe,[16] HROs could present a model for healthcare to navigate environments with complex operations and high risk for catastrophic consequences.[17]

How we respond to medical error is critical; unfortunately, our healthcare system has fallen short. Traditional responses of error focus on blame and punitive measures to protect healthcare institutions and reduce liability. Instead, the healthcare industry should consider collective accountability and the development of a Just Culture.[18] Collective accountability considers who is responsible and what they are responsible for when things go wrong.[19] Collective accountability introduces the idea of shared responsibility within the healthcare institution, rather than individual fault. Taking this approach may help shift the response of healthcare organizations to harm.[20] Collective accountability requires taking responsibility and emphasizes transparency, prevention of the same error or harm from reoccurring, and appropriate patient compensation.[21] Just Culture builds on the goals of collective accountability by focusing on creating an environment where workers feel safe and accountable to engage in error prevention by identifying error and speaking up.[22]

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14.   Vattipalli Sameera, Ashish Bindra, & Girija P. Rath, *Human Errors and their Prevention in Healthcare*, 37 J. ANAESTHESIOLOGY, CLINICAL PHARMACOLOGY 328 (2021).

15.   *High Reliability*, PATIENT SAFETY NETWORK (Sep. 7, 2019), https://psnet.ahrq.gov/primer/high-reliability [https://perma.cc/PZ6T-LDJ8].

16.   *See id.*; *see also* Sameera et al., *supra* note 14.

17.   Sameera et al., *supra* note 14.

18.   *See generally What Is Just Culture? Changing the Way We Think About Errors to Improve Patient Safety and Satisfaction*, MASS. GEN. BRIGHAM (2022), https://www.brighamandwomensfaulkner.org/about-bwfh/news/what-is-just-culture-changing-the-way-we-think-about-errors-to-improve-patient-safety-and-staff-satisfaction [https://perma.cc/WF7T-WZRT].

19.   *See generally* Sigall K. Bell, Tom Delbanco, Lisa Anderson-Shaw, Timothy B. McDonald, & Thomas H. Gallagher, *Accountability for Medical Error: Moving Beyond Blame to Advocacy*, 140 CHEST 519 (2011).

20.   *See id.*

21.   *Id.* at 520.

22.   BRIGHAM *supra* note 18; *see generally* Terry L. vonThaden, Michelle Hoppes, Yongjuan Li, & Nick Johnson, *The Perception of Just Culture Across Disciplines in Healthcare*, 50 PROCEEDINGS OF THE HUM. FACTORS AND ERGONOMICS SOC'Y ANN. MEETING 964 (2006) (explaining that a Just Culture allows members of an organization to openly discuss errors without fear of or reprisals).

Finally, although patients may not be medical experts or have the same level of expertise as a doctor, they must be at the center of their care and the decision-making process.[23] Placing patients, their needs, and their concerns at the center of the healthcare process emphasizes the importance of these individuals. Medical error is not just about liability or protecting the hospital's reputation: it is also about patient safety and the protection of patients and their families.

Part I of this Article introduces the concept of patient safety and the historical response to patient harm. It establishes definitions of patient safety and emphasizes the importance of focusing on harm reduction in lieu of simply reducing error. It also bridges the gap between patient safety and equitable care. Not only should all patients be safe in the healthcare system, but they should all receive the same standard of care.[24]

Part II explores the scope of the problem surrounding medical error. A major problem in addressing medical error is the lack of response in the aftermath of an error. Traditionally, medical institutions either stonewall or lay blame on an individual.[25] Each of these approaches are ineffective as we lose opportunities to learn what went wrong, prevent the same error from reoccurring, and improve the system.[26] Part II also explores definitions of medical error, as scholars and practitioners frequently debate what constitutes an error. Additionally, it highlights the varying harms that error causes. In establishing this harm, this Article highlights the distinct danger that diagnostic error poses to racial and ethnic minorities and women. It also exposes our lack of understanding of how medical error affects health within the LGBTQ+ community.

Part III explores the relationship between medical error and blame. In the aftermath of an error, it is natural to seek someone to blame.[27] Error often occurs due to a series of systemic and human breakdowns; this is particularly true for diagnostic error.[28] A culture of blame prevents

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23.   *See* Gordon D. Schiff, et al., *Diagnosing Diagnosis Errors: Lessons From a Multi-institutional Collaborative Project, in* 2 Advances in Patient Safety: From Research to Implementation 255, 275 (Kerm Henriksen et al., eds., 2005).

24.   *See* Rosanna M. Coffey, Roxanne M. Andrews, & Ernest Moy, *Racial, Ethnic, and Socioeconomic Disparities in Estimates of AHRQ Patient Safety Indicators*, 43 Med. Care 148, 148 (2005).

25.   *See, e.g.,* Ann Hendrich, Christine Kocot McCoy, Jane Gale, Lora Sparkman, & Palmira Santos, *Ascension Health's Demonstration of Full Disclosure Protocol for Unexpected Events During Labor and Delivery Shows Promise*, 33 Health Affs. 39, 42 (2014); *see also* Mello et al., *supra* note 1, at 24 (noting physician fear of increased liability from disclosures and settlement offers).

26.   Andrew A. White & Thomas H. Gallagher, *Medical Error and Disclosure, in* Handbook of Clinical Neurology 107, 114 (L. Bernat James & H. Richard Beresford eds., 2013).

27.   *See generally* Bertram F Malle, Steve Guglielmo, & Andrew E. Monroe, *Moral, Cognitive, and Social: The Nature of Blame, in* Soc. Thinking & Interpersonal Behav. 313 (2012).

28.   *See* Jenicek, *supra* note 8, at 173 (asserting that medical decision making is detailed, complex, and not suited to easily ascribe blame); *see also* White & Gallagher, *supra* note 26, at 108

healthcare institutions from being honest, discussing the error, and reflecting on what went wrong.[29] Defensiveness and stonewalling in response to medical error pose a danger to patient safety and are a missed opportunity to respond to the error and prevent its recurrence in the future.[30] Patients and their families are often left without an understanding as to the harm that occurred and what went wrong.[31]

This Article concludes with a series of proposed solutions. It emphasizes the need to use a multipronged and interdisciplinary approach to address medical error. Part IV explores possible legal solutions (increasing the adoption and use of apology laws and restorative justice), interdisciplinary solutions (communication theory and high reliability organizations), culture development (collective accountability and Just Culture), and placing of patients at the center of care.

I. CHALLENGES TO PATIENT SAFETY

"Understanding how to make healthcare safer is hard and actually making care safer is harder still."[32]

Patient safety focuses on prevention: preventing medical error before it results in death, harm, or injury.[33] The relationship between patient safety and medical error has shifted over time. Unfortunately, key barriers continue to exist in the study of medical error and contribute to the difficulties in assessing and effectively curbing medical error.[34] Reducing medical error is critical to improving patient safety. Progress toward increasing patient safety requires determining what a medical error encompasses, assessing human involvement, evaluating overlooked

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(noting that most errors are not attributable to individual failures but to "a combination of individual and systems failures").

29.   *See* Nancy J. Crigger, *Always Having to Say You're Sorry: An Ethical Response to Making Mistakes in Professional Practice*, 11 NURSING ETHICS 568, 572 (2004) (discussing negative effects that blaming an individual for an error can have on healthcare professionals); White & Gallagher, *supra* note 26, at 115 (discussing emotional impact of errors on clinicians).

30.   *See* Crigger, *supra* note 29, at 572.

31.   *See* White & Gallagher, *supra* note 26, at 117.

32.   CHARLES VINCENT, *The Essentials of Patient Safety, adapted from* PATIENT SAFETY (2d ed. 2010), http://www.iarmm.org/IESRE2012May/Vincent_Essentials.pdf [https://perma.cc/RNP2-RYBF].

33.   *See generally* Haifa A Samra, Jacqueline M. McGrath, & Whitney Rollins, *Patient Safety in the NICU: A Comprehensive Review*, 25 J. PERINATAL & NEONATAL NURSING 123 (2011).

34.   *See* T.B. McDonald, L.A. Helmchen, K.M. Smith, N. Centomani, A. Gunderson, D. Mayer, & W.H. Chamberlin, *Responding to Patient Safety Incidents: The "Seven Pillars"*, 19 QUALITY & SAFETY IN HEALTH CARE 1 (2010).

system-wide issues, and considering missed learning opportunities when an error occurs.[35]

Patient safety, broadly, can be thought of as freedom from accidental medical injury.[36] Patient safety also refers to "the absence of preventable harm to the patient"[37] and encompasses avoidance, prevention, and amelioration of adverse outcomes and injuries that may occur within the healthcare system.[38] Given its intersection with the potential for harm, patient safety plays a prominent role in healthcare.[39] Further, our understanding of how to make patients safe is critical to how we respond to medical error.

Understanding the history and roots of error within healthcare can help improve patient care. Patient safety and medical error have been studied for well over a century.[40] Over time, our perspective on how to view medical error has shifted. In some of the earliest studies conducted in the 1950s, errors in medicine were primarily viewed as "diseases of medical progress."[41] Healthcare at that time dismissed error as merely "the price we pay for modern diagnosis and therapy."[42] Beyond the dismissal of error's dangers, reports during the early study of medical error often only focused on unusual patient reactions or errors that had significant consequence.[43]

The danger and extent of medical error did not come into the public eye until publication of the 2000 Institute of Medicine Report (IOM Report), *To Err is Human: Building a Safer Health System*. IOM Report revealed the widescale effects of medical error.[44] It distinguished four types of error: diagnostic, treatment, preventive, and "other," such as failures of communication, equipment failures, and other system

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35. Richard C. Boothman, Amy C. Blackwell, Darrell A. Campbell Jr, Elaine Commiskey, & Susan Anderson, *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, 2 J. HEALTH & LIFE SCI. L. 125 (2009); Mello et al., *supra* note 1.

36. Ethan D. Grober & John M. A. Bohnen, *Defining Medical Error*, 48 CAN. J. SURGERY 39 (2005); *see also* INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 4 (Linda T. Kohn et al. eds., 2000).

37. Carlotta Piccardi, Jens Detollenaere, Pierre Vanden Bussche, & Sara Willems, *Social Disparities in Patient Safety in Primary Care: A Systematic Review*, 17 INT'L J. EQUITY HEALTH 114, 114 (2018).

38. Grober & Bohnen, *supra* note 36, at 40; *see also* Jeffrey B. Cooper, David Gaba, B. Liang, David D. Woods, & L. N. Blum, *The National Patient Safety Foundation Agenda for Research and Development in Patient Safety*, 2 MEDGENMED: MEDSCAPE, GEN. MED. (2000).

39. Grober & Bohnen, *supra* note 36, at 39.

40. *Id.* at 39–40; *see generally* Robert H. Moser, *Diseases of Medical Progress*, 255 NEW ENG. J. MED. 606 (1956).

41. Grober & Bohnen, *supra* note 36, at 40.

42. *Id.*; *see also* David P. Barr, *Hazards of Modern Diagnosis and Therapy: The Price We Pay*, 159 J. AM. MED. ASS'N 1452, 1452 (1955).

43. *See* Grober & Bohnen, *supra* note 36, at 40; *see, e.g.*, Moser, *supra* note 40; Barr, *supra* note 42.

44. Sameera et al., *supra* note 14, at 328.

failures.[45] Since the release of the IOM Report, recognition of error and its connection to patient safety have remained relevant in research and have influenced how we care for patients.[46] Though the IOM Report addressed diagnostic error, identifying the relationship between patient safety and diagnostic error is relatively recent; only within the past decade have researchers begun to study patient safety strategies with a focus on diagnostic error.[47] The role of diagnostic error in patient safety is now being questioned and these questions are critical to providing high quality and safer care to patients.

A. *Patient Safety & High-Quality Care*

"High-quality health care is, first, safe health care."[48]

Patients should be able to seek healthcare without fear of being harmed.[49] They should be able to expect care and protection—no one wants to experience harm when seeking care. Mistakes and patient harm are inevitable as it is impossible to eliminate all error, but harm should not be a hallmark of our healthcare system.[50] Addressing preventable harm is the least we owe to our patients.[51] In reality, there is much more we can do to increase safety and better protect patients.

Patient safety is an integral part of our healthcare system, but it is also personal. When a family member goes to the hospital, we want them to be safe. When harm occurs, patients and their families are left hurt, traumatized, and in fear of a system that should be designed to keep them safe.[52] The nature and scale of harm within our healthcare system is often hard for patients to comprehend. For patients, exposure to harm feels personal, targeted, and individualized, but in our healthcare

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45.   INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36, at 36.

46.   Sameera et al., *supra* note 14, at 328.

47.   *See* Kathryn M. McDonald, Brian Matesic, Despina G. Contopoulos-Ioannidis, Julia Lonhart, Eric Schmidt, Noelle Pineda, & John P. A. Ioannidis, *Patient Safety Strategies Targeted at Diagnostic Errors: A Systematic Review*, 158 ANNALS INTERNAL MED. 381 (2013).

48.   INST. OF MED. OF THE NAT'L ACADS., PATIENT SAFETY: ACHIEVING A NEW STANDARD FOR CARE 250 (Philip Apsden et al. eds., 2004).

49.   *Id.*

50.   *Id.*

51.   Piccardi et al., *supra* note 37, at 114 (Preventable harm includes the "results of a wrong diagnosis, clinical procedure, side-effects of drugs, or system errors during the process of healthcare administration...").

52.   Nadia N. Sawicki, *Judging Doctors: The Person and the Professional*, 13 AM. MED. ASS'N J. ETHICS 718 (2011).

system, this harm is often widespread and systemic.[53] Further, this harm is not unique to the U.S. healthcare system but occurs worldwide.[54]

Harm is part of healthcare, but not all harm is equal.[55] We assume error occurs randomly among patients.[56] A patient's characteristics are irrelevant to their exposure to error[57]—*right*? Surely, a patient's race and ethnicity are not connected to their exposure to error?[58] Sadly, these assumptions are flawed.[59] Personal and physical characteristics *do* influence the likelihood of experiencing an error.[60] Even when controlling for income and education level, disparities in care based on race and ethnicity persist.[61]

There is also great variation in the *level* of harm that a patient may suffer. While a patient's physical characteristics do affect whether they will experience an error, these same characteristics may also influence the *magnitude* of harm that the patient will suffer.[62] For example, Black women are three to four times more likely to experience complications during childbirth and pregnancy and die from these complications in comparison with white women.[63] These rates are on par with statistics in underdeveloped countries.[64] This is a largely preventable problem, made worse by persistent and increasing racial and ethnic health.[65] A significant factor in this disparity is racism and physician unwillingness to listen to their patients—for example, Black women. There is no genetic factor between race or skin color and causes of maternal illness or death.[66] Indeed, "[r]ace is not a factor for illness and death;" instead, the

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53.   Sameera et al., *supra* note 14, at 328.

54.   *See* VINCENT, *supra* note 32, at 2.

55.   *Id.*

56.   *See id.*

57.   *See id.*

58.   *See id.*

59.   *See id.*

60.   *See id.*

61.   *See id.*

62.   Waisel, *supra* note 11, at 186–92.

63.   Brittany D. Chambers, Brianne Taylor, Tamara Nelson, Jessica Harrison, Arielle Bell, Allison O'Leary, Helen A. Arega, Sepehr Hashemi, Safyer McKenzie-Sampson, Karen A. Scott, Tina Raine-Bennett, Andrea V. Jackson, Miriam Kuppermann, & Monica R. McLemore, *Clinicians' Perspectives on Racism and Black Women's Maternal Health.* 3 WOMENS HEALTH REP. 476, 477 (2022); *see also NIH-funded Study Highlights Stark Racial Disparities in Maternal Deaths.* NAT'L INST. HEALTH (Aug. 12, 2021), https://www.nih.gov/news-events/news-releases/nih-funded-study-highlights-stark-racial-disparities-maternal-deaths [https://perma.cc/9TCN-S96X].

64.   *Systemic Racism, A Key Risk Factor for Maternal Death and Illness,* NAT'L INST. HEALTH (Apr. 26, 2021), https://www.nhlbi.nih.gov/news/2021/systemic-racism-key-risk-factor-maternal-death-and-illness [https://perma.cc/HN7P-3KZQ].

65.   *Id.*

66.   *Id.*

problem is racism.[67] Disparate rates of maternal mortality and the treatment of Black women within our healthcare system reveal a deeper structural problem around rates of error, patient safety, and whom the healthcare system keeps safe.

Not all patients will experience a life-altering or even fatal error.[68] For many patients, an error will have almost no impact on them at all—many smaller errors occur every day. Instead, a minor error will merely interrupt or delay a patient's care.[69] While certain instances of error are less serious for individual patients, they still pose a danger to our healthcare system by presenting "massive and relentless drain on scarce healthcare resources."[70] Error costs money, time, and personnel, even if its impact on the patient is insignificant.

1. Defining Quality of Care

Achieving high quality care in our healthcare system is not simply about the precision of diagnostic or medical decisions but, rather, requires medical professionals' attention to the quality of care. Quality healthcare also encompasses treatment of patients and their families. Patient safety is "the foundation of good patient care,"[71] and a core value of our healthcare system. Quality is integral to conversations about patient safety, but at times has been obscured by differing definitions.

The Institute of Medicine (IOM) defines quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and [is] consistent with current professional knowledge."[72] IOM took this definition and offered six aims of quality that healthcare institutions should strive for to provide patients with high quality care:

> "[H]ealthcare should be –
> (1) Safe—avoiding injuries to patients from the care that is intended to help them
> (2) Effective—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit

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67.   *Id.*

68.   *See generally* Vincent, *supra* note 32, at 2.

69.   *See id.*

70.   *See id.*

71.   *Id.; see also* Grober & Bohnen, *supra* note 36, at 39.

72.   Jo Harris-Wehling, *Defining Quality of Care, in* Medicare: A Strategy for Quality Assurance, Volume II: Sources and Methods 116, 128–29 (Kathleen N. Lohr, ed. 1990).

(3) Patient-centered—providing care that is respectful of and responsive to individual preferences, needs, and values, and ensuring that patient values guide all clinical decisions

(4) Timely—reducing waits and sometimes harmful delays for both those who receive and those who give care

(5) Efficient—avoiding waste, including waste of equipment, supplies, ideas, and human resources

(6) Equitable—providing care that does not vary in quality because of personal characteristics, such as gender, ethnicity, geography, and socioeconomic status."[73]

As reflected in these goals set forth by IOM, building safer healthcare systems requires considering patient safety and quality of care. Despite striving for better practices, the medical system falls short and continues to compromise patient safety.

B. *Patient Safety and Equitable Care*

Patient safety is a priority, but evidence shows persistent disparities in healthcare.[74] Indeed, disparate harm lies within the foundations of the U.S. healthcare system.[75] Research indicates that harm exposure and lower quality of care disproportionately impact vulnerable communities, including ethnic and racial minorities,[76] women, and the LGBTQ+ community.[77] Even when controlling for other factors, such as income and access to care, these populations consistently receive poor quality of care.[78] To this end, IOM's goal of ensuring patient safety and providing equitable care[79] requires recognition of how the medical system impacts specific communities. In this Section, I briefly discuss examples of persistent disparities.

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73.   COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH CARE SYSTEM FOR THE 21ST CENTURY 5–6 (2001).

74.   *See, e.g.*, Coffey et al., *supra* note 24, at 48.

75.   *See* Robert W. Putsch & Linda Pololi, *Distributive Justice in American Healthcare: Institutions, Power, and the Equitable Care of Patients*, 10 AM. J. MANAGED CARE 45 (2004), https://pubmed.ncbi.nlm.nih.gov/15481436/https://pubmed.ncbi.nlm.nih.gov/15481436/ [https://perma.cc/J5DH-HWJN].

76.   *See* W. MICHAEL BYRD & LINDA A. CLAYTON, AN AMERICAN HEALTH DILEMMA: RACE, MEDICINE, AND HEALTH CARE IN THE UNITED STATES 1900-2000 (2001); *see also* Alan Nelson, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, 94 J. NAT'L MED. ASS'N 666, 666–67 (2002); Coffey et al., *supra* note 24, at 48.

77.   *See* Putsch & Pololi, *supra* note 75.

78.   Coffey et al., *supra* note 24, at 49–50.

79.   INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36, at 5.

For one, research inquiries historically ignore and exclude female patients and these patients continue to be overlooked today,[80] specifically regarding treatment of pain. When women express that they are in pain, providers often dismiss this pain as psychological or simply the physical manifestation of stress, anxiety, or depression.[81] Studies indicate that women in pain are more likely to receive prescriptions for sedatives than pain medication.[82] One study found that after coronary bypass surgery, women were only half as likely to be prescribed painkillers, in comparison with men who had undergone the same procedure.[83] Women wait longer to receive an analgesic for acute abdominal pain in the emergency room: on average, a woman's wait time is sixty-five minutes as opposed to forty-nine minutes for a man.[84]

Dealing with pain may appear to be an uncomfortable inconvenience, but gender biases in our healthcare system can be fatal or have serious consequences. In 2000, a New England Journal of Medicine study "found that women are seven times more likely than men to be misdiagnosed and discharged in the middle of having a heart attack."[85] Another study found that doctors misdiagnose heart attacks in female patients because they are trained to look for symptoms more common to heart attacks in male patients.[86]

Racial and ethnic minorities also experience great disparities in the quality and safety of the healthcare they receive.[87] Persistent racism and discrimination is a significant barrier within this system. White Americans often think of racism as a social construct primarily affecting people of color.[88] Racism is more nuanced and can represent both a system of racial disadvantage and a system of reciprocal racial

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80.   *See generally* Karina Davidson, *Women Have Been Overlooked in Medical Research for Years*, NORTHWELL HEALTH, https://www.northwell.edu/katz-institute-for-womens-health/articles/women-overlooked-in-medical-research [https://perma.cc/N9AP-T4UH] (last visited Sept. 14, 2023).

81.   *Women and Pain: Disparities in Experience and Treatment*, HARV. HEALTH PUBL'G: HARV. HEALTH BLOG (Oct. 9, 2017), https://www.health.harvard.edu/blog/women-and-pain-disparities-in-experience-and-treatment-2017100912562 [https://perma.cc/QLM8-QFVB].

82.   *Id.*

83.   *See id.*

84.   *Id.*

85.   *Id.* For the original study, see Elizabeth G. Nabel, *Coronary Heart Disease in Women — An Ounce of Prevention*, 343 NEW ENG. J. MED. 572 (2000).

86.   *See generally* Piccardi et al., *supra* note 37, at 114 ("Patient safety is a quality indicator for primary care . . .").

87.   *See* Ashfaq Chauhan, Merrilyn Walton, Elizabeth Manias, Ramesh Lahiru Walpola, Holly Seale, Monika Latanik, Desiree Leone, Stephen Mears, & Reema Harrison, *The Safety of Health Care for Ethnic Minority Patients: A Systematic Review*, 19 INT'L J. EQUITY IN HEALTH 118, 118–19 (2020).

88.   *See* Max J. Romano, *White Privilege in a White Coat: How Racism Shaped my Medical Education*, 16 ANN. FAM. MED. 261, 261 (2018).

advantage.[89] In thinking about racism in health, it is important to recognize the detriment to certain communities in terms of their health and the inherent advantages given to others. Medical professionals are increasingly aware that social determinants of health—the environments where people are born, learn, work, and play[90]—lead to important health disparities.[91] Unfortunately, many physicians fail to consider racial disparity and how this may affect the health of patients of color, leading to further health disparities and the continuation of racism within medicine.

One form of racially disparate treatment can be identified by reviewing clinical trials, which consistently center white patients. For example, as with many diseases, the bulk of research on respiratory ailments in the U.S. has focused on white European Americans.[92] The focus of clinical trials on primarily white patients is at best misguided and at worst, severely disadvantages communities of color. A study from the University of San Francisco (USF) found that only five percent of the genetic traits linked to asthma in European Americans apply to African Americans.[93] The USF study illuminates how participant inclusion (or exclusion) in clinical studies can exacerbate harm: examining *who* participates and who is the focus for the development of treatments and medicine is critical for closing the treatment gap. The problem goes far beyond asthma; other studies have also shown that different ethnicities have specific genetic mutations which can affect their risk of certain diseases and influence how they respond to medicine.[94] African American children have been severely neglected in asthma research and as a result have died from asthma at ten times the rate of non-Hispanic white children.[95] Beyond racism and implicit biases, structural inequalities based on poverty, race and ethnicity, and gender[96] lead to large discrepancies in health, life expectancy, quality of life, and access to care.[97]

In their 2002 report, IOM suggested that healthcare institutions should work to ensure that clinical practices are uniform and based on

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89.   *Id.*

90.   *See Social Determinants of Health*, U.S. DEP'T HEALTH & HUM. SERVS. (2020), https://health.gov/healthypeople/priority-areas/social-determinants-health [https://perma.cc/H7LM-8EAH].

91.   *See* Romano, *supra* note 88, at 261; Waisel, *supra* note 11, at 186–92.

92.   Marquitta J. White, O. Risse-Adams, P. Goddard , M. G. Contreras, J. Adams, D. Hu, C. Eng, S. S. Oh, A. Davis, K. Meade, E, Brigino-Buenaventura, M. A. LeNoir, K. Bibbins-Domingo, M. Pino-Yanes, & E. G. Burchard, *Novel Genetic Risk Factors for Asthma in African American Children: Precision Medicine and the SAGE II Study*, 68 IMMUNOGENETICS 1, 1–2 (2016).

93.   *Id.* at 2.

94.   *Id.* at 1–2.

95.   *Id.*

96.   Putsch & Pololi, *supra* note 75.

97.   White et al., *supra* note 92.

the best available science to reduce health disparities.[98] This suggestion—while well-intentioned—fails to fully consider the pervasive and systemic nature of bias within the U.S. healthcare system. According to research on implicit bias, many physicians hold an unconscious bias in favor of white people as compared with Black people.[99] This bias, though unconscious, can have real world consequences on the care that patients receive. Bias in decision-making by healthcare practitioners results in greater health disparities and inequity within the U.S. healthcare system.[100] Research shows the extent to which individual physicians are responsible for differences in treatment recommendations with respect to race and sex.[101] One seminal study on physicians' recommendations for cardiac catheterization found that "the race and sex of a patient independently influence how physicians manage chest pain."[102] Minority patients may also be less likely to receive necessary cardiac procedures.[103] Female minority patients may be less likely to be referred for screening mammography.[104]

Each of these examples and the countless others highlighted in the literature indicate that bias, stereotyping, prejudice, and clinical uncertainty from healthcare providers contributes to disparities in the quality of care provided to subgroups.[105]

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98.   Nelson, *supra* note 76, at 667.

99.   David A. Ansell & Edwin K. McDonald, *Bias, Black Lives, and Academic Medicine*, 372 NEW ENG. J. MED. 1087, 1088 (2015).

100.   Putsch & Pololi, *supra* note 75.

101.   *See* Kevin A Schulman, Jesse A. Berlin, William Harless, Jon F. Kerner, Shyrl Sistrunk, Bernard J. Gersh, Ross Dubé, Christopher K. Taleghani, Jennifer E. Burke, Sankey Williams, John M. Eisenberg, William Ayers, & José J. Escarce, *The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization*, 340 NEW ENG. J. MED. 618, 623 (1999).

102.   *See id.*

103.   Lucian L. Leape, Lee H. Hilborne, Robert Bell, Caren Kamberg, & Robert H. Brook, *Underuse of Cardiac Procedures: Do Women, Ethnic Minorities, and the Uninsured Fail to Receive Needed Revascularization?*, 130 ANNALS INTERNAL MED. 183, 183–92 (1999).

104.   *See, e.g.*, Andrew B. Ross, Vivek Kalia, Brian Y. Chan, & Geng Li, *The Influence of Patient Race on the Use of Diagnostic Imaging in United States Emergency Departments: Data from the National Hospital Ambulatory Medical Care Survey*, 20 BMC HEALTH SERVS. RSCH. 840 (2020); Jose M. Quintana, Donald Goldmann, & Charles Homer, *Social Disparities in the Use of Diagnostic Tests for Children with Gastroenteritis*, 9 INT'L J. FOR QUALITY IN HEALTH CARE 419 (1997); Jeffrey J. Bazarian, Charlene Pope, Jason McClung, Yen Ting Cheng, & William Flesher, *Ethnic and Racial Disparities in Emergency Department Care for Mild Traumatic Brain Injury*, 10 ACAD. EMERGENCY MED. 1209 (2003); Kristen J. Wells & Richard G. Roetzheim, *Health Disparities in Receipt of Screening Mammography in Latinas: A Critical Review of Recent Literature*, 14 CANCER CONTROL 369 (2007); Earl S. Ford & Richard S. Cooper, *Racial/Ethnic Differences in Health Care Utilization of Cardiovascular Procedures: A Review of the Evidence*, 30 HEALTH SERVS. RSCH. 237 (1995); David M. Carlisle, Barbara D. Leake, & Martin F. Shapiro, *Racial and Ethnic Disparities in the Use of Cardiovascular Procedures: Associations with Type of Health Insurance*, 87 AM. J. OF PUB. HEALTH 263 (1997).

105.   *See generally* Nelson, *supra* note 76.

C. *Patient Safety and the Law*

Given pervasive health disparities and rampant bias within our healthcare system,[106] a practical solution should extend beyond using uniform practices. Legislation is one of the most important regulatory mechanisms in healthcare.[107] Consequently, the law is a useful tool to improve patient safety as laws can contribute to changes in professional cultures.[108]

One of the most notable examples is the development of the legal doctrine of informed consent. Introduced in the 1970s, this doctrine requires that patients be informed of the risks and benefits of, or possible alternatives to, a medical procedure or treatment before making a healthcare decision.[109] The patient must be allowed to make a voluntary decision as to whether to undergo the proposed treatment or procedure.[110] Informed consent significantly changed the doctor-patient relationship.[111]

Despite the significance of laws in healthcare, medical professionals tend to find legal provisions burdensome.[112] These "laws are not necessarily coercive or burdensome," but they can be adapted to reach their goal in a more efficient and less harmful way.[113] Laws in healthcare serve different purposes. Some laws, such as mandatory reporting, pressure healthcare professionals to take a certain action.[114] The U.S. requires state reporting mandates on persons who interact with vulnerable populations where there may be instances of potential "mistreatment or abuse of those populations."[115] These types of laws vary across states, but generally they include children, the disabled, and the elderly.[116] The

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106. *See, e.g.*, Albert G. Mulley, Chris Trimble, & Glyn Elwyn, *Stop the Silent Misdiagnosis: Patients' Preferences Matter*, 345 BRITISH MED. J. 23, 23 (2012); Chauhan et al., *supra* note 87; Ross et al., *supra* note 104; NAT'L CTR FOR HEALTH STATS., HEALTH, UNITED STATES, 2015: WITH SPECIAL FEATURE ON RACIAL AND ETHNIC HEALTH DISPARITIES (2016); U.S. DEP'T OF HEALTH AND HUM. SERVS., 2016 NATIONAL HEALTHCARE QUALITY AND DISPARITIES REPORT (2017); Nelson, *supra* note 76.

107. Olivier Guillod, *Medical Error Disclosure and Patient Safety: Legal Aspects*, 2 J. PUB. HEALTH RSCH. 182, 183 (2013).

108. *See id.* at 182–83.

109. *See* PARTH SHAH, IMANI THORNTON, DANIELLE TURRIN, & JOHN E. HIPSKIND, *Issues of Concern, in* INFORMED CONSENT (StatPearls Publishing, 2023).

110. *See id.*

111. *See id.*

112. *See id.*

113. *Id.*

114. *See id.*

115. Richard Thomas & Monique Reeves, *Mandatory Reporting Laws*, NAT'L INST. OF HEALTH: NAT'L LIBR. MED. (July 10, 2023), https://www.ncbi.nlm.nih.gov/books/NBK560690/ [https://perma.cc/GRY3-S3T7].

116. *See id.*

mistreatment of children is a serious public health concern, and healthcare providers have an important ethical and legal role to identify and report abuse of children to their appropriate state agency.[117]

Other laws promote professional behaviors, and some are neutral or may try to deter professional behaviors that are perceived as inappropriate.[118] The Patient Safety and Quality Improvement Act (PSQUIA) allows healthcare workers to safely report medical error and unsafe conditions in their work environment without fear of retaliation.[119] In this way, PSQUIA promotes patient safety.

In introducing new laws, it is important to be clear about the purpose and the values of the proposed legislation. In patient safety, it is critical that proposed laws promote values such as transparency, honesty, trust, and justice.[120] Additionally, because laws are designed to "mandate, promote, deter, or prohibit specific human" behaviors, they should be based on empirical evidence that they will work.[121] Studies suggest that developing effective patient safety strategies requires sound evidence, rather than relying on opinions.[122] Consequently, applied research on patient safety is critical to our ability to create effective laws that increase patient safety.[123]

II. MEDICAL ERROR: ESTABLISHING THE PROBLEM

In analyzing the problem and proposing solutions, it is important to understand what medical error is, *when* it occurs, and under what circumstances. Beyond recognizing the context in which medical error happens, it is also important to understand its pervasive nature. The rates of medical error are shocking and pose a great danger to patients and our healthcare system. This Part begins by defining medical error and explores the numbers behind medical error both in terms of harm and cost to society.

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117.   *See id.*
118.   SHAH ET AL., *supra* note 109.
119.   *See* 42 U.S.C. §§ 299b-21–299b-26.
120.   *See* SHAH ET AL., *supra* note 109.
121.   *See id.*
122.   *See id.*
123.   *See id.*

A. *Defining Medical Error*

"Errors mean different things to different people."[124]

When, where, and *how* medical error occurs varies. In this article, "medical error" is defined as a preventable adverse medical event that occurs due to the error. Medical error can—and does—happen in high-risk, complicated clinical scenarios, but it also occurs in simple routine procedures.[125] Several factors contribute to the occurrence of error. For instance, clinical situations may arise that are beyond the control of even the best clinician.[126] Error also results from poor clinical judgment or technique, inadequate patient information, communication breakdowns between health professionals, and overwork and mental lapse of individuals.[127]

We must reduce medical error to improve patient safety. But one question remains—what constitutes a medical error?[128] Unfortunately, there is no simple or even universal response to this question. This makes error difficult to measure. The lack of standard language and overlapping definitions have hindered progress on data analysis, synthesis, and evaluation of medical error.[129] Consider two major categories of error:

1) Errors of *omission*: These errors occur because of an action that is not taken. Examples include failing to strap a patient into a wheelchair or failing to stabilize before patient transfer.[130]

2) Errors of *commission*: These errors result from when incorrect action is taken. Some examples include administering a medication that a patient is allergic to or failing to label a laboratory specimen that is later ascribed to the wrong patient.[131]

In 2004, IOM introduced a definition of medical error that accounted for both *omission* and *commission*. According to IOM, an error in medicine[132] is:

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124.   JAMES REASON, HUMAN ERROR ix (Cambridge University Press ed., 1990).

125.   Coffey et al., *supra* note 24.

126.   *See id.*

127.   *Id.*

128.   Ellen O'Shea, *Factors Contributing to Medication Errors: A Literature Review*. 8 J. CLINICAL NURSING 496, 496 (1999).

129.   *See* Thomas L Rodziewicz, Benjamin Houseman, & John E. Hipskind, *Medical Error Reduction and Prevention*, NAT'L INST. HEALTH: NAT'L LIBR. MED., https://www.ncbi.nlm.nih.gov/books/NBK499956/ [https://perma.cc/Z8LS-A6TV] (last updated May 2, 2023).

130.   *See id.*

131.   *Id.*

132.   INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36.

1) The failure of a planned action to be completed as intended—an error of execution,
2) The use of a wrong plan to achieve an aim—or an error of planning (or commission).

This definition also recognizes the failure of an unplanned action that should have been completed—the omission of an error.

These categories provide a reference point for correcting medical error. Even with this definitional framework, however, meanings of medical error vary. For one, the concept covers a range of harms, arising from: "surgical, diagnostic, medication, devices and equipment, and systems failures, infections, falls, and healthcare technology."[133] Patients may experience error in diagnostic procedures, unanticipated adverse effects of drugs or medical interventions, "undesirable or incorrect surgical decisions and their outcomes," and administration of the wrong medication or dosage.[134] Other types of error may occur, including failures to communicate[135] or technological or equipment failures. When mistakes are made during patient care, they are still medical errors, even if harm is not evident. Medical error may also refer to adverse events—or instances where injury or harm is caused by medical care. While some adverse events are clearly preventable errors, in other cases it is less clear.[136]

Consequently, the term "medical error" is wide and varied, which at times leads to disagreement about whether an error occurred. Though the existence of error is not always apparent or agreed upon, some mistakes are particularly prevalent in our healthcare system. The following list represents some of the most common medical errors in health care:[137]

- Adverse drug events
- Burns
- Equipment failure
- Failure to provide prophylactic treatment (a medicine or course of action used to prevent disease)
- Falls

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133.   *See* Rodziewicz et al., *supra* note 129.

134.   JENICEK, *supra* note 8, at xvi.

135.   Steven E. Raper, *No Role for Apology: Remedial Work and the Problem of Medical Injury*, 11 YALE J. HEALTH POL'Y L. & ETHICS 267, 270–71 (2011) (noting that failures to communicate are among the types of medical errors that can occur).

136.   Angelo P. Giardino & Melissa A. Murrah, *Disclosing an Adverse Event or Medical Error, in* COMMUNICATING WITH PEDIATRIC PATIENTS AND THEIR FAMILIES: THE TEXAS CHILDREN'S HOSPITAL GUIDE FOR PHYSICIANS, NURSES AND OTHER HEALTHCARE PROFESSIONALS 195, 196 (2015) (defining adverse events as any negative event occurring during the patient's care, but noting that some are not readily preventable).

137.   *See* Rodziewicz et al., *supra* note 129.

- Improper transfusions
- Misdiagnosis, delay in diagnosis, or not utilizing the appropriate test as well as a failure to act on the laboratory result.
- Mistaken patient identities
- Pressure ulcers and deep vein thrombosis
- Preventable suicides
- Restraint-related death
- Surgical injuries
- Under and overtreatment or errors in administering treatment (wrong dose or wrong site of administration)
- Wrong-site surgery

Though an extensive list, these examples only scratch the surface of the types of error that can occur within the U.S. healthcare system.

The context under which an error may occur is key. We see "higher rates of error in stressful and fast-paced environments," such as emergency departments, intensive care units, and operating rooms.[138] But consider who is more likely to access their healthcare in these contexts. Research indicates that minority populations experience a disproportionate share of emergency department visits and hospitalizations, particularly when it comes to asthma.[139] Research indicates that Black patients are more likely than white patients to access the emergency department.[140] Unfortunately, the reason behind this racialized use of emergency departments still remains largely unexplored.[141]

Medical error is also associated with "extreme age, high acuity, and new procedures."[142] High acuity refers to patients with challenging conditions and significant or unpredictable healthcare needs.[143] Error also occurs when "necessary personnel are not available"[144] or when multiple

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138.   *See id.*

139.   Timothy H. Self, Cary R. Chrisman, Darius L. Mason, & Mark J. Rumbak, *Reducing Emergency Department Visits and Hospitalizations in African American and Hispanic Patients with Asthma: A 15-Year Review*, 42 J. Asthma 807 (2005).

140.   Lindsay E. Brown, Ryan Burton, Brian Hixon, Manasi Kakade, Parul Bhagalia, Catherine Vick, Andrew Edwards, & Mary T. Hawn, *Factors Influencing Emergency Department Preference for Access to Healthcare*, 13 W. J. Emergency Med. 410 (2012).

141.   *See id.*

142.   *See* Rodziewicz et al., *supra* note 129; *see* Lisa Anne Calder, Alan Forster, Melanie Nelson, Jason Leclair, Jeffrey Perry, Christian Vaillancourt, Guy Hebert, Adam Cwinn, George Wells, & Ian Stiell, *Adverse Events Among Patients Registered in High-Acuity Areas of the Emergency Department: a Prospective Cohort Study*, 12 Can. J. of Emergency Med. 421, 422 (2010).

143.   Kathleen Dorman Wagner, Melanie Hardin-Pierce, Darlene Welsh, & Karen Johnson, High Acuity Nursing 8 (Pearson ed. 2014).

144.   *See* Rodziewicz et al., *supra* note 129.

practitioners are involved.[145] And, when there is lack of expertise or insufficient supervision, error is more likely.[146] Research has found that "students, interns, residents, and fellows may be inadequately supervised due to time constraints or lack of understanding their abilities."[147]

B. *Medical Error: The Numbers*

Aside from the personal or individual harm a patient may suffer, medical error affects a significant portion of the population. Understanding these statistics can help put the problem in perspective and appreciate the true urgency of the situation.

1. Relevant Statistics

While at times medical error may feel remote, error within our healthcare system is quite prevalent. The 2000 IOM Report brought the extent of medical error to the forefront of public awareness and shared some shocking statistics. The Report estimated that 44,000–98,000 Americans die each year due to medical error.[148] Current estimates indicate that medical error in hospitals and clinics results in approximately 100,000 people dying each year,[149] with close to 400,000 hospitalized patients experiencing some type of preventable error each year.[150] Further, research on hospital admissions indicates that "about 4–17% of hospital admissions are associated with adverse medical events and nearly two-thirds are preventable."[151]

Preventable error is a leading cause of death in the U.S.[152] In 2016, for example, estimates of medical error-related deaths hovered around

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145.   *See id.*

146.   *See id.*

147.   *See id.*

148.   INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36; Robert M. Wachter, *Why Diagnostic Errors Don't Get Any Respect—And What Can Be Done About Them*, 29 HEALTH AFFS. 1605 (2010).

149.   *See* Rodziewicz et al., *supra* note 129.

150.   *See id.*

151.   Sameera et al., *supra* note 14.

152.   Martin A. Makary & Michael Daniel, *Medical Error—The Third Leading Cause of Death in the U.S.*, 353 BRIT. MED. J. 236, 236–37 (2016) (estimating that medical error is the third leading cause of death in the country because their statistical calculations suggested a mean rate of 251,454 medical deaths per year from 1999 through 2013, and the CDC only estimates two causes of death occur in higher numbers).

250,000 per year.[153] Other studies suggest that the figure may have been closer to 440,000 deaths per year.[154] In the wake of the COVID-19 pandemic, medical error ranks as the fourth leading cause of death behind cancer, heart disease, and COVID-19.[155] These studies reflect the magnitude with which medical error affects society and rivals numbers introduced by the IOM in *To Err is Human*.[156]

2. Costs of Medical Error

Alongside the harm posed to patients, medical error is expensive. Most of these hefty costs are shifted to outside parties—often to payers, like Medicare.[157] Consequently, research has found that hospitals do not have strong economic incentives to improve patient safety.[158] Patient safety advocates have fought to make the case that if healthcare organizations would only invest in safer practices and systems in the long run, they will benefit from financial returns as costs for medical malpractice and expenses would be reduced.[159]

The associated costs with heavy rates of medical error are not simply the potential loss of life or decreased patient safety in our healthcare system, but the financial toll on our healthcare system and society at large. Research in this area is extensive and varied, but according to some estimates, the costs of medical error account for over $4 billion each year.[160] Other estimates indicate that the cost of medical error alone amounts to approximately $20 billion a year.[161] Medical error results in a heavy financial toll on both the patient and society. This raises the question: Where

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153.   *See* Makary & Daniel, *supra* note 152, at 236–37 (comparing CDC's 1999 study estimate of 44,000 to 98,000 deaths annually with authors' calculation of a mean of 251,454 medical deaths per year from 1999 through 2013).

154.   John T. James, *A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care*, 9 J. PATIENT SAFETY 122, 127 (2013) (estimating that 440,000 preventable adverse events contribute to patient deaths each year).

155.   *Leading Causes of Death*, CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs /fastats/leading-causes-of-death.htm [https://perma.cc/8AK4-3EWT] (last visited Feb. 20, 2024).

156.   INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 109 (Linda T. Kohn et al., eds., 2000) [hereinafter TO ERR IS HUMAN] (estimating that between 44,000 and 98,000 Americans die in hospitals each year due to medical errors).

157.   David M. Studdert, *Who Pays for Medical Errors?: An Analysis of Adverse Event Costs, the Medical Liability System and Incentives for Patient Safety Improvement*, THE COMMONWEALTH FUND (2008), https://www.commonwealthfund.org/publications/journal-article/2008/apr/who-pays-medical-errors-analysis-adverse-event-costs-medical [https://perma.cc/N9P6-3KGC].

158.   *See id.*

159.   *See id.*

160.   *See* Rodziewicz et al., *supra* note 129.

161.   *See id.*

do all these costs come from? What are they for? The mistakes created by error result in additional costs for care, including lost income and household productivity, disability, and medical care.[162] In total, error is estimated to amount to somewhere between $17 billion and $29 billion annually in the U.S.[163]

While medical error is costly, diagnostic error is financially draining. One way to significantly reduce the costs of diagnostic error is to improve the accuracy and timeliness of the diagnosis.[164] Improving this will lower costs for inappropriate testing (e.g., ordering or requiring tests for the patient that are not needed), wrong treatments, and malpractice suits.[165] Making these changes has the potential to save over $100 billion each year.[166]

Diagnostic error is frequently the basis of malpractice suits, and it is costly both financially and in the harm done to patients. From 1986 to 2005, one study estimated that 91,082 diagnosis-related malpractice claims cost around $34.5 billion.[167] The National Practitioner Data Bank (NPBD) reviewed 10,739 malpractice claims all of which arose from 2005 to 2009.[168] Nearly 46% of outpatient claims came from diagnostic concerns.[169] This number dropped to 21.1% when looking at in-patient

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162.   *See* INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36, at 27 (explaining that total costs, including lost income, lost household production, disability, and health care costs for preventable medical errors are estimated to cost between $17 billion and $29 billion, and health care costs account for more than half); Grober & Bohnen, *supra* note 36; Guillod, *supra* note 107, at 182.

163.   Grober & Bohnen, *supra* note 36, at 27 (explaining that total costs, including lost income, lost household production, disability, and health care costs for preventable medical errors are estimated to cost between $17 billion and $29 billion, and health care costs account for more than half); *see also* Grober & Bohnen, *supra* note 36, at 39; Guillod, *supra* note 107, at 182.

164.   COMM. ON DIAGNOSTIC ERROR HEALTH CARE, BD. ON HEALTH CARE SERVS., INST. MED., NAT'L ACADS. SCIS., ENG'G, & MEDICINE, IMPROVING DIAGNOSIS IN HEALTH CARE (Erin P. Balogh et al. eds., 2015); David E. Newman-Toker, Diagnostic Value: The Economics of High-Quality Diagnosis and a Value-Based
Perspective on Diagnostic Innovation, Address at the Modern Healthcare 3rd Ann. Patient Safety & Quality Virtual Con. (June 17, 2015).

165.   *See id.*

166.   *What is Diagnostic Error*, SOC'Y IMPROVE DIAGNOSIS MED., https://www.improvediagnosis.org/what-is-diagnostic-error/ [https://perma.cc/9V9S-XKCQ] (last visited Jan. 20, 2023).

167.   McDonald et al., *supra* note 47, at 381; *see also* Ali S. Saber Tehrani, HeeWon Lee, Simon C. Mathews, Andrew Shore, Martin A. Makary, Peter J. Pronovost, & David E. Newman-Toker, *25-Year Summary of U.S. Malpractice Claims for Diagnostic Errors 1986–2010: An Analysis from the National Practitioner Data Bank*, 22 BMJ QUALITY & SAFETY 672 (2013) (figures are inflation-adjusted to 2010 U.S. dollars).

168.   McDonald et al., *supra* note 47, at 381; Tara F Bishop, et al., *Paid Malpractice Claims for Adverse Events in Inpatient and Outpatient Settings*, 305 JAMA 2427, 2427 (2011).

169.   McDonald et al., *supra* note 47, at 381; Tara F Bishop, et al., *Paid Malpractice Claims for Adverse Events in Inpatient and Outpatient Settings*, 305 JAMA 2427, 2427 (2011).

settings.[170] Even so, the prevalence of diagnostic errors is significant. Scholars have identified diagnostic error as more likely to occur than other kinds of medical error, including "surgical mistakes[] or medication overdoses."[171] And, the "severe patient harm"[172] of diagnostic error is likely to result in the "highest total of [malpractice suit] penalty payouts."[173]

Medical error is also costly in terms of opportunity costs,[174] and preventable medical error contributes substantially to healthcare costs.[175] Money that is used on repeat diagnostic tests or to counteract adverse drug events means there is less money available for other purposes[176]— such as purchasing needed medical equipment, employing additional staff, or otherwise improving the hospital environment and experience of patients. Patients and purchasers are left to bear additional costs when insurance costs and copayments are inflated by services because proper care had not been provided earlier.[177] Addressing, containing, and responding to medical error makes it impossible for the U.S. healthcare system to make full use of billions of dollars.[178]

Unfortunately, not all costs can be measured. Error often results lower satisfaction of both patients and healthcare professionals.[179] And, diagnostic error undercuts patient trust in the healthcare system,[180] undermining their commitment to their own medical care.[181]

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170.   McDonald et al., *supra* note 47, at 381; Tara F Bishop, et al., *Paid Malpractice Claims for Adverse Events in Inpatient and Outpatient Settings*, 305 JAMA 2427, 2427 (2011).

171.   SOC'Y IMPROVE DIAGNOSIS MED., *supra* note 166.

172.   *Id.*

173.   *See* Makary & Daniel, *supra* note 152, at 236–37 (estimating that medical error is the third leading cause of death in the country because their statistical calculations suggested a mean rate of 251,454 medical deaths per year from 1999 through 2013, and the CDC only estimates two causes of death occur in higher numbers).

174.   INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36, at 2.

175.   *See* Rodziewicz et al., *supra* note 129; Coffey, et al., *supra* note 24.

176.   INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36, at 2.

177.   *See id.*; *see also* Rodziewicz et al., *supra* note 129.

178.   INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36 at 2.

179.   *Id.*; *see also* L. Ebony Boulware, Lisa A. Cooper, Lloyd E. Ratner, Thomas A. LaVeist, & Neil R. Powe, *Race and Trust in the Health Care System*, 118 PUB. HEALTH REP. 358, 362–64 (2003) (finding that white patients more likely than other racial groups to trust physicians); Mark P. Doescher, Barry G. Saver, Peter Franks, & Kevin Fiscella, *Racial and Ethnic Disparities in Perceptions of Physician Style and Trust*, 9 ARCHIVES FAM. MED. 1156, 1158 (2000) (presenting analysis showing white patients trust physicians more than other racial groups at statistically significant level).

180.   *See* Makary & Daniel, *supra* note 152, at 236–37 (estimating that medical error is the third leading cause of death in the country because their statistical calculations suggested a mean rate of 251,454 medical deaths per year from 1999 through 2013, and the CDC only estimates two causes of death occur in higher numbers).

181.   *See* L. Ebony Boulware et al., *supra* note 179, at 362–64; Mark P. Doescher et al., *supra* note 179, at 1158.

Additionally, when patients experience a longer hospital stay or disability due to a medical error, they 'pay' with physical and psychological discomfort. Healthcare professionals 'pay' with "loss of morale and frustration at not being able to provide the best care possible."[182] Employers and society in general 'pay' in terms of "lost worker productivity, reduced school attendance by children, and lower levels of population health status."[183]

Medical error is expensive, harmful, and a drain on our systems, resources, and ability to effectively care for patients. Despite the dangers of medical error in general, diagnostic error poses its own set of challenges, as the next Section outlines.

C. *Diagnostic Error & Management*

"Inaccurate or delayed diagnosis is one of the most important safety problems in healthcare today and inflicts the most harm."[184]

Medical error as a whole presents a major concern, but the subset of diagnostic error has one of the highest rates of error.[185] A 2015 quality report by the U.S. National Academies of Sciences, Engineering, and Medicine found that diagnostic error represents a major public health problem, one that will likely affect each person at least once in their lifetime—perhaps with devastating consequences.[186] It is widely known that diagnostic error is common but underemphasized.[187] Despite the knowledge that diagnostic error is widespread, it is difficult to detect, let alone analyze.[188] At times, there can be confusion as to whether a

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182.   Susan Koch, Helen Forbes, & Pauline Wong, Abstract, *Common Medication Errors In The Acute Care Sector, in* MEDICATION MANAGEMENT IN OLDER ADULTS: A CONCISE GUIDE FOR CLINICIANS (2010), https://link.springer.com/chapter/10.1007/978-1-60327-457-9_4#Abs1_4 [https://perma.cc/QYB8-AF6E].

183.   INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36, at 2–3.

184.   NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164, at 1.

185.   Laura Zwaan, Abel Thijs, Cordula Wagner, Gerrit van der Wal, & Daniëlle R. M. Timmermans, *Relating Faults in Diagnostic Reasoning with Diagnostic Errors and Patient Harm*, 87 ACADEMIC MEDICINE 149, 149 (2012).

186.   *See* NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164, at 2; David E. Newman-Toker, Zheyu Wang, Yuxin Zhu, Najlla Nassery, Ali S. Saber Tehrani, Adam C. Schaffer, Chihwen Winnie Yu-Moe, Gwendolyn D. Clemens , Mehdi Fanai, & Dana Siegal, *Rate of Diagnostic Errors and Serious Misdiagnosis-Related Harms for Major Vascular Events, Infections, and Cancers: Toward a National Incidence Estimate Using the "Big Three"*, 8 DIAGNOSIS 67, 67–68 (2021).

187.   *See, e.g.,* Gordon D. Schiff et al., *supra* note 23; David E. Newman-Toker et al., *supra* note 190; David E. Newman-Toker, *A Unified Conceptual Model for Diagnostic Errors: Underdiagnosis, Overdiagnosis, and Misdiagnosis*, 1 DIAGNOSIS 43 (2014); Mark Graber, *Diagnostic Errors in Medicine: A Case of Neglect*, 31 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 112 (2005).

188.   Gordon D Schiff et al., *supra* note 23.

diagnostic error has occurred.[189] In addition to identifying the occurrence of an error, some scholars assert that diagnostic error is both more preventable and more likely to harm patients than other forms of error.[190] Given its widespread nature and harm to patients, diagnostic error is a particularly important problem to address.[191]

Diagnostic error is a subset of medical error and refers to errors related to a missed, delayed, or incorrect diagnosis.[192] Consequently—despite the various errors that may occur in healthcare—diagnostic error is most worrying for many patients.[193] Consequences range from severe[194] to inconsequential.[195] Even with the variation in resulting harm, diagnostic error still poses a significant threat to patient safety[196] and imparts extensive harm onto patients and their families.[197]

Diagnostic error comprises a large portion of all medical error;[198] it is estimated to account for 10–15% of all instances of medical error.[199] Nearly 75% of the serious harms due to diagnostic error were caused by missed vascular events, infections, and cancers.[200] In post-mortem briefings, major diagnostic errors are found in approximately 10–20% of autopsies.[201] Further, the concern for diagnostic error extends beyond medicine and into the courtroom. In malpractice claims, over 30% are classified as diagnostic errors.[202]

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189.   *Id.*

190.   McDonald et al., *supra* note 47; John W Ely, Mark L. Graber, & Pat Croskerry, *Checklists to Reduce Diagnostic Errors*, 86 ACAD. MED., 307, 307 (2011).

191.   *See generally* McDonald et al., *supra* note 47; Ely et al., *supra* note 194.

192.   NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164; Gordon D. Schiff, Omar Hasan, Seijeoung Kim, Richard Abrams, Karen Cosby, Bruce L. Lambert, Arthur S. Elstein, Scott Hasler, Martin L. Kabongo, Nela Krosnjar, Richard Odwazny, Mary F. Wisniewski, & Robert A. McNutt , *Diagnostic Error in Medicine: Analysis of 583 Physician-Reported Errors*, 169 ARCHIVES INTERNAL MED. 1881, 1881 (2009); Julie Abimanyi-Ochom, Shalika Bohingamu Mudiyanselage, Max Catchpool, Marnie Firipis, Sithara Wanni Arachchige Dona, & Jennifer J. Watts, *Strategies to Reduce Diagnostic Errors: a Systematic Review*, 19 BMC MEDICAL INFORMATICS AND DECISION 1, 1 (2019); Ekaterina Bakradze & Ava L Liberman, *Diagnostic Error In Stroke—Reasons and Proposed Solutions*, 20 CURRENT ATHEROSCLEROSIS REPS. 1, 11 (2018).

193.   Laura Zwaan, Martine de Bruijne, Cordula Wagner, Abel Thijs, Marleen Smits, Gerrit van der Wal, & Daniëlle R. M. Timmermans, *Patient Record Review of the Incidence, Consequences, and Causes of Diagnostic Adverse Events*, 170 ARCHIVES OF INT. MED. 1015, 1015 (2010).

194.   *See id.*

195.   John W. Ely et al., *supra* note 194 at 307; McDonald et al., *supra* note 47.

196.   NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164.

197.   *See id.*

198.   *See generally* Schiff et al., *supra* note 192 (2009); Graber, *supra* note 187, at 106; Zwaan et al., *supra* note 185, at 149.

199.   *See* Rodziewicz et al., *supra* note 129, at 18.

200.   *Id.* at 67–68.

201.   NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164.

202.   Zwaan et al., *supra* note 193, at 1015.

In the report *Improving Diagnosis in Healthcare* the Institute of Medicine defined a diagnostic error[203] as the failure to:

  (a) Establish an accurate and timely explanation of the patient's health problem(s); or
  (b) Communicate that explanation to that patient.

Simply put, this definition refers to diagnoses that were missed, delayed, or incorrect.[204]

TABLE 1 DIAGNOSTIC ERROR DEFINED

Delayed Diagnosis	A *delayed* diagnosis refers to a case where the diagnosis should have been made earlier. A delayed diagnosis of cancer is by far the leading entity in this category. One issue is that there are very few strong guidelines on making a timely diagnosis, and many illnesses go under the radar until symptoms persist or worsen.[205]
Wrong Diagnosis	A *wrong* diagnosis occurs, for example, if a patient having a heart attack is told their pain is from acid indigestion. The original diagnosis is later found to be incorrect because the true cause is discovered later.[206]
Missed Diagnosis	A *missed* diagnosis refers to a patient whose medical complaints are never explained. Many patients with chronic fatigue or chronic pain fall into this category, as well as patients with more specific complaints that are never accurately diagnosed.[207]

Note. From "What is Diagnostic Error?," by Society to Improve Diagnosis in Medicine. Erin P Balogh, et al., *Improving diagnosis in health care* (2015).

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203. NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164.
204. *See id.*; Bakradze & Liberman, *supra* note 192, at 11.
205. NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164.
206. *See id.*
207. *See id.*

According to the Joint Commission, diagnostic errors result in death or injury to 40,000 to 80,000 patients each year.[208] Many of these deaths are preventable.[209] Diagnostic error "result[s] in a staggering toll of harm and patient deaths."[210] Nearly one in twenty patients—or 12 million adults in the U.S.—face a diagnostic error each year,[211] and one third of these patients may be seriously harmed.[212] Other studies suggest that as many as one in every six patients are affected by diagnostic error.[213] Further, patient surveys indicate that at least one in three patients has direct, firsthand experience with diagnostic error.[214] These statistics are unsurprising given that diagnostic error often involves a large variety of common diseases, and that related errors have significant potential to do harm.[215]

The danger of diagnostic error extends into the decision-making process, as high rates of error remain an issue in making *diagnostic* decisions. This high rate of error is not unexpected, given that the "medical diagnostic process involves a complex network of interaction between the patient and the healthcare system."[216] This process constantly evolves and often involves a cyclical interaction with patient communication, information-gathering, and data synthesis.[217] Each of these points requires at least one, if not multiple, points of interaction to understand the complexity of each patient's clinical picture and pathology.[218] Given the complexity of this process, failures can occur along the continuum of care.[219] This in turn has the potential to result in missed, inaccurate, or delayed diagnosis as well as inappropriate treat-ment. [220] Within the continuum of patient care, there are differing

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208.   *See* Rodziewicz et al., *supra* note 129; *see generally* NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164; Lucian L. Leape, Donald M. Berwick, & David W. Bates, *Counting Deaths Due to Medical Errors—Reply*, 288 JAMA 2404, 2405 (2002).

209.   *See* Rodziewicz et al., *supra* note 129.

210.   Graber, *supra* note 187, at ii21, ii25.

211.   Hardeep Singh et al., *The Frequency of Diagnostic Errors in Outpatient Care: Estimations from Three Large Observational Studies Involving US Adult Populations*, 23 BRIT. MED. J. QUALITY & SAFETY 727 (2014); NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164, at 105.

212.   Singh et al, *supra* note 211, at 727 (noting their calculations that 12 million adults, or 1 in 20 adults, are affected by diagnostic errors per year in the United States); Hardeep Singh, et al., *Types and Origins of Diagnostic Errors in Primary Care Settings*, 173 JAMA INTERNAL MEDICINE 418, 420 (2013); *see generally* NAT'L ACAD. SCI., ENG'G, MED., *supra* note 164.

213.   *See* Rodziewicz et al., *supra* note 129.

214.   *See* SOC'Y IMPROVE DIAGNOSIS MED., *supra* note 166.

215.   Singh et al., *supra* note 212, at 418.

216.   Dana Siegal, Lindsay M. Stratchko, & Courtney DeRoo, *The Role of Radiology in Diagnostic Error: A Medical Malpractice Claims Review*, 4 DIAGNOSIS 125, 125 (2017).

217.   *Id.*

218.   *Id.*

219.   *Id.*

220.   *Id.*

stages in the diagnostic process.[221] These can be divided into seven components: 1) access and presentation; 2) history taking/collection; 3) the physical exam; 4) testing; 5) assessment; 6) referral; and 7) follow-up.[222] Each of these components helps identify at what point in the diagnostic process an error can occur.[223]

At its core, the diagnostic decision process involves evaluating a patient complaint, developing a differential diagnosis, designing a diagnostic evaluation, and ultimately arriving at a final diagnosis.[224] Diagnostic error occurs in virtually all medical areas. Given the widespread nature of diagnostic error, clinicians should be aware of the most misdiagnosed conditions.[225] Further, they should take extra precautions to determine and confirm the diagnosis.[226]

Despite this need to prevent diagnostic error, data on the most frequently misdiagnosed conditions is limited. Further, scarce research exists as to "which diagnostic processes are most vulnerable to breakdown."[227] Most data pertaining to diagnostic error is drawn from studies of malpractice claims or self-report surveys.[228] Of course, these limitations bake bias into the data[229] A report by the American Medical Association (AMA) advises that steps be taken to "dramatically strengthen the research base for outpatient safety."[230] The AMA specifically highlighted outpatient diagnostic error as an area needing more research, as "understanding the circumstances in which these errors occur in typical practice is a necessary step toward generating preventive strategies."[231] Expanding our research base on diagnostic error is critical as these errors pose great dangers to some of our most vulnerable communities.[232]

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221.   Schiff et al., *supra* note 23, at 261.

222.   *Id.*

223.   *Id.*

224.   *Diagnostic Decision Making*, 1 J. OF HOSPITAL MED: CORE COMPETENCIES IN HOSPITAL MED. 65 (2006).

225.   *See* Rodziewicz et al., *supra* note 129.

226.   *See id.*

227.   Singh et al., *supra* note 212, at 418.

228.   *See id.*

229.   *Id.* (noting that "these methods introduce significant biases that limit the generalizability of findings to routine clinical practice").

230.   *Id.* at 419.

231.   *Id.*

232.   *See generally* Bakradze & Liberman, *supra* note 192; Arthur L. Whaley, *Cultural Mistrust of White Mental Health Clinicians Among African Americans with Severe Mental Illness*, 71 AM. J. ORTHOPSYCHIATRY 252 (2001).

D. *Human Cost of Medical Error*

Despite significant attention[233] and attempts at systemic change, racial and ethnic disparities in healthcare remain a significant public health problem in the U.S.[234] Sadly, these disparities persist across health care settings.[235] Seemingly trivial mistakes can result in severe harm, particularly for vulnerable patient populations.[236] We all make mistakes, but unfortunately in medicine, mistakes can cost the life of a patient.[237] Medical error may occur due to carelessness, lack of adequate knowledge, or due to system error.[238] Even seemingly small mistakes may have horrifying consequences, particularly for vulnerable communities.

In looking at exposure to medical error, vulnerable populations are at risk for not only trivial mistakes but also adverse events, which can be mild, moderate, or severe.[239] Adverse events refer to unexpected medical problems that happen during treatment with a drug or other therapy[240] and may result from mistakes or medical error.[241] The nature of adverse events is that they are unexpected, so one would expect them to occur randomly. Instead, research reflects that these "unexpected" events occur predictably and systematically across race, ethnicity, and socio-economic status.[242] This predictability is true for both adverse events and diagnostic error.[243] This systematic spread of error across specific

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233.	*See* Elizabeth Brondolo, Linda C. Gallo, Hector F. Myers, *Race, Racism and Health: Disparities, Mechanisms, and Interventions*, J. BEHAV. MED. 1, 1–8 (2009).

234.	Ross et al., *supra* note 104; NAT'L CTR. FOR HEALTH STATS., HEALTH, UNITED STATES (2015); U.S. DEP'T HEALTH & HUM. SERVS., 2016 NATIONAL HEALTHCARE QUALITY AND DISPARITIES REPORT (Oct. 2017); Nelson, *supra* note 76.

235.	Ross et al., *supra* note 104; D. R. Williams & R. Wyatt, *Racial bias in health care and health: Challenges and opportunities*, 314 JAMA (2015); David R Williams, Selina A. Mohammed, Jacinta Leavell, & Chiquita Collins, *Race, Socioeconomic Status and Health: Complexities, Ongoing Challenges and Research Opportunities*, 1186 ANNALS N.Y. ACAD. SCIENCES 69 (2010).

236.	*See generally* Robert L Phillips, L.A. Bartholomew, S.M. Dovey, G.E. Fryer Jr, T.J. Miyoshi, & L.A. Green, *Learning from Malpractice Claims About Negligent Adverse Events in Primary Care in the United States*, 13 BMJ QUALITY & SAFETY 121, 121 (2004); S.M. Dovey, D.S. Meyers, R.L. Phillips Jr, L.A. Green, G.E. Fryer, J.M. Galliher, J. Kappus, & P. Grob, *A Preliminary Taxonomy of Medical Errors in Family Practice*, 11 BMJ QUALITY & SAFETY 233 (2002); Eric J. Thomas & Troyen A. Brennan, *Incidence and Types of Preventable Adverse Events in Elderly Patients: Population Based Review of Medical Records*, 320 BMJ 741 (2000).

237.	Casey Flynn, *Three Horrific Medical Mistakes that Scandalize the Profession*, USC ANNENBERG CTR. HEALTH JOURNALISM (May 4, 2016), https://centerforhealthjournalism.org/our-work/insights/3-horrific-medical-mistakes-scandalize-profession [https://perma.cc/UCC3-3ERC].

238.	*See id.*

239.	NAT'L CANCER INST., *Adverse Event*, U.S. DEP'T HEALTH & HUM. SERVS. (2020).

240.	*See id.*

241.	Piccardi et al., *supra* note 37, at 114.

242.	*Id.*

243.	*Id.*

communities indicates that adverse events are not truly random, but instead the harm from error disproportionately falls on individuals that are already vulnerable within our healthcare system.

Racial and Ethnic Minorities

Racial and ethnic minorities experience great disparities in the quality and safety of healthcare they receive.[244] In many cases, these discrepancies are due to socio-cultural factors.[245] Efforts to improve patient safety have underestimated and failed to recognize the critical relationship that exists between culture, language, and the safety and quality of care for patients.[246] Patient safety among racial and ethnic minorities remains a great concern as these populations face a heightened risk of experiencing preventable adverse events.[247]

Despite efforts to improve patient safety and quality of care, there is limited focus on improving safety for ethnic minority populations, which remains an under researched area.[248] To ensure that racial and ethnic minorities receive safe, quality care, and are sufficiently protected, the link between patient safety, culture, and language needs to be recognized. Further, the vulnerabilities of patients from minority cultural and language backgrounds need to be identified and actively addressed in patient safety systems and processes.[249]

Experience of Female Patients

Female patients continue to be overlooked in medicine.[250] Historically, medical education and research center male bodies.[251] Medicine simply assumed that it could extrapolate its male-focused research and

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244.   Ashfaq Chauhan, Merrilyn Walton, Elizabeth Manias, Ramesh Lahiru Walpola, Holly Seale, Monika Latanik, Desiree Leone, Stephen Mears, & Reema Harrison, *The Safety of Health Care for Ethnic Minority Patients: A Systematic Review*, 19 INT'L J. EQUITY HEALTH 118 (2020).

245.   *Id.*

246.   *See* Arthur L. Whaley, *A Two-Stage Method for the Study of Cultural Bias in the Diagnosis of Schizophrenia in African Americans*, 30 J. BLACK PSYCH. 167, 167 (2004); Arthur L. Whaley, *Cultural Mistrust of White Mental Health Clinicians Among African Americans with Severe Mental Illness*, 71 AM. J. ORTHOPSYCHIATRY 252, 252 (2001).

247.   *See generally* Chauhan, et al., *supra* note 244, at 1; Megan-Jane Johnstone & Olga Kanitsaki, *Culture, Language, and Patient Safety: Making the Link*, 18 INT'L J. QUALITY HEALTH CARE 383, 383 (2006).

248.   *See generally id.*

249.   *See generally* Johnstone & Kanitsaki, *supra* note 247, at 383.

250.   *See generally* Katerina Hamberg, *Gender Bias in Medicine*, 4 WOMEN'S HEALTH 237, (2008).

251.   *See generally id.* at 237–38.

data to sufficiently treat other groups.[252] However, research shows that sex-based differences affect health outcomes.[253] One study found significant sex-based differences in various bodily functions, including those of the liver, kidneys, and the digestive system.[254] Additionally, differences have been identified in the way different sexes respond to a disease treatment.[255] Consequently, it is not enough to study males in medicine and assume the findings are equally applicable to females bodies.

LGBTQ+ Population

In recent years, the social climate in the U.S. has witnessed a steady increase in legal rights, social acceptance, and visibility for lesbian, gay, bisexual, and transgender (LGBTQ+) people.[256] Despite this progress, prejudice pervades the healthcare system.[257] Discrimination faced by the LGBTQ+ population extends into healthcare, and a lack of information exists as to the needs and experiences of this population. [258] Without significant research on this population, it is difficult to assess how and the extent to which they are affected by medical error. More research is needed in general about the health and needs of this population, which at present is limited.[259]

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252.   *See generally id.* at 238 (explaining that the roots of gender bias and gender distortion in clinical practice are found at a system level).

253.   *See generally* Emmanuel O. Fadiran & Lei Zhang, *Effects of Sex Differences in the Pharmacokinetics of Drugs and Their Impact on the Safety of Medicines in Women, in* MEDICINES FOR WOMEN 41 (Mira Harrison-Woolrych ed., 2015); INST. OF MED., *Sex Begins in the Womb, in* EXPLORING THE BIOLOGICAL CONTRIBUTIONS TO HUMAN HEALTH: DOES SEX MATTER? 45 (Theresa M. Wizemann & Mary-Lou Pardue eds., 2001).

254.   *See* INST. OF MED., *supra* note 253, at 72 ("[W]omen, but not men, undergo fluctuations associated with the reproductive condition (such as the ovarian cycle and pregnancy) that influence numerous bodily functions (e.g., gastrointestinal transit time, urinary creatinine clearance, liver enzyme function, and thermo- regulation), including brain function.").

255.   *See id.*

256.   Mary E. Kite & Kinsey Blue Bryant-Lees, *Historical and Contemporary Attitudes Toward Homosexuality*, 43 SOC. FOR TEACHING PSYCH. 164, 164 (2016).

257.   *Id.*

258.   Ilan H. Meyer, *Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence*, 129 PSYCH. BULL. 674 (2003); Ilan H. Meyer, *Minority Stress and Mental Health in Gay Men*, J. HEALTH & SOC. BEHAV. (1995); *see also* Kellan Baker, Exec. Dir., Whitman-Walker Inst., Cracking the Code: Using Machine Learning to Identify Transgender People in Medical Claims Data, Presentation at the Am. Pub. Health Ass'n Annual Meeting and Expo (Nov. 2019); Kellan Baker, Exec. Dir., Whitman-Walker Inst., Leveraging the Behavioural Risk Factor Surveillance System for Transgender Health Research, Presentation at the Am. Pub. Health Ass'n Annual Meeting and Expo (Nov. 2019).

259.   *See* Paula L. McNiel & Kathleen M. Elertson, *Advocacy and Awareness: Integrating LGBTQ Health Education Into the Prelicensure Curriculum*, 57 J. NURSING EDUC. 312, 312 (2018).

In particular, research about the health and size of the transgender population in the U.S. is limited.[260] Public health or health services data collection rarely captures gender identity, which makes it difficult to assess the demographics, health, and other characteristics of the transgender population.[261] The absence of information is due to the lack of routine and standardized forms of survey data collection.[262] Recent years have seen a rapid expansion of transgender health research, but this progress "continues to be limited by methodological challenges, including those related to measuring gender identity."[263] Again, given the lack of information about this population, it is difficult to determine the extent and the ways in which they are influenced by medical error.

III. MEDICAL ERROR & BLAME

"To Err is Human."[264]

Despite the Hippocratic Oath's guidance to "keep [patients] from harm," harm persists in the medical field.[265] When an error occurs, the "[healthcare] professionals experience profound pscyhological effects such as anger, guilt, inadequacy, depression, and suicide." [266] This Part investigates the relationship between medical error and blame, which in some cases prevents healthcare institutions from a corrective course of action.[267]

The perpetual culture of blame that exists within medicine is a major barrier in learning from and responding to an error. To err is human.[268] Mistakes made by individuals will always be a part of our healthcare system.[269] A shift is needed in our healthcare system, one that moves away

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260. *See* Kellan Baker, Leveraging the Behavioural Risk Factor Surveillance System for Transgender Health Research, *supra* note 258.

261. Kellan Baker, Cracking the Code: Using Machine Learning to Identify Transgender People in Medical Claims Data, *supra* note 258.

262. *See* Kellan Baker, Leveraging the Behavioural Risk Factor Surveillance System for Transgender Health Research, *supra* note 258.

263. Ariella Tabaac et al., Instructor, Boston Child.'s Hosp., Harvard Med. Sch., Gender Identity in Longitudinal Research: Addressing Changes in Self-Reported Gender Identity in the Growing Up Today Study, Presentation at the Am. Pub. Health Ass'n Annual Meeting and Expo (Nov. 2019).

264. INST. OF MED. COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 36.

265. LUDWIG EDELSTEIN, THE HIPPOCRATIC OATH: TEXT, TRANSLATION AND INTERPRETATION 3 (Henry E. Sigerist ed., 1943) ("I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.").

266. *See* Rodziewicz et al., *supra* note 129.

267. *See* Nancy J. Crigger, *Always Having to Say You're Sorry: An Ethical Response to Making Mistakes in Professional Practice*, 11 NURSING ETHICS 568, 572 (2004) (discussing negative effects that blaming an individual for an error can have on healthcare professionals); White & Gallagher, *supra* note 26, at 115 (discussing emotional impact of errors on clinicians).

268. TO ERR IS HUMAN, *supra* note 156.

269. *See* Rodziewicz et al., *supra* note 129.

from a strong culture of blame, shame, and punishment to one that recognizes safety challenges and the potential for introducing viable solutions.[270] Rather than searching for a way to deflect responsibility or pin the problem on a scapegoat, healthcare institutions need to "establish a culture of safety that focuses on system improvement."[271] This can be accomplished by framing medical error as a challenge that need to be addressed.[272]

A. *Blame In Medicine*

"Errors must be accepted evidence of system flaws not character flaws. Until and unless that happens, it is unlikely that any substantial progress will be made in reducing errors."[273]

Medical error is a leading cause of death in the U.S.[274] It is often difficult to uncover and address medical error.[275] Even if an error is discovered, difficulties remain in addressing the problem and establishing a system to reduce or prevent the reoccurrence of the error.[276] Blame is a big challenge to sufficiently responding to an error because it shifts focus away from addressing the error at hand. Research shows that recognizing that an error has occurred, learning from it, and working toward preventing the same error in the future can help improve overall patient safety.[277] This may sound like a relatively simple solution, but the reality is that this process is fraught with challenges and the ever-growing complexity of our healthcare system.

When an error does occur, there is a societal expectation that someone is at fault. There is a desire to assign blame, punish the individual. Through lawmakers, our system has created an intolerance for error in healthcare and built expectations that our systems should be error-free.[278] But this hardline perspective could not be further from the truth. An error is often the result of a wide range of factors that extend beyond an individual's conscious control.[279]

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270.   *See id.; see also What Is Just Culture?, supra* note 18; Lambert et al., *supra* note 1, at 2492; McDonald et al., *Responding to Patient Safety Incidents, supra* note 36.

271.   Rodziewicz et al., *supra* note 129; *see also* Thomas H. Gallagher et al., *Disclosing Harmful Medical Errors to Patients: Tackling Three Tough Cases*, 136 CHEST 897 (2009); Thomas H. Gallagher et al., *Disclosing Harmful Medical Errors to Patients*, 356 NEW ENG. J. MED. 2713 (2007).

272.   *See* Rodziewicz et al., *supra* note 129.

273.   Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851, 1857 (1994).

274.   Rodziewicz et al., *supra* note 129.

275.   *Id.*

276.   *See id.*

277.   *See id.*

278.   *See* Charles Vincent, THE ESSENTIALS OF PATIENT SAFETY 4 (2d. ed. 2011).

279.   *See id.* at 7; *see also* Rodziewicz et al., *supra* note 129.

In the early 1990s, psychologist James Reason established the Swiss Cheese Model (SCM).[280] This model has become the dominant paradigm used in analyzing medical error and patient safety incidents.[281] Reason used the image of Swiss cheese to explain the occurrence of system failures, like those seen in the aftermath of a medical error.[282] Based on this metaphor, in a complex system, dangers are prevented by a series of barriers.[283] Despite the barriers in place, each layer of protection has unintended weaknesses or holes—hence the likeness to Swiss cheese.[284] The weaknesses present in each barrier are unpredictable, and the "holes" may open and close at random.[285] When all the holes in each barrier align, the danger reaches the patient and causes harm.[286] The SCM proposed by Reason can help healthcare institutions reflect on the weaknesses and problems within the healthcare system overall, as opposed to focusing on the individual.[287]
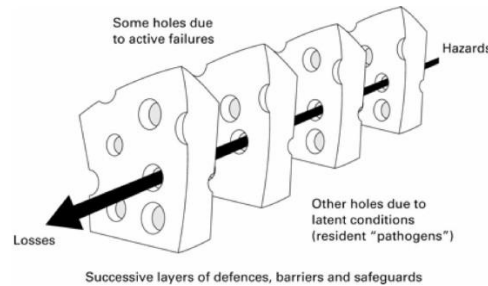

FIGURE 1. SWISS CHEESE MODEL BY JAMES REASON PUBLISHED IN 2000.[288] DEPICTED HERE IS A MORE FULLY LABELLED BACK AND WHITE VERSION PUBLISHED IN 2001.[289]

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280.   Justin Larouzée & Franck Guarnieri, *From Theory to Practice: Itinerary of Reasons' Swiss Cheese Model*, EUR. SAFETY AND RELIABILITY ASS'N (2015), https://www.researchgate.net/publication/282940101_From_theory_to_practice_Itinerary_of_Reasons%27_Swiss_Cheese_Model [https://perma.cc/J5EL-29UZ].

281.   Thomas V. Perneger, *The Swiss Cheese Model of Safety Incidents: Are there Holes in the Metaphor?*, 5 BMC HEALTH SERV. RSCH. 1 (2005).

282.   *Id.* at 2.

283.   *Id.* at 1.

284.   *Id.*

285.   *Id.*

286.   *Id.*

287.   *Id.*

288.   James T. Reason, *Human Error: Models and Management*, 320 BMJ 768, 769 (2000).

289.   James T. Reason, Jane Carthey, & M.R. de Leval, *Diagnosing "Vulnerable System Syndrome": An Essential Prerequisite to Effective Risk Management*, 10 Suppl II QUALITY IN HEALTH Care ii21, ii21 (2001).

Given that medical error results from multiple converging factors—as opposed to individual control—there needs to be greater understanding by the public and legislature as to fault and how to address error.[290] Further, reducing medical error cannot rely solely on discipline and training.[291]

B. *Professional Liability & Blame*

"Medical malpractice claims help us to see past the surface of medical errors to the deeper vulnerabilities and potentially broken aspects of our healthcare delivery system."[292]

Medical malpractice is a specific subset of tort law that deals with professional negligence.[293] Medical malpractice suits handle professional liability and are both common and controversial.[294] The legal rules related to professional liability serve two different functions.[295] One is that a victim of negligent care should receive fair compensation, and the second is that these legal rules serve to encourage healthcare providers to improve care and deter them from causing damage.[296] Despite these two underlying goals, the tort system is not designed to simultaneously compensate the victim and prevent similar harm from recurring in the future. As opposed to addressing the underlying harm of medical error, malpractice suits find fault and assign responsibility for the harm suffered by the patient.

The courtroom is an ineffective space to determine why an error occurred as it is not designed to address the harm that patients have suffered across the board. Instead, a court proceeding is an exercise in fault finding. Malpractice suits seek to find fault, and, if warranted, award just compensation to the harmed patient. Tension persists between our medical malpractice system and the movement for greater patient safety. [297] Attorneys believe that the threat of litigation will

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290.   *See* Rodziewicz et al., *supra* note 129.

291.   Charles Vincent, The Essentials of Patient Safety 7 (2d. ed. 2011).

292.   Dana Siegal et al., *The Role of Radiology in Diagnostic Error: A Medical Malpractice Claims Review*, 4 Diagnosis 125, 125 (2017).

293.   B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 Clinical Orthopedics & Related Rsch. 339, 340 (2009).

294.   Medical Malpractice & The U.S. Health Care System (William M. Sage & Rogan Kersh, eds., 2006).

295.   Guillod, *supra* note 107, at 183.

296.   *Id.*

297.   David M. Studdert, Michelle M. Mello, & Troyen A. Brennan, *Medical Malpractice*, 350 New Eng. J. of Med. 283, 287 (2004).

encourage doctors to practice medicine more safely. Instead, doctors and healthcare institutions stonewall information and often refuse to acknowledge or discuss the error out of fear of impending litigation. This fear is not unfounded: the tort system introduces a punitive, individualistic, adversarial approach.[298] This approach goes against the patient safety movement, which emphasizes a non-punitive, systems-oriented, and cooperative strategies approach.[299]

Over time, a culture of blame has developed around medical malpractice, as these suits are an exercise in fault finding. Tort law targets individual physicians, assigns blame, and exacts compensation[300] on the basis that the physician breached their duty and caused harm to the patient.[301] The potential threat of patients filing a malpractice suit poses a major challenge toward improving patient safety and the reliability of healthcare organizations.[302] Consequently, the fear of malpractice suits leads medical professionals to be wary of patient safety efforts, which in turn discourages transparency.[303] Presently, little to no legal protection exists for transparency when an error occurs.[304]

Our attempts to address medical error overemphasize who is at fault for the patient's harm. This response, along with overused medical malpractice litigation, feeds into defensive behaviors.[305] This defensiveness may lead hospitals to be uncooperative. Institutions may also stand firm on their actions and insist that they handled the case appropriately and according to industry standard. An increase in defensive actions leads to greater costs and higher risks to patients and their safety.[306] Blame produces a defensive reaction where healthcare professionals double-down on their actions and either refuse to, or out of fear, are unable to investigate the error. A lack of communication produces gaps in our understanding about the occurrence of an error and poses great risks to patients.

The overuse of blame and punitive measures indicates that our medical malpractice system is not working. There is a clear need for a different approach to medical error. This approach should be multifaceted, involving workplace culture, institutional organizations, and our

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298. *Id.*

299. *Id.*

300. *Id.*

301. Guillod, *supra* note 107, at 183.

302. Maurizio Catino, *Blame Culture and Defensive Medicine*, 11 COGNITION, TECH. & WORK 245 (2009).

303. Studdert et al., *Medical Malpractice*, *supra* note 297, at 287.

304. *Id.*

305. Catino et al., *supra* note 302, at 246.

306. *Id.*

legal system.[307] Using blame or punishment does not increase the reliability or safety of our healthcare system, nor does it effectively deter error.[308]

Transparency is key to the patient safety movement. To learn from error, we must identify when one has occurred. To successfully identify error, an environment that supports openness and honesty when an error occurs is essential. This transparency must extend beyond the medical team—hospitals and healthcare institutions must also be honest with patients about medical error.[309] Recognizing that most error is due to systemic failure as opposed to an individual clinicians' incompetence or carelessness is a step in the right direction.[310] Legislators also need to introduce additional legal protections to help support transparency, as it is critical to move away from using information gathered about an error as grounds to establish liability.[311]

1. The Law Works Against Disclosure

In addressing patient harm, courts emphasize compensation to the patients as opposed to understanding what really happened or why the error occurred.[312] This disconnect between the court and patient harm is not new[313] and stems from evidence law.[314] It is difficult to determine *ex post* what happened to a patient.[315] Courts struggle to prove medical negligence and causation.[316] This may be why many medical malpractice claims settle outside of court.[317] In looking at malpractice litigation, judges have held physicians liable where the practitioners were not negligent, and they have denied compensation in cases where the physician was at fault. And, in the court system, liability is based on personal fault. The centrality of blame in the aftermath of an error and within

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307.   *Id.* at 245.

308.   *Id.*

309.   Studdert et al., *Medical Malpractice, supra* note 297, at 287.

310.   *Id.*

311.   *See* Jean-Pierre, *supra* note 1, at 327.

312.   Guillod, *supra* note 107, at 183.

313.   *See id.; see generally* Paul C. Weiler et al., A Measure Of Malpractice: Medical Injury, Malpractice Litigation, and Patient Compensation (Harvard Univ. Press 1993).

314.   *See* Guillod, *supra* note 107, at 183.

315.   *Id.*

316.   *Id.*

317.   *See* Jessica B. Rubin & Tara F. Bishop, *Characteristics of Paid Malpractice Claims Settled In and Out of Court in the USA: A Retrospective Analysis,* 3 BMJ Open 1 (2013).

malpractice suits creates a culture of secrecy.[318] In turn, healthcare institutions move away from patient safety efforts.[319] This makes it difficult to determine how or why an error occurred—making it almost impossible to prevent its recurrence.[320]

In consideration of patient safety, the law typically focuses on addressing harm suffered by the patient.[321] There is minimal focus on disclosure of medical error, especially when that error did not result in harm to the patient.[322] Some estimates suggest that 98,000 people die in the U.S. each year due to medical error.[323] Other research places that estimate as high as 440,000.[324] Despite this variation in the number of deaths that occur annually, one million or more *total* medical errors are estimated to occur each year.[325] This number is far greater than the estimated number of reported harmful mistakes.[326] In general, physicians agree that harmful errors must be disclosed to the patient.[327] But when the error does not result in harm, physicians are less inclined to disclose it.[328] Little research exists about how to handle cases of near misses or "nonharmful errors."[329] And any research related to the disclosure of such events is not widely discussed in medicine.[330] In addition to this lack of research, considerations of the legal implications around disclosing an error that did not result in harm are key. Legal advice given to physicians has emphasized not disclosing an error when no harm resulted—and not

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318.   *See* Donald M. Berwick & Lucian L. Leape, *Reducing Errors in Medicine: It's Time to Take This More Seriously*, 319 BRIT. MED. J. 136, 136 (1999).

319.   Ann Hendrich, Christine Kocot McCoy, Jane Gale, Lora Sparkman & Palmira Santos, *Ascension Health's Demonstration of Full Disclosure Protocol for Unexpected Events During Labor and Delivery Shows Promise*, 33 HEALTH AFFS. 39, 39 (2014) (arguing that placing blame hinders "open communication" with patients about errors).

320.   Steven E. Raper, *No Role for Apology: Remedial Work and the Problem of Medical Injury*, 11 YALE J. HEALTH POL'Y L. & ETHICS 267, 270 (2011)

321.   Guillod, *supra* note 107, at 183.

322.   Guillod, *supra* note 107, at 183.

323.   *See* Troyen A. Brennan, Lucian L. Leape, Nan M. Laird, Liesi Hebert, A. Russell Localio, Ann G. Lawthers, Joseph P. Newhouse, Paul C. Weiler, & Howard H. Hiatt, *Incidence of Adverse Events and Negligence in Hospitalized Patients — Results of the Harvard Medical Practice Study I*, 324 NEW ENG. J. OF MED 370, 373 (1991) (noting that "[a]mong the 2,671,863 discharges from New York hospitals in 1984, we estimate that there were 98,609 adverse events."); *see also*, Wachter, *supra* note 148.

324.   James, *supra* note 154, at 127 (estimating that 440,000 preventable adverse events contribute to patient deaths each year).

325.   Catherine J. Chamberlain, Leonidas G. Koniaris, Albert W. Wu, & Timothy M. Pawlik, *Disclosure of "Nonharmful" Medical Errors and Other Events: Duty to Disclose*, 147 ARCHIVES OF SURGERY 282, 284 (2012).

326.   *Id.*

327.   *Id.* at 283.

328.   *Id.* at 282.

329.   *Id.*

330.   *Id.*

to apologize when an error does result in harm.[331] Unfortunately, this legal advice allows secrecy and denial to thrive in the aftermath of an error.[332] The patient does not understand what happened to them or what went wrong, and unfortunately, physicians lose critical opportunities to respond to and learn from the error that occurred.[333]

This traditional stance of denial and stonewalling intrinsic in the law and medical culture[334] is short-sighted and fails to deal with the severity of medical error and the harms it poses to patients. Concern about legal consequences detracts from practitioners' focus on correcting for harm.[335] Legal liabilities loom over physicians who may admit to making an error.[336] What is more, even though a court can award a patient plaintiff damages, a money judgment may not what the patient seeks.

In taking legal action, patients frequently desire to understand what went wrong or to receive an apology.[337] Silence is a "flawed strategy" as many filed lawsuits stem from a lack of transparency and poor doctor-patient communication. One study identified these four points as the top reasons patients decide to sue: (1) to "prevent the error from happening again," (2) receive an explanation as to what happened, (3) "get an admission of error," and (4) help the physician understand how the patient felt because of the harm.[338] When patients were asked what could

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331.   Guillod, *supra* note 107, at 183.

332.   *Id.*

333.   *See generally* Boothman et al., *supra* note 35; Lambert et al., *supra* note 1.

334.   Mello et al., *supra* note 1.

335.   Ann Hendrich, Christine Kocot McCoy, Jane Gale, Lora Sparkman, & Palmira Santos, *Ascension Health's Demonstration of Full Disclosure Protocol for Unexpected Events During Labor and Delivery Shows Promise*, 33 HEALTH AFFS. 39, 39 (2014) (noting physician fear of both litigation and increases in malpractice insurance premiums as a result of error disclosure); Mello, *supra* note 1, at 24 (noting physician fear of increased liability from disclosures and settlement offers); Jean-Pierre, *supra* note 1, at 349.

336.   *See* Albert W. Wu, Layla McCay, Wendy Levinson, Rick Iedema, Gordon Wallace, Dennis J. Boyle, Timothy B. McDonald, Marie M. Bismark, Steve S. Kraman, Emma Forbes, James B. Conway, & Thomas H. Gallagher, *Disclosing Adverse Events to Patients: International Norms and Trends*, J. PATIENT SAFETY 43, 45-46 (2017) ("There is concern internationally about the impact that increasing disclosure may have on litigation."); *see also* Lauris C. Kaldjian, Elizabeth W. Jones, Barry J. Wu, Valerie L. Forman-Hoffman, Benjamin H. Levi, & Gary E. Rosenthal, *Disclosing Medical Errors to Patients: Attitudes and Practices of Physicians and Trainees*, 22 J. GEN. INTERNAL MED. 988, 990, 991 tbl.2 (2007) ("Of the faculty and resident physicians, 10% reported that on at least 1 occasion they had chosen not to tell a patient that a medical mistake had occurred because of concerns about legal liability."); Jean-Pierre, *supra* note 1, at 349.

337.   *See* McDonald et al., *Responding to Patient Safety Incidents*, *supra* note 36, at 13 (describing the importance of apology and explanation to patients in the disclosure process); Jean-Pierre, *supra* note 1, at 345–47.

338.   *See* Rocke & Lee, *supra* note 2, at 550 (citing Charles Vincent et al., *Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 LANCET 1609, 1611 tbl.3 (1994).

have prevented them from filing suit, the most common response was a request for an explanation and an apology.[339]

To encourage more open disclosure from physicians, several countries have introduced disclosure laws, which mandate the disclosure of medical error under specific circumstances. Several countries have also introduced apology laws, or laws that state an apology given after an adverse event cannot later be used in legal proceedings. In the U.S., thirty-eight states (including the District of Columbia) have introduced apology laws or disclosure protections.[340] Despite their widespread use, these laws offer varying levels of protection, and often, physicians are unaware of their existence or what information is legally protected.[341]

The actual effect of these laws—in the U.S. or abroad—on professional behavior is debatable. Little evidence exists that such laws have significantly encouraged the open disclosure of medical error.[342] This could be due in part to the lack of information about the operation of these laws. Despite the limited evidence, providing patients with an apology is key. Extensive research supports the power of apology,[343] particularly after an individual suffered harm. Apologies may "restor[e] [a patient's] sense of dignity and power."[344] Individuals who apologize receive benefits, as their "self-worth and morality" are validated.[345] Further, it is important not to underestimate the symbolic value of the law.[346] Introducing disclosure and apology laws along with other patient safety norms can help encourage medical customs to evolve.[347] These laws can help transparency and disclosure become a part of how healthcare professionals respond to error.

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339.   Charles Vincent, M. Young, & A. Phillips , *Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 LANCET 1609, 1612 (1994).

340.   Hicks & McCray, *supra* note 1.

341.   Jean-Pierre, *supra* note 1, at 369–73.

342.   Robbennolt, *supra* note 13, at 463.

343.   *See, e.g.*, Hicks & McCray, *supra* note 1; Crigger, *supra* note 29; William M. Sage, Thomas H. Gallagher, Sarah Armstrong, Janet S. Cohn, Timothy McDonald, Jane Gale, Alan C. Woodward, & Michelle M. Mello, *How Policy Makers Can Smooth the Way for Communication-and-Resolution Programs*, 33 HEALTH AFFS. 11 (2014); Andrew A. White & Thomas H. Gallagher, *Medical Error and Disclosure*, HANDBOOK OF CLINICAL NEUROLOGY (L. Bernat James & H. Richard Beresford eds., 2013); *Restorative Justice*, *supra* note 6.

344.   Jennifer Wimsatt Pusateri, *It Is Better to Be Safe When Sorry: Advocating a Federal Rule of Evidence That Excludes Apologies*, 69 KAN. L. REV. 173, 174 (2020).

345.   *Id.*

346.   Guillod, *supra* note 107, at 183.

347.   *Id.* at 183–84.

C. *Blame & Bias in Healthcare*

"Nearly every physician will be involved in a serious medical error at some time in his or her career and likely will experience strong emotional reactions from the event. Unfortunately, the medical culture has encouraged perfectionism, isolation, and individual blame."[348]

Despite our propensity to lay blame on medical professionals,[349] some error may not be preventable. Practitioners can only make use of our current technology and the resources they have available. Technology and accessible resources may pose limitations, making it impossible to prevent an error.[350]

Differences in technology and access to resources raise concerns as to the type of care patients may experience based on where they receive hospital care. An association exists between patient safety, racial/ethnic background, and socioeconomic status.[351] This connection likely stems from where these groups are more likely to receive care.[352] The question remains: *Do minorities receive poorer care in general or is this population more likely to get care at hospitals that have higher rates of patient safety problems?* Research suggests that providers who serve minority populations, and the hospitals where minorities receive care, generally provide a lower quality of care and treatment. Further, minorities tend to have less access to resources and technology that could improve health outcomes, in contrast to healthcare institutions that primarily provide care for white patients.[353] Part of the concern with disparities in care and exposure to harm and medical error may be due to differences in access to high-quality hospitals.[354]

Disparities in healthcare and rates of medical error present difficulties for vulnerable populations. Blame allows rates of error to go unchecked. This is dangerous for vulnerable populations: blame and bias harm these groups and removed opportunities for recourse. Resolving the focus on blame in the legal system will help improve patient safety overall as institutions and healthcare professionals can have conversations about what

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348.   Jennifer J. Robertson & Brit Long, *Suffering in Silence: Medical Error & Its Impact on Health Care Providers*, 54 J. EMERGENCY MED. 402, 408 (2018) (emphasis added).

349.   Catino et al., *supra* note 302, at 246.

350.   Christopher M. Wittich, Christopher M. Burkle, & William L. Lanier, *Medication Errors: An Overview for Clinicians*, 89 MAYO CLINIC PROC., 1116, 1120 (2014) (noting that "technology such as physician order entry and bar code–assisted administration systems require considerable financial investment, health care professional training, and system maintenance.").

351.   Coffey et al., *supra* note 24, at I-50, I-54–55.

352.   *See id.* at I-55.

353.   *See id.*

354.   *See id.*

when wrong and implement changes. Addressing bias will be much more complex and require an understanding that not all patients receive the same care. Further, these inequalities cannot fully be explained by differences in socio-economic status, culture, patient preferences, racial variation in disease severity, educational level, or access to higher quality hospitals.[355] Disparities in health reflect why it is key to examine exposure to error among our most vulnerable populations.

1. Overlooking Vulnerable Populations

Medical error and diagnostic error are a problem for everyone. But these errors disproportionately harm some of our most vulnerable communities—racial and ethnic minorities[356] and sexual and gender minorities.[357] Part of the diagnostic process is listening to the patient and considering their wants and needs.[358] Unfortunately, the medical community has historically ignored and overlooked these populations, causing a loss of understanding of their health and healthcare needs.[359]

It is important to listen to a patient explain their health and what they are experiencing. A patient's story is critical for making a diagnosis. Being able to come to a clear and conclusory diagnosis is considered a foundational skill within medicine.[360] The right treatment for a patient depends on the right diagnosis.[361] Over the years, medicine has advanced; there are more diagnostic technologies and more treatment options.[362] As diagnostic tests have increased in accuracy, this makes it easier to overlook an error. The expansion of diagnostic tests and technological advances—while beneficial—have allowed doctors to rely less on listening to patients and patient testimony when making treatment decisions and determining the cause of illness.[363] This is problematic,

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355.   *See, e.g.*, Andrew B. Ross et al., *supra* note 104, at 2; Williams & Wyatt, *supra* note 235, at 355; Williams et al., *supra* note 235, at 69; Coffey et al., *supra* note 24, at 154–55.

356.   *See* Glenn Flores & Emmanuel Ngui, *Racial/Ethnic Disparities and Patient Safety*, 53 PEDIATRIC CLINICS N. AM. 1197, 1200–03 (2006); Dayna Bowen Matthew, Just medicine: A cure for racial inequality in American health care 103 (NYU Press 2018).

357.   David E. Newman-Toker et al., *Missed Diagnosis of Stroke in the Emergency Department: A Cross-Sectional Analysis o f a Large Population-Based Sample*, 1 Diagnosis 162, 166 (2014) (finding that women are more likely than men to have their strokes misdiagnosed).

358.   *See* Mulley et al., *supra* note 106, at 23.

359.   David R. Buchanan, *Autonomy, Paternalism, and Justice: Ethical Priorities in Public Health*, 98 AM. J. PUB. HEALTH 15 (2008).

360.   *See* Mulley et al., *supra* note 106, at 23.

361.   *See id.*

362.   *Id.*

363.   *See id.*

given that a patient's story plays an important role in determining a diagnosis.

Further, sidestepping a patient's individual needs is dangerous for vulnerable groups who have historically been overlooked. In the past, medical paternalism allowed doctors to make treatment decisions for patients without regard to their wishes.[364] The doctor's knowledge and expertise overrode patient wishes, especially among those who were seen as less intelligent or incapable of discussing their own bodies.[365] In a sense, this technology may be used to replace the patient and their desires for treatment. For instance, clinical information systems, like computerized provider order entry can help to reduce medical error, increase standardization in practice, and improve the quality of patient care.[366]

Unfortunately, these same systems can have unintended, adverse consequences. One concern is overdependence on this technology.[367] If systems are down, chaos ensues without sufficient backups in place. Physicians may also maintain high expectations as to the data accuracy and processing, and some physicians may struggle to work efficiently without the presence of computerized systems.[368]

Another consideration is that the doctor may simply rely on the technological outputs opposed to what the patient is telling them. And for patients who have been historically ignored and overlooked, this is particularly problematic. A qualitative study conducted of Black men living in Chicago found these men felt as though they were being characterized as "a young black hoodlum."[369] For these men, even when advocated for involvement in their care, they were not taken seriously. These men also expressed concerns over cultural and language differences and often felt unheard and overlooked in hospital and care settings.[370] In instances like these, technology provides a convenient way to continue to overlook vulnerable populations. Health professionals can assess what is wrong with the patient without listening to or engaging with the patient.

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364. *See generally* David R. Buchanan, *Autonomy, Paternalism, and Justice: Ethical Priorities in Public Health*, 98 AM. J. PUB. HEALTH 15 (2008).

365. *See id.*

366. *See* Emily M. Campbell, Dean F. Sittig, Kenneth P. Guappone, Richard H. Dykstra, & Joan S. Ash, *Overdependence on Technology: An Unintended Adverse Consequence of Computerized Provider Order Entry*, 2007 AMIA ANNU. SYMP. PROC. 94, 94 (2007).

367. *See id.* at 97.

368. *See id.* at 95–97.

369. Joseph E. Ravenell, Eric E. Whitaker, & Waldo E. Johnson Jr., *According to Him: Barriers to Healthcare Among African-American Men*, 100 J. NAT'L MED. ASS'N 1153, 1157 (2008).

370. *See id.*

Reaching a diagnosis challenges the culture of medicine and the idea that science, and science alone, should make the final medical decision.[371] This assumption is convenient but also dangerous for doctors and patients.[372] It allows doctors to perceive themselves as experts who make decisions and for patients to believe that the doctor knows best. Although convenient, this assumption is flawed.[373]

IV. RECOMMENDED SOLUTIONS

Responding to medical error is not a one-size fits all approach. In fact, there are different ways to approach this problem, help reduce error, and create safer systems overall. Scholars argue that to succeed in reducing error, physicians, nurses, pharmacists, and administrators would need to fundamentally change the way they think about error.[374] Research indicates that the answer to successfully addressing medical error does not lie within medicine, but instead in other disciplines, like psychology.[375] Other research highlights the need to use the law to tackle and improve rates of error.[376]

The traditional responses to medical error centers on a culture of blame and an over-reliance on unrealistic perfectionism,[377] which stresses that a good physician does not make mistakes. Instead of using blame, impractical standards, and punitive measures to help regulate or reduce rates of error, healthcare needs to move towards a culture of safety to help create a fundamental change in medical culture.[378] Healthcare institutions must shift to create an environment of openness and transparency. History with medical error shows that focusing on fear and a repression of information in the aftermath of an error fails to protect patients, is financially costly,[379] and is detrimental for the medical malpractice system.

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371. *See* Mulley et al., *supra* note 106, at 23.
372. *See id.*
373. *See id.*
374. Vincent, *supra* note 32, at 4.
375. *Id.*
376. Guillod, *supra* note 107, at 183.
377. *See* Robertson & Long, *supra* note 348, at 402.
378. *See, e.g.*, Guillod, *supra* note 107, at 183.
379. *See* Daniel W. Tigard, *Taking the Blame: Appropriate Responses to Medical Error*, 45 J. MED. ETHICS 101 (2019).

A. *Legal solutions*

(1) Apology Laws & Legal Protection for Full Disclosure

Ideally, in the aftermath of an error, healthcare professionals and healthcare institutions would have legal protections in place to allow them to reveal the error and disclose what went wrong. This is an important part of addressing the harm that patients suffer from. After an error occurs, patients want to know what went wrong and to receive an apology.[380] Further, by bringing the error to light, healthcare institutions can reexamine why the error occurred and introduce changes to prevent that type of harm from reoccurring.

One legal solution is to expand and increase use of current apology laws.[381] Apology laws, if drafted broadly enough and with sufficient built-in protections, can help implement legal protections to allow healthcare professionals to apologize and have open, honest conversations about the error.[382]

Without legal protection to apologize and disclose the error, medical error will continue to be buried behind stonewalling tactics and medical malpractice litigation. Currently, healthcare professionals are up against an adversarial legal system[383] that uses apologies and explanations of why the error occurred as evidence of wrongdoing and liability. Apology laws that offer protection for both apologies and disclosure of the error are necessary to encourage healthcare institutions to have these open conversations.[384]

(2) Apology Laws & Protections of Apologies

"Not all apology laws are created equal—and few provide adequate protection for the truly penitent physician."[385]

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380.   *See* Lambert et al., *supra* note 1, at 2492, 2494.

381.   Hicks & McCray, *supra* note 1.

382.   *See* Jean-Pierre, *supra* note 1, at 367–69.

383.   *See* Rocke & Lee, *supra* note 2, at 550–51; Robbennolt, *supra* note 13, at 485, 491, 502, 504, 515; Studdert et al., *Medical Malpractice, supra* note 297, at 286.

384.   *See* Jean-Pierre, *supra* note 1, at 383–84.

385.   Hicks & McCray, *supra* note 1 (emphasis added).

Former Massachusetts State Senator, William L. Saltonstall developed a framework for apology law in Massachusetts[386] after his daugher died in a car accident.[387] The driver admitted he never apologized out of fear that the apology would be used against him in court.[388] From this personal experience, Senator Saltonstall proposed the first apology law to mitigate this fear.[389] Texas followed next. Though the Texas law differed in that this legislation did not protect "statements concerning negligence or culpable conduct."[390] After these initial beginnings other states followed suit with their own version of apology laws. Building on the foundation set by Massachusetts and Texas, Colorado's apology framework was the first to encompass protections for individuals working in healthcare.[391] The Colorado statute applies a bit more broadly and expressly contemplates medical malpractice lawsuits, protecting expressions of sympathy or admissions of fault by medical providers who harm a patient.[392]

Apology laws play an important role in responding to medical error. These laws provide an avenue for physicians and healthcare insstitutions to recognize their mistake and extent human empathy without fear of a lawsuit.[393] Under the current system, ideal apology laws would protect both the apology and full disclosure. Still apologies alone hold power, consequently apology laws that only protect the apology are important for patients.[394] After an error occurs, patients want to know what

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386. Brittany Brooks Frankel, *"I'm Sorry, Mississippi": An Argument for Enactment of a Physician Apology Statute by the Mississippi Legislature*, 37 MISS. COLL. L. REV. 191, 192 (2019). The Massachusetts apology law retains the same as the 1986 version:

> Statements, writings or benevolent gestures expressing sympathy or a general sense of benevolence relating to the pain, suffering or death of a person involved in an accident and made to such person or to the family of such person shall be inadmissible as evidence of an admission of liability in a civil action.

Act of Dec. 24, 1986, ch. 652, 1986 Mass. Acts 1199 (codified at MASS. GEN. LAWS ch. 233, § 23D (2021)).

387. Frankel, *supra* note 386, at 192–93.

388. *See id.* at 193.

389. *See id.*

390. Act of Apr. 15, 1999, ch. 673, 1999 Tex. Gen. Laws 3244 (codified at TEX. CIV. PRAC. & REM. CODE ANN. § 18.061 (West 2021)); *see also* Frankel, *supra* note 386, at 193 (finding that Texas's change "began the diverse approaches to apology laws").

391. Frankel, *supra* note 386, at 193; *see* Act of Apr. 17, 2003, ch. 126, 2003 Colo. Sess. Laws 940 (codified at COLO. REV. STAT. § 13-25-135 (2021)).

392. Frankel, *supra* note 386, at 192; *see also* Hicks & McCray, *supra* note 1.

393. *See* Benjamin J. McMichael, R. Lawrence Van Horn, & W. Kip Viscusi, *"Sorry" Is Never Enough: How State Apology Laws Fail to Reduce Medical Malpractice Liability Risk*, 71 STAN. L. REV. 341, 350 (2019); *see* Pusateri, *supra* note 344, at 202–16 (discussing the benefits of apologies on the individuals involved and society generally).

394. *See* Crigger, *supra* note 29, at 574 ("A recent study [...] also reported that 95% of the public responders surveyed agreed with the statement that: 'Physicians should be required to tell patients when errors are made in their case.'").

happened, but they also want an apology. The power of an apology cannot be underestimated, particularly in situations where harm has occurred.

Apologizing is beneficial for both the physician and the patient after an error has occurred.[395] An apology allows the patient to be seen and heard. Apology laws also implement important legal protections. Beyond human empathy, the impetus behind most apology laws is to "reduce the risk of apologizing for defendants by making statements of apology, sympathy, and condolence inadmissible in any subsequent trial."[396] In addition, apology laws can reduce the occurrence of litigation.[397]

(3) Restorative Justice

Apology laws can help lower the defendant's risk in medical malpractice litigation, but apologies in and of themselves are innately important and reflect a sense of ownership and responsibility for the harm done. In this respect, the power of apologies can be connected back to the idea of restorative justice. Though traditionally viewed through the lens of criminal law, restorative justice can also be applied in the medical error context.[398]

Restorative justice introduces a novel approach to criminal justice that seeks to repair harm; it provides a space for those who were harmed and those responsible for perpetrating that harm to communicate.[399] Restorative justice focuses on those who "have been harmed and the harms they have experienced."[400] This approach is based on the understanding that "crime is a violation of people and relationships."[401] Further, this method is rooted in "principles of respect, compassion, and inclusivity."[402] Within the restorative justice process, the "victims are

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395.   Pusateri, *supra* note 344, at 202 ("[A]pologies benefit injured parties by restoring their sense of dignity and power, apologizers by affirming their self-worth and morality, and society by decreasing aggression and revenge."). For additional discussion of the benefits of apologies on the individuals involved and society generally, see *id.* at 202–16 and Jean-Pierre, *supra* note 1, at 369–73.

396.   McMichael et al., *supra* note 393, at 344–45.

397.   *See id.* ("[S]tate lawmakers have been very clear that in passing these laws, they seek 'to reduce lawsuits and encourage settlements' . . . ." (footnote omitted)); Robbennolt, *supra* note 13, at 463 (noting that legal scholars suggest apologizing can help avoid litigation altogether).

398.   *See Restorative Justice, supra* note 8.

399.   *Id.*

400.   *Id.*

401.   *Id.*

402.   *Id.*

empowered to participate more fully than in the traditional system."[403] This type of approach could be key in responding to medical error.

Restorative justice moves away from harm, blame, and denial. Under this approach, parties thoroughly discuss the harm instead of focusing on liability. This method challenges traditional responses to medical error, which avoid taking responsibility and double-down on the actions that caused the harm.[404] Restorative justice focuses on communication and openness—values that need to be brought into how we respond to and communicate about a medical error. Restorative justice could be key in how we respond to error as it moves the patient away from an adversarial position and instead places the harm done to the patient at the forefront. Consequently, the emphasis is no longer on protecting the healthcare institution or seeking to avoid or reduce liability, but on the patient.

B. *Interdisciplinary Solutions*

Successfully responding to medical error and reducing harm to patients requires looking beyond the confines of medicine and the legal system. High rates of medical error continue to occur. Responding in the aftermath of an error is a complex problem that will need to draw on different fields to help target this concern. Relevant research in the field of communication emphasizes the power of apologies and the need to redesign our responses to error using facets of communication theory.

(1) Communication and Resolution Programs

Communication and Resolution Programs (CRPs) are key to reducing medical error. They provide an opportunity to reduce error and reexamine both bias and the poor treatment of marginalized communities within the medical system, which begins to repair trust.[405]

CRPs provide a comprehensive and systematic approach for responding to harm patients have experienced from their healthcare provider.[406] CRPs introduce a thorough framework that incorporates apologies and

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403.   *Id.*

404.   *Id.*

405.   Boothman et al., *supra* note 35, at 125; Mello et al., *supra* note 1, at 20.

406.   COLLABORATIVE FOR ACCOUNTABILITY AND IMPROVEMENT, COMMUNICATION AND RESOLUTION PROGRAMS (CRPS): WHAT ARE THEY AND WHAT DO THEY REQUIRE?, https://communicationandresolution.org/pix/Collaborative_CRP_Essentials.pdf [https://perma.cc/UE99-6F3X] (last visited Nov. 13, 2023).

open communication with patients and their families.[407] This open communication presents a unique opportunity to begin to rebuild trust and address the unique harm suffered by vulnerable populations.[408] Beyond this, CRPs emphasize and allow for improved communication between patients and healthcare professionals.[409] This communication involves much more than an apology and can be critical in addressing and responding to the wide variety of emotions that patients may experience in the afternmath of a medical error.[410]

Communication theory and CRPs introduce more complex forms of communication to help create a space where patients and healthcare providers can have a productive conversation about the error and the harm that occurred.[411] Addressing medical error requires understanding how to talk about the harm done and to communicate a plan that successfully responds to the error and prevents the same harm from reoccurring.[412] It also requires looking to how other fields with high pressure work environments mitigate the risk of harm.[413] For these reasons, it is critical that healthcare institutions continue to expand their understanding of high-reliability organizations.

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407. McDonald et al., *Responding to Patient Safety Incidents*, *supra* note 36, at e14 (concluding that disclosure of medical errors is rare despite the "seven pillars" safety incident response program); *id.* at e13 (discussing apology as a pillar of CRPs).

408. *See* Lorens A. Helmchen, Michael R. Richards, & Timothy B. McDonald, *Successful Remediation of Patient Safety Incidents: A Tale of Two Medication Errors*, 36 Health Care Mgmt. Rev. 114, 120–22 (2011) (identifying benefits of CRP approach over "deny and defend" in remediating patient harm, while recognizing that mere study of two patient safety incidents is "not definitive"); *see also* B. A. Liang, *A System of Medical Error Disclosure*, 11 Quality & Safety Health Care 64, 67 (2002) (calling for apology and disclosure from entire system, rather than individual practitioner, "after a thorough review of the relevant [apology] law in the provider's locality"); McDonald et al., *Patient Safety Strategies Targeted at Diagnostic Errors*, *supra* note 47, at 3 (finding that adoption of CRP principles by UIMCC led to 189 system improvements over two years); Mello et al., *supra* note 1, at 27–29 (drawing lessons from six medical centers that adopted CRPs, but cautioning that "understanding the full effects of a CRP requires longer observation than was possible" in this instance).

409. *See* McDonald et al., *Responding to Patient Safety Incidents*, *supra* note 36, at e12–e13 (discussing open communication as a pillar of CRPs).

410. *See* Betsy Lehman Ctr. Report, *supra* note 10, at 15 ("For people who receive it, open communication is associated with lower levels of adverse health impacts and health care avoidance[.]"); McDonald et al., *Responding to Patient Safety Incidents*, *supra* note 36, at e13 (discussing apology as a pillar of CRPs).

411. McDonald et al., *Responding to Patient Safety Incidents*, *supra* note 36, at e14 (concluding that disclosure of medical errors is rare despite the "seven pillars" safety incident response program); *id.* at e13 (discussing apology as a pillar of CRPs).

412. Agency for Healthcare Rsch. & Quality, Communication and Optimal Resolution (CANDOR) (2022), https://www.ahrq.gov/patient-safety/capacity/candor/index.html [https://perma.cc/33VY-D4FG] (last reviewed November 2023) (containing eight modules and additional case studies to assist CRP implementation).

413. Mark R. Chassin & Jerod M. Loeb, *High-Reliability Health Care: Getting There from Here*, 91 Milbank Q. 459 (2013).

(2) *High Reliability Organizations*

System wide changes may help minimize harm. High reliability organizations (HROs) provide a model: HROs are organizations that work under high pressure, extremely dangerous conditions but manage to maintain low catastrophe rates.[414]

Like healthcare organizations, HROs (like the aviation industry and nuclear power stations) delegate a high degree of responsibility to the individual and collective skills of human operators.[415] The label of "high reliability" originates from how these organizations respond to the following question: "How many times could this operation have failed [whatever the nature of the work is] with catastrophic results that did not fail?"[416] If the answer is *repeatedly* (meaning this could have failed repeatedly and did not), then the organization qualifies to be labeled as a HRO.[417] High reliability refers to the idea than an organization is able to complete a high-risk task, while simultaneously minimizing the occurrence of "adverse events."[418]

Addressing medical error also requires a focus on safety and accident prevention.[419] HROs such as aircraft carriers, electrical power grids, wildland fire fighting,[420] and nuclear power plants are committed to safety at the highest level.[421] HROs function under hazardous conditions, yet experience fewer than expected adverse events.[422] HROs are preoccupied with failure and error.[423] When an error occurs, HROS analyze the event and, if needed, implement a system wide change to prevent the occurrence of similar errors in the future.[424] Given their experience with the potential for catastrophic events in high pressure situations, HROs present a model that healthcare organizations could draw off of to further address error and human decision-making.

414.	*See* Sameera et al., *supra* note 14, at 328.

415.	*See id*; Luke Yip & Brenna Farmer, *High Reliability Organizations—Medication Safety*, 11 J. Med. Toxicology 257, 257–61 (2015).

416.	Yip & Farmer, *supra* note 415, at 258.

417.	*Id.*

418.	*Id.*

419.	*See, e.g.*, Kathleen M. Sutcliffe, *High Reliability Organizations (HROs)*, 25 Best Prac. & Rsch. Clinical Anaesthesiology 133, 134 (2011).

420.	Marlys K. Christianson, Kathleen M. Sutcliffe, Melissa A. Miller, & Theodore J. Iwashyna, *Becoming a High Reliability Organization*, 15 Critical Care 314, 314 (2011).

421.	Sutcliffe, *supra* note 419, at 133.

422.	*Id.*

423.	Yip & Farmer, *supra* note 415, at 258.

424.	*Id.*

Consequently, HROs offer a model for an "error-resilient system."[425] Noticing their successes, healthcare institutions adopted prevention strategies from HROs.[426] Specifically, many safety and improvement practices seen in anesthesiology were taken from the aviation industry.[427] Based on the success of HROs, medicine can take lessons from the progress in safety in other fields, like aviation.[428]

C. *Cultural and Environmental Shift*

(1) Collective Accountability

In addition to legal protections that engender open, honest conversation and exploration of the success of other fields, it is also important to change our perspective on and treatment of medical error. One way to do this is to focus on collective accountability. Within healthcare, accountability has long been acknowledged as a central issue and remains at the core of healthcare professionalism.[429]

Within the context of medical error, accountability is defined as a "set of expectations for the appropriate response to harmed patients."[430] These expectations are based off ethical norms, principles of patient safety, and the patient's preferences.[431] Accountability as used around adverse events and medical error also incorporates three key principles:

    (1) Transparency (reporting the event to the institution, as well as disclosing and apologizing to the patient and their family),

    (2) Preventing recurrences by fixing the underlying problem at the institutional level following root cause analyses, and

    (3) Providing appropriate patient compensation.[432]

Broadly, collective accountability "requires doctors to adopt transparent behaviors, learn new skills for improving team performance, and participate in institutional safety initiatives to evaluate errors and

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425.   Sameera et al., *supra* note 14, at 328.

426.   *See id.*

427.   *Id.*

428.   Chassin & Loeb, *supra* note 413, at 459.

429.   Sara Van Belle & Susannah H. Mayhew, *What Can We Learn On Public Accountability From Non-Health Disciplines: A Meta-Narrative Review*, 6 BMJ OPEN 1, 1 (2016).

430.   *Id.*

431.   *Id.*

432.   *Id.*

implement plans for preventing recurrences."[433] It also compels healthcare institutions to focus on team training, develop nonpunitive reporting systems, provide support to healthcare professionals in the aftermath of an error, and create a system to fairly compensate patients who are harmed by error.[434] Developing a culture within medicine centered around collective accountability may help to "overcome longstanding professional and societal norms" that both reinforce individual blame and hinder patient safety.[435]

(2) Just Culture

Just Culture refers to a system of shared accountability.[436] Within Just Culture, organizations are accountable for the systems they have created; they are also responsible for employee behavior and responding to this behavior in a fair and just manner.[437] In turn, employees are responsible for the "quality of their choices and for reporting errors and system vulnerabilities."[438] Creating a safe and transparent environment encourages error reporting, which can help improve the care offered to patients.[439]

Just Culture also creates an "environment where workers feel safe enough and accountable enough to engage in the prevention of errors."[440] This type of environment encourages individuals "to advocate for improvement in error reduction ... without reproach."[441] Just Culture does not mean there is no accountability;[442] individuals are in an environment that is nonpunitive, but they are still responsible for their acts.[443] Adopting a Just Culture would allow for an institutional shift in how healthcare organizations view error and respond to the blame culture that permeates healthcare.

Working in an institution that embraces a Just Culture means more security around individual decisions.[444] In this environment, a doctor's specific responsibilities can be viewed within the framework of team

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433.   *Id.* at 419.
434.   *Id.* at 521.
435.   *Id.* at 519.
436.   *What Is Just Culture?*, *supra* note 18.
437.   *Id.*
438.   *Id.*
439.   *Id.*
440.   James E. Stein & Kurt Heiss, *The Swiss Cheese Model of Adverse Event Occurrence—Closing the Hole*, 24 SEMINARS PEDIATRIC SURGERY 278, 280 (2015).
441.   *Id.*
442.   *See id.*
443.   *Id.*
444.   *What Is Just Culture?*, *supra* note 18.

delivery as opposed to that of an individual.[445] Further, Just Culture requires recognizing that humans are not perfect.[446] This directly counters the longstanding perspective on perfectionism, which assumes good doctors don't make mistakes. Within a Just Culture, when an individual makes a mistake, they should be "embraced in the process of trying to understand why the error was made rather than punished for the mistake."[447]

How we respond to medical error matters—both in the treatment of the patient who has experienced harm and the hospital staff who may be involved. For example, a true account that occurred in an intensive care unit in Ontario, Canada helps illustrate why compassion can make the occurrence of an error a moment to reflect and learn how to prevent its reoccurrence.

1. Developing a Just Culture Matters

Over thirty years have passed since Michael (at the time, a nurse early in his career) committed a near-fatal medication error with one of his patients. Michael had administered the right drug, but to the wrong patient.[448] On the day of the incident, Michael had two patients in his care—one with high potassium levels and one with low potassium.[449] Michael had been directed to inject the medication, which contained potassium, into the patient who had low levels. Instead, he injected the patient with high levels of potassium with even more potassium. The instant Michael administered the medication, he knew he had made an error—and his thoughts took a turn for the worst. He feared for the patient's life and the loss of his career or license.

Despite his fear, Michael disclosed the error to other physicians working that day immediately allowing a team of doctors and nurses to attend to the patient. As care of his patient was passed onto others in the hospital, Michael spent an entire shift in fear for the patient and for his own future in medicine. When it became clear that the patient would survive, Michael was able to discuss the situation with the head nurse. Michael expected the nurse to discipline him or send him home; instead,

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445. Bell et al., *supra* note 19, at 519.

446. *What Is Just Culture?*, *supra* note 18.

447. *Id.*

448. *Near-Fatal Medication Error Leads Nurse to Make Patient Safety a Priority*, Healthcare Excellence Can. (Oct. 30, 2017), https://www.healthcareexcellence.ca/en/resources/healthcare-provider-stories/near-fatal-medication-error-leads-nurse-to-make-patient-safety-a-priority/ [https://perma.cc/T8T9-VL9D].

449. *Id.*

her first comment was this: "What did you learn?" The head nurse then proceeded to tell Michael to slow down: "Settle down. Stop. Double check."[450] These were all the things Michael knew he should have done.

Michael's story reflects the importance of having compassion and communicating with hospital staff. This example helps to illustrate the intent behind having healthcare institutions adopt a Just Culture.

D. *Patient Focus*

(1) Patient Centered Care

Finally, as we move forward with addressing harm done to patients, it is critical to keep patients at the center of care and decision-making. This requires moving our focus away from assigning blame to individuals and reducing liability to emphasizing patient safety and inclusion within the healthcare process.

A potential avenue to improve patient safety is to take a patient centered approach. Moving away from an over reliance on technology toward greater involvement with patients and their families can lead to a safer environment for patients.[451] Research suggests that engaging patients helps them to become 'coproducers' of safer medical diagnosis practices.[452] Given this potential, more research is needed to examine how engaging patients and their families in the prevention of diagnostic error can help reduce its occurrence.[453]

Specifically, one way to get patients more involved is to focus on improving communication. IOM has stated that "communicating accurate and timely diagnoses to patients is an important component of providing high-quality care."[454] Addressing systemic and communication breakdowns may help address medical error—which continues to threaten our goals for higher quality care.[455]

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450.   *Id.*

451.   *See* Judith L. St. Onge & Robin B. Parnell, *Patient-Centered Care and Patient Safety: A Model for Nurse Educators*, 10 Teaching & Learning in Nursing 39, 42 (2015); Mary K. Walton & Jane Barnsteiner, *Patient-Centered Care, in* Quality and Safety in Nursing: A Competency Approach to Improving Outcomes 61, 62, 65 (2d ed. 2017).

452.   *See* Schiff et al., *supra* note 23.

453.   *See* McDonald et al., *Patient Safety Strategies Targeted at Diagnostic Errors, supra* note 47, at 381.

454.   Improving Diagnosis in Health Care, *supra* note 164, at 82.

455.   *Id.*

CONCLUSION

This Article has examined the persistence of medical error, the challenges to patient safety, and the many costs to society. Error is a well-known problem in our healthcare system, but much of the research overlooks the additional burdens faced by vulnerable populations. To that end, this Article has emphasized the human cost of error and has highlighted the fact that the occurrence of error is not equal but instead disproportionately affects racial and ethnic minorities and women. Insufficient research exists on medical error and the LGBTQ+ and trans communities, but this lack of research reflects another way that these populations are overlooked. Each of these communities continues to suffer and bear the brunt of error as we fail to effectively create safer systems.

One major challenge to reducing error is the legal system's focus on blame. Society is eager to assign blame and punish the individual who did wrong. This completely goes against the nature of how medical error occurs—as it is often the result of a series of systematic failures—and the overemphasis on blame fails to create a space to allow healthcare institutions to discover the error, reflect, resolve the error, and make changes to create safer systems. Instead, blame feeds into our medical malpractice system but does little to reduce risks to patients or sufficiently respond to patient harm.

Addressing this problem, I have recommended solutions designed to reflect on the many types of approaches that exist—beyond medical malpractice—that can help increase patient safety. In introducing a series of proposed solutions, our healthcare institutions may move beyond blame. Healthcare organizations should actively focus on disclosing the error allowing them to focus on patient safety rather than the denial that harm occurred. Creating a safer system for patients requires a multi-pronged approach that builds upon the strategies proposed in this Article. As society works toward building a safer healthcare system overall, it is key to keep in mind that error is a human problem. Vulnerable populations disproportionately suffer and often have the most to lose within our healthcare system. Further, the successful reduction of error depends on embracing approaches across various fields to help address the longstanding dangers posed by medical error.