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FUNDAMENTALS OF MEDICAL ETHICS

Responding to Medical Errors — Implementing the Modern Ethical Paradigm

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Ms. Z. is a 45-year-old woman recently diagnosed with breast cancer. Seven months ago, she reported a breast lump to Dr. C., her primary care physician. The physician noted a cystic area, but since Ms. Z. was starting her menstrual cycle, Dr. C. recommended reexamination. Dr. C. then went on leave, and Dr. B. assumed the patient's care. Ms. Z. saw Dr. B. several times for high blood pressure but did not mention the breast lump, and Dr. B. had not noticed this problem in her medical record. Last month, with her blood pressure now controlled, Ms. Z. asked Dr. B. about the breast lump, noting that it was growing. She was subsequently diagnosed with cancer and has returned to talk with Dr. B.

Responding to a medical error is daunting. Clinicians in Dr. B.'s situation experience the emotions every human feels when something has gone wrong: remorse, frustration, embarrassment, and fear. Perfectionism can also increase clinicians' reluctance to confront problems.

Traditionally, recommendations regarding responding to medical errors focused mostly on whether to disclose mistakes to patients. Over time, empirical research, ethical analyses, and stakeholder engagement began to inform expectations — which are now embodied in communication and resolution programs (CRPs) — for how health care professionals and organizations should respond not just to errors but any time patients have been harmed by medical care (adverse events). CRPs require several steps: quickly detecting adverse events, communicating openly and empathetically with patients and families about the event, apologizing and taking responsibility for errors, analyzing events and redesigning processes to prevent recurrences, supporting patients and clinicians, and proactively working with patients toward reconciliation. In this modern ethical paradigm, any time harm occurs, clinicians and health care organizations are accountable for minimizing suffering and promoting learning. However, implementing this ethical paradigm is challenging, especially when the harm was due to an error.

Historically, the individual physician was deemed the "captain of the ship," solely accountable for patient outcomes. Bioethical analyses emphasized the fiduciary nature of the doctor–patient relationship (i.e., doctors are in a position of greater knowledge and power) and noted that telling patients like Ms. Z. about harmful errors supported patient autonomy and facilitated informed consent for future decisions. However, under U.S. tort law, physicians and organizations can be held accountable and financially liable for damages when they make negligent errors. As a result, ethical recommendations for openness were drowned out by fears of lawsuits and payouts, leading to a “deny and defend” response.

Several factors initiated a paradigm shift. In the early 2000s, reports from the Institute of Medicine transformed the way the health care profession conceptualized patient safety.[1] The imperative became creating cultures of safety that encouraged everyone to report errors to enable learning and foster more reliable systems. Transparency assumed greater importance, since you cannot fix problems you don’t know about. The ethical imperative for openness was further supported when rising consumerism made it clear that patients expected responses to harm to include disclosure of what happened, an apology, reconciliation, and organizational learning.

In 2001, the Joint Commission began requiring health care organizations to adopt policies to inform patients of “unanticipated outcomes.” The Lexington Veterans Affairs Healthcare System and the University of Michigan generated interest in CRP adoption after reporting early successes with their programs.[2,3] The Agency for Healthcare Research and Quality catalyzed progress by funding research on responding to harm and developing the Communication and Optimal Resolution toolkit.

Two features of CRPs’ vision of the ethics of accountability are noteworthy. First, this conceptualization emphasizes that after harm occurs, all clinical team members (e.g., technicians, nurses, doctors) and health care organizations have a duty to make choices that minimize its impact. The suffering that patients and families experience from the harmful error itself is compounded, and often exceeded, when they do not receive a transparent, compassionate, and accountable response.[4] Second, this paradigm acknowledges that enacting these choices is challenging. At their core, CRPs codify the concept that after a clinician or organization has made a harmful error, they have a duty to help patients understand what happened, support them in coping, and prevent recurrences, recognizing that this obligation is fundamental to the respect and dignity owed to every patient. When clinicians and organizational leaders appreciate the values underlying CRPs, they may be motivated to take these uncomfortable steps.

Research has been critical to CRP expansion. Several studies have demonstrated that CRPs can enjoy physician support and operate without increasing liability risk. Nonetheless, research also shows that physicians remain concerned about their ability to communicate with patients and families after a harmful error and worry about liability risks including being sued, having their malpractice premiums raised, and having the event reported to the National Practitioner Data Bank (NPDB).[5] Successful CRPs typically deploy a formal team, prioritize clinician and leadership buy-in, and engage liability insurers in their efforts. The table details the steps associated with the CRP model, the ethical rationale for each step, barriers to implementation, and strategies for overcoming them.

The growth of CRPs also reflects collaboration among diverse stakeholder groups, including patient advocates, health care organizations, plaintiff and defense attorneys, liability insurers, state medical associations, and legislators. Sustained stakeholder engagement that respects the diverse perspectives of each group has been vital, given the often opposing views these groups have espoused.

As CRPs proliferate, it will be important to address a few key challenges and open questions in implementing this ethical paradigm.

First, organizations will have to ensure that CRP implementation is aligned with ethical principles and their own stated mission. Incomplete CRP implementation is ubiquitous. Faithfully implementing CRPs is especially difficult in environments with limited resources (e.g., safety-net hospitals or freestanding outpatient clinics), urban areas where the liability risk is higher than average, complex cases such as those in which it’s unclear whether the error caused harm, and cases of delayed diagnosis (e.g., the unknown extent of Ms. Z.’s harm would make the conversation with her more difficult and complicate reconciliation). Incomplete implementation fuels critics’ concerns that CRPs are merely claims-management programs for obvious harmful errors. Health care organizations’ boards of directors and adminis-

CRP Model for Responding to Harmful Medical Errors.*

CRP Step	Ethical Rationale	What Should Happen in the Case of Ms. Z.	Common Barriers	Organizational Strategies to Address Barriers
Clinician immediately reports event to organization	Unknown errors cannot be fixed Every clinician is obligated to improve the system	PCP reports delay to a designated office (e.g., patient safety), triggering CRP	Clinicians’ fear of punitive consequences for themselves or others Inadequate follow-up on safety reports	Adoption of a just culture (no punishment for human error, discipline for intentional actions) Better loop closure
Prompt, honest, and empathetic communications with patient	Empathetic and honest information sharing is essential to patient autonomy and informed decision making	CRP team works with PCP to arrange conversation with Ms. Z. to acknowledge delay, apologize, promise follow-up, and answer her questions	Fear that conversation will increase liability Not knowing what to say	Just-in-time support from CRP team to ensure and guide open, empathetic conversations
Support for all needs of patients, including psychological and logistic support	The responsibility to minimize patient suffering after harm includes supporting patient needs however possible	CRP offers and helps Ms. Z. find short- and long-term psychological and other support resources	Belief that patient needs are limited to disclosure, apology, and financial compensation	CRP offers and helps find necessary supports for patients
Psychological support for clinicians	Organizations are obligated to support clinicians’ psychological well-being	CRP team offers (and provides) psychological support for PCPs and anyone else involved	Shame, concern that seeking help is a sign of weakness, and fears about confidentiality	CRP ensures involved clinicians receive offers of support (often provided by clinical leadership), including access to confidential peer-support programs
Event analysis and prevention planning	Delivering safe health care requires learning from mistakes to prevent recurrences	Organization investigates what happened and takes steps to reduce the likelihood of a repeat event (e.g., if Dr. C.’s automated reminders in the electronic health record were not visible to Dr. B., provide a software fix)	Expertise and resources are required for timely investigation Effective improvements are often difficult to design and implement	CRP informs patients how organization will prevent similar events in future Development of safety and risk teams with necessary expertise on investigations and intervention design
Reconciliation	When error causes harm, justice and equity principles call for proactive efforts (e.g., not waiting for a claim) toward reconciliation	If the investigation uncovers a harmful error, organization apologizes and works with Ms. Z. to determine what she needs (e.g., compensation, prevention) If the investigation determines there was no harmful error, organization provides full details of the results	Traditional deny-and-defend approach Belief that if patients want financial compensation, they will ask for it	CRP proactively coordinates with liability insurers and seeks reconciliation with patients

* Tools to help organizations implement high-fidelity communication and resolution programs (CRPs), including a communication tip sheet, are available at https://communicationandresolution.org/tools-and-resources/. PCP denotes primary care physician.

trative leaders should prioritize and provide adequate resources for their CRPs, including training for executives, program leaders, and risk managers. Whether organizational leaders will demonstrate the commitment required to ensure that CRP implementation is principled and consistent remains an open question.

A second key challenge is interfacing with the medical liability system. It's encouraging that several liability insurers now support CRPs. However, a strong barrier to CRPs has been fear of liability risk and difficulty changing longstanding claims-management processes, even among insurers that say they're enthusiastic about this approach. For example, an important function of insurers is to defend claims. Whose perspective should prevail if a provider believes a harmful error was made but the insurer believes the event is defensible? In addition, CRPs may appropriately settle cases on behalf of an organization for a systems failure, obviating the requirement to report a particular physician to the NPDB. Is this approach reasonable, even though it could make it more difficult to identify physicians who are repeatedly involved in substandard care? Finally, patients may be more likely to receive greater compensation when represented by legal counsel, but such representation can be costly and hard to find. What role should CRPs play in encouraging patients to seek representation and helping them find an attorney?

An audio interview with Thomas Gallagher is available at NEJM.org

Third, organizations need to figure out how to balance commitment to transparency with protective privileges and agreements. It is somewhat paradoxical that although CRPs are rooted in a commitment to transparency, investigations into possible errors may be shrouded in secrecy. Quality improvement, peer review, and attorney–client privileges create "safe spaces" for organizations to examine quality-of-care challenges, but these privileges can inhibit the flow of information to patients and the public. Moreover, many liability settlements are accompanied by nondisclosure agreements, which may severely limit what, if anything, patients and families can say about the event that affected them. These restrictions, in turn, can both exacerbate patients' distress and inhibit prevention of errors at other organizations, running counter to the greater goals of CRPs. How public should the investigatory findings and ultimate resolution of a CRP case be?

A fourth challenge is ensuring that programs aimed at promoting transparency do not lead to unintended consequences. Open communication with patients is fundamental to CRPs. However, well-meaning clinicians sometimes rush to be open with patients but fail to prepare, and they may end up sharing information that is inaccurate and speculative, or they are perceived as lacking empathy. Patient trust that is lost during these first conversations is almost impossible to regain. How can organizations strike the right balance between encouraging both openness and discipline in communications about harm with patients and families without causing clinicians to question the sincerity of their organization's CRP?

Despite these challenges, CRPs are increasingly recognized as the standard for responding to errors. Recently, the President's Council of Advisors on Science and Technology (PCAST) Working Group on Patient Safety publicly presented its recommendations to PCAST for "A Transformational Effort on Patient Safety." The working group recommended that the Centers for Medicare and Medicaid Services require the implementation of CRPs in order to achieve resolution in cases of patient harm (https://www.youtube.com/watch?v=oc7b5Ut5dwQ). Regulatory mandates that organizations deploy evidence-based CRPs and demonstrate reliable implementation seem inevitable.

Medicine exists as a public trust, with the expectation that the profession will self-regulate. Today, in the wake of all harmful errors, bioethical principles require that clinicians and health care organizations demonstrate transparency, compassion, and accountability and proactively meet patient needs. These steps cannot only increase trust in the health care system, but also help it improve.

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1. Institute of Medicine Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academies Press, 2001.

2. Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. Ann Intern Med 1999;131:963-7.

3. Kachalia A, Kaufman SR, Boothman R, et al. Liability claims and costs before and after implementation of a medical error disclosure program. Ann Intern Med 2010;153:213-21.

4. Moore J, Bismark M, Mello MM. Patients' experiences with communication-and-resolution programs after medical injury. JAMA Intern Med 2017;177:1595-603.

5. Gallagher TH, Boothman RC, Schweitzer L, Benjamin EM. Making communication and resolution programmes mission critical in healthcare organisations. BMJ Qual Saf 2020;29:875-8.

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Looking AHEAD to State Global Budgets for Health Care

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Fourteen years after the passage of the Affordable Care Act (ACA), the value-based care movement is facing hard truths. An evaluation of 49 of the first payment and care-delivery models implemented by the Center for Medicare and Medicaid Innovation (CMMI), which was established by the ACA, showed that the vast majority haven't achieved the goal of reducing health care spending.[1] The Congressional Budget Office (CBO) reported that, despite its initial projection that these models would result in nearly $3 billion in net savings between 2011 and 2020, CMMI actually increased federal spending by $5.4 billion over its first decade.[1] Although this analysis excluded the Medicare Shared Savings Program — a signature initiative that has produced moderate savings — the findings are sobering.

In the wake of these disappointing results, CMMI is advancing new approaches. In September 2023, the Centers for Medicare and Medicaid Services (CMS) announced an ambitious model — States Advancing All-Payer Health Equity Approaches and Development (AHEAD). The AHEAD model moves toward population-based payment at the state level and has three goals: curbing cost growth, improving population health, and advancing health equity. States can now apply to participate in this voluntary model, with a preimplementation period beginning in 2024 and a performance period of 8 to 9 years, lasting through 2034. AHEAD will employ several strategies to achieve its goals, each of which has both promising features and limitations.

First, AHEAD will use global budgets as the primary strategy for curbing cost growth. Under this payment scheme, health systems are assigned budgets to finance the full range of medical services for a specified patient population. Hospitals will receive biweekly payments from Medicare that are based on historical revenue and their patients' medical needs. If these payments exceed the costs of providing care, hospitals will keep the excess revenue. Conversely, if hospital expenditures exceed the payments, hospitals will absorb the additional costs. The rationale for this model is that fixed budgets — which are independent of the volume and type of services provided — create incentives to reduce unnecessary utilization and to shift investment away from high-intensity services and toward primary and preventive care. Global budgets also present an opportunity to control the growth of health care spending. Capping annual budget increases at the rate of inflation could slow spending growth, thereby generating savings for Medicare and state governments. AHEAD builds on the experiences of Vermont, Pennsylvania, and especially Maryland, which experienced slower spending growth in some areas after implementing global budgets for its hospitals in 2014.[2]

Second, AHEAD seeks to improve population health by elevating primary care. Global budgets theoretically encourage investment in preventive services because reducing avoidable hospitalizations will be financially beneficial. In Maryland, however, global budgets weren't consistently associated with increases in primary care use, which suggests that implementing global budgets alone may be inadequate to shift care patterns.[4] AHEAD invests in primary care more directly by offering enhanced payments to outpatient practices (including federally qualified health centers and rural health clinics) that make advances in areas such as behavioral health integration, care coordination, and screening for social needs. CMS expects these payments to average $17 per patient per month, which could drive hundreds of thousands of dollars in