Chapter 25
Communication and Resolution Programs

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Case Studies

Case 1: Ahmad

Ahmad, a 28-year-old man, presented to the emergency room of an academic hospital, with bleeding from the nose and mouth. He was cyanotic, struggling to breathe with O_2 saturations in the mid to high 80s. History included two prior visits to urgent care at a local community hospital for unexplained nose bleeds; each time he had been referred to his primary care physician. Imaging in the emergency room revealed a mass which appeared to be in his pulmonary artery and a working diagnosis of clot vs tumor was made. Bronchoscopy by pulmonary medicine revealed active bleeding but the origin was unclear. Following bronchoscopy, physicians met to discuss treatment options when the pulmonary artery ruptured leading to sudden cardiopulmonary arrest. Resuscitation failed, and the patient was pronounced dead. Ten family members (only one of whom spoke English) had assembled in the waiting area while the patient was being seen. A clerical staff member, indifferent to the unfolding crisis, was the family's only point of contact until a physician bluntly informed them that the patient had died. The family reacted emotionally with death threats and broken furniture. Police were called, family members were subdued and eventually escorted out of the hospital.

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Case 2: Caroline

Emergency Medical Services (EMS) transported Caroline, a 46-year-old single mother of two teenagers, found down on the kitchen floor for no known reason. She had a high BMI, but was otherwise healthy. EMS recorded her complaint: "I can't move my legs" with their impression of "R/O kidney stones." Caroline was evaluated and labs and images were obtained. She was admitted to a med surg floor. Two hours later, she was able to ambulate without pain. The workup failed to reveal evidence of kidney stones and the patient was ambulatory and seemed improved. Worried that her teenage children were unsupervised, Caroline expressed a strong desire to go home. Vital signs were stable and she was discharged by the hospitalist with instructions to follow up with her primary care physician.

Two days later, she was found dead on a couch at home. On autopsy, the cause of death was a ruptured aorta. An attorney retained by the family filed a notice of intent to file a wrongful death claim alleging medical malpractice for failing to diagnose and treat an aortic dissection.

Introduction

According to Donald M. Berwick, the birth of the modern patient safety movement can be marked definitively by Lucian Leape's "magisterial December 1994 article in the Journal of the American Medical Association: Error in Medicine" and as he describes it, "Within just a few years of Lucian's call to arms, massive shifts were underway in healthcare's awareness of and concern about patient safety and its defects" [1]. Since then, the scope of patient safety has expanded as experts from fields as disparate as aviation, the nuclear industry and the automotive industry have sought to apply their processes to make healthcare "safe." The most ambitious among those advancing the "science of safety" are the proponents of "high reliability organizations" who argue that the only acceptable goal for clinical medicine is "Zero Harm." [2].

But what exactly is "harm" in clinical medicine? Clinical medicine is inherently dangerous. Almost nothing in clinical medicine does not cause or risk harm of some sort. No surgery can be accomplished without damage to skin and tissues, structures like nerves and blood vessels with concomitant exposure to unintended bleeding and infection. Radiology studies expose patients to harmful radiation. Screening colonoscopies risk injury by introducing tissues to foreign objects that sometimes cause tears or perforations while tumors can be missed due to technological and human limitations. Even the most seemingly benign clinical treatment, like the routine prescription of an antibiotic for a child's first ear infection can cause horrific consequences, like the children in two different malpractice claims I defended, one in Michigan and one in Ohio, who died gruesome deaths when a standard dose of Amoxicillin triggered Stevens-Johnson syndrome that spiraled into life-ending complications in each. Others can grapple with the challenge of defining "harm" in

clinical medicine and wrestle with whether attaining "zero harm" is even realistic, but for this chapter, the ambiguity is a suitable place to begin a critical examination of the way clinical medicine has, for a very long time, responded to unintended clinical outcomes.

Paradoxically, responsibility for healthcare's response to adverse clinical outcomes has been, and remains today chiefly the province of legal and insurance professionals, not clinical leaders. Those who lead clinical medicine and patient safety, arguably the very best suited to direct the response to patients harmed, have accepted and continued to accept the status quo in spite of the myriad ways that litigation-influenced responses impede efforts to improve clinical safety and actually perpetuate the litigation cycle in a sad spiral that only intensifies harm to patients, families, and healthcare professionals alike. The harm enigma bedevils clinical medicine even now while it keeps busy a sizeable portion of the legal profession and court systems both civil and criminal, a legion of regulatory agencies, patient safety experts, peer review processes, and so on.

There is a better approach. Communication and Resolution Programs (CRPs) conspicuously align the foundations of patient safety improvement with organizational and personal responses to patients who suffer unintended clinical outcomes. The model breaks the entrenched addiction to litigation-as-the-only-response by intentionally meeting patients' and families' emotional and informational needs after clinical harm; the combined compassion, honesty, and speed of engagement offers the chance to mitigate further harm to those patients and clinical staff involved in adverse events while speeding clinical improvement. Yet, movement toward CRPs continues at a snail's pace. In this chapter, I will discuss operational and outcomes differences with CRPs but in order to understand the fundamental difference, it is useful to understand how the status quo became the status quo.

Historical Perspective on Malpractice

Scholars, historians, and commentators variously trace the concept of medical malpractice as far back as 2030 BC when the Code of Hammurabi reportedly declared, "If the doctor has treated a gentleman with a lancet of bronze and has caused the gentleman to die, or has opened an abscess of the eye for a gentleman with a bronze lancet, and has caused the loss of the gentleman's eye, one shall cut off his hands" [4]. Commentators report that the first recorded medical malpractice case in English jurisprudence occurred in 1374 when a physician was sued for improperly treating a patient's hand [5]. By the 1800s, medical malpractice lawsuits appeared with some regularity in American civil litigation reports. "By the mid-nineteenth century," Kenneth De Ville, author of *Medical Malpractice in Nineteenth Century America: Origins and Legacy* [6], writes, "commentators in medical literature rarely expressed incredulity or astonishment when a patient sued a physician. They had begun to view the malpractice suit as ***a ubiquitous and possibly permanent fixture of medical practice***" [6] (emphasis added).

Two hundred years of conditioning taught American physicians two unfortunate lessons, both of which confound patient safety today: (1) because patient harm is unavoidable, being sued is inevitable and consequently, (2) these are matters for the legal profession (and by extension, the insurance industry) to manage. "Professional liability insurance has become society's chief agency for the distribution of the cost of malpractice by the medical profession" proclaimed the Duke Law Journal [7]. The year was 1960 and with remarkable prescience, the author(s) predicted the sharp rise in malpractice claims and judgments, the deterioration of the patient–physician relationship, increases in insurance premiums, and a growing demand for higher and higher policy coverage. In recognition of "the greatly increasing incidence of malpractice litigation," the author(s) acknowledged that responsibility would fall to the insurance industry to employ "risk controls" for the protection of their financial assets. Centuries of resignation to patient harm and the inevitability of litigation did not just prioritize financial loss over all other considerations, they left the medical community almost completely off the hook for injuries caused by avoidable errors. It is hardly surprising that the embrace of a response to injured patients expressly designed to serve patient safety toward an audacious goal of achieving zero harm has been glacial.

Yet, traditional legal/insurance-driven responses to patient harm have not been helpful to healthcare's healing mission. As early as 1940, commentators were decrying the loss of the traditional patient–physician relationship [8]. In 1959, an article in the Saturday Evening Post observed:

"American doctors are well aware of the restorative effect that their sympathetic interest can have on a patient. But today many people have an image of the modern doctor that is infinitely far from this ideal of medicine. In the place of the kindly, concerned doctor they see a bronzed man in a white coat who sits in his office, cold and bored….

The medical profession is frank to admit that some bad blood has welled up recently between patients and physicians, and it is worrying about how to get rid of it. The profession fears that something may be going wrong with American medicine's proudest boast, the warm and wonderful "doctor-patient relationship" [9].

Professional liability insurance companies challenged steadily increasing lawsuits with armies of malpractice trial lawyers incentivized by billable hours who leveraged a cottage industry of expert witnesses willing to testify for handsome fees. As predicted in 1960, costs soared, verdicts were publicized, insurance premiums rose steadily, insurance underwriting and renewal practices were refined and unhappy patients were labeled "litigious." The self-fueled spiral was established and the medical community soon viewed itself as prey for opportunistic patients spurred on by lawyers:

"Physicians revile malpractice claims as random events that visit unwarranted expense and emotional pain on competent, hardworking practitioners…" [10].

"For over a century, American physicians have regarded malpractice suits as unjustified affronts to medical professionalism and have directed their ire at plaintiffs' lawyers… and the legal system in which they operate" [11].

Physicians marched on state capitals [12] and pressured lawmakers for tort reforms [13] that increasingly shielded them (and their insurance companies) by making claims procedurally more difficult to bring and less lucrative. They banded together to resist meaningful peer review which led to regulatory devices like the National Practitioner Data Bank in an effort to track erstwhile physicians allowed to move freely by a profession that resisted meaningful self-policing.

Almost lost in the adversarial spiral was the uncomfortable truth that far too many patients were being harmed by preventable and avoidable (sometimes even criminal) errors. Lucian Leape recalls that in 1985, medical malpractice was considered a full-blown crisis. "Doctors seemed to complain about being sued all the time, but no one knew the facts," he writes. And specifically, no one knew how many patients were harmed by substandard care, no one knew how many suits were really being filed and no one knew the cost of the paradigm in place, the only paradigm anyone really knew at that point [14]. Neither did anyone openly question the incongruity of a physician holding a patient's life in their hands one moment and abandoning the unfortunate patient who sustained an unplanned clinical outcome the next.

Still, some thought to explore the causes of the malpractice crisis. Gerald Hickson, MD and his team concluded that 43% of a group studied sued their caregivers for damages from perinatal injuries when they suspected that those caregivers and healthcare organizations had been less than forthright about mistakes in care [15]. Moved by two large malpractice judgments in 1987 against the Veterans Administration Hospital in Lexington, KY, Chief of Staff Steve S. Kraman, MD and VA attorney Ginny Hamm envisioned a "humanistic risk management policy" that relied on early detection of patient harm, honest disclosure, and negotiation of settlements where appropriate. Defying conventional wisdom that honesty would lead to increased claims and financial catastrophe, their experience "suggests, but does not prove the financial superiority of a full disclosure policy" [16].

The Michigan Model

In 2001, in what became known as "the Michigan Model," the University of Michigan Health System systematized key elements described by Kraman and Hamm but for a markedly different reason: to prioritize patient safety. Michigan dared to question the centuries-old resignation that litigation was an inescapable part of Medicine. The Michigan model marked an important shift that would prioritize patient safety goals instead of claims, but would also eliminate the ways in which "deny and defend" impeded safety improvement [17]. The Michigan Model alternative not only demonstrated financial cost savings in the short term for the same reasons Kraman and Hamm reported, but several other measures improved: the approach truncated the time from the "date of loss" to closure, for instance [18]. The effort pointedly aimed to reinforce a culture of clinical accountability which logically should lead to safer care, durable claims reduction, and important collateral

benefits including improved clinical staff morale, and an approach to peer review that is a proactive and integral component to their culture of safety.

The Michigan Model came to the attention of Senators Clinton and Obama [19] who also sponsored the National Medical Error Disclosure and Compensation Act (MEDiC) [20]. Though it failed to pass, as Lucian Leape observes, patient safety as the fix for malpractice was "on the national agenda." In 2008, the Agency for Healthcare Research and Quality (AHRQ) awarded multiple grants to study the wider application of the model which eventually led to the publication of the CANDOR toolkit [21].

Communication and Resolution Program (CRP)

Academics have since called the approach Communication and Resolution Programs (CRP), an unfortunate label that spotlights potential claims instead of clinical accountability for preventable errors and prompts patients to bristle at the notion that they ever experience full "resolution" of the consequences of the medical mistake which harmed them. As a result, many organizations still view CRP through a claims lens, selectively recognizing and settling some cases without litigation—a helpful, but hardly new risk and claims management practice that misses the deeper benefits of a true CRP [22].

CRP's primary goal is to complement patient safety efforts, not simply amend a litigation-oriented claims management reaction to a potential malpractice claim. It is a goal realized by a consistent, compassionate and honest approach to patients harmed in their care. The organizational response to patient harm should mirror the values underpinning organizational commitment to high reliability, clinical excellence, and patient centricity.

Nine Essential Elements of CRP Elements

In this section, I describe how the nine essential elements of CRP complement the cultural foundations of medicine and discuss the practical application to the above case studies.

1. **Capture all unintended clinical outcomes, not only potential claims.** Consistent with the fundamental instinct of a healer and healing institution to instinctively run to a patient who needs healing, it is opposite of the pronounced caution of traditional risk-averse responses that results in functional abandonment of the patient harmed in an adverse event. Medicine's inherent risk—the reality that even reasonable care can lead to tragic outcomes and decades of concern about being sued - conditions healthcare professionals to treat every patient who experiences a less-than-desirable outcome as a potential claimant, precisely the opposite of the ideal compassionate patient–provider relationship.

2. **Secure the clinical environment.** Traditional legal instructions not to change the way the clinical care in an adverse event was delivered for fear of having the improvement portrayed as an admission that the previous care was negligent is at best short-sighted to the point of cynical, unethical and immoral at worst: if one patient was harmed, others are at risk. To expose other patients to a known risk in a misguided attempt to preserve a defense to a potential malpractice case is simply unjustifiable and the harm from that traditional instruction expands to the broad audience of healthcare providers involved, eroding any effort to build a culture of continuous clinical improvement. Needless to say that from a practical perspective, it is short-sighted and ill-advised.

   In Caroline's case, the missed diagnosis was "defensible" even with a careful critical analysis of her presentation and the emergency medicine care. In a defensive approach, the business of constructing that defense would have masked the real gap in Caroline's care: she was admitted with a very serious clinical complaint—she could not move her legs—which was left unexplained at the point of discharge. The dangers of "anchoring" to a presumed diagnosis and not viewing her clinical presentation broadly to entertain plausible explanations was an important lesson to be learned and communicated [23], but might have been obscured by a myopic defensive response to allegations made in a lawsuit.
3. **Engage and support the patient and family.** Defensive responses would have surely led to labeling Ahmad's family as disruptive or dangerous. In both cases, stonewalling traumatized family members would only have deepened and extended the trauma as they struggled to understand the deaths of their loved ones. Survivors would have formed conclusions based on their worst fears applied to incomplete or inaccurate information. The sooner traumatized people receive a compassionate and high-quality response, the better chance of ameliorating the emotional impact and duration [24]. CRP-modeled responses call for engaging the families of patients harmed in any adverse events even before the quality of the care can be evaluated fully; the goal is not to "disclose" any speculation in that first engagement. Healthcare staff instead is trained to demonstrate continuing and compassionate commitment to the patient and family, concentrating on the patient's new needs, committing to a *future* disclosure once facts are confidently understood while avoiding uninformed explanations in the heat of the moment.

   Engaging the patient and family immediately offers another unique benefit: a critical opportunity to learn information that only the patient may know that could be valuable to causal investigations to follow. In a litigation-oriented response, that information is rarely collected except maybe in testimony years later and never used in root cause analyses. In Ahmad's case, the discovery of the clerk's otherwise well-known-but-never-discussed aversion to people of Arab descent was important to an organization dedicated to patient centricity, one that had already invested considerable resources to improving patient experience. There was no way to know how many other patients and families the clerk had offended, but the revelation only obtained by engaging Ahmad's family could assure that no others would be harmed.
4. **Engage and support the caregivers.** For generations, healthcare providers have been effectively isolated after an adverse event by risk management admonitions

not to talk to anyone other than their assigned defense counsel [25, 26]. Perhaps no other characteristic of traditional legal responses has been so damaging to clinicians' best interests: healthcare professionals already reeling from the event with complex emotions are further isolated and other patients are at risk by healthcare professionals expected to resume clinical duties while distracted, defensive, distraught. Responding to unintended clinical outcomes and not waiting for claims to be asserted opens an important opportunity to attend to healthcare professionals' emotional well-being quickly and compassionately.

5. **Conduct a rigorous investigation in collaboration with safety.** This element is a key change from traditional ways of responding to patient harm. In a deny-and-defend culture, instances of patient harm often come to light only after a claim is asserted. And at that point, the key question: "Is this case defensible?" usually translates to: "Can we find an expert to support this defense?"

   "Is this defensible?" is the wrong question to ask! In a CRP model, the more important questions are, "Did this care meet our expectations?" "Are we proud of this care?" and "*Should* we defend this care?" These questions often lead to different responses. In Ahmad's case, the clinical care was entirely appropriate. Instead of labeling the family as dangerous, the family was called to a meeting with the five physicians involved in Ahmad's care. And though the meeting began in an emotionally charged atmosphere, one-by-one with compassion, with images and models, the physicians described the clinical challenge, their actions and their reasoning. They demonstrated their own humanity and the family could readily see that the physicians themselves were struggling with their inability to save Ahmad. By the end of a nearly three-hour meeting, family members were consoling Ahmad's physicians. The clear, compassionate explanation averted a misguided lawsuit.

   Understandably Caroline's family focused on the emergency care she received which was, even after intense scrutiny, deemed appropriate. In a litigation-focused response, risk management's advice would be to avoid any contact with the family entirely and wait to see if they pursued a claim. A significant percentage of patients harmed never come to the attention of the legal system [27, 28] and even if the family sought legal advice, there was a substantial chance that the lawyers would not get it right. Plaintiffs' lawyers' ability to analyze the quality of care is dependent on the accuracy of the factual information and quality of experts available to them; a layman with limited guidance could easily focus on the emergency medicine decisions, overlooking the clinical decisions that were made after Caroline had been admitted. If the goal is mainly to avoid financial payment for medical errors and optimally positioning the case for litigation, stonewalling this family may have been a rational choice. Defending a case in which the care was problematic, however, communicates the same financial priorities to the organization's staff at the expense of a culture of openness and honesty pivotal to a safety priority.

6. **Communicate widely to patient, caregivers, and organization.** This element is completely counterintuitive to proponents of deny and defend. It challenges the hardwired fight or flight response and flies in the face of longstanding

conventional-but-unproven certainty that we cannot afford to be honest about mistakes let alone broadcast the truth or memorialize mistakes in writing. True CRPs are highly disciplined, requiring risk management staff and clinical leadership to know the difference between speculation and hard facts, but appreciating the critical importance of open acknowledgment of mistakes to a culture of safety. Within weeks of the investigation of Caroline's death, all three emergency departments operated by the health system were in-serviced with her story and the case was embedded into residency training. The story was shared with the patient safety organization operated by the state's hospital association and presumably shared with the PSO's members.

In Ahmad's case, a family meeting was arranged. Using imaging and an anatomical model, five physicians chronologically presented what they did in Ahmad's care and why. The family received a thorough explanation of what happened. No lawsuit was filed.

7. **Respond consistently with conclusions from the investigation.** In this element, health systems respond in ways that are congruent with their findings. In this regard, CRPs represent a departure from long-established claims management decisions to defend even care that may privately be regarded as substandard, but conversely to settle cases for financial and risk avoidance reasons even where the care met standards of care. In litigation-driven responses, it is customary to view every case as having some settlement value, often measured against the anticipated cost of defense no matter how baseless the allegations. Both practices are counterproductive to patient safety. Publicly defending substandard care effectively eliminates meaningful peer review that may be warranted and sends seriously mixed signals to the clinical staff about organizational priorities. So-called nuisance settlements telegraph to patients, the trial bar and healthcare professional that responding to unplanned harm is a "lawyers' game."

   CRPs instead, rely on early communication in all cases of harm, including those in which the care proved to be reasonable. In this way, patients are reassured that the patient–provider relationship remains unshaken and misguided lawsuits are intercepted before patients, families, and their lawyers invest in litigation before they know the full facts. One of the most consistent ways in which CRPs save money is the avoidance of claims not pressed. Winning the confidence of the medical staff is critical to a CRP's goal of achieving accountability for mistakes that cause harm. As sad as Ahmad's death was, the organization refused to behave as though his physicians did anything wrong clinically to cause his death. Making a full explanation headed off an expensive claim. In Caroline's case, litigation was also avoided: despite the family's clinically-unwarranted focus on her emergency medical care, a settlement was reached after fully disclosing that though the emergency medicine course was reasonable, the discharge decision was problematic. They were reassured that lessons were learned, and efforts made to protect future patients. Patient safety was advanced, the individual interests of everyone involved were served and all involved avoided the high costs of litigation, emotional and financial.

8. **Hardwire lessons learned.** In both cases, the healthcare system embraced the lessons learned, building Caroline's clinical presentation into a grand rounds and residency education and using the discovery of the clerk's prejudice from Ahmad's case to highlight ethnic sensitivity across the system.
9. **Measure different metrics.** What an organization chooses to measure speaks volumes about its priorities. In organizations with litigation-sensitive responses to patient harm, overall malpractice costs are measured and used as proof that the organization and its staff are victims of windfall-motivated patients. Consider how paradoxical that patient image is to the central clinical mission of healthcare organizations! How incompatible it is compared to the reasons individual professionals dedicate themselves to medicine! That measure warns the organization and its staff that the patients they aim to treat could turn on them as soon as clinical care doesn't go as planned. The cost exceeds dollars and cents: it erodes the very mission itself. In finance-preoccupied healthcare environments, executives can recite to the penny how much they spend on malpractice, but they can never answer a more pertinent question: "How much *should* you have spent?" As careful as some healthcare organizations may consider themselves, none are immune from harming patients by avoidable, preventable medical mistakes. If they're not distinguishing between undesirable clinical outcomes that happened despite appropriate care from harm caused by avoidable medical errors, and if they're not doing their best to rectify the harm they caused in such cases, by definition they are not accountable. And if they are not accountable, they will predictably not advance the safety of their clinical care, they will not maintain an environment where their staff can find joy and meaning in their work, they will not offer a uniformly positive clinical care experience to their patients and their peer review efforts will never advance clinical care.

Conclusions and Key Lessons Learned

- Healthcare professionals have known since Hammurabi's time that intended clinical outcomes cannot be guaranteed and their patients can find themselves worse off for their efforts. Compared with "an eye for an eye" justice, litigation as an outlet for unhappy patients surely represented serious evolutionary progress. Lawyers and courts consequently preceded patient safety experts by hundreds of years, so it should be no surprise that even today we instinctively regard patient safety concerns as a legal matter before viscerally recognizing opportunities to advance clinical safety.
- CRP-style approaches represent the next evolutionary step on Medicine's path to zero harm. As tragic as unintended clinical harm may be to the patient affected, organizations employ CRPs because the most important patient in their eyes is the person who has not been harmed yet. CRPs are careful to align organizational responses to unplanned clinical outcomes with that imperative in mind while attentively eliminating the myriad ways in which "deny and defend" undermines

the predicates to patient safety. CRPs require discipline and consistency and carry their own risks, but happily the approach effectively promotes patient safety as a priority, saves money by right-sizing malpractice costs and effectively puts a reliable price tag on preventable mistakes. Consistently applied principled responses enhances organizational reputations and increases public trust. On an individual level, CRP's outcomes generally serves all concerned: patients and staff alike are spared the brutal experience and expense of unnecessary litigation, lasting emotional harm is ameliorated for patients and staff, patient safety-as-a-priority is emphasized and real and useful peer review is energized.

- No patient chooses to be harmed when they entrust themselves to healthcare; healthcare, however, can choose its response when unintended harm occurs. Before the patient safety movement, patient harm seemed unavoidable, litigation inevitable. There is a better way, but it is up to clinical leaders to insert themselves, raise their voices and insist that all patients benefit from their missions, visions, and values, including patients harmed in the course of their care and especially patients who have not been harmed yet.
- Questions to ask:

1. Have you thoughtfully examined the way your organization responds to unintended clinical harm? Do the practices serve or undermine patient safety?
2. Patient safety is not only the responsibility of clinical care professionals but must be a priority for those entrusted non-clinical critical functions in complex organizations. Does your organization clearly communicate that at all organizational levels including risk and legal professionals? And measure performance against impacts to the mission, vision, and values of your organization?
3. Does your organizational structure afford clinical leaders a voice in the way its risk and claims management processes serve its mission, vision, and values, promotes patient safety as a priority, and avoids practices that undermine investments in patient safety?
4. Have your organization's risk and claims management professionals been charged with the responsibility to advance, not impede patient safety priorities?
5. In its response to patient harm, does your organization confidently differentiate care that caused harm despite reasonable care from harm caused by preventable medical mistakes? And does it respond to the affected patient consistently with those conclusions?

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