

Virtual Mentor
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First, Do No Harm

From the Editor

- Systemic Problems and Personal Accountability** 589
Ishani Ganguli

Educating for Professionalism

Clinical Cases

- After the Apology—Coping and Recovery After Errors** 593
Commentary by Andrew A. White and Thomas H. Gallagher
- Labeling an Adverse Drug Event “Preventable”** 601
Commentary by Dan Blumenthal
- The Problem with Hand-Offs** 609
Commentary by David B. Nash

Bander Essay Contest

- 2010 Winning Essay**
Medical Ethics and Retail Clinics 612
Thomas Heyne

Medical Education

- Improvement Science—A Curricular Imperative** 620
Samara Ginzburg

The Code Says

- The AMA Code of Medical Ethics’ Opinions on Patient Safety** 626

Journal Discussion

- Medical Error and Individual Accountability** 629
Kavitha V. Neerukonda

State of the Art and Science

- Open-Source Health Care Software** 632
Adrian Gropper

Law, Policy, and Society

Health Law

- The Jury Is Still Out on Health Courts** 637
Valarie Blake

Policy Forum

- Patient Safety Organizations Are Step 1; Data Sharing
Is Step 2** 642
Allan S. Frankel

Medicine and Society

- Resolving Harmful Medical Mistakes—Is There
a Role for Forgiveness?** 647
Nancy Berlinger

History, Art, and Narrative

Medical Narrative

- Learning to Care about Patient Safety** 655
Elaine Besancon

Op-Ed and Correspondence

Op-Ed

- Never Events? Well, Hardly Ever.** 659
Paul F. Levy

Resources

- Suggested Readings and Resources** 663

- About the Contributors** 676

Upcoming Issues of *Virtual Mentor*

- October: Doctors after Hours
November: Health Reform and the Practicing Physician
December: The Power of Diagnosis
January: Vaccines and Ethics

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LETTER FROM THE EDITOR

Systemic Problems and Personal Accountability

“First, do no harm.” It was the most recognizable line of the oath we dutifully recited as graduating medical students on that sweltering afternoon in June, and it was an obvious moral imperative: in a profession dedicated to healing people, we should not make them worse.

Yet preventable medical errors—like hospital-acquired infections and injuries, wrong-site surgeries, and incorrectly dosed medication—are at least as frequent and pernicious as they were when the now-famous 1999 Institute of Medicine report on errors first shocked the health care community [1, 2]. By recent estimates, medical errors occur in one out of three hospital admissions [3] at an annual cost of \$17.1 billion [4]. Anyone who has spent time in the hospital wards or the clinic knows just how easily a detail in a patient’s history can be dropped or a drug list left unconfirmed and how quickly a workaround can become the norm. So how do we as clinicians stay true to our oath? In this month’s issue of *Virtual Mentor* we ask how we, as clinicians, stay true to our oath.

Now, for some definitions. When we refer to medical errors, we are talking about preventable harms or injuries to patients that are the direct result of our medical interventions. Patient safety is the emerging discipline that seeks to analyze and minimize these errors, otherwise known as preventable adverse events. In the past few decades, we have seen a distinct shift in ways of thinking about patient safety and medical errors. We have moved away from blaming individuals for mistakes and from simply asking them to work harder. Instead, there has been a strong push to address the systemic flaws that contribute to a given error and to redesign these processes to prevent future mistakes [5].

As David B. Nash, MD, MBA, writes in his clinical case commentary, effective communication among members of the health care team is key to such efforts. Paul F. Levy, former CEO of Boston’s Beth Israel Deaconess Medical Center, argues in his op-ed that financial deterrents, and even the now-popular checklists [6], will not eliminate the most serious medical errors until institutional culture promotes a shared sense of responsibility for patients. Citing the example of a wrong-site surgery at his own hospital, he makes the case for transparency as an agent for change. Adrian Gropper, MD, highlights the role of health software in shaping these systems; he argues that open-source electronic medical records would help to standardize care across sites and would promote innovative responses to the needs of health care teams.

Some are concerned, however, that the pendulum of blame might have swung too far in the systems direction. Kavitha V. Neerukonda, JD, MHA, reviews an article in which health policy experts Robert Wachter and Peter Pronovost consider if “no-blame” policies diminish individual clinicians’ accountability and therefore might explain lack of improvement in rates of hand washing and other safety measures [7].

So what is the extent of a physician’s responsibility to her patients when she has limited time and competing work demands? Dan Blumenthal, MD, MBA, tackles this difficult question in the context of outpatient medicine, in which the patient’s participation in his or her care is particularly meaningful. As we are learning, asking patients to take an active role in their care can make it safer.

The medical community has learned the importance of disclosing what mistakes do occur despite our best efforts and apologizing for them [8]. But should we ask or expect harmed patients to forgive their care givers? In exploring this question, Nancy Berlinger, PhD, writes about the cultural underpinnings of our society’s views on forgiveness and argues that self-forgiveness may be just as important and difficult to achieve.

For many, medical error is synonymous with lawsuit, and, in fact, a recent study estimates that by the time they turn 65, 75 percent of physicians in low-risk specialties and 99 percent in high-risk specialties will have been sued [9]. Valarie Blake, JD, examines health courts, a new approach to mitigating the disruption and cost of our current medical malpractice system that is now being tested.

Inherent in the study of patient safety is the imperative to measure our errors to better learn from them. Allan S. Frankel, MD, considers the history and the ethical implications of patient safety organizations, created by Congress in 2005 to confidentially collect adverse event data on a grand scale.

Patient safety is a particularly challenging concept for medical trainees, who are more likely than not to be involved in errors and are extremely sensitive to their consequences [10, 11]. In a clinical commentary, Andrew A. White, MD, and Thomas H. Gallagher, MD, reflect on the impact of committing an error on the trainee’s well-being and ability to care effectively for other patients, and on the responsibilities of the trainee and his or her institution to address the error.

For then medical student Elaine Besancon, MD, classroom lessons in patient safety meant little until she watched her mother suffer as a result of multiple medical errors. In a moving personal narrative, she writes about how her experience playing the dual roles of patient advocate and trainee fueled her passion for patient safety and her conviction that safety training should be emphasized early and often.

And finally, in her medical education piece, Samara Ginzburg, MD, shares strategies for doing just that. She writes about ways to teach both patient safety and quality

improvement to medical students, based on her experience helping to create such a curriculum for a New York medical school that opened its doors last month.

Of course, there is much more to say about patient safety than we could fit in these (web)pages. Still, I hope that this issue will provoke discussion and help you to reexamine your own practice and that of your institution through the lens of safety.

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CLINICAL CASE

After the Apology—Coping and Recovery After Errors

Commentary by Andrew A. White, MD, and Thomas H. Gallagher, MD

It's nearly the end of his internship year in internal medicine and Jason, who intends to become a rheumatologist, is feeling more and more confident about his abilities as a physician. Just before he signs out after a night on call, he gets a page from the floor nurse about one of his patients, Maude, a 70-year-old woman recovering from pneumonia. She has a headache. Jason goes in to see her and asks her a few questions. "I'm doing okay, doctor," she tells him. "Just the usual body aches of old age, and now this headache. I can't wait to get home to my husband, my grandkids, and my television set. When do you think I'll get out of here?" Jason examines her and, convinced this is a typical tension headache, he reassures her that she'll be home soon, writes an order for ibuprofen, and heads out.

When he returns a day later for rounds, he learns that Maude has lost vision in both eyes. The night-float resident, Miguel, has started her on glucocorticoid therapy for temporal arteritis but fears this treatment is too late to save her vision. Miguel tells Jason, "When you have an elderly lady with a headache and body pains, you always think temporal arteritis, you do the definitive diagnostic test—temporal artery biopsy—and you start her on steroids. Next time, man. Next time." Jason goes to see Maude and her family. They are devastated by the news that she may not be able to see again.

Jason feels tremendous guilt and remorse about missing the diagnosis, and his confidence is shaken. The teaching physician, Dr. Joynt, notices that Jason isn't as sharp as usual. He seems distraught on rounds for several days in a row, so Dr. Joynt asks him if he's okay. Jason wants to confide in Dr. Joynt, a rheumatologist who has become a mentor to him, but he worries that he will look stupid in front of the man who might write his letter of recommendation for fellowship.

Commentary

Jason's dilemma will resonate with anyone who has known or suspected that he or she made a harmful error. Jason's experience is not unusual. Errors are common in health care, and many result in patient injury or death [1]. Trainees, in particular, report that experience with medical errors often begins early in training [2-4]. In one survey, 79 percent of fourth-year students and 98 percent of senior residents had been personally involved in a medical error [5].

The Emotional Effects of Errors

Errors may beget significant ethical, emotional, and professional challenges for trainees [6, 7]. This scenario illustrates the powerful emotions many physicians feel after making a mistake, as well as challenges specific to trainees, such as the impact of the error on the relationship with a supervisor.

Following involvement in an error, health care workers at all levels of training commonly experience a complex range of feelings including guilt, self-doubt, embarrassment, disappointment, self-blame, a sense of inadequacy, and fear [8, 9]. Surveys have also found that involvement in a harmful error can lead to difficulty sleeping, reduced job satisfaction, and anxiety about future errors [10]. These emotions may persist for months or years and contribute to the already substantial stress of medical training by triggering burnout and depression [11].

Prospective studies of residents have found evidence of a vicious cycle in which errors lead to burnout and depression, which in turn provoke increased involvement in errors [11-13]. This phenomenon could compromise both the safety of patients and the mental health of residents. In an effort to break this cycle, some health care systems have begun to create programs to support health care workers after errors [14, 15].

Such programs are the exception rather than the rule, however, and it is not known whether they are effective. Recent surveys of attending physicians throughout the United States and Canada indicate widespread deficiencies in the support they received from hospitals after errors [10]. The lack of support at many institutions is compounded by physicians' reluctance to meet with counselors, in part due to the difficulty of taking time to meet with them, the belief that the available support will not help, and fear that the discussion will not be kept appropriately confidential. Consequently, many health care workers suffer and cope alone [16].

Although coping styles vary, there is an emotional recovery trajectory common among those involved in harmful errors [17]. Following an initial period of confusion and inner turmoil, clinicians often experience intrusive thoughts as they replay and reevaluate the event in their minds. Subsequently, many health care workers talk about the event with a trusted confidant, seeking reaffirmation of their integrity and competence [6, 8, 9, 17]. Talking about the mistake is central to recovery, and many residents discuss mistakes with fellow residents [11, 18]. However, some trainees do not know where to turn for support [19, 20].

The culture of medicine has traditionally fostered mistaken ideals of infallibility and perfectionism, making some training environments hostile to the open discussion of errors [21]. In blame-oriented environments, trainees may adopt counterproductive coping mechanisms such as denial, distancing, and discounting the impact of the error [22]. These approaches may dampen distress, but they also threaten the individual's capacity to learn from the event. In this case, Jason's peer responds in a

nonjudgmental way, but misses a key opportunity to acknowledge and talk about Jason's emotional state.

Clinicians should be aware that discussing the details of an error with a colleague could make that person a potential witness in a malpractice case, unless the conversation takes place as part of a protected quality improvement (QI) program. This remote risk has led to overly conservative advice from lawyers discouraging discussion of errors. The solution is not for clinicians to avoid the topic but for institutions to link emotional support to protected QI activities. Clinicians should be able to trust that conversations with peers about their emotions are not admissible as evidence in the event of a lawsuit.

Although some health care workers remain persistently traumatized by an error, most ultimately move on to restored well-being after a period of recovery [17]. In addition to talking about the error with a supportive colleague, accepting responsibility appears to promote healing. Residents who acknowledge responsibility for an error often have a period of heightened distress but express an enhanced ability to learn from the mistake and to make constructive practice changes [4, 18]. Accepting responsibility may occur through reflection or conversation with peers or supervisors and ideally yields a deeper understanding of the systems issues and the individual cognitive or procedural mistakes that led to the error.

Physicians who neglect these opportunities for professional growth may instead adopt an unnecessarily cautious approach to future patients, resulting in either underuse of appropriate care for fear of adverse events or wasteful and defensive overuse of tests and treatments [23]. We recommend that trainees involved in errors remain attentive to basic self-care. This includes maintaining an exercise regimen, avoiding alcohol and drugs, and even considering taking time off from clinical work in deeply upsetting cases.

The Fallout for Patients

For many physicians, disclosing the error and apologizing to the patient helps alleviate guilt and distress [24], but disclosure of harmful errors is recommended regardless of the perceived benefit to the physician [25]—the purpose of apologizing is to meet the emotional needs of the patient, not to unburden the physician [24]. Although this case does not describe the details of the conversation between Jason and Maude, we learn that she and her family are devastated and can imagine the significant discomfort and uncertainty Jason must have faced before talking to them. He might have wondered, “Will she blame or even sue me? How should I prepare for the conversation? How should I describe my role in the error?”

Unfortunately, few trainees have been taught how to disclose errors, and most do not have experience disclosing an error that has resulted in permanent harm, such as this one [5]. Furthermore, trainees may struggle to take the actions patients desire, such as clearly explaining what caused the error, apologizing, or describing how similar errors will be prevented in the future [26]. These difficulties emphasize the

importance of residents' discussing errors promptly with their supervising attending physician before approaching the patient. In this case, Dr. Joynt could lead Jason through a potentially difficult conversation with Maude. He could also catalyze the process of rebuilding Maude's trust in Jason. This is particularly relevant for trainees, because some patients may already be wary of them due to their limited experience.

Impact on the Attending Physician-Trainee Relationship

Like Jason, many residents are uncertain about how to approach their supervising physician after an error. Evidence suggests that residents often choose not to disclose their mistakes to the attending physician [11, 18]. They may fear being blamed or belittled for their errors, want to avoid disciplinary action, and worry that supervisors might evaluate them poorly [4]. In this case, Jason feels dependent on Dr. Joynt's support for his career goals. Among a sample of primary care preceptors, nearly half acknowledged that a trainee's error would negatively influence their written evaluation of the trainee [27]. However, preceptors were more likely to respond positively to trainees who reacted without defensiveness and offered to apologize to the patient, suggesting an approach for Jason to take with Dr. Joynt.

We encourage Jason to discuss this error with his attending physician for other key reasons. First, attending physicians can be an important source of emotional support for trainees. Dr. Joynt could normalize Jason's fallibility and his emotional response by sharing an experience with a related error [19]. Dr. Joynt should also remain vigilant for signs of burnout and depression among his colleagues, including Jason. Second, many academic institutions have policies that require trainees to promptly discuss errors with the attending physician who bears final authority for the patient's care. The attending physician is often best suited to address the resulting treatment needs and report the error to institutional quality improvement leaders for system change.

Finally, trainees are particularly likely to be unable to discern between preventable and unpreventable adverse outcomes due to their lack of experience. This could lead to disclosure of incorrect information about the event, engendering preventable confusion and mistrust after an already upsetting adverse outcome. Supervising physicians can apply their extensive clinical experience to let trainees know whether they have erred and to offer insight into the nature of the error.

Looking at Causes: Missed Diagnoses

Regarding the cause of this misdiagnosis, Jason probably misjudged the serious nature of Maude's headache for several reasons. First, his lack of experience played a role in his failure to recognize the constellation of symptoms that suggests temporal arteritis. However, many experienced physicians could have missed this disease due to framing bias that allows misleading clues to unduly influence the diagnosis. Jason may have framed the situation as a search for a benign problem because Maude reassured him that she was "OK." Jason's pretest considerations were most likely swayed by knowing that temporal arteritis is an uncommon inpatient diagnosis but

tension headache is relatively common. Further, temporal arteritis is unrelated to Maude's admitting diagnosis of pneumonia, meaning he would have had to invoke a second, unexpected disease rather than adhere to a unifying diagnosis.

The definitive test for temporal arteritis is invasive and generally not available after hours, making it impossible to rule out that cause readily. Finally, one wonders if Jason felt pressure to wrap up his work quickly at the end of the day, either due to duty-hour concerns or a desire for personal time. Jason may have faced an ethical dilemma that forced him to balance respecting duty-hour regulations and their attendant patient safety benefits against Maude's need for a thorough evaluation. In combination, these biases and barriers led to premature diagnostic closure, curtailing sufficient consideration of more serious etiologies for Maude's headache.

Although missed diagnoses represent an important cause of harm to patients, they receive less attention than other causes of patient harm [28, 29]. This is partially because they are underreported, there is insufficient scientific understanding of them, and effective tools have not been created to analyze and address the cognitive errors that lead to misdiagnosis [30]. Nevertheless, there are some steps that institutions and individual physicians can take to prevent diagnostic errors. Health care organizations should prevent excessive workloads, guard against inadequate orientation or supervision, and address latent systems flaws that disrupt the integrity and flow of information [31]. Additionally, institutions should foster a culture in which well-intentioned clinicians are not penalized for errors that result from faulty systems or justified risk. (In Jason's scenario, direct supervision of his exam and decision making would be unusual. Furthermore, there is no evidence he intentionally took unjustified risk in not calling for help.) Feedback about his reasoning and more deliberate avoidance of bias could help him to avoid cognitive pitfalls and overconfidence in the future [32]. Training programs should promote greater understanding of cognitive traps such as framing bias and techniques such as metacognition that instruct physicians to reflect on how they are analyzing a problem [33].

In summary, we recommend that Jason speak with Dr. Joynt about the error in a way that acknowledges accountability and conveys his desire to learn from the experience. We would expect Dr. Joynt to provide emotional support, share his experience with error, guide the disclosure process with the patient, and finally help shape Jason's clinical reasoning skills. Ideally, Jason would mature professionally, recover emotionally, and deepen his ability to reason when faced with future diagnostic dilemmas.

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Thomas H. Gallagher, MD, is an associate professor in the Departments of Medicine and Bioethics and Humanities at the University of Washington in Seattle. His research interests include the disclosure of adverse events and medical errors to

patients, interprofessional communication, and transparency in health care. He is currently leading research and demonstration projects that promote open disclosure of medical errors and systems to better support distressed health care workers.

Related in VM

[Medical Culture and Error Disclosure](#), May 2008

[Disclosing Error to a Patient](#), August 2005

[Resolving Harmful Medical Mistakes—Is There a Role for Forgiveness?](#) September 2011

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CLINICAL CASE

Labeling an Adverse Drug Event “Preventable”

Dan Blumenthal, MD, MBA

Dr. McKinley walks briskly into her office and consults her computer screen, then her watch. Way behind schedule, and it’s only 2 p.m., she thinks. A typical afternoon in her primary care clinic. She takes a swig of her coffee, peeks into the waiting room where six patients are sitting, and sweeps into exam room 2.

Mr. Chen is a 75-year-old man, recently emigrated from China, who speaks very little English. He has come with his adult son, who is proficient in English, for a follow-up on his high blood pressure. Mr. Chen’s son reports that his father has followed Dr. McKinley’s advice to eat less salt and exercise for 30 minutes a day. Because his in-office blood pressure is still elevated, Dr. McKinley decides to prescribe a low-dose beta-blocker. She carefully explains how to take the drug by halving each pill and asks Mr. Chen if he is taking any other medications, including complementary or alternative medicines. He hesitates, then says no. For a moment, Dr. McKinley wonders if her patient has told her the whole story and asks him again. He says no. She asks if he understands her instructions, and he says yes. Dr. McKinley leaves Mr. Chen and his son to tend to her next patient, who has been waiting for more than an hour with shaking chills and fever.

Mr. Chen goes home and begins taking his beta-blockers at twice the prescribed dose because he does not understand that he must halve the pills. As it turns out, he is also taking a Chinese herbal supplement that he does not believe Dr. McKinley would consider medicine. The double dose of beta-blockers, combined with the herbal supplements, causes acute hypotension, and Mr. Chen falls, breaking his hip.

Commentary

In *To Err is Human*, its 1999 landmark report on errors in health care, the Institute of Medicine (IOM) estimated that errors account for up to 98,000 deaths and 1 million preventable injuries in the United States each year [1]. The IOM report emphasized that lapses in patient safety are both common and costly and catalyzed efforts by many health care systems to identify and address errors and their underlying causes [2]. Nonetheless, recent evidence indicates that error rates have not declined appreciably in the decade since this report was published, and errors remain a significant cause of morbidity and mortality both in the United States and throughout the rest of the world [2].

While errors in ambulatory care environments have not been studied as extensively as those that occur in inpatient settings, approximately 1.2 billion outpatient

physician visits occur in the United States each year [3, 4]. Moreover, the available evidence indicates that preventable adverse drug events, including major medication errors like that in this case, are common in outpatient settings and lead to significant morbidity, mortality, and health care spending [3, 5-7]. Indeed, preventable adverse drug events occur far too frequently in our health care system. Mr. Chen's case affords an excellent opportunity not only to delve into the causes of and appropriate responses to adverse drug events in outpatient settings, but also to highlight a physician's ethical duties to prevent, report, and assist in addressing the root causes of errors in ambulatory care.

Terminology

An adverse event (AE) is an injury to a patient resulting from a medical intervention. AEs can be classified as preventable or unpreventable. A medical error, or preventable adverse event (pAE), is defined as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim” [8]. Errors can be further classified into errors of omission—which occur when a necessary action is not taken—or errors of commission, which result from an incorrect action [3]. Minor errors (or errors resulting in minor harm) are pAEs that lead to “prolonged treatment or [cause] discomfort”; major errors (or errors resulting in major harm) are those that cause serious disability or death [9].

An adverse drug event (ADE) is a patient injury due to a medication [5]. A medication error, or preventable adverse drug event (pADE), is “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer” [10].

This definition does not provide objective criteria for determining the “preventability” of an adverse event. Because error classification can be subjective, some may question the morality of the labeling process. Consequently, they may be less willing to accept and admit that an adverse event was, in fact, preventable. Put another way, the fact that error classification is open to interpretation may lead a physician to feel more justified in denying that he or she has caused a preventable adverse event.

Medication Errors in Ambulatory Care

ADEs and pADEs are quite common in ambulatory care settings. According to a recent review of the literature on outpatient ADEs, the median incidence is 15 out of every 1000 person-months (the number of people in a study cohort multiplied by the number of months they were observed). Roughly 20 percent of ADEs are considered preventable and can therefore be classified as errors. Importantly, the majority of outpatient pADEs will lead to, or necessitate, hospital admission [3].

Mr. Chen's case draws attention to a diverse array of risk factors for, and causes of, errors in ambulatory care. These contributing factors can be broadly grouped into six categories: (1) patient-related causes, (2) physician-related causes, (3) medication-

related causes, (4) causes related to the health care delivery organization, (5) causes related to the health care system, and (6) causes related to health care professionals other than the patient's physician. Mr. Chen's case highlights at least three patient-related risk factors for a pADE: (1) Mr. Chen's use of an *undisclosed* complementary or alternative medicine (CAM), which increases his risk of suffering a drug-drug interaction; (2) his limited English proficiency (LEP), which heightens the risk of communication mishaps; and (3) Mr. Chen's age, which elevates his risk of suffering both preventable and unpreventable ADEs [11, 12].

Let's look at the physician-related risk causes of the error that Mr. Chen suffers. First, Dr. McKinley fails to adequately question Mr. Chen about his use of CAM. The ethical principles of nonmaleficence and beneficence dictate that Dr. McKinley must be sure that she has all information that she deems necessary and obtainable before making recommendations to her patients. While Mr. Chen's hesitation in answering Dr. McKinley's question about his use of CAM does give Dr. McKinley pause, she responds by repeating her initial question. Not surprisingly, she gets the same answer. Had she used a different approach to assess CAM use—by clarifying that CAM includes all herbal supplements, teas, foods that he believes have medicinal properties, and pills that are not prescribed for him by a physician or purchased in a pharmacy—Mr. Chen might have given her more information.

Second, while she asks Mr. Chen if he understands her directions about how to take his new medication, she does not *assess* his understanding by asking him to repeat her instructions back to her. Third, Dr. McKinley allows Mr. Chen's son to interpret for him, despite evidence (of which Dr. McKinley might not be aware) indicating that professional interpreters commit fewer interpretation errors than do ad-hoc interpreters, including those who are fluent in both English and the patient's preferred language [13, 14].

Dr. McKinley must give Mr. Chen her full and undivided attention during his visit. She must also fully consider, and do everything in her power to mitigate, potential harms that could result from her interventions. Yet Dr. McKinley must also balance her ethical obligations to Mr. Chen with similar ethical obligations to her other patients—one of whom is acutely ill. Striking this balance can be particularly difficult when concurrently caring for an acutely ill and a well-appearing patient. As healers, we, like Dr. McKinley, may feel as though a sick patient needs us more than a seemingly healthy one. We may even consciously or unconsciously reallocate our time between them accordingly. But, it is at these times that we must be most aware of the tendency to gravitate towards the ill and make doubly sure that in doing so we do not simultaneously violate our ethical obligations to the healthy.

Furthermore, the ethical principle of respect for autonomy dictates that Mr. Chen should make his own decisions about his care—including whether or not to continue drinking herbal tea while taking a beta-blocker, or to take twice the prescribed dose—as long as he is deemed competent to do so. Dr. McKinley's responsibility is to ensure that he is fully informed about, and understands, how to use a medication

appropriately and that he is aware of the potential benefits and risks associated with taking this medication. While we might assume that Dr. McKinley discussed these benefits and risks with Mr. Chen, the case does not clarify that this conversation took place. If she did not present the benefits and risks of beta-blocker therapy to Mr. Chen she would have violated his right to autonomous and fully informed decision making. Furthermore, by allowing Mr. Chen to leave her office without understanding how to mitigate the potential risks of this new medication, she would also potentially be undermining her own ethical obligation to do no harm.

Mr. Chen's medications—both new and old—contribute to this error as well. Beta-blockers and other “cardiovascular drugs”—including antihypertensives, antiarrhythmics, and digoxin—are implicated in ADEs more often than any other class of medications [6]. Other medication classes commonly associated with ADEs include diuretics, contraceptives, central nervous system medications (including antidepressants, antipsychotics, and antiepileptic medications), analgesics (including opioids and nonopioids), anti-infectives, hypoglycemics, and anticoagulants [3, 5, 6]. Of course, even if Mr. Chen had told Dr. McKinley about his herbal supplement, she might not have known about its effects on blood pressure and potential interactions with a beta-blocker.

Features of Dr. McKinley's organization most likely also contributed to this error. Dr. McKinley's workday is consistently hectic. While she may think that she has learned to cope with being overworked and running behind with patients, her tight schedule forces her to rush. Indeed, knowing that her next patient has been waiting “for over an hour with shaking chills and fever,” Dr. McKinley may well have made a conscious decision not to question Mr. Chen at greater length about his medication regimen, educate him more completely, or request a professional interpreter for Mr. Chen's visit. A recent survey of primary care physicians supports the links between physicians' work burden and patient safety in ambulatory care. In this study, a majority of clinicians surveyed strongly agreed that a “heavy workload” increases rates of medication errors [12]. It is also quite plausible that Dr. McKinley did not request a professional interpreter because her institution does not provide easy access to them. If she believes that her clinic schedule, or any other organizational factor, prevents her from providing the standard of care to all of her patients, she has an ethical duty to advocate for institutional changes that enable her to meet these standards.

Solutions

In retrospect, at least three actions *could* have prevented this adverse event. First, Dr. McKinley should have devoted additional effort to investigating Mr. Chen's use of other medications, including CAM. Dr. McKinley rightly recognizes that Mr. Chen's hesitation when answering her question about medication use is a sign that he may be using medicines that she isn't aware of. However, she fails to recognize or address the possibility that he doesn't fully understand what she means by “medicine” and “alternative medicine.” Dr. McKinley should define these terms for Mr. Chen and provide him with specific examples of a range of complementary and

alternative substances and activities. If Dr. McKinley is specific with Mr. Chen about the exact pieces of information that she is looking for, she can be more confident about his answers.

Second, instead of asking Mr. Chen if he understands her instructions about how to use the beta-blocker, Dr. McKinley should ask Mr. Chen to tell her exactly how he plans to use it. The difference between these two methods of assessing understanding cannot be overestimated; while the former strategy forces the physician to trust the patient's assessment of his or her own understanding, the latter tactic allows the clinician to evaluate the patient's comprehension of instructions. Given that the elderly are at high risk for ADEs, that beta-blockers are commonly implicated in ADEs, and that up to 65 percent of pADEs—and the majority of pADEs requiring hospitalization—originate at the time that a drug is prescribed, Dr. McKinley should not allow Mr. Chen to leave her examining room without demonstrating that he understands how to take the beta-blocker as prescribed [3].

Third, if professional interpreters are easily accessible, Dr. McKinley should request one for Mr. Chen's visit. Many physicians in Dr. McKinley's position would allow Mr. Chen's son to interpret for him, not only because he speaks English and because Mr. Chen does not appear to object to having him do so, but also because requesting an interpreter disrupts work flow. Indeed, even if a professional interpreter were accessible, Dr. McKinley may perceive that the costs of requesting and waiting for an interpreter exceed the benefits of using one in this case. Nonetheless, the evidence indicates that professional interpreters improve patient safety, and Dr. McKinley should attempt to use one if at all possible [14]. More than 8 percent of the U.S. population speaks little or no English, and federal laws mandate that doctors provide patients with free access to professional interpreters [13]. Thus, if interpreter services are not readily accessible in Dr. McKinley's organization, she must work with her colleagues and organization's administrators to address this critical systems-level issue.

Here again, Dr. McKinley must weigh her ethical responsibilities to Mr. Chen, and his ethical right to autonomous decision-making, with similar ethical duties to her other patients. If requesting an interpreter would disrupt her work schedule so greatly that it compromised her ability to care for her other patients, then Dr. McKinley may be ethically justified in not doing so. However, if Mr. Chen did not feel comfortable using his son as an interpreter, or if Dr. McKinley questioned the ad-hoc interpreter's ability to facilitate clear communication with Mr. Chen, then she is ethically bound by the principles of beneficence and nonmaleficence to use a professional interpreter. Indeed, Dr. McKinley is morally responsible for actions that Mr. Chen takes based on her recommendations and guidance.

In addition, Dr. McKinley could work with her organization to ensure that clinicians' busy schedules do not compromise patient safety, without, of course, compromising her ability to care for patients. If she anticipates devoting so much time to quality improvement and patient safety initiatives that she is unable to meet her ethical duty

to help all of her patients, she is morally responsible for finding an alternative, and equally effective, source of care for them.

While many primary care physicians would love to spend more time with each of their patients—and Mr. Chen’s case makes clear that spending additional time with patients can improve health care quality—financial, logistical, and demand-related realities prevent them from doing so. Physicians in ambulatory care practices must come up with thoughtful, systematic, and team-oriented approaches to ensuring patient safety in settings in which physicians’ time with their patients is limited. For example, computerized physician order-entry (CPOE) systems may reduce rates of ADEs, particularly those stemming from failure to identify drug allergies and drug-drug interactions and inappropriate dosing [4, 15]. Clinics can use nurses, pharmacists, and physician assistants to verify patients’ medication regimens, educate them about how to use a medication, and effectively evaluate patient understanding of these instructions. Some evidence also indicates that having pharmacists review clinicians’ prescriptions can reduce rates of ADEs [12]. These and other strategies for improving the quality of health care delivery in ambulatory care lie at the core of efforts to “reinvent primary care” around innovative delivery models like the patient-centered medical home [16, 17].

Responding to Errors in Ambulatory Care Settings

This case also raises at least two critical questions about the patient-physician relationship and the appropriate response to a preventable adverse event: what is the extent of Dr. McKinley’s duty to Mr. Chen, and how should she respond to this error? The ethical principle of nonmaleficence frames Dr. McKinley’s most basic obligation to Mr. Chen: to do no harm. The error caused Mr. Chen significant physical harm and mostly likely also precipitated emotional hardships, including depression, anxiety, or mistrust of his physician or the health care system. Thus, Dr. McKinley’s initial responsibility to Mr. Chen is to do everything in her power to remedy these harms and reestablish the integrity of their relationship. Dr. McKinley must be honest with Mr. Chen about what caused his fall and take responsibility for her role in this pADE [18]. Furthermore, the ethical principle of beneficence dictates that Dr. McKinley act to benefit future patients (including Mr. Chen)—to take appropriate steps to address the root causes of this error, a few of which were discussed above.

These obligations inform the actions Dr. McKinley should take. First, Dr. McKinley should express sympathy for Mr. Chen’s fall and broken hip. Second, she should disclose to Mr. Chen that his fall was probably caused by an interaction between his beta-blocker and his herbal supplement. She should also acknowledge and apologize for her failure to identify his use of herbal tea and his lack of understanding of how to use his beta-blocker. From an ethical perspective, disclosing and apologizing for a medical error is the most appropriate course of action [19]. Moreover, physician disclosure and apology has been shown to improve patient satisfaction, trust in physicians and the health care system, and the strength of the patient-physician relationship [18, 20]. Studies have shown that routine disclosure of medical errors

does not increase the risk of malpractice litigation and, in certain instances, may actually lower the likelihood that a patient will file a claim [20, 21].

Dr. McKinley should also report the error to her institution's patient safety committee or a patient safety organization (PSO). Error reporting helps to ensure the accuracy of institutional efforts to monitor error rates, facilitates efforts to address their root causes, and improves organizational learning from mistakes—all of which can help prevent future errors. Most hospitals and many clinics have implemented formal systems for reporting errors. Lastly, Dr. McKinley should work with her colleagues to identify any additional root causes of this error and to develop sustainable methods of mitigating the array of individual and systemic factors that precipitated it.

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CLINICAL CASE

The Problem with Hand-Offs

Commentary by David B. Nash, MD, MBA

Aidan is on the first emergency shift of her third-year surgery rotation. When her resident hands her the file for her first patient, a 60-year-old man with textbook symptoms of appendicitis, she is excited to work on the case. Aidan meets the patient, Ed, takes a thorough history, and does a physical exam that confirms the diagnosis.

She discovers in her history taking that the patient has a diagnosis of Crohn's disease but has not had symptoms for decades and writes this in her note. She reassures Ed that appendicitis is easily treated with a surgery that gets you home the next day. She presents the case to the resident on call. Two hours later, the resident reports to the attending on-call surgeon, who is busy with a trauma case. Hours pass and personnel change. Aidan spends time with Ed, a pleasant architect with a gentle wit.

The new attending surgeon quickly reads the patient note and orders a CT scan, thinking that the patient might be having a flare-up of Crohn's disease. The patient waits another hour for a CT scan, which reveals an inflamed appendix. A nurse notices that the patient hasn't gone to the OR yet and is concerned, but doesn't feel comfortable bringing this up with the resident or the surgeon. An hour later, when Ed finally gets to the OR, his appendix has ruptured, and the surgeons have to cut out several feet of his small bowel.

When Aidan reports back to the hospital the next day, she sees that Ed hasn't left. He has developed a surgical site infection. Ed is upset about his long wait in the emergency department and about complications from what he thought was a routine surgery. He ends up staying in the hospital for an extra week to recover.

Aidan wonders whether this outcome is the result of a medical error or errors. She goes to speak about the case with Dr. Sark, who performed Ed's surgery. He tells her "stuff happens." He explains that hindsight is 20/20 but that these sorts of events are inevitable in a busy emergency department. When she asks him if someone should disclose or apologize to the patient, he says no.

Commentary

This seemingly straightforward case illustrates many of the ethical and process-related challenges that clinicians face every day. I believe that there are four critical points in the case that deserve further evaluation and commentary.

The first touch point is the transition in care from one attending physician to another. Sometimes we call this a hand-off. The new attending surgeon has supposedly read the patient note without examining the patient and reflexively orders an abdominal CT scan because of a history of Crohn's disease. We are told, however, that the patient has not had a flare-up of Crohn's disease in "decades." One attending surgeon did not speak to another, which also contributed to the unnecessary CT. Had they had an opportunity to see one another face-to-face and possibly even examine the patient together, I'm confident that a superfluous CT scan would have been avoided, obviating the subsequent cascade of events.

The second touch point in this case is the role of the nurse. The nurse noticed that the patient had not gone to the OR in a timely manner but "felt uncomfortable" bringing this up with either the resident or the attending surgeon. This speaks to the fact that the hospital has done little to implement what has come to be called a "just culture," following the work of David Marx and others [1], which empowers frontline workers like nurses to intervene when they notice process failure. It takes a deep understanding of the various roles in the health care system and a commitment from senior leadership to promote a culture in which accountability is shared among all caregivers. In my view, this nurse certainly should have spoken with the resident and the attending physician to express his or her concerns. If they truly believed that the patient is at the center of all that physicians do, the resident and surgeon would have been receptive to such an intervention.

The third touch point that warrants attention in this case is the fact that the patient, Ed, developed a postoperative surgery site infection. A surgery site infection is preventable—even with a ruptured and infected appendix. The Jefferson School of Population Health has just completed a collaborative project with several key stakeholders, including the North Shore Long Island Jewish Healthcare System (winner of the NQF 2010 National Quality Award), Aetna, and the Northeast Business Group on Health, to develop an initiative to educate, engage, and empower patients [2]. Had Ed had an opportunity to review this type of resource, he might have been able to participate more fully in his own care. Shortly, information regarding an institution's surgery site infections rates will become publicly available; I'm confident that, with greater scrutiny, they will decrease. We know that sunshine is indeed the best disinfectant.

The fourth and final touch point in this case is the question of whether someone should ultimately apologize to the patient for both the delay in the surgery and the infection. In my personal view, someone most definitely should. In this case, that person should be the surgeon who operated on Ed. Clinicians bear a great deal of responsibility to recognize system failure and improve procedures that affect patients. When these procedures fail, we have an ethical obligation to apologize to the patient and take action so that future patients are not harmed by the same failed procedures. Only through our deep understanding of the process of care can we ever hope to improve them. Dr. Sark, the second surgical attending, has little or no understanding of the systems-bound nature of what we do every day. If he had, he

would have known that physicians have two jobs: job one is doctoring, and job two is improving job one.

In summary then, there are four ethical and systems touch points in this case. Regrettably, cases like this are the norm. It will take a major cultural and educational commitment on the part of all of our leaders to see that a case like this never happens again.

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BANDER CONTEST WINNING ESSAY

Medical Ethics and Retail Clinics

Thomas Heyne

Scenario

Dr. Bunell was surprised to see Mrs. Scott and her second-to-youngest child when the office assistant showed them into his exam room.

“Long time, no see, Mrs. Scott,” he said. “Everyone’s been well, I take it?”

“Well, I’m worried about this one,” she said, looking down on her son who sat in her lap. Dr. Bunell figured he must be about 5 years old by now.

“I’ve been taking the boys [she had four] to the SureCare Clinic at the mall for the last 2 years,” Mrs. Scott said. “I can get their immunizations there, get them seen for colds and bouts of poison ivy. My oldest even got his physical to be on a pony league team last spring.” She took a breath. “And it’s so quick and far less expensive than coming here. With a family of six,” she said, “it makes a huge difference in medical bills.”

Before Dr. Bunell could speak, Mrs. Scott started again.

“But, we’ve been treating this one,” she looked down again, and Dr. Bunell wished she’d say the lad’s name because, to tell the truth, he’d forgotten it, “with antibiotics for 3 weeks and he seems to be getting worse, not better. Just look at him.”

Visits like Mrs. Scott’s were becoming familiar to Dr. Bunell. More and more of his patients were showing up after long periods during which he figured they had been well and had had no need for medical care. He found out, instead, that they had been going to retail clinics for the “everyday stuff,” and making appointments with him only when something more serious cropped up. It would be months or years since he had seen them and he’d have no record of what had transpired at the clinics.

A family practice specialist, Dr. Bunell did not know the best and most professional way to manage this situation. Some of his colleagues had told their patients that they (the physicians) had to manage all the care or none. But Dr. Bunell didn’t know if that was ethical; besides, it was entirely unenforceable. How would one know if a patient had received care elsewhere between visits to the doctor’s office?

On the other hand, Dr. Bunell's practice depended on routine immunizations, sports physicals, and treatment of everyday infections and injuries. He wasn't a hospitalist, after all. This was a medical and business problem, as he saw it.

Response

"The health and life of my patient will be my first consideration." So rang the Declaration of Geneva of 1948, attempting to respond to Nazi atrocities by revitalizing and reinterpreting the Hippocratic Oath. Many of the leaders at Geneva were also familiar with the words "It is much more important to know what sort of a patient has a disease than what sort of a disease a patient has" [1]. So spoke Sir William Osler, the famous polymath who established medical residency programs and effectively brought medical education into the wards.

Together, the principles of Geneva and of Osler may provide guidance even for the medical dilemmas of today, including those dilemmas related to business ethics. For example, one important question has arisen as a result of the rise of nontraditional retail clinics [2]. Namely, many a physician must now ask herself, what should one say or do with a patient who opts to receive most of his routine care at a retail clinic—coming to his primary care physician only sporadically, for more pressing problems? After describing this quandary in greater detail, I shall attempt to answer it in two parts: first, by considering the "health and life of the patient" and second, by considering "what sort of patient has the disease" (the nonmedical factors that influence the patient). Next, I will discuss how the particular status of the physician herself might affect the question. I shall conclude with practical recommendations for the physician.

What precisely is the problem? In the past 10 years, and as a result of multiple factors—including an increase in costs, in the number of uninsured patients, and in corporate expansion—the number of retail-based clinics has grown exponentially, from only one clinic in 2000 to nearly 1,200 clinics by the end of 2009 [2-4]. The clinics, typically located in large retail stores such as Walmart, Target, and especially CVS (owner of the most widespread version, MinuteClinic), offer minimal waiting times for walk-in visits, most commonly with a nurse practitioner [5]. A short list of health problems accounts for nearly 90 percent of visits: the list included upper respiratory infections, pharyngitis, otitis media, otitis externa, conjunctivitis, and urinary tract infections. In addition, many patients come to receive immunizations; indeed, this is the main reason for visits from most elderly patients [3].

Importantly, these same issues account for 28.2 percent of children's and 12.5 percent of adults' visits to a primary care physician (PCP); furthermore, such simple visits require less office time from the PCP [3]. Given the significant overlap between the problems treated, the concern is that "as [retail] clinics proliferate and their use increases, PCPs may see reduced demand to treat minor conditions.... Losing shorter, simpler visits could have a financial impact on PCPs' practices" [2]. Not surprisingly, the American Academy of Family Physicians and American Academy of Pediatrics have both repeatedly raised objections to retail clinics [6, 7].

On the more individual level, a single family practitioner or pediatrician might well ask, what am I to do with the parent who brings her child to me only sporadically, but receives most of her acute care, immunizations, and sports physicals at retail clinics?

When considering this and other medical ethical questions, one may recall the fundamental principle evoked at Geneva: what is best for the physical health of the patient? To quote the famous Oath attributed to Hippocrates: “Whatever houses I may visit, I will come for the benefit of the sick.” In more modern terms, the principles of beneficence and nonmaleficence require that a physician work toward the patient’s good—in particular, by being competent in her chosen field, by discussing the known benefits and risks of medical interventions or alternatives, and by allowing the autonomous patient to make an informed choice. If, for example, the data indicated that retail clinics consistently produced health outcomes superior to those achieved by primary care, it would be the physician’s ethical and professional responsibility to divulge this information to the patient.

As it is, however, there are insufficient data to show that retail clinics have superior outcomes than those of the “medical home” model, which generally includes a PCP. Although recent studies have suggested that retail clinics and PCP offices have similarly positive health outcomes when treating a few simple conditions (such as otitis media, pharyngitis, and urinary tract infections), a number of legitimate concerns have been raised about such studies—including that otitis media and pharyngitis often resolve without therapy [8-10]. Currently, the evidence showing equal or superior outcomes from retail clinics is still somewhat limited and disputed [2].

On the other hand, one finds less-disputed evidence for superior outcomes when health care has the qualities of a “medical home,” namely being “accessible, continuous, comprehensive, family-centered, [and] coordinated” [11]. The study results are most impressive for children with special health care needs (such as asthma), but researchers have also shown moderately improved outcomes even with non-special needs children and adults who have a “medical home” or “regular source of care” [11-13]. These improved outcomes include earlier diagnosis, better needs recognition, less emergency department (ED) use, fewer hospitalizations, better monitoring, fewer prescriptions, lower cost, increased satisfaction, and decreased health care disparities [12]. Significantly, these positive results are seen more commonly in patients who identify with a particular person (such as a PCP) rather than a particular place [12].

Thus, as a physician, one has a duty is to inform the patient that there may be a risk of somewhat worse outcomes from health care that is discontinuous and uncoordinated—whether at EDs or at retail clinics—particularly for any complicated or chronic medical problems. Of course, one should hardly claim that retail clinics are all bad—indeed, some data suggest that patient satisfaction with such clinics is generally high, and that visits to retail clinics do not increase the rate of return visits

to the PCP's office (for an unsolved problem) [14-16]. Nonetheless, there remain significant risks from fragmented care, namely missing potentially complicated problems, repeating tests, immunizations, and prescriptions, and neglecting a patient's larger developmental, social, or family issues [10, 17]. Even those in favor of retail clinics have noted several potential problems. There is no assurance that records of visits will be sent to the PCP, and, for example, 30 percent of patients visiting retail clinics actually have no PCP at all [8, 15].

One can imagine numerous potentially serious scenarios. If the patient had slowly fallen off the growth curve, or if he had an infection history consistent with common variable immunodeficiency, such important problems might be missed if there were no PCP with consistent chart documentation. In sum, it is the responsibility of the physician to serve the "health and life" of her patients by at least mentioning that having a regular medical home may lead to better outcomes than using a retail clinic. Some patients might be particularly receptive to such a conversation [18].

On the other hand, a patient is more than a conglomeration of pathologies and immune defenses, and "health" is influenced by a great deal more than organic disease processes. One recalls Osler's words, "[know] what sort of a patient has a disease." The empathetic physician must be aware of larger issues affecting the welfare of the patient, including finances and scheduling. A parent who takes her child to retail clinics might well prefer more regular visits with her PCP, but the cost—particularly when compared to those retail clinics—may seem prohibitive. Furthermore, time and transport may be serious issues for the parent [2]. All of these factors are particularly significant today, when money, employment, and inexpensive transport are all in short supply. Since a physician should hardly expect her patients to become impoverished (itself a poor prognostic factor for disease) in the interest of seeking medical care, the physician should do her best to accommodate families in difficult situations.

At the same time, one must not forget the physician herself. There is more than one person in the patient-physician relationship, and the physician's own position could certainly change her options. For example, if the physician is particularly well-off, perhaps she could afford to offer lower prices or free visits for patients in special circumstances. On the other hand, perhaps the young physician—in order to pay her debts or support her family—has a very busy practice with many patients but little time for volunteering. And perhaps one of her patients has refused to follow physician advice regarding retail clinics. When confronted with the consistently uncooperative patient (who might distract from her ability to care for other patients), she might ask herself, can I legally "fire" such a patient?

The question is somewhat complicated; to begin with, a physician certainly cannot discriminate on the basis of race, national origin, sex, religion, or disability [19]. Nonetheless, several judges have stated that a physician may legally withdraw from a nonemergent case if she gives the patient sufficient written notice, to allow the patient time to "procure other medical attention" [20]. Although laws vary by state,

some “legally justifiable reasons for terminating a patient” may include the patient’s missing appointments, failing to pay bills, behaving offensively, or being consistently uncooperative with the treatment plan [19, 21]. Using the last criterion, a physician might terminate a patient who failed to make the recommended follow-up appointments (for routine vaccines, for example) and instead visited retail clinics—despite the physician’s continued requests to the contrary. Nonetheless, what is legal is not always what is ethical...or charitable.

There are a number of ways that a physician can attempt to accommodate both the best health interests of the patient and the patient’s socioeconomic context without violating her own financial needs and tight schedule. First, the physician or her team could investigate financial assistance options, such as Medicaid or CHIP, to help the patient maintain consistent care with the PCP. As a second option, the physician could employ a nurse practitioner or physician assistant to provide the patient with care that is both affordable and continuous—the latter a requirement of the “medical home.” Indeed, nurses in many countries serve as primary care providers, with no worse (and oftentimes better) health care outcomes than the United States [12, 22]. Furthermore, employing a NP or PA could also allow the physician to increase his patient load.

Thirdly, the PCP might consider practices that reduce the patient’s inconvenience, waiting time, and cost, such as answering simple questions via phone or e-mail, utilizing focus groups (e.g., for well-child care issues), and using either previsit checklists or questionnaires from staff (such as medical assistants) [23]. Fourthly, although the physician should probably not encourage the use of retail clinics, she could request that any patients going to such clinics maintain a portable record (as required in France) documenting the retail visits, or (better) that the patient have the retail clinic fax all documentation from each visit (as recommended by the AAP) [6, 22].

Finally, the physician might recommend the patient enroll in a local program for low-resource families, such as Dallas Parkland Hospital’s Community-Oriented Primary Care (COPC) Program, which provides the poor with continuous and coordinated care—i.e., a medical home for the indigent [24]. These recommendations are not mere hypotheses; even as a student, I have personally witnessed each of them effectively put into action. Thus, an ethical physician should use one or more of these options to accommodate the patient’s situation without compromising either care quality or the physician’s own livelihood.

As we have seen, the fundamental principles laid down by Hippocrates, William Osler, and the Declaration of Geneva may shed light upon the dilemmas faced even in twenty-first-century America. A physician must serve the health of her patient foremost. In the case of retail clinics, such service may require informing her patients about the improved health outcomes from care that is consistent and comprehensive. However, a physician should also treat the person qua person, which may involve some alternative to full-fee care with the physician. Individual doctors need not

follow an unbending formula. Ultimately, the core of medicine remains the personal relationship between a physician and a patient. In the case given, even a sympathetic look, nod, or touch could go a long way toward calming the rushed and worried mother of the patient—thereby opening the door to an ethical and mutually acceptable solution.

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MEDICAL EDUCATION

Improvement Science—A Curricular Imperative

Samara Ginzburg, MD

In 1999, the Institute of Medicine (IOM) released *To Err is Human* [1], which estimated that 44,000 to 98,000 deaths occur each year in U.S. hospitals from injuries and complications of care and that the majority of these were preventable through the proper redesign of care delivery. This was followed in 2001 by *Crossing the Quality Chasm* [2], which highlighted the urgent need to incorporate patient safety and quality improvement into the daily work of health care professionals, and throughout the medical education continuum.

To date, efforts made to address these needs in both undergraduate [3] and graduate medical education [4] have fallen short, and the needs remain unmet [5]. At Hofstra North Shore-LIJ (Long Island Jewish) School of Medicine, we are launching with our inaugural class a 4-year curriculum in patient safety, quality, and effectiveness.

One of the first concerns that arises when considering and discussing the topics of safety and quality is nomenclature. Many keywords are used to refer to these topics, including but not limited to: patient-centered care, family-centered care, outcomes research, interprofessional education, team-based care, systems-based practice, practice-based improvement, and efficiency care. These terms are related through the IOM's six "Aims for Improvement" [2], inasmuch as care starts with patients (patient-centeredness) and practitioners must work together through a collaborative approach involving other professionals, patients, and families to deliver the right care (care that is safe, effective, efficient, equitable) at the right time (timely).

Striving to satisfy the IOM's six aims is known as practicing "improvement science," which has been defined by the NIH-supported Improvement Science Research Network as, "all aspects of research that investigate improvement strategies in health care, systems, safety and policy" [6]. Improvement science is the basis for the ACGME core competencies of practice-based learning and improvement and systems-based practice.

There are many barriers to developing a curriculum in improvement science, the greatest being lack of space in an already full curriculum. Others include the fear that basic sciences will be compromised, uncertainty of curricular content and lack of physician expertise in improvement science, and institutional culture. Improvement science involves working smarter, not harder—doing and improving one's work simultaneously. This same approach can be used to incorporate improvement science into a curriculum. In curricular reform, there is an opportunity to use Toyota's "lean"

approach and eliminate “waste” and then to begin integrating improvement science into existing content (see later examples). Given our professional responsibilities as physician educators, improvement science is an imperative, regardless of the curricular circumstances [1, 2, 5, 7].

The first step in creating a curriculum in improvement science is to bring together a design team, which may include patient care professionals with strong interests in areas related to improvement science—safety, quality, business administration, professionalism, simulation, anesthesiology, economics, public health, population health, quality—along with improvement council members, patient advocates, statisticians, community leaders, ethicists, organizational leadership such as chief patient safety and quality officers, chief medical and nursing officers, and others who work in hospitals and undergraduate medical education training programs.

The design group then needs to identify, in the form of learning objectives, the content they would like expressed through the curriculum. Expert recommendations for content can be found in *Preparing Medical Students for the Continual Improvement of Health and Health Care: Abraham Flexner and the New “Public Interest”* [8], *Designing a Patient Safety Undergraduate Medical Curriculum: The Telluride Interdisciplinary Roundtable Experience* [9], and *Eight Knowledge Domains for Health Professional Students* [10]. The ACGME Bulletin *Change and Improvement in the Learning Environment* [4] is an excellent resource for developing an institutional disclosure program and addresses the barrier of institutional culture.

Once the learning objectives are written, the next step is determining where this content will live in the curriculum. The choices usually include isolated individual sessions (e.g., one session per year), a thread of related sessions (e.g., one session per month that relates to prior sessions), a block of dedicated time (e.g., one-month elective), or a longitudinal experience (e.g., weekly sessions for 4 years). Whether a team is working as part of a total curricular reform or adding this content into an existing curriculum will dictate which of these options is most feasible.

Having determined where in a curriculum this content will live, the team can then approach the task of allocating the learning objectives to the appropriate sessions and determining the pedagogy for those sessions. Here it is helpful to consider Kolb’s experiential learning model [11], which stresses the role experience plays in learning, a critical component of improvement work. Applied to improvement science, Kolb’s model includes (1) reflective observation (watching others engage in and thinking about improvement work), (2) abstract conceptualization (understanding the theory and having a clear grasp of improvement science), (3) concrete experience (receiving practical tips and techniques from a subject matter expert), and (4) active experimentation (caring for patients while engaging in improvement work). Pedagogical approaches should vary to allow these different components of experiential learning to take place.

The continuous longitudinal integrated clerkship (CLIC) model can be used as the basis for a core experiential curriculum (including all its components), upon which a patient-centered curriculum in improvement science can be built. The CLIC model, in which students follow patients across time through different venues, establishes three types of continuity—continuity of care, continuity of curriculum, and continuity of supervision [12]. Students following patients longitudinally are natural observers of health care systems, and there is an opportunity to create a fourth continuity relationship in CLICs between student and health care system. This relationship, yet to be investigated seriously, has great potential.

As they follow patients longitudinally, students can be prompted to notice and describe safety and quality issues. They can be asked to describe a situation in which a patient didn't receive the right care at the right time or one in which finances affected care. This is a form of "reflective observation" that engages the students in recognizing firsthand that gaps in care exist.

At selected intervals, students can be brought together in small groups for a discussion facilitated by content experts, perhaps drawn from the design team, in which students present their patients' stories in response to a particular prompt. Using the themes brought out by these student presentations, groups can discuss related foundational topics and engage in "abstract conceptualization," learning necessary theory and how to apply it.

Students can then apply this knowledge as "active experimentation" by returning to the clinical setting and practicing their newly acquired skills, generating process maps and performing point-of-care assessments for patients and clinical teams by analyzing processes, patterns of interruptions, and inefficiencies; drafting aims; reviewing evidence; discussing measurement; collecting data and selecting outcomes for study; and participating in Plan-Do-Study-Act (PDSA) cycles [13]. They bring the results of their work back to the group and their facilitator for discussion and the "concrete experience" of getting expert feedback and cycling between performing improvement work and receiving expert coaching.

CLIC is currently used in the third year of medical school, and some of the new medical schools are planning to begin a version of CLIC in the first year. If CLIC begins earlier in training and is inclusive of an improvement science curriculum, the opportunity exists for a 4-year developmental, experiential curriculum in improvement science. Third- and fourth-year students could become team members and ultimately team leaders on inpatient or outpatient improvement teams, graduating with the knowledge, skills, and attitudes they need to become physician leaders of health care improvement.

For medical schools that need to fit improvement science into an existing curriculum, consideration of some of the following pedagogical approaches commonly used in other schools as well as publicly available resources can be helpful.

Root cause analysis (RCA) is a process used to identify the cause(s) of an undesired outcome or adverse event in order to create effective corrective actions to prevent that problem from recurring. Many hospital departments perform RCAs on a regular basis, bringing together an interdisciplinary team to investigate the event and devise solutions for prevention. By participating in real or simulated RCA, students can gain exposure and begin to develop skills needed to approach undesired outcomes; gain appreciation for the insight and contributions of interdisciplinary team members, human-factors engineering, systems errors, and institutional culture towards errors; and acquire skills needed to begin devising solutions for them. Morbidity and mortality conferences often employ a RCA approach. The Institute for Healthcare Improvement has RCA-type case studies available for use on its web site [10].

Case studies are often used in business school education and are available for use in medical education. These cases are in-depth studies of a specific situation, for example health care delivery in a third-world country, that do not provide answers but allow students to study a problem in depth, use critical thinking, and apply their knowledge to analyze the case and draw conclusions. Skills learned from case studies include critical thinking, analysis, and knowledge of contributors to health outcomes in areas like public health, business decisions, and medical economics. Case-study analysis can be facilitated by people familiar with this pedagogy, through MBA or MPH programs, for example.

Simulation provides learners an opportunity to participate in performance-based acquisition of clinical skills in a psychologically safe environment for constructive discussion about errors and without adverse consequences. Simulation can be used for training purposes as well as for assessment of a team's clinical performance. By participating in simulation, learners can move from pure knowledge about clinical skills to performance of those skills, with the opportunity for direct coaching for improvement in real time. Simulation provides learning opportunities for development of knowledge, skills, and attitudes related to personal improvement, crew resource management (CRM), and patient safety as individuals and as members of health care teams.

Live or videotaped stories of medical errors told by patients or their family members help listeners appreciate the importance of patient safety and quality outcomes and recognize the reality of these cases, and they engage and awaken the listener's professional responsibility to participate in improving care. A content expert should facilitate discussion of these stories, whether they are videos or presented live by panels of patients who have experienced errors.

Online materials on improvement science topics are available for self-directed learning or as the basis for group instruction. The IHI Open School and MedEdPORTAL both feature excellent resources [14, 15].

The time has arrived for all medical educators to consider how to implement an improvement science curriculum in their institutions' undergraduate medical education and on into GME and CME in effective ways. This can be done by eliminating waste from a curriculum, tapping into an institution's existing improvement science resources, developing a fourth continuity relationship with the health care system in a CLIC, and creatively integrating improvement science into curricular experiences so that we equip physicians with the knowledge, skills, and attitudes they need to lead and transform the delivery of health care in our country.

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THE CODE SAYS

The AMA *Code of Medical Ethics*' Opinions on Patient Safety

Opinion 8.12 - Patient Information

It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care.

Ethical responsibility includes informing patients of changes in their diagnoses resulting from retrospective review of test results or any other information. This obligation holds even though the patient's medical treatment or therapeutic options may not be altered by the new information.

Concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with a patient.

Report issued March 1981; updated June 1994.

Opinion 8.121 - Ethical Responsibility to Study and Prevent Error and Harm

In the context of health care, an error is an unintended act or omission, or a flawed system or plan, that harms or has the potential to harm a patient. Patient safety can be enhanced by studying the circumstances surrounding health care errors. This can best be achieved through a legally protected review process, which is essential for reducing health care errors and preventing patient harm.

1. Because they are uniquely positioned to have a comprehensive view of the care patients receive, physicians must strive to ensure patient safety and should play a central role in identifying, reducing, and preventing health care errors. This responsibility exists even in the absence of a patient-physician relationship.
2. Physicians should participate in the development of reporting mechanisms that emphasize education and systems change, thereby providing a substantive opportunity for all members of the health care team to learn. Specifically, physicians should work with other relevant health care professionals to:

- a. Establish and participate fully in an effective, confidential, and protected error-reporting mechanism,
 - b. Develop means for objective review and analysis of reports regarding errors, and to conduct appropriate investigations into the causes of harm to a patient,
 - c. Ensure that the investigation of causes of harm, and the review and study of error reports result in preventive measures that are conveyed to all relevant individuals,
 - d. Identify and promptly report impaired and/or incompetent colleagues so that rehabilitation, retraining or disciplinary action can occur in order to prevent harm to patients,
3. Physicians must offer professional and compassionate concern toward patients who have been harmed, regardless of whether the harm was caused by a health care error. An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability.
 4. Physicians have a responsibility to provide for continuity of care to patients who may have been harmed during the course of their health care. If, because of the harm suffered under the care of a physician, a patient loses trust in that physician, the obligation may best be fulfilled by facilitating the transfer of the patient to the care of another physician.
 5. Physicians should seek changes to the current legal system to ensure that all errors in health care can be safely and securely reported and studied as a learning experience for all participants in the health care system, without threat of discoverability, legal liability, or punitive action.

Report issued December 2003, based on [Ethical Responsibility to Study and Prevent Error and Harm in the Provision of Health Care](#), adopted June 2003.

Opinion 9.032 - Reporting Adverse Drug or Device Events

A physician who suspects the occurrence of an adverse reaction to a drug or medical device has an obligation to communicate that information to the broader medical community, (e.g., through submitting a report or letter to a medical journal or informing the manufacturer of the suspect drug or device). In the case of a serious adverse event, the event should be reported to the Food and Drug Administration (FDA). Spontaneous reports of adverse events are irreplaceable as a source of valuable information about drugs and medical devices, particularly their rare or delayed effects, as well as their safety in vulnerable patient populations. Although premarketing and mandated postmarketing studies provide basic safeguards for the public health, they suffer from inherent deficiencies that limit their ability to detect rare or unexpected consequences of drug or medical device use. Physicians who prescribe and monitor the use of drugs and medical devices constitute the group best able to observe and communicate information about resulting adverse events.

Serious adverse events, such as those resulting in death, hospitalization, or medical or surgical intervention, are the most important to report and are the only adverse events for which the FDA desires a report. Certainty, or even reasonable likelihood, of a causal relationship between the drug or medical device and the serious adverse event will rarely exist and is not required before reporting the event to the FDA. Suspicion of such a relationship is sufficient to give rise to an obligation to participate in the reporting system.

Report issued June 1993, based on [Reporting Adverse Drug and Medical Device Events](#), adopted June 1993; updated June 1994.

Opinion 9.14 - Quality

As professionals dedicated to promoting the well-being of patients, physicians individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable.

While responsibility for quality of care does not rest solely with physicians, their role is essential. Individually and collectively, physicians should actively engage in efforts to improve the quality of health care by:

1. Keeping current with best care practices and maintaining professional competence.
2. Holding themselves accountable to patients, families, and fellow health care professionals for communicating effectively and coordinating care appropriately.
3. Monitoring the quality of care they deliver as individual practitioners—e.g., through personal case review and critical self-reflection, peer review, and use of other quality improvement tools.
4. Demonstrating a commitment to develop, implement, and disseminate appropriate, well-defined quality and performance improvement measures in their daily practice.
5. Participating in educational, certification, and quality improvement activities that are well designed and consistent with the core values of the medical profession.

Issued November 2009, based on [Quality](#), adopted June 2009.

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JOURNAL DISCUSSION

Medical Error and Individual Accountability

Kavitha V. Neerukonda, JD, MHA

Wachter RM, Pronovost PJ. Balancing “no blame” with accountability in patient safety. *N Engl J Med.* 2009;361(14):1401-1406.

The tenth anniversary of the Institute for Medicine’s report *To Err is Human* has sparked much discussion on the status of patient safety, whether we have made progress, and what we should be doing to continue our efforts to decrease errors. In their article “Balancing ‘No Blame’ with Accountability in Patient Safety,” Wachter and Pronovost examine how the traditional blame-oriented culture has evolved into a widely accepted “no-blame” culture and how that should now be balanced with individual accountability in patient safety. Their analysis proposes that while “no blame” should be embraced, it is not always the most appropriate framework; accountability should be emphasized when necessary [1].

Wachter and Pronovost begin by acknowledging that most errors are caused by good, hardworking people who are trying to do what’s best for their patients. Some leading institutions in patient safety, however, have begun to question the sole embrace of the “no-blame” culture and the safety risks it poses in and of itself. The authors use hand hygiene as a prime example. There is ample evidence that cleansing has been approached as a systems-level problem, removed from the context of blame. But with many interventions, such as administrative championship of improving hand hygiene, information campaigns, and strategic placement of hand-gel dispensers—in place for as long as a decade—hospitals continue to have low hand hygiene rates, and very few have sustained rates above 80 percent. The authors suggest the hand hygiene problem is no longer a systems issue; it is an accountability issue. They also mention widespread national education campaigns and success stories regarding wrong-site surgery and bloodstream infections that, nevertheless, have not wiped out all errors [2].

The authors go on to propose that the reason some patient safety issues remain unresolved even after an extensive systems review and change is a lack of accountability [3]. Absent a penalty, health care professionals may perceive that the intervention is ineffective and choose not to bother with changing their habits. Once a reasonable safety rule has been broken more than once, and ample education, counseling, and other means of positive corrective action have not fixed the problem, the authors think that sufficient penalties should enforce accountability.

They do not propose punishing those who do not have the appropriate education, knowledge, and training. They fully acknowledge that education and awareness are by far the most critical pieces of this puzzle. But, they say, if those are not enough, then more drastic measures are essential. The authors propose different levels of punishment—education and loss of privileges for 1 or 2 weeks, with counseling depending on the nature and number of the violations. They also emphasize the need for consequences to be consistent among physicians, nurses, and technicians, regardless of their employment status [4].

Wachter and Pronovost believe that accountability is necessary in some instances of repeated deviation from the norm to correct the fundamental misunderstanding of the nature of errors that pervades health care, as opposed to, for example, the airline industry's view of errors. Granted, pilots and other industry personnel are employees of a company, whereas many physicians are self-employed or employed by a large private practice group and contract with hospitals. Inherently, the latter arrangement emphasizes autonomy, and hospitals shy away from making physicians do things they do not wish to do or understand for fear of losing them [1].

Wachter and Pronovost argue that, despite these differences, health care should take a page from the airline industry's playbook: after a reasonable safety rule has been clearly vetted by experts (e.g., pilot checklists prior to takeoff), it should be widely adopted and strictly adhered to. The failure to enforce these rules allows the culture to shift from one of "accountability" to one of "no blame" [3]. In the end, Wachter and Pronovost acknowledge that balancing the "no-blame" culture with accountability will be tricky [4] at best.

In his 2011 commencement speech at Harvard Medical School, Atul Gawande proposed a somewhat different approach. He asserted that health care professionals from all parts of the care spectrum should work as pit crews for patients. This means cultivating skills currently uncommon in the health care world. Gawande focuses on three: (1) the ability to recognize when you've succeeded and when you've failed for patients; (2) the ability to devise solutions for the system problems that data and experience uncover (for example, by use of checklists); and (3) the ability to implement, at scale, the functioning of colleagues along the entire chain of care as pit crew members [5]. Gawande stated, "These values are the opposite of autonomy, independence, self-sufficiency. Many doctors fear the future will end daring, creativity, and the joys of thinking that medicine has had. But nothing says teams cannot be daring or creative or that your work with others will not require hard thinking and wise judgment" [5].

Gawande's approach calls for accountability to be diffused throughout the team. Though this is not incompatible with Wachter and Pronovost's approach, it takes a different tone. Wachter and Pronovost appear to feel that a certain degree of harshness is necessary to make the needed changes. Gawande, on the other hand, does not explicitly state that individual physicians should be targeted for corrective

action; instead, he focuses on holding the entire team accountable, an approach that may be more palatable to health care professionals.

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STATE OF THE ART AND SCIENCE

Open-Source Health Care Software

Adrian Gropper, MD

Software tools are yet another new technology competing for the attention of physicians. Medical software is evolving rapidly from a record-keeping tool to a communications system to a source of decision support and plays the role of a medical device or clinical service. Unlike devices and services, however, most medical software is not regulated, placing the burden of safe and effective use on the physician. Yet physicians who would hesitate to use a device or service without some understanding of how it works pay little attention to the fundamentals of their software. Perhaps this is because they feel that software technology is not under their control, but, as with other important tools, physicians influence institutional purchases and can often supplement institutional infrastructure with personal tools.

Definitions

“Open-source” and “closed-source” refer to the way that software is created and maintained. The methodologies for creation and maintenance of closed-source software, e.g., Internet Explorer, are not evident to the user. The choice between open- and closed-source software has deep implications for safety and effectiveness because software design methods are seldom peer-reviewed and software errors are not always evident.

Open-source software is like a textbook or patent in that it is available for all to see and improve. Closed-source software is secret—a black box not subject to peer review or independent improvement. As medical software becomes increasingly mission-critical, physicians should become increasingly skeptical of software secrecy and the inability to peer-review closed-source software.

Despite the obvious benefits, open-source software is still rare in medical practice because, as with music and other information-based products, it is easy to copy. Software creators will not switch to producing open-source products voluntarily because they stand to lose money by doing so. Only physicians can drive this change, and this paper describes the reasons why doing so is important to our profession and our patients.

Existing Open-Source Software in Medicine

While open-source software is still rare for doctors, there are a few examples of success. The most prominent by far is the Veterans Administration’s VistA electronic health record (EHR), and a number of foreign and domestic spin-offs, including a venture-capital funded Open Vista that has been certified as satisfying

federal requirements for “meaningful use” of EHR and is therefore eligible for federal subsidy. With over 100 modules, VistA is among the most extensive EHR implementations available and includes support for inpatient care, outpatient care, and imaging.

Developed more recently, the Direct Project hosted by the Department of Health and Human Services is open-source software for secure e-mail to replace the fax as the primary means of communication between practices and even with patients. Direct Project has many unique features as a result of its noncommercial open-source design, including universal addressing that is not tied to a particular vendor or institution. Universal addressing, like modern e-mail, does not restrict communications to members of a particular exchange. This technology has been readily adopted for physician-to-physician communications by a wide range of vendors and physician organizations, including the American Academy of Family Physicians and health information exchanges in a number of states. For patients, Microsoft offers secure Direct Project inboxes along with their personal health records.

Another example of open-source software success is the OsiriX radiologist workstation. This full-featured radiology viewing and interpretation system integrates 3D and web-access features that are rarely included in commercial workstations that cost tens of thousands of dollars each. The OsiriX open-source approach encourages doctors to write their own extensions for image analysis and workflow automation. Because radiology workstations are regulated as medical devices by the FDA, a number of commercial vendors now offer FDA-registered versions of the free open-source OsiriX for a fraction of what proprietary workstations cost.

Advantages of Open Source

Open-source software offers the same benefits in medicine as it does in other fields. These include ethical advantages, access, innovation, cost, interoperability, integration, and safety.

Ethical advantages. Much has been said about the ethical advantages of “free” software in general, and it is particularly true in a profession in which the sharing of instantly available, accurate information can make the difference between life and death. As medical software begins to offer decision support, risk management, performance rating, and analytic features, physicians should not accept black boxes and secret formulas that constrain sharing and intimately affect patient care and remuneration.

Access. Open-source software reduces disparities because it is, almost without exception, free and accessible to all, domestically and around the world. Open-source software can be easily developed, adapted, and used anywhere, much as books and research papers are today, and the fiscal benefit to both developed and developing nations is obvious. In our globally interconnected world, the

dissemination of medical knowledge and best practices could be even more important than the low cost. Open-source projects such as OpenMRS are widely used to run major public health initiatives concerning HIV/AIDS, tuberculosis, and malaria.

Innovation. Open-source software promotes innovation in the same way that publication of research and methods does. It can be combined and extended in the same way that research can, which is a major reason why, once it is established in a field, it is difficult to surpass in terms of features and performance. The Firefox and WebKit (Apple Safari and Google Chrome) web browsers are examples of open-source software that has come to dominate a major category.

Ending vendor lock-in. Anyone who remembers the days when cell phone numbers were tied to carriers knows the meaning of lock-in. Changing from one proprietary electronic health record to another is expensive and disruptive and often results in information loss. Proprietary software is designed to make migration difficult. By making the cost of switching high, vendors can charge more for upgrades and support than they could if switching were easy or inexpensive. Open-source software vendors have no incentive to lock in users and, even if they did, they would be unable to prevent a service provider from altering the software to eliminate this design feature. The vendor lock-in business model also works against the adoption of standards.

Interoperability, integration, and standardization. Common terminology and effective communication, essential to medical science and public health, depend on standardization. The Framingham Study, for example, would have significantly less impact if every participating lab measured the cholesterol of its patients in a proprietary way. As physician income becomes increasingly tied to patient outcomes and dependent on coordination of care, lack of interoperability, integration, and standardization has begun to impact clinical practice. It is hardly surprising that interoperability and integration costs related to proprietary health care software are extremely high and that the true value of health care services is difficult to measure and compare.

Standardization can undermine a proprietary software vendor's ability to control the customer by making it easy to transfer essential information to another system. Standardization costs proprietary software vendors twice: first, in direct cost when they have to write the software according to somebody else's specifications (the standard), and second, in opportunity cost, when it reduces the price they can charge for upgrades lest the customer switch to a competitor. Web browsers once again offer an example, as we recall the days before open-source browsers when some web sites and applications would only work in Internet Explorer. Because proprietary vendors will drag their feet on standardization, physicians, as ethical professionals, must insist on open-source software to drive standardization that will allow objective comparison of treatment alternatives.

Support. Ongoing support for a medical device or service is clearly critical to effective practice. Proprietary software puts the physician at the mercy of the vendor, who is often more interested in acquiring new customers than serving locked-in customers. Open-source software, by definition, allows users to choose their support service provider. Unlike proprietary vendors, open-source support providers have to compete for the user's business. Open-source software also benefits from free community support. The broad ability of users to adopt and improve software creates diverse, global communities on the Internet with significant incentive to help each other.

Bug fixing and patient safety. Finally, open-source software excels where proprietary software cannot in bug fixing and patient safety. Open-source software communities have a strong incentive to publicize bugs—if only because they are a waste of time—and sophisticated users can fix the bugs themselves. Even more important, open-source software is not forced to reinvent code that has already been developed by others. The quality of proprietary software suffers greatly from the secrecy of its internal workings. Unlike a medical device or service that is subject to inspection and incremental refinement, new proprietary software from a given vendor is likely to include many of the errors and patient safety problems that other vendors have solved. Open-source software, on the other hand, mirrors typical medical research practice by reusing proven code and promoting transparency with equivalent benefits of patient safety.

Drawbacks to Open-Source Software

Investment and business issues are certainly the major drawbacks to the creation of open-source software. Rapid software development can be capital-intensive; new software categories appear as proprietary software years before open-source versions become available, and initial development can be slow to address market-driven needs. Open-source software depends on grants for research, and it can be overly academic in its design and too specific to a particular niche to have sustainable and clinically robust support communities. Because relatively few medical open-source projects currently have commercial support organizations, typical users need more sophisticated and more costly in-house support.

Summary and the Cloud Future

For all the reasons above, medicine stands to benefit as much or more from adoption of open-source software than other professions and applications. The penetration of open-source software in electronic health records will increase as the market segment matures and ethical advantages, interoperability, and patient safety become key differentiating factors. Increasingly, new cloud software services based on a combination of open-source and proprietary software will enter the market to compete with traditional proprietary software on the basis of lower cost and better support. Cloud services such as IBM's Watson, national and global in scope, will drive interoperability and consistent outcome measures at a much faster rate than proprietary software.

Medical software is rapidly becoming a patient-safety issue in clinical practice, but it is not currently subject to the regulation that physicians have come to expect for their devices and ancillary services. Advocating for open-source software is one thing that every physician can do that serves both the patient, public health, and the profession.

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HEALTH LAW

The Jury Is Still Out on Health Courts

Valarie Blake, JD, MA

In many physicians' minds, patient safety is closely linked to medical malpractice and the legal and financial consequences doctors confront when something goes wrong. Medical malpractice is a booming \$55.6-billion business that accounts for 2.4 percent of annual health care expenditures [1]. The implications of a runaway medical malpractice system for the cost of health care generally has driven the call for reform and health courts have been proposed as one solution.

Health courts take malpractice claims out of regular courts and allow them to be handled by an administrative process, with a number of key differences from traditional malpractice. Proposals for health courts have been introduced by a number of organizations (including the American Medical Association), but the most recent model comes from Common Good, a bipartisan public interest group, and the Harvard School of Public Health [2, 3].

Health court hearings differ from malpractice procedures in many ways. Instead of juries, health courts rely on specially trained health care judges, and plaintiffs (those bringing the suits) need not necessarily have attorneys [4]. Second, a plaintiff has to prove only that his or her injury could have been avoided if best practices had been followed, rather than satisfying the more difficult standard that physician negligence contributed to the injury [4]. An unconscious emergency room patient, for example, who is allergic to latex and exposed to it during emergency surgery could still be compensated because the situation was avoidable, even though the surgeon wasn't negligent [4]. The surgeon, in following best practices, could have found a way to check the chart quickly without delaying surgery [4].

A third difference lies in the fact that compensation for injuries is based on expert evidence rather than a jury decision [4]. As Philip G. Peters [5] explains, compensation for pain and suffering, usually a big moneymaker in malpractice claims and varying widely from case to case, is capped and determined according to a formula based on the severity of the injury [6]. Fourth, compensation decisions establish precedence that judges can look to in making decisions about similar future cases. In traditional suits, damages are decided anew in each case [4]. Lastly, guidelines are in place to assist in assigning damages [4].

Health court proposals vary in some details. Some propose that a single court govern all patients and providers in a single geographic or clinical area, while the Harvard/Common Good proposal advocates that a court govern a single group of

insurers [4]. Some favor health experts over judges [7]. Additionally, some argue that a plaintiff who is unhappy with his award should only be able to appeal to an administrative judge within the health court system, while others support appeals through regular medical malpractice claims [7].

The concept of a health court as part of medical malpractice reform has been controversial. This article summarizes the pros and cons of health courts as a solution to climbing medical malpractice and health care costs.

A Need for Change

Some supporters of reform [8] allege that the current system allows frivolous claims and sky-high awards and that the time and cost of bringing a suit prevent many valid claims from getting off the ground [9].

Others, however, question the need for reform, citing the 90 percent of malpractice suits that are settled before going to trial [10]. This suggests that most of the cost of health care in this country is not linked to medical malpractice but to the high cost of care itself, and, because malpractice accounts for only 2.4 percent of all health expenditures, reform would not have a meaningful impact on overall cost [11].

Constitutionality of Health Courts

Another significant debate centers on the legality of health courts. Specialized administrative courts are not unique; similar types of courts have been formed to handle workers' compensation, vaccine injury, and tax claims. A key difference, one scholar [12] argues, is that each of these three courts adjudicates federally-created public rights, not state-created private rights [13]. The role of state law is important here. Almost every state guarantees a right to a jury trial for private civil matters, and the proposed health courts might butt heads with this protected right [14, 15]. Moreover, the right to a jury trial in federal courts is secured by the Seventh Amendment. Depending on their design, health courts could infringe this right [16].

Typically, legislatures must show that, when stripping citizens of a right, they provide a more or less equal trade-off, a concept called *quid pro quo* [17]. The three types of courts mentioned above are no-fault models, meaning that the plaintiff doesn't have to prove blame [13]. In contrast, the health courts plaintiff must prove that the injury was avoidable (even though he or she doesn't have to prove negligence). Hence, health courts may not satisfy *quid pro quo* because they strip the injured of a right to a jury trial without providing them an equal benefit—no burden to prove blame [17].

Legal challenges may also occur under state equal protection clauses, which require like treatment of like individuals or classes. If the health courts are introduced within particular medical centers or for specific types of injuries or events, injured parties within the health court system could argue they are receiving treatment unequal to that outside the system—their damages are capped, whereas damages for persons suing under other torts are not [18].

Claims that power is being abused are also possible. The legislative, executive, and judicial branches are meant to be independent and coequal [19]. If health courts amount to a misappropriation of power by the legislature or transfer of judicial power to the executive branch, they may be subject to legal challenge [19].

Capped, standardized damages are a trait of health courts that might pose a legal problem for health courts in states that have rejected caps. Some states (e.g., Illinois, Wisconsin) have struck down attempts to cap the amount of damages that a plaintiff can claim in a medical malpractice case [20].

Fairness

Is the health court model as fair as traditional medical malpractice suits? Supporters [21] argue that health courts make relief more accessible to everyone. Many individuals never bring suit for their medical injuries because of the high cost and length of malpractice claims (which may last 5-10 years) [22]. Health courts allow persons who had valid injuries but could not afford lawyers to make claims and would provide relief for those with injury claims that are valid, but too small to justify full-blown litigation [4]. While health courts enable wider access, they also entail less compensation per person, causing some to argue that they favor doctors and institutions over injured parties [23].

Critics of health courts point to studies suggesting that jury verdicts are often quite fair and studies have shown a “strong correlation between the merits of malpractice claims and the outcomes of litigation” when juries are in charge [24]. Conversely, judges may have more specialized expertise in the area of health care reform than juries and may therefore be superior fact finders, leading to better and more consistent verdicts [25].

Patient Safety

Whether or not health courts will lead to better patient safety is hotly contested. Supporters say that shifting the burden of proof from negligence to avoidability will encourage doctors to admit mistakes, allowing them and their institutions to more easily and openly address safety issues [25].

Others argue, however, that the health-court model of lumping together negligent acts and those that were merely avoidable creates less transparency, leading to “more brazen malpractice because of reduced fear of being shamed amongst medical peers and less fear of financial loss” [26].

Current Status

In 2010, President Obama called for “demonstrations of alternatives to resolving medical malpractice disputes, including health courts” [7, 27]. His 2012 budget allocated \$250 million through 2016 for the Justice Department to “provide incentives for state medical malpractice reform,” some of which will presumably involve study and potential piloting of health courts [28]. Similar models are

cropping up in actual practice around the country. A \$3-million federal grant has funded a pilot “judge-directed negotiation” court system in parts of New York (including Bronx, Manhattan, and Brooklyn). This system is like health courts in that it favors judges over juries, but the model focuses more on settlement out of court than on an administrative court process.

With health care costs and budgeting center stage in the political arena, medical malpractice cost-reducing ideas will continue to be an important topic. The jury is still out on whether health courts will be the cure for rising health care costs, but much attention should be paid to these and other models as we continue to reshape health care provision in the future.

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POLICY FORUM

Patient Safety Organizations Are Step 1; Data Sharing Is Step 2

Allan S. Frankel, MD

The health care industry will forever require careful oversight to ensure safety. It suffers from the ubiquitous and very human trait of reaching out towards desired goals and concentrating on attaining products, while putting fewer resources into the commensurately necessary safety nets and safety measurement systems. There is no reason to presume this trait will change. We see it manifest wherever humans push the envelope: in deep-sea oil exploration, e.g., Deepwater Horizon, and nuclear power, e.g., the Fukushima Daiichi Power Plant [1]. We obtained oil and nuclear power, we presumed safety, but paid great human and environmental costs because of inadequate safety defenses. The difference in health care is that our disasters tend to be many episodes of single deaths and human suffering rather than a single episode with many deaths and injuries. As a result, meaningful patterns of systemic failure are difficult to identify and easier to ignore. To safeguard, we must attend to failure.

The Patient Safety Act of 2005 [2] created patient safety organizations (PSOs) to confidentially collect and aggregate data on adverse events from health care organizations on a large enough scale to generate insights of value for clinical improvement. There is precedent for the act in the Aviation Safety Reporting System (ASRS), which serves as a reminder that confidential reporting systems over time can be effective. The ASRS had detractors for years after its inception but has proved to be of great value [3].

The PSOs protect the confidentiality of adverse event data by building upon peer review, the method that states use to protect an organization's quality and safety data from lawsuit discovery, in part to aid learning and improvement. In most states, the protection built into peer review ends when quality and safety data leave the walls of the health care institution. The Patient Safety Act extends legal protection to a PSO to facilitate the collection of a wide range of data from many organizations, but with caveats. The protection and confidentiality afforded to PSOs mandates that analysis of aggregated data must occur for learning and improvement. The logic is sound; the goal of the PSO is to generate action, not to collect data.

Patient safety organizations move us in the right direction. The authors of the Patient Safety Act recognized the many challenges of collecting accurate data [4]; how, for example, human beings resist admitting wrong [5, 6], yet have a propensity to blame [7, 8]; the detrimental influence of legal malpractice on our learning [9]; the myths about patient expectations after an adverse event [10]; and the glacially slow

incorporation of effective teamwork and improvement into our culture [11]. Given these challenges, there is little surprise that physicians and organizations underreport adverse events and won't voluntarily make data available for public scrutiny.

Why Congress would confer the privilege of legal protection to PSOs and limit public access to their data, and why, overall, this is ethically practical and a reasonable but incomplete first step warrants some reflection. Characterizing health care's effort at self-policing and identifying the factors that influence it will help put the current situation into context.

Health care was once offered through a guild of independent practitioners who occasionally plied their trade within common walls called hospitals. In that setting, physicians were responsible for self-policing as the mechanism to ensure the safest and most reliable care [12]. Some of their efforts were laudable, others offensive. The American Medical Association's 1847 *Code of Medical Ethics* required that members not criticize other members, an example of physicians' closing ranks against other clinicians and patients. In her book on medical ethics, Virginia Sharpe relates how this compact resulted in the burning of a scathing report on the quality of medical schools in the United States in the early 1900s before the report was made public. The burning initiated what ultimately became known as the Flexner Report. Frequently, but not always, the gentlemanly code [13] promoted ethical behavior but also helped shape the complex, error-prone system of health care we have in place today.

Although health care systems in most advanced countries are now large, industrial, and complex, the old model of self-policing has remained fully intact, a relic that is useful but inadequate in light of the fact that so much of care today is a team effort. There is a hodgepodge of publicly available information obtained as a result of required regulatory and governmental reporting that ostensibly measures the safety of health care. However the metrics are only partly the right kind of data, and they're not particularly accurate. Whole sets of cultural and risk data are ignored, and a considerable amount of information collected by the health care industry remains unavailable to the public. Health care is not unique in measuring the wrong things.

The book *Moneyball* explains how the RBI (runs batted in) metric used in baseball is influenced mostly by chance (a given player's RBI depends on the players who happen to bat and get on base before him), yet this metric has been used for a century to characterize a baseball player's excellence. One professional baseball team, the Oakland Athletics, capitalized on this fallacy for a number of years with great success, allowing them to spend 1/6 of what other good teams spent on player salaries and still get to the playoffs [14]. Similarly, in health care we classify the best 100 hospitals [15], the best 50 hospitals [16], the best international health care institutions [17], and the like, using measures that may have no bearing on safety and reliability of care. The bald truth is that even those deeply knowledgeable about health care don't have available to them a set of reliable measures that identify the "best" safe and reliable institution.

The reports about best hospitals are based on reputation, imperfect quality data, and self-assessment and do not include the very important measures of culture, risk, and reliability. Furthermore, in what could be perceived as a conflict of interest, some organizations publish metrics of safety and then offer commercial services to help those same hospitals improve. We can achieve a materially better understanding of safe and reliable health care if we aggregate public health care data and other selected data that is now strictly private.

It is in this setting that Congress addressed the practical aspects of collecting data about adverse events, near misses, and errors. So far, however, the PSOs have not achieved anything even close to their potential. It is difficult to collect adverse events manually, and human beings don't like to report their own errors of omission, commission, and lapses in judgment or memory. In fact, they won't reliably do so, and so far, they're not. PSOs may well become the repositories of increasingly important data, and they may play a major role in safeguarding the learning process that is necessary in our health care industry. But part of this future success will rely not on person-dependent reporting but on a combination of automation and person-dependent oversight.

The Internet, easy access to computers, and electronic health records are making real-time electronic collection of adverse events in large health systems a reality, theoretically bringing us closer to achieving a real national assessment of care safety. A census approach that looks at hospital databases might finally produce a view of the "real" number of potential and adverse events, the denominator in the risk equation. That number has been elusive, sought after for the past 20 years since the 1991 Harvard Practice Study identified that we are an error-prone industry [18]. It is now on the horizon and brings us closer to quantifying risk in hospitals in a standard and comparable fashion using meaningful measures. Combined with the increasing sophistication of how we measure culture and attitude [19], we might finally be able to identify the organizations capable of delivering stellar care and to pinpoint those most in need of improvement. This requires measures of culture, processes, outcomes, and adverse events. PSOs can collect all this data.

But the Patient Safety Act is flawed; PSOs are not required to share their data, which limits the ability to achieve a much-needed national perspective. Regardless, it is a step in the right direction. Organizations are getting their hands around the measurement of health care culture in earnest for the first time and are beginning to really measure risk. The culture and risk insights that ensue [1] will change the way leaders manage health care, alter how we view organizational excellence, and most likely lead to safer and more reliable care.

PSOs make sense for learning, and confidentiality is appropriate to increase the amount and quality of data collected. To reach full potential, however, PSOs must find ways, or be required, to aggregate their findings.

Maybe it is wishful thinking, but at some point an organization with a prescient leader who understands reliability and the factors that predispose to excellence may make some of this data publicly available and not implode but improve. The Lexington, Kentucky, Veterans Affairs Medical Center did so with disclosure of adverse events to patients in 1987 [20, 21], followed very successfully by others like the University of Michigan [22] health care system. In those cases, it took singular individuals to start the process. That will certainly portend a shiny new day.

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MEDICINE AND SOCIETY

Resolving Harmful Medical Mistakes—Is There a Role for Forgiveness?

Nancy Berlinger, PhD

What ought to happen after one person harms another person he or she was trying to help? Physicians may wonder if the answer to this question includes the word “forgiveness.” A focus-group study of academic and community physicians, published in the *Journal of the American Medical Association* in 2003, reported that physicians “experienced powerful emotions following a medical error [and] felt upset and guilty about harming the patient.... For many physicians, the most difficult challenge was forgiving themselves for the error” [1]. In the opinion of a study participant, “Forgiveness is something that I think is tougher for the physicians to give themselves than to get from the patient” [2]. The study’s authors concluded that “the notion of a ‘blame-free’ culture of errors did not diminish these physicians’ anguish and sense of culpability for errors.... Better institutional support for caregivers involved in errors would help them focus their attention on the affected patient” [3]. A recent book co-authored by Thomas H. Gallagher, MD, the lead investigator for this study, also highlights the psychological impact of making mistakes and disclosing them: “Deciding how to share the facts of the situation and avoid speculation while simultaneously managing feelings of guilt, the urge to assign blame, and the desire to protect oneself is hardly an easy task” [4].

Why Is Forgiveness an Ethical Issue for Physicians and Patients?

Ethics, including medical ethics, always has a social dimension. The values expressed in principles such as “do no harm” concern our actions with respect to persons and things other than ourselves. Ethics is more than rules of conduct, and, as these examples suggest, it involves close attention to the emotions present in an ethically challenging situation, including the physician’s own emotions. In the aftermath of medical harm, ethically sound practice entails the care of injured patients and their families through truth telling, apology, and fair compensation, actions that are likely to involve the physician responsible for the patient’s care at the time of the injury and may involve other professionals and administrators as well. (Fair compensation, for example, will usually require collaboration between the physician and an institution’s risk manager.)

A large literature suggests that the emotional impact on physicians of bad outcomes, such as the experience of being “fired” by a patient or family, should be recognized [5]. The physician whose self-confidence has been shaken by one case is still being relied on to provide care to other patients. The ethical dimensions of medical harm therefore include how the involved physician recovers from such incidents.

This recovery may involve the desire for forgiveness. Forgiveness is a word that has two contradictory meanings. We're accustomed to "forgiving" family members and friends after minor (or major) arguments. In these cases, "forgiveness" is understood to mean reconciliation, or at least agreeing to get along until the next argument. However, we may also "forgive" a loan to a family member, or the library may "forgive" our late fees. In these cases, "forgiveness" is understood to mean detachment, an end to a debt or other obligation between two parties. When we speak about forgiveness after medical harm, which kind of "forgiveness" do we mean? The kind that brings people together? Or the kind that allows them to detach from one another? These are important questions, because medical harm occurs in different types of health care relationships. How does "forgiveness" work in the relationship between a patient and a primary care physician? How does it work in the relationship between a hospitalized patient and the members of a health care team, or between a patient and a medical or surgical specialist who may not have much of a "relationship" at all? How do you forgive a "system" for a "systems error"? And what about "self-forgiveness"? Does that count?

What Are the Sources of Our Ideas about Forgiveness?

How a culture frames the human potential for error can influence how a person shaped, in some way, by this culture thinks about forgiveness as a possible response to human error. For example, in the Hebrew Bible, the word "*het*" appears 595 times, more than four times as often as its nearest synonym. This word for "error" has often been translated as "sin." A more accurate translation of "*het*" would be "to miss the mark," like an archer who takes aim at a target and misses, or a traveler who misses the correct turn, or a physician who orders the wrong drug, or a pharmacist or a nurse who doesn't catch the mistake in the order. The knowledge is there, the skill is there, the intent is there, but the action doesn't go as planned. The experience of making a medical mistake can feel like the experience of "missing the mark."

However, the same incident of "missing the mark" (for example, a harmful medication error) may be framed as a technical error by the culture of medicine; a potential claim by risk management; a systems failure by patient safety; an injury with medical, financial, and psychological consequences by the harmed patient or the patient's family; and a psychologically and professionally traumatic event by the individual clinicians involved. By appreciating the different ways in which the same incident can be framed, one can see how the expectations of each party concerning the resolution of such cases are likely to differ.

So how does the harmed party forgive the person or system that has missed the mark, resulting in the harm? Jewish traditions concerning forgiveness emphasize concrete, interpersonal obligations. "*Kapparah*," a Hebrew word associated with rituals of atonement, refers to the reconciliation of the person who has committed an error with the person he or she has injured. These rituals are enacted by observant Jews each year prior to Yom Kippur, the Day of Atonement. ("*Kippur*" and "*kapparah*" share the same root). Within the Jewish tradition and the Christian traditions that followed from it, forgiveness is a response to two discrete actions or series of actions: an

acknowledgment of the error by the person who has made it, a practice often called “confession,” and efforts by this person to make amends for the harm he or she has done, practices often called “repentance” or “atonement.” Forgiveness is the outcome of this relational ethical process.

In medicine, this process is set in motion by the discovery that what has happened was, in fact, a mistake, and should not have happened. Truth telling and apology are forms of confession, while providing fair compensation and analyzing and changing how work is performed with the goal of preventing future mistakes are forms of repentance or atonement.

Jewish and Christian traditions around error and forgiveness are powerful, if not always acknowledged, influences on Western culture and Western medicine. The practices that medical sociologist Charles Bosk describes in *Forgive and Remember*, his classic ethnographic study of the surgical mortality and morbidity conference (M&M), are clearly based on these traditions [6]. There is confession through the self-critical “hair-shirt” ritual of publicly describing the incident to one’s peers and superiors. There are acts of repentance through assigned tasks and close supervision. And there is official forgiveness by a senior surgeon, who functions as deity, high priest, judge, pastor, peer group representative, and injured party.

The injured party—the patient, or the loved ones of a deceased patient—is excluded from this forgiveness ritual. Yet patients and families also have ritual needs and expectations in the aftermath of medical harm. A well-designed disclosure process should take these needs and expectations into account by talking with patients and families about their experiences, good and bad [7].

In the Jewish and Christian biblical traditions, the deepest meaning of forgiveness is detachment, of not being bound by error. The metaphor associated with forgiveness is the cancellation of a financial debt that can never be repaid and reflects a culture in which debt-servitude was common. Yet the idea of forgiveness as reconciliation may also be closely associated with these religious norms. Patients and health care professionals alike may base their ideas about what “good” people are supposed to do after one person harms another on lessons they learned as children, whether these lessons were conveyed in terms of religious beliefs and practices, or simply as good manners: “you mess up, you ’fess up.” In the aftermath of medical harm, individuals who hold these values may be unsure whether their goal is the reconciliation of persons. Becoming free from the error itself as a source of continued suffering for patients, families, and clinicians may be an appropriate goal whether or not individual persons wish to be reconciled.

Influential traditions are not universal norms. Not everyone uses the same metaphors, learns the same prayers, has the same parents, or thinks about human relationships the same way. For example, forgiveness as a metaphor for a relationship between individuals may not make sense in religious traditions such as Hinduism or Buddhism in which a concept of the self as independent from other persons is not the

norm. In traditions such as Buddhism, in which suffering is recognized as an inevitable feature of human existence, compassion (literally, “suffering with”) may be the most common metaphor for the repair of damaged relationships. In a culturally diverse society like the United States, where the physician population and the patient population may have been shaped by a variety of religious and other cultural experiences, it is important to recognize the largely Western sources of medicine’s metaphors and expectations concerning error and forgiveness while also recognizing that the metaphors and expectations of individual clinicians and individual patients may derive from other sources or from a combination of traditions.

Is Forgiveness Good for Us?

Research by some clinical psychologists and social scientists suggests that the ability to forgive may be characteristic of an emotionally healthy person, that a refusal to forgive may be associated with behaviors ranging from holding grudges to perpetuating civil conflicts, and that these unhealthy behaviors can be modified [8]. Other scholars and clinicians have criticized efforts to prescribe forgiveness as a therapeutic intervention, arguing that these efforts fail to recognize forgiveness as an individual’s personal response to the experience of being harmed [9]. As legal scholar Martha Minow points out: “Fundamentally, forgiveness cannot be commanded” [10].

This body of empirical research does not, as yet, address forgiveness after medical harm directly, so these findings cannot be applied directly to this situation. However, because the idea that forgiveness is good for people is an attractive one in this culture (witness the popular magazine articles), it is worth seeing whether that idea works when someone who expected to be helped has been harmed. Right away, there is a problem if we identify forgiveness as a characteristic of an emotionally healthy person and then describe an injured patient as if he or she is willfully holding a grudge if he or she cannot offer forgiveness. The routine characterization of harmed patients as “angry” patients reflects this still-common failure to acknowledge that anger is an appropriate response to this situation and also to acknowledge who is accountable for making things right after harm. This can also happen at the organizational level when a hospital characterizes itself as a “blame-free” culture but fails to explain how this helps patients. Will this new culture dismiss patients and families who seek explanations or compensation for harm as troublemakers who are looking for someone to blame?

There is a further caution with respect to prescribing forgiveness broadly as an intervention. As human beings, we may be reluctant to say, “I forgive you” if we believe that we are merely excusing bad behavior rather than responding to changed behavior. Psychologists call the pressure to offer forgiveness prematurely “pseudo-forgiveness” or “role-expected forgiveness,” and some have suggested that therapeutic interventions that aim to produce forgiveness are unsound in that they place responsibility for the resolution of harm on the harmed party, who may also be the less-powerful party [11]. The patient who feels pressured to offer “pseudo-

forgiveness” may get angry—and may eventually file a lawsuit. The discovery of a harmful mistake leads directly to the words “I’m sorry.” But the words “I’m sorry” do not lead directly to the words “I forgive you.” This is not solely a matter of the right words.

What about Self-Forgiveness?

Forgiving oneself for harming a patient is not at all the same thing as making it possible for this patient to choose to offer forgiveness. However, a physician who, through his or her actions, supports the ability of a patient to forgive may also need to practice self-forgiveness, so he or she is able to get back to work. But what does “self-forgiveness” mean beyond an intuitive sense of wanting to be free of the burden of guilt?

Philosopher Charles Griswold rightly distinguishes between forgiveness, which can be granted only by the injured party, and self-forgiveness. In self-forgiveness, according to Griswold, “the injury that one has done to oneself—precisely in injuring another” is the catalyst for confessing to oneself [12]. So if the discovery of the mistake leads directly to the words, “I’m sorry,” the discovery of the harmful mistake also initiates a parallel process that can lead to self-forgiveness, as the physician grapples with the “existential blow” of having harmed a patient [13].

Jeffrey Blustein, a philosopher and medical ethicist, argues that self-forgiveness, like forgiveness, is a feature of “taking responsibility for one’s past” [14]. In Blustein’s view, “the past” should not be reduced to a moral checklist of what we have done and what we have failed to do, but should be viewed in psychological and narrative terms: “what one has shown oneself to be like by what one has done” [15]. Our own past, as we understand it, is something that ought to be accessible and useful to us; physicians, for example, are accustomed to drawing on their years of clinical training and experience. If we are unable to forgive ourselves for something in our past, there will be a break in the story as we know it. We are going to have difficulty understanding the content of our own character. And we may have difficulty anticipating how well we will respond to a similar situation in the future.

Blustein reminds us that any genuine process of forgiveness is not automatic:

Self-forgiveness, like forgiveness of others, is ordinarily a process that has to be gone through: it takes time and often not a little effort to suppress or forgo one’s self-directed negative feelings.... One cannot forgive oneself for what one has done if one is not prepared to take responsibility for it, and the explanation of the failure to take responsibility for some problematic part of one’s past might be that one cannot or will not forgive oneself for it.... insofar as it is a flaw in a person that he is not self-forgiving, it is also and for the same reasons a flaw in a person that he does not take responsibility for his past [16].

What do we make of this tough-minded philosophical account? On the one hand, a physician who is not self-forgiving either fails to acknowledge his or her own certain

fallibility or else views himself or herself as a moral monster, irredeemably flawed. Neither of these is a trustworthy position from which to move forward and to help others. On the other hand, making self-forgiveness into a mere refrigerator-magnet affirmation means the physician is skipping the hard work of figuring out what, exactly, he or she is on the hook for.

The process of self-forgiveness is likely therefore to be a messy one, as the physician wrestles with his or her own emotions and sense of responsibility concerning his or her own actions and also, perhaps, wrestles with emotions directed toward others involved in a systems error: Why didn't that pharmacist catch the mistake in my order? Why didn't that nurse question that order? Do they share responsibility for this harm, or is it all on me? And how can I talk about this with them so we can continue to work together?

In the same essay, Blustein writes that self-reproach makes sense only “for something over which one had some control” [17]. Separating one’s emotional response to a distressing situation (what happened to that patient was terrible!) from one’s praiseworthy or blameworthy actions within those areas under one’s control (what was my role in what happened to that patient?) involves reflection on these questions: Do I feel bad about this situation because it’s inherently tragic? Or do I feel bad because I had an opportunity to do some specific good or prevent some specific harm—and I blew it? This is a complicated question, because medical mistakes happen inside of complex systems.

Richard Cook, an anesthesiologist who studies systems such as health care that are “intrinsically hazardous” and “possess potential for catastrophic failure,” points out that working in such a system “requires intimate contact with failure” [18]. That is, the physician or other worker should be able to imagine how a tolerably safe situation (what Cook calls “the envelope”) can slip into an unsafe situation, and “how their actions move system performance towards or away from the edge of the envelope” [19].

Conclusion

So what should physicians do in the aftermath of medical harm, with respect to forgiveness? What helps the injured party? And what helps the physician recover from this incident? The physician should not expect to hear the words “I forgive you” from an injured patient or family, even after disclosure, apology, and assistance in securing fair compensation have taken place. Asking for forgiveness may be oppressive to a patient or family still grappling with the fact of the harm, the impact of the harm, and their own emotional response to the harm. Asking them, during a time of crisis and even bereavement, to offer a premature, formulaic response is simply too much to ask. The process of forgiveness may be the work of months or years.

At the same time, however, the physician can work toward self-forgiveness, by taking responsibility for his or her past, by working to understand his or her role in

an incident that slipped beyond the envelope of safety, and by responding to the needs that have been created as the result of harm. Valuing forgiveness as a desirable and authentically human response to human error in medicine requires physicians and their colleagues to create the conditions that will help those who have been harmed to offer forgiveness, and that will also help those whose actions have caused harm to be restored, as healers.

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MEDICAL NARRATIVE

Learning to Care about Patient Safety

Elaine Besancon, MD

Most of us can recall a particularly memorable patient who inspired or altered our career path. My patient was a 63-year-old woman with inflammatory breast cancer who had been in remission and asymptomatic until her family suddenly couldn't wake her one morning. She was admitted to the hospital and diagnosed with meningeal metastases. Her husband, son, and daughter were by her bedside all day, nearly every day. Despite their best efforts to be vigilant and the fact that she was in a "top 100" hospital, her care was hardly error-free, and the family's grief was compounded by her frequent falls, a black eye from an errant stethoscope, several severe drug side effects (one of which left her nearly comatose for a month before the offending drug was recognized and discontinued), one narrowly avoided unnecessary neurosurgical procedure, and the administration of an incorrect intrathecal chemotherapy drug.

Some days brought nightmarish scenes that further emphasized how difficult it was to keep such a complex patient safe. One morning I walked in to find her hands and forehead covered in blood. While hallucinating and between nursing checks, she had pulled out every cranial staple from her recent neurosurgery by hand, an event that put her at great risk for infection. Needless to say the scene also shook the family's confidence in the care team. Though the medical team tried everything to get her stable enough to go home, the severity of her illness, combined with the complications of numerous adverse events, kept her in the hospital, where she slowly died over the course of 6 months.

The patient I've described was my mother. I was the daughter who sat by her bedside for months, watching the challenges of caring for a complicated patient through the eyes of a family member rather than those of a medical student. Of all the subjects I had been taught during medical school, the one I felt was most important during my mother's hospitalization was also one I'd learned least about implementing in my daily practices: patient safety. Of course we'd had some instruction in the subject—we'd had several lectures on concepts like "Toyota Lean" and the "swiss cheese model" of error occurrence. But these concepts had often seemed too business-oriented or administrative to be directly relevant to trainees who chose medical school because of a love of science and patient care.

Even if we had been inspired to become more involved in safety practices, they were always discussed in generalities with little instruction about how to adopt them other than by being vigilant, writing thorough sign-out notes, and perhaps discussing

appropriate patients at morbidity and mortality conferences. Following my experiences with my mother, I attempted to figure out how to report errors or near misses I witnessed in our hospital while on third-year rotations. But I found that, as a medical student, it was impossible for me to report an error through the usual channels—our computer system wouldn't even accept it.

Treating patient safety as an afterthought in the medical school curriculum invites students to continue to treat it that way after medical school and into their careers. But medical school is the perfect time to emphasize patient safety and quality improvement. Medical students have not yet been desensitized to the inefficiencies and unsafe practices that many seasoned health care professionals not only tolerate but are often not even consciously aware of. Learning patient safety must be a hands-on experience, however, for it to truly resonate with students.

Though I am now passionate about the topic, I rarely thought much about it until my mother's hospitalization, despite the lectures and tutorial cases I'd had in medical school. Hypothetical cases may be acceptable for an introduction to the field, but, just as hypothetical cases in pathophysiology are supplanted by experience with real patients for which there is no substitute, patient safety education should not be relegated to the realm of the theoretical.

The 2011 ACGME requirements mandate more direct involvement in patient safety for residents [1], which is an important step in the right direction. Similar training can easily be extended to students as well. Though some have cited the admittedly numerous barriers to curricular reform [2], not the least of which are funding and staffing issues, basic safety experience for students need not be expensive. Interventions as simple as allowing medical students to report the errors and near misses they witness and sit in on preexisting safety committee meetings would cost little but go a long way towards exposing trainees to the importance of safety and quality improvement efforts.

It also became clear to me during my mother's hospitalization that the frontline caregivers were the individuals most likely to notice areas for improvement in the day-to-day operations of the hospital. At her institution, this included physician's assistants and nurses; at my current institution, it also includes residents and medical students. During my mother's hospitalization, these frontline caregivers were far more aware of areas in the hospital that needed improvement than were members of the patient safety committee (mostly attending physicians, department leaders, and administrators). Unfortunately, there was a large disconnect between these two groups.

A factor that contributed to my mother's many falls during her periods of delirium was that the cords for the bed alarm and the chair alarm were identical and only one could be plugged in to the monitoring device at a time. This meant that there was no way for a busy nurse to assess which alarm was active with a quick glance—one would have to stop and trace the cord all the way back from the monitor to the chair

or bed to confirm that the correct alarm was plugged in. Many of the nurses knew this, and several easy fixes leap to mind for this problem, but the nurses had no clear procedure for informing those who could do something about the problem, nor did they seem to feel that it was their responsibility to find a way do so. I'm in no way faulting the nurses in particular for this failing—what I wish to say is that issues of safety, until they resulted in a catastrophic outcome, often fell outside of nearly everyone's job description. To remedy this, the culture of safety needs to extend not just to medical trainees, but also to any hospital employee who interacts with patients or observes patient care. All of these individuals should have easy access to a mechanism for reporting safety concerns.

There is one other important group of individuals that is almost never included in calls for more inclusive safety efforts: family members. Family members can find it difficult to speak up when we have safety concerns. Even as a medical trainee, I worried about asking questions of my mother's care team. What if I annoyed them? What if we became labeled a "difficult family"? Would my mom's care suffer as a result? Often, especially early in her hospital course, I opted not to voice any safety concerns because of fears like these.

I've heard many other reasons that family members don't speak up—we feel it's not our place, that the medical team is too busy, or that the staff would surely have noticed if something were wrong. Caregivers often allow—or even encourage—these attitudes to persist. As a result, family members become involved in the safety process only when they think something disastrous has happened and file an incident report, a complaint, or a lawsuit.

It is undeniable that rounds are speedier when family members do not ask questions or interject comments during our presentations. However, because nationally standardized medical records systems are still far in the future and frequent handoffs and cross-coverage have become unavoidable realities, patients' family members can be the best sources of continuity. Often they've been present for every ED visit, outside hospital stay, and outpatient appointment. A couple of months into my mother's hospital stay, details like her need for a much lower dose of phenytoin than the average patient had been buried deep within her chart. Frequently, all that kept a harried covering physician from administering an overdose when she was seizing was our family's intervention. Several times when we weren't there overnight, an excessive dose was given and Mom would sleep for days. Though this is an extreme example, more purposeful involvement of the family has the potential both to reduce errors and increase family satisfaction if it is clear that physicians are attempting to address their concerns.

As a family member, I found the errors that affected my mother to be the most distressing part of her illness. Now, as a physician, worrying that I will commit an error that causes my patients to suffer is a powerful motivator for my patient safety work. But as much as I hope I can make a difference in my institution, a culture of safety won't come from a few individuals who feel strongly about these issues

working in each hospital. Not until safety is an emphasized part of everyone's job description can we hope to reduce dramatically the great number of preventable errors taking place in our hospitals. I hope that in the future we can design novel educational interventions that convince medical personnel to prioritize safety issues, so that they won't have to be convinced, as I was, by watching patients like my mother suffer.

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OP-ED

Never Events? Well, Hardly Ever.

Paul F. Levy

The well-bred Captain Corcoran of the HMS Pinafore was clear in his intent and could be forgiven a bit of braggadocio, but his affectionate crew was quick to remind him of his flaws and get him to be a touch more modest. Likewise, we can be sure that surgeons who perform medical procedures are clear in their intent—avoiding harm to patients. But their performance, too, belies this intent more often than we would like.

The Centers for Medicare and Medicaid Services have labeled avoidable adverse outcomes “never events,” and will not pay for treatment of these outcomes [1]. The most visible “never event” in the eye of the public is a wrong-site surgery. Some of these events are terribly dramatic and sad, like the removal of a noncancerous kidney in Minnesota in 2008 [2]. Others are of less life-threatening import, like a wrong-side ankle surgery in Boston in that same year [3].

Any doctor who has carried out a wrong-site procedure understands that this is a searing event, both personally and professionally. No possible punishment is more effective than the alarm, embarrassment, and shame already felt by the doctor. And yet the rates of wrong-site surgeries remain essentially constant [4-7]. An article in the *Archives of Surgery*, for example, noted that self-reported data from 2002 through 2008 revealed a persistently high frequency of surgical “never events” and that “the main root causes leading to wrong-patient procedures were errors in diagnosis (56.0 percent) and errors in communication (100 percent), whereas wrong-site occurrences were related to errors in judgment (85.0 percent) and the lack of performing a ‘time-out’ [before surgery] (72.0 percent)” [8].

The regulatory response to this problem is based on the old principle: “When you have a hammer, everything looks like a nail.” In this case, the hammer employed by governmental and private payers is simply a refusal to pay for such events. There seems to be a view that financial punishment will act as a deterrent. But we have seen that it does not.

What does work? Some, looking at the airline industry example, extoll the virtue of checklists. If only, they say, surgeons and other members of the OR team were to go through a preoperative checklist, the number of wrong-site procedures could be dramatically reduced.

But, as Captain Chesley Sullenberger notes, “a checklist is not sufficient. What makes it effective are the attitude, behavior, and teamwork that go along with the use

of it” [9]. It is important to confirm that the listed actions have actually taken place. This confirmation will only occur if there is sufficient trust and mutual respect among the OR staff that any member of the team can say to the surgeon, “Excuse me, have we properly carried out that step?”

The basis for this kind of behavior is codified in an environment in which “crew resource management” (CRM) has been taught and adopted. There, everyone in the room has a shared sense of responsibility for the outcome of the case. CRM is powerful for a team that works together often; it also enables a group of people who have never worked together to carry out a compact of defined goals and responsibilities.

When CRM was first introduced into the airline industry, some pilots thought it was a threat to their autonomy. Sullenberger writes, “In the old days, we had cowboys who didn’t believe in checklists.” Over time, though, the pilots came to understand that they were more likely to be successful in their tasks if they were part of a well-functioning team. They learned to reduce variation in their practice, to standardize the aspects that could be standardized. “Let the exceptional things be difficult,” grew to be the expectation among all pilots.

The parallels to surgery are clear. Hospitals that have engaged in CRM have found it to be helpful. At Beth Israel Deaconess Medical Center, for example, CRM was introduced in the Department of Obstetrics and Gynecology after the tragic loss of a baby and the near-death of the mother [10]. After the CRM curriculum was modified for clinical application, 220 staff received training to incorporate its principles and concepts into their daily work processes. The result was a dramatic reduction in major adverse obstetric events, which improved overall patient safety and the quality of obstetric care and reduced malpractice liability exposure [11].

As recently as 2006, though, some in surgery rejected much that is known about process improvement from other industries. An article in the *Archives of Surgery* concluded:

Wrong-site surgery is unacceptable but exceedingly rare, and major injury from wrong-site surgery is even rarer. Current site-verification protocols could have prevented only two-thirds of the examined cases.... No protocol will prevent all cases. Therefore, it will ultimately remain the surgeon’s responsibility to ensure the correct site of operation in every case [12].

This assertion is reminiscent of Captain Sullenberger’s description of the airline pilots before they found the correct path. Can surgeons and other doctors find their way? It is heartening that the thinking of at least one of the authors of the above-cited paper has changed [13].

In the face of slow progress, there is little doubt why the regulatory hammer is employed. But it is a crude tool. Its effectiveness as a deterrent is minimal because it

does not address the structural issues underlying the problem. It emphasizes a particular outcome rather than a process that will achieve it. It penalizes people when it is too late to make a difference. Finally, it serves mainly to create resentment among those who are targets for improvement. Such is often the nature of regulation, no matter how well intended.

What, then, is the solution? It relies on the profession rather than those on the outside. In addition to employing CRM it is time for doctors and hospitals to be much more transparent about the errors that do occur. David Ring, a surgeon at Massachusetts General Hospital, is an exemplar in this regard. Dr. Ring was convinced that the profession would be better off if he published an article about his own surgical error [14]. He understood that acknowledging the manner in which errors occur is the first step to eliminating them in the future.

Likewise, when there was a wrong-site surgery at Beth Israel Deaconess in 2008, circulation of the story to staff throughout the hospital [3] enabled us to achieve widespread interdisciplinary participation in redesigning the work flow in our ORs. As I noted at the time:

The wide disclosure of a “never” event in a blame-free manner resulted in an intensity of focus and communal effort to solve an important systemic problem, resulting in redesign of clinical procedures, buy-in from hundreds of relevant staff people, and an audit system that will monitor the effectiveness of the new approach and leave open the possibility for ongoing improvement. If you ever needed a clear example of the power of transparency, here it is [15].

Transparency, combined with a commitment to and training in crew resource management, enables doctors to hold themselves accountable to the standard of care they would wish for their own family members. This combination of ingredients offers far more potential than financial penalties or other regulatory actions for sustained process improvement in the operating rooms of America.

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Paul F. Levy was president and chief executive officer of Beth Israel Deaconess Medical Center in Boston from January 2002 to January 2011.

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