

Virtual Mentor
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System Constraints on Optimal Care

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From the Editor

Optimizing Medical Care with the Support and Limitations of Health Care Systems

Imagine a resident who cannot get her patient the drug he desperately needs because his health insurance does not cover the medication that the hospital has on its formulary. Or the surgeon who leaves the operating room after a difficult procedure, unsure of how much to reveal to his patient about the nature of the complications because he fears that he will not be compliant with the hospital's risk management policies or that the patient may file a lawsuit against him. Now consider a quality improvement program that alters a clinic's functioning so that the doctor is no longer running an average of 30 minutes late for his appointments. Finally, think about an affiliation between a practice of internists and a nearby radiology clinic that facilitates easier access to radiology services and reports; though this seems straightforward enough, the agreement may be prohibited by federal anti-kickback laws. Each of these examples illustrates an interaction between a physician and the larger system in which he or she practices medicine.

Physicians care for patients within a framework of complex systems that, like the support beams of a building, provide the foundation for and define the limits of the structure they support. In health care, these systems operate at many levels and take many forms: ancillary medical services, institutional policies, private and governmental insurance regulations, the medical malpractice system, and national and international bodies that govern health policy.

Systems impact patient care because doctors must balance what they think is medically optimal with the limits of the relevant systems in which they function. This issue of *Virtual Mentor* examines ethical controversies that arise when systems influence medical practice. It introduces clinical scenarios in which lab results go missing due to a processing error, "secret shoppers" are used to assess and improve quality of medical service, insurance coding regulations restrict care, malpractice liability and risk management impose on the patient-doctor relationship, and a patient who has broken U.S. law by paying for an organ transplant in another country seeks posttransplant care in the U.S.

Stepping back from specific clinical situations, *VM* next examines efforts to improve health care through system changes. The medical education article discusses a residency program that trains physicians and staff in collaborative systems-based practice competencies. The journal discussion broaches a topic that has faced recent public scrutiny—the ethical status of quality improvement initiatives. Drawing from

one of our cases, the clinical pearl examines the risks of and indications for amniocentesis.

Governmental laws and regulations are analyzed in the health law primer on ERISA's provisions that restrict insurance companies' liability, and in the policy forum on Medicare's "never-events" initiative. The medicine and society piece describes an innovative proposal for reforming health care based on the principles of industrial engineering. Our history-of-medicine and medical humanities articles examine, respectively, the evolution of complex medical systems and the philosophical basis for balancing generalized regulations with individualized exceptions to these rules. Finally, our op-ed author contends that medical education needs to better equip students with knowledge of the laws that affect their day-to-day practice.

Without health care institutions, medical support services, insurance agencies, governmental programs, and regulation of health care, medical practice would be a far more primitive profession conducted in private homes or offices. Without access to the complex technologies and services available in modern medical facilities, the health of the public and of individual patients would inevitably suffer.

Caught between the load of complex medical systems and the basic needs of patients, physicians must figure out how to provide optimal medical care within the structure of health care systems. Should they comply with systems constraints? Should they push to reform them? Or should physicians ultimately take responsibility for restructuring the systems themselves?

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CLINICAL CASE

Physician's Accountability for System Failure

Commentary by David Lovinger, MD

Mrs. Taylor went to see her internist because she had been suffering from shortness of breath during her usual exercise routine for several months. Otherwise, she was in excellent health. When her symptoms did not improve after several weeks, her internist ordered a chest X-ray that revealed an opacity in the right lower lobe of her lung. A follow-up CT scan showed an effusion, so her internist referred her to Dr. Jones, a pulmonologist, for a thoracentesis and further workup.

When Dr. Jones walked into the exam room, Mrs. Taylor seemed nervous. "Doctor, I had terrible complications with an epidural when giving birth to my second child, and ever since then I've been terrified of needles and medical procedures," she stated. "Is there any way I can be put under for this?" After speaking with Mrs. Taylor at length Dr. Jones convinced her to proceed with the thoracentesis using local anesthesia, which is standard of care practice. The tap went smoothly despite Mrs. Taylor's anxiety and complaints of pain, and Dr. Jones drained 750 milliliters of fluid from his patient's chest. Dr. Jones sent four vials of the fluid for laboratory analysis. As she left the clinic, Mrs. Taylor exclaimed, "Thank heavens that's behind me!"

After two weeks, Dr. Jones had not received the report from the lab. Normally, results were faxed to his office within 7-10 days. When Dr. Jones called the lab to inquire about the status of the tests, an employee reported that they had never received the samples.

Dr. Jones checked Mrs. Taylor's chart and found no lab order sheet. When he spoke to his nurse about the lab order, she confirmed that she had prepared the paperwork and sample to be sent for testing. Dr. Jones also spoke to Greg, the clinic staff member responsible for sending lab specimens to the lab and learned that he had not been in the office the day of Mrs. Taylor's thoracentesis; his substitute was a staff floater who was filling in for the day.

Mrs. Taylor was scheduled to return to the clinic the next day for her results. Dr. Jones faced the task of telling her about the lost sample and the remaining diagnostic options. He also wondered how he could prevent a recurrence.

Commentary

This is a difficult and all-too-common scenario in clinical medicine: an error occurs that exposes a patient to harm, it is not obvious who is at fault, and there is no clear

guidance about how to address the error. Though Mrs. Taylor was not harmed by the first procedure, she will need to have the thoracentesis repeated if the fluid re-accumulates. If the fluid does not re-accumulate, she may need to have a more invasive diagnostic procedure such as a needle biopsy or even an open biopsy procedure such as a thoracoscopy. Then there is the matter of Mrs. Taylor's anxiety at having to face a feared procedure a second time and the psychological distress inherent in the situation because cancer is the suspected diagnosis. The difficulty here is compounded by the fact that it is not clear who bears the ultimate responsibility for the mistake of the lost sample. This scenario also generates a number of vexing questions about how to proceed with this patient, both ethically and clinically; how to prevent this or a similar situation from happening again; and how to improve the administrative process so that these occurrences are less likely.

At the center of the case is the concept of “systems failure” and how it relates to personal responsibility and individual accountability. The idea that systems—as opposed to individuals—can be responsible for errors is a modern construction that has roots in aviation and the military. The clarion call for medicine to reduce errors and improve patient safety was the 2001 Institute of Medicine (IOM) report, *Crossing the Quality Chasm: A New Health System for the 21st Century* [1]. In this document, the Committee on Quality Health Care in America called for systematic and system-wide changes to address substantial deficits in patient safety and health care quality. Though some have argued that a focus on systems ignores individual responsibility [2], this either/or approach misses the point. A systems approach to analyzing an event like the one in the case of Dr. Jones and Mrs. Taylor looks at ways that the workflow in the clinic (i.e., “the system”) could be configured to eliminate certain types of errors. In his book *Complications*, Dr. Atul Gawande describes how the field of anesthesiology used a systems approach to reduce anesthesia deaths from roughly 1 in 10,000 to 1 in 1,000,000, a hundredfold reduction [3].

Another prominent theme in this case is the disclosure of error. Though medical ethicists and professional societies have stressed physicians' ethical obligation to tell patients about unexpected events that have implications for future care [4] many practitioners (and risk managers) have long feared the consequences that admissions of responsibility and apologies could bring. A policy enacted by the Veterans Affairs Medical Center in Lexington, Virginia, in 1987 that requires complete and honest disclosure seems, however, to have resulted in no financial penalty [5]. Other organizations have had similarly encouraging results, yet such disclosure policies are still more the exception than the norm [6].

Given all this, telling Mrs. Taylor of the lost sample is not only warranted, but prudent. But how should Dr. Jones go about sharing this information with Mrs. Taylor, and is there any guidance available for practitioners, most of whom have no experience with this practice? In 2003, the National Quality Forum published “Safe Practices for Better Healthcare” [7], which outlines standards for disclosure of unanticipated outcomes with patients. These recommendations include providing

facts about the event, disclosing the error or system failure, expressing regret, and offering a formal apology if the outcome was caused by error or system failure.

That medical errors constitute an epidemic is an oft-stated truism that belies the complexity of the issue. Relying on studies in the literature, the 1999 landmark study, *To Err is Human: Building a Safer Health System*, concluded that at least 44,000 and perhaps as many as 98,000 lives were lost each year from preventable medical errors [8]. This startling number was not accepted without dispute [9], and the issue of preventability was debated [10], but the original research was compelling [11]. The report has gained wide currency throughout the health care system and its recommendations have led to a variety of efforts to improve patient safety. Further, this report helped spur health care organizations to implement computerized physician order entry (CPOE) systems, which have been shown to reduce medication errors and adverse drug events substantially [13].

Returning to our case, the patient, Mrs. Taylor, was exposed to the risks inherent in a thoracentesis without any diagnostic benefit because the sample that was collected was lost. Though the benefits of the procedure are believed to greatly outweigh the risks, a thoracentesis can cause bleeding or infection at the test site and possibly a collapsed lung, which could require a more invasive procedure, like the insertion of a chest tube, and could even be fatal. Though Mrs. Taylor's anxiety about having the procedure does not factor into whether or not there was an error, nor where the responsibility for that error lies, it will heighten her distress at this unanticipated outcome.

Dr. Jones has several obligations if he is to address Mrs. Taylor's concerns. The first is to discover what happened and why. The case is silent on what exactly could have happened, but it does seem to suggest that responsibility for the error lies with the staff floater. In fact, the problem is more likely to be found in the failure of the clinic's workflow procedure to effectively track the movement of specimens. That the clinic has to rely on temporary staff who are not familiar with standard policies and procedures obligates those who work there to create a safer and more reliable system.

Dr. Jones's second obligation is to discuss the events with Mrs. Taylor honestly and frankly, inform her of what he will do to prevent this error from happening again, and apologize for the distress he and the office have caused. Finally, Dr. Jones should help Mrs. Taylor with the financial and insurance consequences of the initial procedure, which, while clinically warranted, was not properly carried out. Mrs. Taylor should not be held responsible for the costs of the procedure. As the IOM suggests, to err is indeed human, but ultimately those who work within health care systems have an obligation to effect changes that minimize error rates and place the systems on a more secure foundation.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

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CLINICAL CASE

Transplant Tourism: Treating Patients when They Return to the U.S.

Commentary by Sally Satel, MD, and by Andrew J. Aronson, MD, MBA, MPH

Mr. Lawrence, a 50-year-old man with diabetes, is on dialysis for chronic renal failure and on the waiting list for a kidney transplant. Because he is in relatively good health, he is low on the list. His physicians advise him that he could be on the list for up to 3 years and that his health during that time would not be jeopardized, aside from the risks and inconveniences associated with long-term dialysis. Mr. Lawrence is divorced and on bad terms with his ex-wife; he has no children and has contacted his sister and her family to see if any of them could be a living donor. His sister is obese, at risk for diabetes, and is not a suitable donor candidate; no other family members or friends are willing to consider donating a kidney to Mr. Lawrence.

Unable to find a living donor and dismayed at the thought of remaining on dialysis for years, Mr. Lawrence decided to use his financial resources to purchase a kidney and undergo a transplant in China. He spent 2 months in China after the surgery, where he was cared for by a local transplant team that provided postoperative care, including monitoring his renal function and managing his immunosuppressant medications. The surgery occurred without any significant complications, and Mr. Lawrence's recovery was excellent.

A month after his return to the United States, Mr. Lawrence ran out of the medications that his doctors in China had prescribed, including his immunosuppressants. He knew that failing to take the medication could cause graft rejection, so he made an appointment with Dr. Roberts, a nephrologist at a local academic center who specialized in care of renal transplant patients. Dr. Roberts was aware that many of the organs secured in China came from executed prisoners who did not always consent to organ donation. Further, Dr. Roberts was wary because purchasing organs was illegal in the U.S. Having worked in the transplant field for several decades and witnessed numerous changes in the regulations about and care of transplant patients, Dr. Roberts understood how difficult it was to secure an organ, but didn't want to be perceived as condoning Mr. Lawrence's actions.

Commentary 1

by Sally Satel, MD

Is it ethical for Dr. Roberts to treat Mr. Lawrence? Yes. Qualms about the circumstances surrounding a patient's activities are not a reliable ethical guide for physician behavior; if that were the case, the American Medical Association would

have condemned the medical treatment of convicted rapists, child molesters, and murderers long ago. Instead, the organization affirms the ethical imperative to treat such patients [1]. Similarly, doctors in the military would have no obligation to treat enemy combatants or prisoners of war, as they do under the Geneva Convention [2].

Mr. Lawrence, himself, is right to feel a sense of urgency. Patients on dialysis have shorter lifespans than kidney recipients. According to the U.S. Renal Data Service, a 50-54-year-old man on dialysis has an expected remaining lifetime of 6 years. With a new kidney, he may expect 16 years of life—a decade more [3]. And while dialysis patients have a significantly diminished quality of life compared to the general population [4], transplant patients report enjoying as good a quality of life as the population overall, sometimes even better [5].

In the nephrology community, my colleagues and I agree that the unspoken standard is to treat patients who have obtained organs overseas. Last year, the ethics committee of UNOS (United Network for Organ Sharing, the federally appointed agency charged with coordinating all organ donations and allocations), resolved that, while the individual physician does not have a duty to treat this type of patient in a nonemergency situation, the medical community as a whole does have such an obligation. In general, the resolution says, “physicians are encouraged to provide care” [6]. My own anecdotal experience reveals that many nephrologists have asked themselves at one time or another, What would I do if I, or a loved one, needed an organ? In the end, it is hard to fault someone who is trying desperately to save his own life.

Some physicians, however, prefer not to treat a person who went abroad for an organ. Doing so, they believe, would make them complicit in organ trafficking. In such instances, the responsible course of action is for the physician to inform the patient of this position up front and, if the patient decides to pursue an organ overseas, refer him or her to a local colleague who is willing to provide follow-up care when he or she returns.

“Transplant tourism” exists because the supply of organs in the United States is inadequate to meet demand. In the U.S, as in all countries except Iran, transplant policy relies upon altruism. While noble in spirit, this mandate creates its own form of coercion. Desperate patients feel they have no choice but to rent billboards to solicit donors, join online organ matching sites, and impose upon ambivalent relatives. Some—no one knows how many—go abroad despite the sickening knowledge that their new organ might come from an executed prisoner in China or an illiterate laborer in India.

Though UNOS opposes transplant tourism, the practice theoretically lightens the agency’s allocation burden [7]. After all, every time a person removes himself from the waiting list, he helps other candidates advance in the queue because there is one fewer claim on the limited pool of cadaver organs.

The most critical point in any debate about physician responsibilities to transplant tourists is that organ trafficking is a symptom of a shortage. To view organ trafficking simply as a moral failing of the patient or a contained problem in and of itself is woefully misguided. Underground markets develop predictably when demand is great and supply is small. And given the symbiotic nature of the relationship between trafficking and the global shortage, it will be nearly impossible to affect one but not the other. Thus, clamping down on illicit sales without first expanding the pool of available organs will mean more deaths from end-stage renal disease. Most likely, it will also drive trafficking rings further underground, increasing the risks to recipients and donors.

Possible Solutions

The way to starve this corrupt and unauthorized market is to make it easier to obtain an organ in the U.S. To do so, Congress would have to lift the ban on incentives for donations so that the effect of donor compensation on the organ pool could be studied. Transplant surgeons, legal scholars, and economists have long urged the application of incentives to motivate donation.

What kinds of incentives could be offered to individuals amenable to relinquishing a kidney while still alive? Perhaps the federal government could offer lifetime Medicare coverage or a deposit into a 401(k) retirement plan, tax credits, tuition vouchers for the donor's children, long-term nursing care, family health insurance coverage, life and nonfatal injury insurance, a charitable contribution in the donor's name, or cash payments distributed over time. Under this scheme, Medicare would underwrite the incentives in light of the fact that it already pays for dialysis treatment, which has greater long-term costs than transplants [8].

A central concern about any enrichment plan is the potential for donor exploitation—especially of low-income individuals who will be the most likely to find incentives for donation attractive. This is why donor protection is the linchpin of any compensation model. Standard guidelines for physical and psychological screening, donor education, and informed consent could be formulated by a medical organization, such as the American Society of Transplant Surgeons, or another entity designated by the federal Department of Health and Human Services. A waiting period of 3 to 6 months could be built into the process to ensure that the prospective donor has had ample time to think through the implications of the commitment. Monitoring the donor's posttransplant health is also important and should include annual physicals and laboratory tests for 1 to 2 years after donation. With such protections guaranteed, the motive for relinquishing a kidney—out of generosity or self-interest—is less important than increasing the supply of kidneys to ameliorate suffering.

These broad proposals and variants on them need considerable elaboration. There is no denying the political and practical challenges that come with introducing compensation into a 20-year-old scheme built on the premise that generosity is the only legitimate motive for donating an organ. Yet, as death and suffering mount,

constructing an incentive program to increase the supply of transplantable organs becomes a moral imperative.

Many of the quandaries that plague transplant medicine—from optimal allocation policy to the relationship of American physicians to the worldwide organ market—flow from the need to ration scarce resources. Without bold and creative steps to increase the supply of transplantable kidneys, there will be no respite from tragic choices such as the one that Mr. Lawrence made out of desperation. It is vital that physicians like Dr. Roberts treat patients who have made these choices.

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Commentary 2

by Andrew J. Aronson, MD, MBA, MPH

There is professional consensus that the recipient of an illegally obtained organ is medically disadvantaged for several reasons—increased morbidity due to a greater risk of infection, lack of indicated medications, and greater frequency of postoperative complications [1]. The American Society of Transplantation (AST) declared in its “Position Statement on Transplant Tourism” that it “strongly supports the provision of optimal medical care to all transplant recipients, including those who receive a transplant abroad whether from a living or deceased donor, kidney or other organ” [2]. I have no doubt that this is the standard accepted by the transplant community because patient welfare, which includes trying to avoid the need for retransplantation, is the primary concern of all transplant physicians.

In keeping with the spirit of the AST position statement, I do not believe that Dr. Roberts faces any legal or ethical constraints in providing care to Mr. Lawrence. Presumably Mr. Lawrence has the same insurance benefits he did before his transplant, which makes the financial aspect of his long-term care less burdensome. Although Dr. Roberts might disapprove of Mr. Lawrence’s traveling abroad and participating in “transplant tourism,” he certainly knows that the wait for a kidney by an adult with diabetes can be very long and that the morbidity and mortality of dialysis patients are significant. I think it is realistic to assume that anyone facing this reality who had the means to procure an organ abroad would at least consider it. No matter how Mr. Lawrence went about obtaining his new kidney, his postoperative care now takes priority over any other concerns, and Dr. Roberts is in no way condoning his patient’s actions by treating him.

The most tragic aspect of this case is that the U.S. shortage of organ donors is so dire [3]. Our current organ donation system is based on a model of altruistic donation. Unfortunately the difference between the number of organs needed and the number donated continues to grow wider despite increased efforts to promote both cadaveric and living organ donation by government agencies, transplant and nephrology organizations, patient organizations, and others. It is projected that by 2010, the UNOS kidney waiting list will have 100,000 patients and that the average wait time will be nearly 10 years [4]. The transplant community has responded to the shortage by developing strategies to expand the number of available organs by, for example, accepting donations after cardiac death and from live donors and by using extended criteria donors—that is, allowing patients between the ages of 50-59 with two or more specific conditions that would have previously excluded them (cerebrovascular

death, serum creatinine levels greater than 1.5 mg/dL, and a history of hypertension) to be donors [5]. Moreover, governmental agencies have initiated first-person consent programs so that family members need not be consulted about a person's interest in organ donation [6].

Taking a different approach, others have advocated a regulated system of financial incentives for living kidney donors. Arthur Matas has proposed a model using the infrastructure already in place for deceased donor evaluation and allocation [7]. He suggests providing living donors with long-term health care and posttransplantation follow-up. Before this can happen, UNOS and Congress would have to agree on legislation to relax the current restrictions that prohibit financial compensation for the donation of an organ [8]. A widely held concern about any compensation system is that it would exploit the poor and members of minority communities who would be disproportionately tempted to donate. I have been told by Francis L. Demonic, MD, that The Transplantation Society has been crafting a statement against organ trafficking, commerce in organs, and the exploitation of the poor. Michelle Goodwin [9], however, writes persuasively that these predictions are not necessarily going to come true, and she argues that, in fact, the communities that The Transplantation Society is trying to protect would benefit from the increased availability of both compensated and altruistic donations.

Clearly those who do purchase organs abroad—despite the restrictions—and have successful transplants decrease the number of patients who are on the U.S. waiting list for organs and also, potentially, lower the cost of medical care in the U.S., since the patients who travel abroad pay their own expenses. Even though they may be at higher risk for some complications, treatment for these patients is not likely to be as costly as the actual surgery and associated hospital care. There have been proposals by both insurance companies and legislative bodies, for example in the West Virginia legislature, that encourage health care tourism and may lead to an increase in the practice [10], which contradicts the position of UNOS and federal legislation.

In conclusion, efforts are being made to increase the availability of organs in the United States so that it will be unnecessary to worry about the increased risks and uncertainties of going abroad or the exploitation of vulnerable people in the U.S. The current shortage of organs and the growing number of those on organ wait lists places pressure on the medical community to find ways to encourage both cadaveric and living donations. These pressures will undoubtedly change our current approach to organ donation and require the cooperation of medical communities, patient advocacy groups, government agencies, legislatures, and insurance companies.

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Virtual Mentor

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CLINICAL CASE 3

Securing Diagnostic Services within System Constraints

Commentary by Bruce Patsner, MD, JD

Dr. Simpson was performing ultrasound-guided amniocentesis on Mrs. Clark, a 36-year-old woman in her 16th week of pregnancy. She had been trying for several years to conceive a child but had had two previous miscarriages, both during the first trimester. Due to her age and a remote history of trisomy 18 in her family, she had undergone amniocentesis with each pregnancy to assess chromosomal abnormalities.

While using ultrasound to guide the amniotic fluid collection needle, Dr. Simpson thought he saw a complex lesion behind Mrs. Clark's uterus. With ultrasound, he could see that the mass was approximately 11cm; it was predominately cystic but had some debris, septations, and possibly a solid component. Further evaluation was needed to determine the composition of the mass with certainty.

Normally, Dr. Simpson would have sent his patient for Doppler ultrasound to help distinguish an inflammatory from a malignant process. He knew that the hospital he was affiliated with did not provide radiology services to patients on Medicaid for workup of asymptomatic conditions. If he referred Mrs. Clark to a public hospital where she would not be responsible for the cost of the test, the wait time could be months. Dr. Simpson was concerned that, if his patient had to wait that long, her condition would be significantly more advanced and far more likely to threaten her health and her pregnancy. Furthermore, if surgical resection ultimately were required, the delay would put that surgery in the third trimester of pregnancy when it would be technically more difficult due to the size of the uterus. The ideal time to resect a pelvic mass during pregnancy is in the second trimester, when the uterus is not too big and the threat of spontaneous abortion is much lower than in the first trimester.

Dr. Simpson was aware that, if the patient were complaining of symptoms caused by this condition, the test would be given a different procedure code. Because the state Medicaid program offered satisfactory reimbursement for therapeutic radiology procedures, his hospital would accept Mrs. Clark for the procedure. Dr. Simpson asked Mrs. Clark if she had any pain in her pelvis, lower back, or bladder. She replied, "A little pressure around my pelvis and lower back from time to time, and I definitely have to urinate more often than normal." Dr. Simpson reasoned that Mrs. Clark's description could well apply to the normal symptoms associated with pregnancy. Yet if he did not categorize her as having symptoms that qualified her for the higher-level ultrasound at his hospital, she might go untreated for months. He was concerned that the lesion he saw could be either an infectious or neoplastic

process, and either case could have potentially dangerous consequences for Mrs. Clarke's pregnancy and her general health. He thought about how he could get the radiology department in his hospital to perform the procedure.

Commentary

As a physician, Dr. Simpson is under no legal obligation to provide care to a particular patient unless he has agreed to do so [1]. But once treatment has been initiated, indicated by entering into a patient-physician relationship, Dr. Simpson's ethical and legal responsibilities are clear: he has a duty to preserve and protect the health of his pregnant patient, Mrs. Clark, and her unborn child. This fiduciary relationship is characterized by the highest duty of care towards both patients. The same duty—and the same standard of care—bind the physician, even if payment is going to be reduced or services provided free of charge [2].

Because Dr. Simpson has discovered a condition that might compromise the health of his patient, her fetus, or both, he is obligated to investigate further. He has two clear legal responsibilities here. One is to practice medicine that complies with national standards of care, i.e., to not commit medical malpractice. The second is to comply with federal and state law. He might break these laws if he were to bill Medicaid for a higher level of services than actually provided, a practice known as “upcoding.” Another way in which Dr. Simpson could break the law would be to misrepresent the patient's condition as one for which Medicaid provides reimbursement when, in fact, it does not. Both actions have the potential to produce more profit, and, although the latter appears to be in the patient's best interest, both actions are illegal and unethical.

Medicaid Coverage

Medicaid is a combined state-federal health coverage program for low-income individuals enacted in 1965 as Title XIX of the Social Security Act. At the present time, Medicaid covers 1 in 7 Americans, more than any other public or private insurer in the United States, including Medicare [3].

Maternity costs, particularly for inpatient medical care, comprise a significant percentage of Medicaid charges. Medicaid pays for routine prenatal visits, prenatal vitamins, ultrasound and amniocentesis screening, delivery services, and two months of post-partum care. Most state Medicaid programs outline in great detail which obstetrical and ancillary services are covered, which conditions might be compensated at a higher rate, and the proper coding for services and procedures.

Unlike Medicare, which is one large system, Medicaid is actually 50 different state systems and thus more vulnerable to fraud. According to the Government Accountability Office, up to \$20 billion worth of fraud against Medicaid programs occurs annually [4]. Medicaid fraud can take many forms, including but not limited to billing for services not rendered or products not delivered, performing and billing for unnecessary medical services, double billing, or upcoding.

Submission of a fraudulent bill for Medicaid services is a violation of the False Claims Act. Individual states and the federal government have Medicaid Fraud Control Units to investigate and prosecute illegal acts related to Medicaid funds.

Medicaid fraud has potentially serious consequences for both physicians and hospitals. Depending on the severity of the infraction and the amount of money defrauded from state and federal funds, penalties may range from civil fines to exclusion from participation in Medicare and Medicaid. Penalties also include possible imprisonment [5]. For hospitals or hospital systems, a criminal conviction for Medicaid fraud can lead to collapse due to loss of revenue, funding for medical education loans, and operating licenses [6]. In lieu of costly corporate criminal trials, prosecutors have begun using Deferred Prosecution Agreements [7], which may impose far-reaching penalties and obligations on health care organizations in exchange for avoiding loss of Medicaid eligibility.

Dr. Simpson's Choices

Dr. Simpson's financial responsibilities are undefined in the present clinical scenario. We do not know about his contractual relationship with the hospital. He should disclose to all patients any financial interests he has in the radiology unit where Mrs. Clark is being seen and in any radiology center to which she might be referred. Dr. Simpson must be familiar with anti-kickback regulations and hospital and medical staff bylaws that might subject him to disciplinary action. These concerns aside, Dr. Simpson must do what is medically appropriate and necessary to properly evaluate his patient and face the financial consequences of his decision later. To send Mrs. Clark to the public hospital, thus delaying necessary, time-sensitive services (in this case the work-up of a suspicious pelvic mass) simply to minimize financial loss for himself or the hospital is malpractice and unethical.

Dr. Simpson must find a legal, ethically acceptable way to get Mrs. Clark the more advanced radiological services she needs at his private hospital rather than risk complicating any treatment because of the certain delay at the public hospital. In the case scenario as written, Dr. Simpson has two acceptable options. First, because he cannot know definitely that Mrs. Clark's symptoms are *not* due to the unsuspected retro-uterine mass, he can legitimately refer her as a symptomatic patient; he need not misrepresent her condition in order to obtain Medicaid payment. Second, Dr. Simpson might be able to refer her to the private hospital without financial penalty because she has an unrelated, new medical condition that was found incidentally at the time of planned amniocentesis and requires further evaluation. In some states this is sufficient indication for more advanced radiological evaluation, different coding, and higher payment, depending on the options available for Medicaid obstetrical patients. Both options avoid either upcoding a lesser service or performing a more expensive service that is not indicated and therefore not reimbursable.

In light of the possible serious consequences of delaying Mrs. Clark's work-up, Dr. Simpson should accurately report his secondary finding and the patient's symptoms on the Medicaid bill and schedule the Doppler ultrasound at the private hospital.

Doing anything less than securing the timely and appropriate care for his patient would be an ethical, and possibly legal, failing on Dr. Simpson's part.

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CLINICAL CASE

Medical Culture and Error Disclosure

Commentary by Amy G. Lehman, MD, MBA

Dr. Jackson and his resident, Kim, were performing surgery on Mr. Frank, a patient with recurrence of a metastatic germ cell tumor. The standard of care for this surgery includes retroperitoneal lymph node dissection. Before the surgery, Dr. Jackson told Mr. Frank about the procedure and its risks, benefits, and alternatives. Mr. Frank was made aware that the surgery carried significant risk of bleeding and the need for blood transfusions; his informed consent to the surgery was documented and placed in the medical record.

During the lymph node dissection, several small blood vessels were inadvertently severed, and Mr. Frank lost enough blood to require a transfusion of one unit of red blood cells. Although Mr. Frank's blood pressure was borderline low for several minutes during surgery, the procedure was completed without other complications, the remaining tumor and lymph nodes were removed, and Mr. Frank emerged from anesthesia in good condition.

Before Kim left the operating room, she told Dr. Jackson she would speak with the patient's family and let them know that the surgery went well and that Mr. Frank had received a blood transfusion because several vessels had been cut.

Dr. Jackson responded, "There's no need to inform them of the nicked vessels. Patients know that bleeding and blood transfusions are a risk of the surgery, and Mr. Frank was no exception. He signed the consent saying he was aware of these risks. If we told patients every time something unplanned happened in medicine, we would spend all our time defending lawsuits. Patients simply aren't capable of understanding the idiosyncrasies of medicine. I've talked to my malpractice insurance company and a malpractice attorney about these types of situations. They both advised me that when something happens like this that's not a black-and-white error there's no need to tell the whole story unless there's some lasting effect, or I think it's in the best interest of patient care. All that we need to do is tell Mr. Frank and his family that he lost a lot of blood and needed a transfusion."

Kim spoke with the family immediately after the procedure and informed them that the surgery went well, with only a minor complication that involved some blood loss and the need for a transfusion. Several hours later, Dr. Jackson gave Mr. Frank the same explanation.

Having recently attended a training session with the hospital risk management department, Kim knew that the hospital had a policy of full disclosure when there were clear medical errors. She had even heard that lawsuits might occur less frequently if physicians disclosed their errors and apologized. But she was not sure that this situation qualified as a clear error, whether she was obligated to contact risk management, what the consequences might be for her and Dr. Jackson if she didn't report this, or whether she might face a lawsuit if the patient found out about the nicked vessels.

When Kim saw Mr. Frank the next day, she reiterated what Dr. Jackson had said about the surgery. Mr. Frank asked her if he would recover from the blood loss okay, and Kim stated that he might feel a little more tired than usual for a few days and that the blood loss might delay his recovery by a day or two, but that the blood loss would not affect his ability to make a full recovery.

Commentary

Kim, the surgery resident in this vignette, is put in a difficult moral and professional position, one that many medical students and residents have experienced [1]. On one hand, physicians and physicians-in-training are expected to tell the truth. On the other hand, the institution of medicine has created an entirely separate and mostly unspoken culture built around secrecy and nondisclosure [2, 3]. Often, students and residents choose to ignore their ethical concerns in order to fit in with this culture, believing their grades and professional success depend upon it.

Many of the strategies employed by malpractice litigators and risk managers reinforce secrecy, creating containment-like mindsets in physicians and adversarial relationships between patients and patients' families and physicians. Physicians' and hospitals' fear of lawsuits is widespread, and much has been written about "defensive medicine" [4-7], i.e., physicians' attempts to ward off lawsuits by ordering excessive diagnostic testing and performing invasive procedures. This approach can subject patients to unnecessary risk and inflate costs. Attending physicians are likely to experience more direct pressure from medical malpractice and institutional risk-management systems than are residents, and clinical experience among attending physicians changes their perception of risk [8]. Thus, an institution-wide disconnect is created between the physicians' concerns and goals at different points along the training spectrum. Generational differences in opinions about how to handle conflict resolution may also pose a barrier to a more transparent risk management system. All of these systemic factors become more complex when medical errors occur.

Deciding to Disclose

Mr. Frank's case creates a particular conflict for Kim. The medical culture tells her that it is her duty to obey Dr. Jackson's decision not to discuss the reasons behind Mr. Frank's need for a blood transfusion. This same culture teaches physicians that they should not question the actions of their colleagues [9]. Her own moral sense and the enlightened policies of her hospital's risk management department guide her

towards telling Mr. Frank that Dr. Jackson's nicking of the blood vessel led to his needing a blood transfusion. Kim's initial response, validated by risk management, reflects a change that is slowly transforming how doctors and hospitals deal with disclosure of errors. This case also depicts the difficult position residents find themselves in when their more recent education conflicts with long-standing policies and attitudes among more senior physicians.

Another change is taking place. Patients, on the whole, used to be obedient and passive participants in their medical care; if doctors prescribed a treatment plan, they would follow it. Patients rarely complained to their practitioners about the "service" they were getting and rarely questioned medical decisions. Patients today are far more likely to express dissatisfaction with their physician, challenge clinical recommendations, and share their experiences with others [10, 11]. This new patient behavior makes nondisclosure by physicians a risky strategy: if patients or families are suspicious or undergo unexpected treatments, they are more likely to press for information. Cagery or incomplete responses from physicians only inflame suspicion and distrust.

Kim, a product of more recent medical education, has a heightened appreciation of these new patient-doctor dynamics. She wants to preserve the trusting relationship she and Dr. Jackson have with Mr. Frank by discussing the outcome of the operation fully, including the nicking of several blood vessels. She also wants to apologize because an error in technique has occurred. A number of recent studies have lent support to the effectiveness of this strategy, and several institutions have adopted programs that require disclosure of error [12-15].

Current evidence suggests that disclosure does not necessarily result in a higher rate of malpractice suits [13, 14, 16, 17]. While "the jury is still out" [18], this conclusion continues to be analyzed from several perspectives [19-21]. Nevertheless, what seems clear is that disclosure creates a better relationship between doctors and their patients, whatever the legal consequences [22]. Moreover, patient safety advocates believe that telling patients about medical errors is an integral part of root-cause analysis, which can help identify system-level problems and individual responsibility in the commission of the error [16, 23].

In certain cases, it is difficult to determine whether an error has actually occurred. When physicians and surgeons treat severe or complex diseases, the complication rate is often higher. Experts in their respective fields must determine what the acceptable rates and types of complications are for various operations and procedures. If, in this case, the cutting of small vessels is a known and likely complication of retroperitoneal lymph node dissection, then Dr. Jackson's error was not the cutting of the vessels but neglecting to tell Mr. Frank during the consent process that cutting of small vessels was a known and likely complication of his surgery. Bleeding and infection are a risk of any operation; surgeons have the professional and ethical responsibility to disclose those specific, known risks. In

cases of complex illness, clear communication and trust between health care professionals and patients is even more crucial.

How will these new policies and attitudes be communicated to the medical profession at large, and how can we determine if physicians are actually fully disclosing errors to their patients [24]? Ultimately, regulatory bodies like JCAHO (the Joint Commission on the Accreditation of Healthcare Organizations) or governmental oversight via the Medicare program may have to enforce the change in practice. The Center for Medicare and Medicaid Services has already initiated a nonpayment policy for avoidable hospital complications [25], but this may not be enough to change the culture of medicine. The best way to transform the medical profession into one that embraces disclosure and open communication is for the change to come from within. Many medical school curricula are beginning to address this topic by spending more time on ethics, patient safety, and medical error disclosure. If medical students and residents are educated to identify normative errors and are empowered to ask questions about specific errors that require advanced knowledge, than perhaps the frequency of situations such as the one Kim is faced with in this scenario will decrease.

Conclusion

Trust between a physician and his or her patient is at the very core of the patient-doctor relationship. Hiding from, obscuring, or omitting facts and details in conversations with patients, particularly in the face of a medical error, erodes that trust. Full disclosure, whether it increases malpractice liability or not, is the appropriate ethical path. While hospitals wait for more conclusive data on the effect that truth-telling and apologizing have on medical malpractice claims, patients and their families who have been harmed by medical errors continue to suffer with no explanation about how they ended up in their current predicaments. The trust between patient and doctor, however, demands disclosure even in cases where obvious or lasting harm has not occurred. Patients should not feel that their doctors are their adversaries. If they do, medical practice as we know it will be in serious jeopardy, and the only winners will be malpractice litigators.

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CLINICAL CASE

Do Secret Shoppers Have a Place in Medicine?

Commentary by James C. Loden, MD, and Richard C. Frederick, MD

The staff at Urban Clinic had gathered for a morning meeting. Jim, the executive director, waited until everyone had coffee and had found a place to sit. Then he began, “Today I want to brief you on a new quality program. We’re going to try a mystery shopper technique starting as soon as we can. You’ve probably heard about how this works in retail stores. I think it could help us improve patient satisfaction and office efficiency.

“What happens is, some trained market researchers will call the office to see how the phone system works and how the staff handles the calls. They’ll make appointments and they’ll arrive early and observe the staff and the environment. A few of them—pretty good actors I might add—will actually go through with a physician encounter.

“When we get the results from all this, we’ll know a lot more about how to improve the quality of our patient experience. Any questions or comments?”

George, one of the internists, said, “It sounds okay Jim, but we’re not exactly running a Wal-Mart here, are we?”

“Well, we aren’t the first to try this. Massachusetts General has been running a similar quality improvement program for 8 years,” said Jim.

“I’m still skeptical; we haven’t got the money that some large institutions have, and it doesn’t seem totally fair to be so devious,” George mused.

Other staffers worried about the additional time it would take and who would be blamed or even fired if the results were bad.

Jim closed the meeting by saying he’d take all the comments into account before they rolled out the final version of the program. “Thanks for your input. Remember, we’re in a competitive marketplace. And we owe it to our patients to do our best on all fronts.”

Commentary 1

by James C. Loden, MD

For the last 2 years I have employed “secret shoppers” to evaluate Loden Vision Centers, a Nashville-based practice that employs three ophthalmologists and two

optometrists. Sixty percent of the practice revenue comes from insurance and Medicare, and 40 percent, from elective refractive surgery. There are approximately 53 other physicians in the area with whom we compete for clients.

Given this competitive practice environment, we are constantly looking for ways to improve our client-to-client referrals. Many ophthalmology journals discuss marketing and practice growth strategies. One article that particularly caught my attention was about a company that conducted ghost-shopping in medical settings. As founder and managing partner for Loden Vision Centers, I had had suspicions that the staff was not always as mindful about service and other patient satisfaction markers when a supervisor was not present. I questioned whether we—and I include myself in this—were really delivering the high-quality care that I perceived we were. These nagging concerns led me to try a ghost-shopping program. After we were assessed, several deficiencies (and several successes) were identified. In one instance, I thought we were weak in a particular area, but this was not borne out in the evaluation.

Results of Our Experience

There were a couple of areas we learned we could improve on, and at least one where no change was needed.

1. *Directions.* More than 50 percent of our secret shoppers reported difficulty or great difficulty finding our offices. Although it is easy for me to get there—I drive to work everyday—we found that many people struggled just to locate the building. In response, we made our maps easier to read, improved Internet directions to the facilities, and posted pictures of the offices on our web site.
2. *Employees don't always perform as trained.* Some of my suspicions were validated. The secret shoppers found that employees did not always wear name tags, introduce themselves, explain how or why tests were being performed, or tell clients in the exam room who would be coming in next and the approximate time of the doctor's or technician's return before leaving the room. I learned that I consistently left the exam room without asking clients whether they had any questions.
3. *A few positives.* We learned, for example, that we didn't need to upgrade our reception area. We had contemplated a major renovation of this space and it was estimated to cost at least \$50,000. Before proceeding with these plans, we asked our secret shoppers for their recommendations. We found that our facility more than met expectations for our type of practice, and no facility upgrades were recommended.

Making the Decision to Use Ghost Shoppers

In our case scenario, we see a confrontation between Jim and George. Jim wishes to improve patient care and the patient experience, but George is skeptical of using secret shoppers to achieve this goal.

I believe that the decision to employ a secret shopper should not be a group decision but one made by the practice manager and senior managing partner who alone should know that secret shopping is going to occur. I would also suggest that the office manager not be told the times and dates of the visit so that a true evaluation of day-to-day operations can be made. It is our experience that when staff are told they are going to be assessed within a certain time frame, they maintain a high level of care for that period and then gradually return to their old habits.

When the results of the secret shopping visits are available, the initial evaluations should be discussed in a staff meeting and presented in a positive light. During this meeting, the areas where improvement is needed should be talked about and corrective steps decided upon. A second round of secret shopping should be performed to see whether the staff has implemented the changes that came about after the initial assessment. Punitive action should not be considered unless there is repeated failure to act in accordance with established performance guidelines.

I do not believe that words such as “devious” and “spying” are accurate in describing secret shopping. *Employees, including doctors, are paid to do specific tasks; if they choose to perform at a level that is less than acceptable, they need to improve or find other jobs.* It is the responsibility of management to assure a quality client experience—and this experience is affected by all employees, from the one with the lowest salary rank to the most senior partner. In fact, I think it is more devious to allow an underperforming facility to make health care decisions for a client than to use secret shoppers as a quality improvement tool. I side with Jim, who says we owe it to our clients to do our best.

Assessing the Case

The complaints lodged by George are typical of comments made by uninformed, noncompetitive physicians and employees. The fees charged by secret shopping companies are nominal compared to the gross income lost due to poor client experiences. During the entire shopping process, a practice may lose three to five billable patient encounters per physician. This is a miniscule amount of time and it can help you to serve your clients significantly better in the long term. To use time and money as an excuse not to engage in secret shopping is short-sighted behavior.

George’s comment that “we’re not running a Wal-Mart here, are we?” shows the lack of business acumen that I see in so many of my fellow physicians. No, we aren’t and shouldn’t be a discount store, but we *are* a business. If we can’t make money, we can’t keep the doors open. In these days of declining reimbursement fees, if we want to run a successful medical practice, we must provide better, more efficient care than the physicians we are “competing” against. We must look to the retail industry at

times for ideas on how to judge whether doctors and staff alike are delivering the care that clients, partners, and other staff members deserve.

The number of elective surgery procedures I perform has increased by 100 percent since instituting secret shopping because our client-to-client referrals have increased. I credit much of this to the experience of secret shoppers, which helped our office improve client experiences before, during, and after their operative procedures.

For practices and facilities that are not in competition for potential clients, secret shopping still makes ethical and financial sense. Overhead costs are quickly driven up by employees who perform their job inefficiently. In fact, there are times when employees may take histories and perform tests and labs in a way that could adversely affect diagnosis and outcomes. From a physician standpoint, even if you have a line of clients or patients at the door, do you really want a physician partner who is either short and curt with them or inefficiently verbose?

No matter the size or the makeup of your practice, I think you will find the experience of using secret shoppers rewarding and insightful rather than unethical and devious, as many who are uninformed about the practice predict.

James C. Loden, MD, is the founder and president of Loden Vision Centers in Nashville. He is a board-certified member of the American Academy of Ophthalmology and is a member of the Society of Excellence in Eyecare (SEE).

Author Disclaimer

Dr. Loden has granted permission to the secret shopper company he employed to post a statement of his satisfaction with, and intent to continue using, their services on their web site. He received and will receive no payment or discounted services for this testimonial.

Commentary 2

by Richard C. Frederick, MD

The use of a secret shopper to assess the delivery of patient care raises many ethical dilemmas, including the effect that this practice has on the patient-physician relationship, the stewardship of scarce health care resources, impact on the care given to patients, and exposures (e.g., to radiation, blood products, etc.) for physicians, staff, and the sham patient. This practice highlights the crisis of medical professionalism—failure to view the physician as a professional. Finally there is the huge question about the consequences of using deceit in a field where truthfulness is a core virtue. Introducing this competitive market tactic reduces the practice of medicine to a business model and will imperil both the members of the profession and its patients.

Trust

The traditional patient-physician relationship requires that both parties be open and honest. Edmund Pellegrino has defined the patient-physician relationship as a healing relationship that places a much higher fiduciary responsibility on the parties involved than a simple agreement or business contract [1]. The labels that we give to the parties involved reflect this; we are patients and physicians, not customers and providers. The difference is more than semantic [2]. The business adage “let the buyer beware” is reprehensible if applied to medical care. Trust and honesty on the part of both patient and physician are implicit in that covenantal relationship.

In our case scenario, appointments and time will be taken away from real people with real needs and illnesses so that sham patients can be seen. In some instances sham patients have presented to overcrowded emergency rooms with chest pain [3]. This type of complaint mobilizes a rapid and coordinated response from the entire health care team, leading to others’ being triaged to lesser importance. How could the hospital administration defend this exercise to someone who suffers an adverse outcome while waiting his turn behind the person who is only pretending to be sick? Moreover, how would we justify using a hospital bed with all its attendant resources for a fake illness [4]? Again, what if that bed or the primary care nurse or respiratory tech were needed for a real patient waiting for care? The medical-legal implications are not inconsequential. Radiologic and laboratory testing are an integral part of our diagnostic tools. Consider the scenario where a nurse or lab tech gets a needle stick while treating this “planted” patient and develops hepatitis or HIV.

Institutional Review Boards (IRBs) are in place to protect our patients when human subjects research is proposed. The use of any form of deceit in medical research has been looked at with some suspicion by IRBs because of the history of ethical abuses in research [5]. I believe that the same level of concern should apply to this sort of patient encounter tool.

Medical Professionalism

Medical professionalism is in crisis [6], and the situation will only get worse if we use deceit in daily practice. Ethics in business is desirable. Ethics in medicine is essential. Patient advocacy is not an option for physicians; it is a necessity. Society recognizes this and has allowed the profession to be largely self-regulating. It is interesting—and sad—that in our case, this same level of autonomy is not granted intraprofessionally.

The executive director in our scenario informs the staff physicians that the “secret shopper” program is going to happen with or without their assent. These types of top-down declarations reduce physicians to tradespeople, and not professionals, and the distinction between the two is significant [7].

Concerns about the use of secret shoppers have led the Illinois State Medical Society to ask the American Medical Association to further explore these practices [8]. Assessing our effectiveness in real patient encounters is important, and it is being

done in a variety of ways that have proved effective and that do not endanger patient welfare. Peer QA, feedback from colleagues, and post-encounter surveys such as the Press Ganey questionnaires are helpful evaluation tools. In Peer QA, patient charts are routinely reviewed by other physicians, both internal and external, to assess the quality of care given. The Press Ganey survey allows institutions to assess the same concerns that secret shoppers assess, but relies on real patients. Use of these measures has resulted in behavior changes and has positively affected market share in this competitive environment [9].

One wonders how effective the secret shopper can be in assessing physicians' most important roles. If these people are not sick, frightened, tired, and vulnerable like real patients, how helpful is their appraisal to the physician whose patients *are* frightened and vulnerable? Although it is becoming a lost art, our response to real suffering continues to be an essential part of our care [10].

Finally, we teach our residents and medical students that when we are not truthful with our patients, we violate their trust. We also put into question the next physician's truthfulness. We have all heard a patient say, "Those doctors at that institution lied to me, so I trust none of them." In reality maybe only one physician lied, but all are tarred with the same brush. Trust is fragile, and, once violated, it is hard to restore. But trust goes both ways. Are we physicians not human too? Once we are fooled by these "good actors," will there be an element of doubt about the legitimacy of the next patient with a similar complaint? I work in an emergency room and have been lied to frequently, but not by my administration or the executive director of my group. Cynicism, already a problem in medicine, will only be made worse by the use of official deceit. As physicians in a profession where high ethical standards are essential, deceit, however well meaning, is not a tool we should use.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

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MEDICAL EDUCATION

The Ambulatory Long Block: A Systems-Based Practice Innovation

Eric J. Warm, MD

Everyone in healthcare really has two jobs when they come to work every day: to do their work and to improve it [1].

—*Paul Batalden and Frank Davidoff*

The Accreditation Council for Graduate Medical Education (ACGME) has defined competency in systems-based practice as “an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care” [2]. Applying this definition, residents are expected to:

1. Work effectively in various delivery settings and systems relevant to their clinical specialty;
2. Coordinate patient care within the system relevant to their clinical specialty;
3. Incorporate cost awareness and risk-benefit analysis in patient care or population-based care, as appropriate;
4. Advocate for quality patient care and optimal patient-care systems;
5. Work in interprofessional teams to enhance patient safety and improve quality of care; and
6. Participate in identifying systems errors and in implementing potential systems solutions [2].

Many residency programs are located in complex, poorly coordinated medical centers that lack the tools, incentives, or freedom from regulatory pressure to address systems-based practice competency fully [3-5]. Over the past 3 years the University of Cincinnati Department of Internal Medicine has improved systems-based practice training in the ambulatory setting through our involvement with the Academic Chronic Care Collaborative (ACCC) [6] and ACGME’s Educational Innovations Project [7].

Our residency program consists of 108 residents (69 of whom are categorical, i.e., with the University of Cincinnati Department of Internal Medicine for the duration of their residency), based in a large academic health center. The categorical resident ambulatory setting is an urban safety-net practice with approximately 19,000 patient visits per year located next to the main teaching hospital. After our participation in the ACCC, we adopted the chronic care model—a primary care-based framework that identifies four essential interdependent components (self-management support, delivery-system design, decision support, and information technology) within the

broader context of the community and health care system [8-11]. We transformed our practice to incorporate these essential components by (1) instituting a disease registry to track process and outcome measures (information technology); (2) creating weekly interprofessional team meetings that include residents, faculty, nurses, social workers, pharmacists, administrators, office staff, and patients (delivery-system design); (3) imbedding evidence-based guidelines, such as insulin titration flowsheets, directly into daily workflow (decision support); (4) training our residents and staff to help patients make behavior changes (self-management support techniques); and (5) learning how to engage our leaders and the community to aggressively pursue scarce resources for patients who cannot do so themselves.

Initial results were promising but quickly reached a plateau. Although willing to participate in the improvement process, residents were effectively excluded from doing so due to the traditional demands of a heavy inpatient load. We believed it would benefit both their education and patient care to include them in a more meaningful way, so we redesigned our residency program as part of the ACGME's Educational Innovations Project (EIP) [7], a program that provides flexibility with traditional accreditation requirements to encourage the development of innovative training models.

The centerpiece of our EIP is a year-long ambulatory practice experience combined with elective and clinical research time called the "long-block." From November of their second year to October of their third year, residents move from working primarily on inpatient and ICU services to an expanded outpatient experience. During this long-block, residents see patients in the general medicine practice for three 4-hour clinic sessions per week, but they are expected to make an appearance (e.g., to answer messages, etc.) every day. One half-day per week is reserved for ambulatory education topics, a quality improvement curriculum, and the interprofessional team meetings. During quality improvement sessions, residents are instructed on how to enhance organizational performance by using improvement models [12] and learn how to run plan-do-study-act cycles. They also learn how to create a problem statement, construct a fishbone diagram of contributing causes, and prioritize problems and solutions.

At the team meetings, residents and staff track aggregate clinical process and outcome measures in reports generated from the disease registry database. Each resident receives a quarterly personal score and rank on each outcome measure, comparing his or her performance to that of peers and the group as a whole. The long-block format allows us to assign responsibility and accountability for a given population of patients to each resident. In this way residents begin to look beyond the simple dyad of the patient-doctor relationship to the broader realm of their patient population and the society surrounding them. Residents use clinical data to prioritize personal and group-wide improvement projects. Overall resident evaluations include personal quality data as well as participation levels in longitudinal improvement projects.

An example of such a project began when residents found that only 19.5 percent of eligible women over 65 had received a bone densitometry (DEXA) scan. It was also discovered that a prominent endocrinologist had recently set up a private DEXA scanner and had diverted much of the hospital's bone scan business. Residents and staff struck a deal with the hospital that allowed eligible women seen in the practice to go for same-day DEXA appointments in the hospital's radiology department. The DEXA scan rates increased quickly and significantly. The same technique was then used to arrange same-day mammograms.

In another example, residents reviewed the registry data on influenza vaccines and determined that, despite an equal offer rate, black patients accepted vaccinations at a lower rate than white patients. They also found that black nurses offered the vaccine less frequently than white nurses. Residents then designed projects (currently ongoing) to understand the reasons for patients' refusal of flu shots and nurses' neglect in offering them in hopes of designing interventions to close these gaps. Our influenza vaccination rate reached all-time highs this year with the coordinated efforts of our residents, staff, and hospital administration. We printed flu season educational materials in the fall, created and advertised special flu shot clinics for our patients, electronically called all of our patients in October and reminded them to get vaccinated, and in late January used the registry to identify patients who had not yet received vaccinations and called them personally to offer one. As of March 8, 82.9 percent of all patients with diabetes, and 74 percent of all patients over the age of 50 in our practice had received or been offered influenza vaccinations.

A third example of a longitudinal improvement project was instigated at one of our team meetings. Review of the disease registry showed that only 29 percent of our patients with diabetes had received a dilated eye exam in the past year. Residents had already reviewed this problem and, using a fishbone diagram, had developed an extensive list of reasons for the low rate. At first the problem seemed insurmountable because it appeared there were not enough ophthalmologic resources to serve our predominantly low-income patients. After learning of this at the team meeting, one of the nurses thought she could solve the problem. She called the benefits managers of Ohio Medicaid HMOs and created a list of eye care resources for our patients. We are now working on a specialized referral sheet that includes addresses and bus lines that our patients can use to arrange dilated eye exams.

At the beginning of the year each resident was assigned to follow one of our measures of process or outcome (e.g., eye and foot exams for those with diabetes, tetanus shots every 10 years) and then asked to perform an evidence-based literature search on that measure. Residents presented their findings to the group and argued to keep the measure the same, change it, or drop it all together. A group discussion followed, and consensus was reached regarding each measure.

These examples demonstrate the tremendous coordination and effort it takes for members of the health care team with different skills and expertise to change a system as complex as ours. We have seen significant improvement in many process

and outcome measures of care and in patient, resident, and staff satisfaction [13]. We believe our residents are succeeding with their systems-based practice competency because, rather than simply adding quality improvement to already busy schedules, we put the new curriculum “in the water.” Every day while they are on the long-block, residents assess and improve quality of care within a cohesive team.

Our specific model may not be generalizable to every residency program, but we believe important aspects of it may be. Good care requires interprofessional teams driven by clinical data. Residents must be an integral part of these teams to achieve optimal success, and they should be given protected time in which to learn systems-based practice skills. Finally, improvement efforts are best when they are continuous rather than intermittent or one-offs, and they should directly impact the patients for whom the residents care.

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JOURNAL DISCUSSION

Keeping Patients Safe: The Ethics of Quality Improvement

Sara Platte, MD

Lynn J, Baily MA, Bottrell M, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med.* 2007;146(9):666-673.

The quality improvement (QI) movement is not unique to health care. An essential part of business, manufacturing, and engineering, the theories and practice of QI have become incorporated into American medicine out of necessity. Like any complex, multifaceted procedure, health care delivery is not without error or need for improvement. In its 2001 report *Crossing the Quality Chasm*, the Institute of Medicine (IOM) identified six characteristics of quality health care: it is safe, effective, patient-centered, timely, equitable, and efficient [1]. Most QI activities aim to achieve these characteristics by changing either clinical practice itself or the systems of care delivery within which clinical practice occurs. QI has become so critical to medical practice that it is one of the core competencies required of residency training programs by the ACGME (Accreditation Council for Graduate Medical Education) [2]. Further, the American Board of Internal Medicine and other certification organizations require physicians to self-evaluate their practice performance [3].

What could be ethically controversial about quality improvement? Implicit in what I have said so far is that improvement in how medicine is practiced and delivered must be *measured*. And it is the methods by which quality improvements are measured that cause the controversy. Many believe that the distinction between human subject research and QI has not been adequately delineated, and this lack of clarity can lead to ethically complex situations.

In 2003 the Hastings Center convened a panel of experts to set up guidelines for the ethical conduct of QI. Their recommendations were published in the *Annals of Internal Medicine* in 2007 [4]. In this consensus statement, three main questions were addressed [5]:

1. What is QI and what is its role in health care?
2. What ethical standards should QI activities meet?
3. What arrangements must be made to ensure that QI research is conducted ethically?

Clearly defining the purpose and role of QI in health care is the starting point for determining the ethical standards for research. The group defined QI as “systematic,

data-guided activities designed to bring about immediate improvements in health care delivery in particular settings” [6]. They also referred to it as “a form of experiential learning” that “always involves deliberate actions expected to improve care, guided by data reflecting the effects” [6]. This definition makes clear that QI is not a search for new knowledge about a subject but an attempt to apply proven standards to existing procedures. And, as highlighted by the authors, QI has long been a part of health care—although not always formally—and has successfully improved many areas of care [6].

One of the major concerns some have about QI methodology is that, because it observes and documents the effects of newly implemented changes on patients, it should be held to the ethical requirements that the Office for Human Research Protection has set forth for human subjects research; that is, that Institutional Review Boards (IRBs) approve the research methodology. The members of the Hastings Center working group, however, stated that QI should not be held to the same review process as human subjects research because of its inherent alignment with patients’ interests and low potential for patient harm. They write, “QI generally aligns with patients’ interests, presents lower risks than continuing with usual care..., demands the participation of all to be effective, arises from a responsibility of professionals and patients alike and has no history of ethics scandals” [7]. Instead, they suggest that the ethical oversight of QI should become “part of an enhanced accountability system for professional responsibility and the supervision and management of care” [7].

While the group recommended that this system of professional responsibility remain separate from traditional IRB regulation, health care organizations must have systems in place to monitor the ethical conduct of QI and to recognize when extra precautions, such as specific informed consent from participants or formal protocol submissions to the IRB, might be warranted [8]. The Hastings Center group concluded that, because most QI activities apply existing knowledge to local situations, they do not qualify as research [9]. In situations in which an activity is designed to *both* improve local care and produce broadly generalizable knowledge, however, the more rigorous standards of research ethics should rightfully be applied [9].

Ultimately, the authors advocate further discussion and review by regulatory agencies of the ethical requirements arising from QI activities to ensure that these activities are both ethical and feasible [10]. The group specifically recommended that:

1. Professional organizations and educational leaders emphasize the responsibility of health professionals to engage in QI;
2. Health care organizations clarify the role of QI activities to patients and explain their participation;
3. Leading QI groups develop guidance on methodology and dissemination of results;

4. Health care organizations develop internal management and supervision of QI and overlap projects; and
5. Accrediting bodies expand external accountability for QI and help ensure that it meets ethical standards [10].

This consensus statement continues to provide clear guidelines on the ethical requirements QI activities should meet and is timely because QI activities are becoming a standard requirement of clinical practice. The Centers for Medicare and Medicaid Services started its Physician Quality Reporting Initiative in 2007, offering payment incentives to participating physicians [11]. Although QI activities are becoming a certification requirement, there is still some uncertainty about their implementation. In January 2008, controversy was reported in both the lay and academic presses when an op-ed in the *New York Times* publicized the use of checklists to decrease rates of hospital-acquired infections in ICUs at Johns Hopkins University and the Michigan Health and Hospital Association [12]. Some characterized this form of QI as human research and therefore subject to IRB approval and federal regulation.

Investigation by the Department of Health and Human Services concluded that the Johns Hopkins and Michigan Health and Hospital Association activities had not violated any laws or government standards because “regulations [for human subjects research] do not apply when institutions are only implementing practices to improve the quality of care” [13, 14]. Some areas of the checklist activity *did* require IRB approval, and the checklist controversy remains a prominent example of the confusion that these activities have generated. It illustrates how the Hastings Center group’s article can alleviate some befuddlement.

QI is an essential part of clinical practice and, as such, must be held to the ethical standards used to guide patient care. Whether it also must be held to human subjects research standards will be further debated by regulatory organizations. The Hastings Center group has presented a much-needed consensus statement on how health care organizations should approach QI activities. The group’s arguments for protecting QI activities from additional external regulation are robust and compelling. Quality improvement activities are at the heart of improving health care delivery, and physicians and organizations should be encouraged to participate in them while adhering to ethical standards. Ultimately, QI is about keeping patients healthy and safe.

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CLINICAL PEARL

Amniocentesis: Indications and Risks

Maura Parker Quinlan, MD, MPH

Amniocentesis is an invasive procedure that requires removing a sample of amniotic fluid to obtain fetal cells for chromosome analysis. Generally not performed earlier than 15 weeks gestation, the procedure is done under ultrasound guidance. Although some pain is associated with amniocentesis, it is generally well tolerated without the need for anesthesia. Five to 10 percent of pregnant women choose to have the test [1, 2]. Maternal age over 35 is the most common current indication for amniocentesis [3].

Amniocentesis was developed in the 1960s, and until 2007 it was offered almost exclusively to women with an identified risk for carrying a fetus with a genetic disorder that could be detected by traditional karyotyping. This included women over 35, those with a previously affected child, those with a family history of a genetic disorder, and those with a serum screening positive for Down syndrome or trisomy 18. Amniocentesis was also offered to women who showed fetal structural irregularities on ultrasound that could be markers for chromosomal abnormalities.

Counseling a patient about the risks and limitations of the test is essential, both before and after the procedure. Some women—those who, for example, would not choose to terminate their pregnancy under any circumstances—may feel that an invasive test is unnecessary, particularly if they see no advantage to knowing about a genetic disease before the baby's birth. Other women may want to proceed with an amniocentesis to prepare for the care of an affected child, even if they would not choose to terminate the pregnancy.

The indications for offering amniocentesis were revised by the American College of Obstetricians and Gynecologists (ACOG) in a 2007 practice bulletin that included a new recommendation for Down syndrome screening [4]. The new standard of care no longer uses maternal age as the basis for deciding whether to offer genetic screening or other invasive tests like amniocentesis. Rather, ACOG's goal is to offer screening tests with high detection and low false positive rates to all women [5]. The 2007 bulletin advises physicians to counsel patients of all ages about the risks and benefits of genetic testing and to let the patient decide whether the benefits of obtaining the test results are worth the risks. In short, the goal is to make all tests for fetal chromosome abnormalities more accessible to all women. On a practical level, physicians should inform their patients that not all health insurance companies cover procedures like amniocentesis for women under 35 who have no risk factors.

Risks Associated with Amniocentesis

Amniocentesis was not offered to all women in the past because the increased risk of pregnancy loss after the invasive procedure did not seem balanced by the potential for benefit among women at low risk for having a fetus with an abnormal karyotype. As recently as 10 years ago, the risk for pregnancy loss after amniocentesis was thought to be approximately the same as the baseline probability that a 35-year-old woman would have a child with Down syndrome—about 0.5 percent or 1 in 200 [6]. The risk of injury to the mother or fetus during amniocentesis is extremely low. The primary concern that should be conveyed to patients is the risk of miscarriage after the procedure, but that risk is difficult to calculate because studies with adequate controls are lacking and because risk of miscarriage is already higher for most of the women who choose to undergo amniocentesis.

A 2007 systematic review of data compiled from 29 studies of amniocentesis found that the risk of miscarriage within 14 days of the procedure was 0.6 percent, pregnancy loss before 24 weeks (the age when a fetus is considered to be viable) was 0.9 percent, and the total pregnancy loss at any point following amniocentesis was 1.9 percent [7]. Even with these general percentages, the authors of the review article caution that the “lack of adequate controls tends to underestimate the true added risk of prenatal invasive procedures” [8]. A Cochrane review of 14 randomized studies that compared the safety of amniocentesis and chorionic villus sampling (another form of prenatal diagnosis) found that amniocentesis increased the already-known 2 percent risk of pregnancy loss by 1 percent [9]. The controversy continues with a 2008 report from a single institution documenting more than 50,000 cases (with controls) over 16 years and indicating an amniocentesis-related pregnancy loss of 0.13 percent [10].

Benefits of Amniocentesis

The benefits of amniocentesis are numerous. The results may reassure an anxious couple that the fetus has normal chromosomes. Conversely, it may confirm a suspicion raised by ultrasound or serum screening and help the couple decide whether to terminate the pregnancy or continue and prepare for the unique needs of the child. Genetic testing performed on the cells extracted during amniocentesis does not eliminate the possibility of significant or lethal structural anomalies, but the latter are easily found on a detailed anatomy ultrasound.

Amniocentesis has an essential place in prenatal genetic diagnosis, although it is not without risk. Obstetricians should offer screening to all patients and have a frank discussion about how the knowledge will help the couple and about the small, but real, risks involved in acquiring that knowledge.

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HEALTH LAW

ERISA: A Close Look at Misguided Legislation

Lee Black, JD, LLM

The Employee Retirement Income and Security Act (ERISA) was enacted in 1974 primarily to address concerns about the solvency of pension funds and whether employees would get the retirement benefits their employers had promised [1]. There was an additional worry that those responsible for investing the funds did not always act in the best interests of employees and that state laws did not provide uniform remedies.

Although pension funds were ERISA's primary target, the legislation was broad and incorporated "employee *welfare* benefit plans" into its regulations, thereby including "medical surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment..." [2]. The reason for incorporating health benefits into the law was to ensure that these funds were also safeguarded and that employees had access to information about them.

The protection of employer-sponsored health benefits to ensure adequate coverage of medical expenses is a worthy aim. When ERISA was enacted, employers were routinely offering health benefits to entice employees. Regulation of insurers, however, differed from state to state, so one objective of the legislation was to place employer-sponsored benefit plans under a single regulatory scheme—and ERISA did that. The effect of the law, though, was to exclude these health benefit plans from much of the state law enforcement that would otherwise apply to them, and this exclusion turned out to have unintended consequences that I will explain shortly.

Preemption, Savings, and Deemer Clauses

ERISA is a complex law that uses somewhat ambiguous language to set up what is, essentially, a skeletal regulatory system for employer-sponsored health plans. There are three provisions that are most important in determining whether state law or the federal scheme regulates an insurer. The first states that "the provisions of [ERISA] shall supersede any and all State laws [that] relate to any employee benefit plan" [3]. The savings clause is next, and provides that "nothing in [ERISA] shall be construed to exempt or relieve any person from any law of any State which regulates insurance..." [4]. Finally, the "deemer" clause prevents an employee benefit plan covered by ERISA from being deemed an insurance company for the purposes of submitting that plan to governance by state laws that regulate insurance companies or contracts (note that laws that regulate insurance *companies* are different from laws that regulate insurance) [5].

What does all this mean? Most state contract and tort laws are superseded by ERISA. State laws that specifically regulate insurance, however, generally still apply to benefit plans covered by ERISA. For patients, this means that most meaningful redress for harms caused by decisions of a benefit plan are unavailable.

Congress intended for ERISA to help employees by protecting their benefits. Yet, discussion about ERISA provisions as they pertained to health benefits was sparse. Originally narrow in scope, the language of the legislation was broadened to preempt “state law relating to ‘any employee benefit plan’” [6]. There is virtually no evidence of how Congress intended ERISA to relate to health benefits. Consequently, courts have had to provide their own interpretations about when ERISA supersedes state laws, and these interpretations have changed dramatically over the years.

ERISA and Managed Care Organizations

When ERISA was enacted, the health insurance system primarily reimbursed care that was delivered on a fee-for-service basis; that is, insurers paid physicians *retrospectively* for services that had been rendered at rates set by the physicians. In the ensuing decades, managed care organizations (MCOs) emerged as a reimbursement alternative to fee-for-service. Under managed care, physicians are paid *prospectively*, with insurers generally paying physicians a specified amount per *patient* per year, rather than by *service*. This system was designed to control costs by giving physicians an incentive to limit services to those that are truly necessary. The managed care system generated many disputes over which specific procedures the insurer would reimburse, and when these disputes went to court, ERISA was often invoked.

In early ERISA benefits decisions, courts took an expansive view of ERISA’s preemption clause, deciding that Congress must have envisioned the broadest scope for the federal law in order to prevent health plans from having to deal with conflicting state laws. The seminal case of *Pilot Life Insurance Co. v. Dedeaux* in 1987, based on Pilot Life’s decision to terminate disability benefits, provided the Supreme Court with an opportunity to examine the full extent of the ERISA preemption clause [7]. Mr. Dedeaux claimed that Pilot Life breached its contract by improperly denying coverage. Breach of contract is a state common law claim. The court decided that the common law breach of contract claim, because it applied to all contracts and not just insurance, was not a law “which regulates insurance” [8], hence Dedeaux could not seek redress under state laws. The result of the ruling was that lawsuits related to improper processing of benefits claims (benefits decisions) fell entirely within the scope of ERISA preemption and were subject only to the civil remedies ERISA provided, and not to state law remedies [9].

The real effect of *Dedeaux* when applied to MCOs is that they are liable only for the cost of the denied treatment and, possibly, for attorney fees. Even if the insurer denies coverage for a procedure or service that is explicitly covered and the insured is injured because of the denial, there can be no damages for pain and suffering, and no wrongful death claims if the insured dies while waiting for treatment.

The immunity from state law claims still stands for employer-funded health plans that wrongfully deny benefits. Some court decisions, however, have created a subtle distinction between wrongful denial of benefits and treatment decisions. If an *insurer* denies benefits on grounds that a particular treatment is not appropriate, claims filed by the insured are still primarily subject to state laws. If the decision to deny coverage is made by a *treating physician* employed by an MCO, the Supreme Court has ruled that these are “mixed benefit-treatment decisions” and are covered under ERISA [10].

The exact scope of MCO liability under ERISA is still in flux. A 2002 Supreme Court decision upheld an Illinois statute that required independent medical review of a denial by an insurer [11]. According to the court, this law regulated insurance and therefore was not preempted by ERISA. Two years later, however, the Supreme Court found that claims filed under the Texas Health Care Liability Act alleging that MCOs improperly refused to cover a specific drug in one case and additional days of hospitalization in another were entirely superseded by ERISA [12].

Clearly the law on MCO liability is not settled. One judgment held that certain decisions made by insurers could be litigated under state law [11], but lawsuits based on that decision were overridden 2 years later [12]. Overall, judicial decisions holding that MCO liability is limited to remedies provided in ERISA protects insurers substantially, but at some potential risk to physicians.

ERISA and Physicians

ERISA does not protect physicians from state law liability for malpractice or other claims related to medical care. ERISA applies only to health plans and not to the basic decision maker in the patient-physician relationship. This may be because physicians were generally independent of insurers at the time the law was passed.

Today, however, the financial structure of physician-insurer relationships greatly limits the autonomy of physicians. MCOs are much more involved in treatment decisions than were fee-for-service insurers. The Supreme Court has recognized that financial incentives may play a role in physicians’ decisions, but it has chosen not to expand the scope of ERISA health plan liability on this basis [10]. Even if the incentives tempt physicians to limit care, the Court has reasoned that, “the check on this influence...is the professional obligation to provide covered services with a reasonable degree of skill and judgment in the patient’s interest” [13].

What this means for physicians is that they may be the only truly liable party in a claim for malpractice if a health plan covered under ERISA denies coverage. As stated earlier, if a patient is injured because of a denial of a claim for benefits, the remedy from the MCO is to pay the insured what the procedure would have cost if it had been approved. In malpractice, however, damages can be both compensatory (such as economic loss) and punitive, and physicians may have to bear the costs of litigating and paying these claims.

Conclusion

The Employee Retirement Income Security Act has an innocuous title; for those in fear of loss of retirement benefits, the law has provided some reassurances that benefit managers will be held to account. But the limited language concerning health benefits has had far-reaching, broad effects on medical liability—and on the health care system—that are not as beneficial as the title of the act makes it seem.

One objective of the medical malpractice system, whether or not one believes it works, is to ensure that those who make poor decisions are accountable for their mistakes. In the past, physicians were the primary decision makers in medicine and generally faced sole responsibility for any injury to their patients. In the world of managed care, plan administrators infringe upon the traditional autonomy of physicians by reviewing and determining whether the care a physician recommends is covered by the plan and whether it is necessary. Under ERISA, though, liability risk for MCOs and physicians may not be proportional to their respective roles in determining care.

ERISA has the effect of diminishing liability expertise for health plans and, along with it, the responsible decision making that medical malpractice is intended to encourage. This in turn may affect how physicians make decisions (for example, electing more conservative treatments or only those deemed permissible by the insurer) and permit insurers to act less conscientiously and less in the interest of patient care.

It will be up to the courts to define further how ERISA impacts traditional remedies and up to Congress to provide more specific guidelines. In an industry as heavily regulated as health care, it takes more than the basic standards provided in ERISA to ensure the safe and effective care of patients.

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POLICY FORUM

Medicare's "Never-Event" Initiative

Jared Hossack, MD, MBA

A 47-year-old man had been noticing changes in his left testicle for a few months, specifically that the testicle was becoming painful and atrophied. After tests determined that a malignant growth was causing the changes, the man was scheduled for surgery to remove the testicle. When he awoke after surgery, the patient discovered that his right testicle, the normal one, had been removed [1]. How could this have happened?

In their 1999 report, *To Err is Human: Building a Safer Health System*, the Institute of Medicine estimated that between 44,000 and 98,000 deaths occurred annually in the U.S. due to preventable medical errors [2]. The Centers for Disease Control and Prevention (CDC) reported that, in 2002, 99,000 deaths resulted from mostly preventable hospital-acquired infections [3]. It has also been reported that medical errors may account for 2.4 million extra hospital days and \$9.3 billion in excess charges (for all payers) [4]. Due to these alarming statistics and shocking medical errors like the one described above, there have been efforts nationwide to improve medical care delivery and enhance reporting of and accountability for adverse events caused by the health care system.

One such effort is sponsored by the National Quality Forum (NQF), a nonprofit organization with diverse stakeholders across the public and private health sectors. This voluntary, consensus-based, standard-setting organization was established in 1999 with a mission to improve the quality of American health care through a variety of means. In 2002, the NQF endorsed a list of 27 (later changed to 28) largely preventable, serious adverse events deemed to be "of concern to both the public and healthcare professionals and providers; clearly identifiable and measurable; and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare organization" [5]. The events were categorized as being related to surgery, products or devices, patient protection, care management, environment, or criminal acts.

In 2003, the state of Minnesota adopted this list of so-called "never events" and has since required that all state-licensed health care facilities publicly report the occurrence of these events. The state also mandates that health care facilities investigate each occurrence, report its underlying cause, and take action to prevent similar events. Finally, the state provides a forum for hospitals to share reported information and to learn from one another.

The Minnesota experience has shown that there are consistently between 100-150 never events statewide each year [6]. Ten other states now require hospitals to track, analyze, and publicly report some or all of the NQF “never events.” Although reporting is a step in the right direction, stronger incentives may be needed—public reporting has been shown to be less effective at initiating change than the combination of reporting and financial punishments [7]. Aetna and other private insurers have adopted this dual strategy by refusing to pay for services billed as a result of never events. The Centers for Medicare and Medicaid Services (CMS), is also making patient safety and accountability a priority by initiating its own never-event program.

The current Medicare reimbursement system, which is used by most other insurers, is based on a perverse payment scheme that provides incentives for unwanted behavior. In this system, hospitals and other care facilities are paid for all conditions for which a patient is treated during a hospital stay, including those that develop as a result of a preventable harm. Hospital payments for Medicare patients are based on Diagnosis Related Groups (DRGs). A Medicare patient’s hospitalization is assigned to one of 538 DRGs, determined by the principal diagnosis, additional diagnoses, and the procedures performed on the patient. Patients within the same DRG are expected to use, on average, the same amount of hospital resources. The DRG system provides increased reimbursement for certain comorbid conditions and complications, regardless of whether the complication or comorbidity was present at admission or acquired in the hospital [8].

To eliminate some of these perverse financial incentives, and in response to a mandate in the Deficit Reduction Act (DRA) of 2005, the CMS devised a plan to prevent hospitals from getting paid for the additional costs of treating patients who acquire conditions as a result of a hospital stay. When this rule takes effect on October 1, 2008, Medicare will no longer pay the extra cost of treating eight “largely preventable” medical harms [8]. This list includes three of the NQF’s serious preventable events, in addition to bed sores, falls, and three hospital-acquired injuries and infections (see figure 1). In 2009, CMS plans to add hospital-acquired blood infections, blood clots in the legs and lungs, and pneumonia contracted from a ventilator to the list. Under this new rule, hospitals will not be paid for treatment of any of these conditions unless it was present when the patient was admitted. To facilitate the identification of pre-existing conditions, CMS has developed a “present-on-admission” indicator code that hospitals are required to enter for secondary conditions in patients discharged on or after January 1, 2008.

Figure 1. Hospital-acquired conditions selected for fiscal year 2008 Final Rule [8]

1. Serious preventable event—object left in place during surgery
2. Serious preventable event—air embolism
3. Serious preventable event—blood incompatibility
4. Catheter-associated urinary tract infections

5. Pressure ulcers (decubitus ulcers)
6. Vascular catheter-associated infection
7. Surgical site infection—mediastinitis after coronary artery bypass graft surgery
8. Hospital-acquired injuries—falls, fractures, dislocations, intracranial injury, crushing injury, burn, and other unspecified effects of external causes

Pay-for-performance reimbursement programs designed to attach *positive* financial incentives to better quality health care have been gaining in popularity among health care purchasers—insurance companies, employers, the government, and other groups that pay physician salaries and reimburse care. These programs, however, have evoked ambivalent responses. Proponents argue that the programs will increase accountability among physicians and organizations that provide care and make value-based purchasing possible. Opponents warn of the potential unintended consequences of such plans [9-11], e.g., attempts by physicians and health care facilities to avoid more complex patient cases.

The CMS never-event initiative is based on a concept similar to pay-for-performance but functions punitively. Because both depend on financial incentives, many of the unintended effects of incentive plans are likely to apply to the CMS penalty plan. For example, a major concern with both the CMS initiative and pay-for-performance is the potential diversion of resources from needed services to implementation costs. This may in turn raise overall costs as hospitals try to integrate strategies and programs that meet the proposed requirements.

Catheter-related urinary tract infections, one of the hospital-acquired conditions listed on the CMS no-payment plan, can be used as an example to demonstrate the potential for increased cost or diversion of resources under this program. In response to the no-payment rule, hospitals and physicians may increase urinalysis testing, when not medically indicated, to identify urinary tract infections prior to admission.

New policies that withhold reimbursement also carry the risk of encouraging “gaming” of the system. Despite the intent to make health care more transparent and accountable, the CMS never-event initiative may be a disincentive to the reporting of adverse events. Is a health care worker more likely to report a mistake if the result is praise or punishment? A punitive environment obviously results in less reporting than one that is neutral or rewarding. The executive vice president of the American Medical Association, Michael D. Maves, warned Medicare that the CMS no-pay plan may result in “significant unintended consequences,” including the denial or delay of care to certain at-risk patients [12]. Hospitals may also be penalized unfairly if these so-called “preventable” adverse events are in fact not preventable but unavoidable and occur at some rate, regardless of whether safe, standard practices are followed.

All agree that preventable errors should be eliminated from medical care. How to best accomplish this goal, however, remains unclear. The CMS and others are taking

steps to improve the situation but these are not the final answer either. Each plan should be carefully scrutinized, monitored, and adjusted to avoid undesirable or unfair results. Since each interested party will be affected differently, all stakeholders should participate in the feedback and monitoring process. In Minnesota, where never-events monitoring has existed since 2003, monthly “town hall” meetings take place at which hospital officials share ideas about how best to avoid future occurrences. The CMS has employed the services of the non-profit think tank RAND Corporation in several projects, including the revamping of the DRG system. Town hall-type feedback meetings with representative stakeholders and objective, unbiased analysis from a group like the RAND Corporation may limit the unintended consequences and ease the implementation of the CMS’ never events plan.

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MEDICINE AND SOCIETY

Can Health Care Engineering Fix Health Care?

Peter J. Fabri, MD, PhD

Start with the assumption that U.S. health care is badly broken and very expensive, plagued by inefficiency, waste, error, and duplication, and that this all is further compounded by inequities in distribution and access, safety issues, and disruptive behavior. In some ways this is like having an old, expensive car that you really like. It fits your self-image. It's quick and agile. But it constantly requires adjustment, goes through tires quickly, has only two seats, gets poor gas mileage, and costs a lot to insure. For a while, it might make sense to keep finding the money to deal with the problems and limitations, but eventually it makes sense to get a car that actually meets your needs and not your memories. Since we can't just get rid of our health care system—the socioeconomic cost would be crippling—and replace it with a new one, the only rational alternative is to roll up our sleeves and actually fix it.

By fix the health care system, I mean improve efficiency, minimize waste and error, limit duplication and unnecessary redundancy, develop “supply chain” approaches to distribution and access, design with safety in mind, and change the culture of the workplace. If this hadn't already been done in many U.S. industries, it might sound specious. But in fact health care is one of the holdouts, protected in its “cottage industry” safehouse, veiled in an aura of professionalism—individual doctors have professionalism, whereas “health care” is a trillion dollar industry—and, much like the quality and computerization movements within health care, is at least a decade behind the times.

How can I make these claims? A practicing academic physician for 35 years, I finally recognized that I was spending more and more of my time “making up” for the failures of the system, while becoming increasingly worried about safety. Then, I suddenly became a patient and directly witnessed how bad the system actually was. After recovering from my illness, I decided that I needed to do something. As I attempted to analyze the situation, I realized that the problems with health care were not primarily managerial and financial in nature but were systems and process problems, the domain of the industrial engineer. So I went back to school and earned a PhD in industrial engineering.

As I sat in class or worked on projects in manufacturing, assembly lines, statistical quality control, computer simulation, optimization, project management, and the like, I didn't see machine components traveling down assembly lines or robots assembling cars. I saw hospitals and clinics and operating rooms. Instead of the black

and white, right and wrong world I had known in medicine, I saw probability distributions, uncertainty, and decision analysis. And I learned about just-in-time inventory systems and Lean-Six Sigma [1]. While relearning calculus, differential equations, and several new computer languages, I envisioned new ways to interpret lab results, sequence imaging procedures, and decrease individual variability. As I memorized the equations for bottleneck analysis, down time, and throughput, I saw outpatient clinics and emergency departments.

Fixing health care will largely be a re-education process before it can become a re-engineering process. Much of the inertia and resistance to change is a matter of the culture and attitudes of medicine, carefully mentored during medical school and residency. Fixing health care will require individuals who are “bilingual” in health care and in systems engineering. It will require training highly visible and credible physicians and nurses to become analytical problem solvers and systems thinkers, while at the same time acclimating systems engineers to the culture, values, and terminology of the hospital and of the physician and recognizing how different they often are. And it will require training an entire cohort of individuals in new competencies that have either slipped through the cracks of current education (for example, where does one actually learn how a hospital works?) or represent new territory, like designing safe systems for new technology.

I realize that I have had two unique opportunities: I was a graduate student with tenure, and I started a sabbatical shortly after graduation. On sabbatical at a major university with a college of medicine and a college of engineering, I clarified the competencies of a health care engineer and drafted a curriculum that might allow them to be learned. I also had the opportunity to meet with leaders of the American Medical Association, the Joint Commission on the Accreditation of Healthcare Organizations, the Accreditation Council for Graduate Medical Education, the American Board of Medical Specialties, the American College of Surgeons, and the Department of Veterans Affairs. After initial skepticism, each organization seemed to develop an enthusiastic interest in the concept of fixing health care. I spoke with leaders in industry and found a similar acceptance. There appeared to be a general realization that something needed to be done, and a willingness to consider that health care engineering could be the route.

I am not alone. The University of South Florida Colleges of Medicine and Engineering, where I serve on the faculty and completed my graduate training in health care engineering, has been asked to participate in a multi-university proposal for a National Science Foundation grant. Our proposal, which has made the cut for serious consideration, would create the first officially recognized Health Care Engineering Research Center, distributed over five major universities. The grant focuses on developing programs in three areas (advancing data-driven predictive modeling, enabling the care cycle, and catalyzing transformational changes) and in three domains (discovery, development, and deployment).

Every journey begins with a single step. So, too, this journey must start somewhere—not everywhere—and must achieve some tangible, early success. Patient safety, which no card-carrying health care professional can reasonably ignore, is the natural starting point. Formal, structured programs in patient safety should be mandated in undergraduate medical education, graduate medical education, and continuing medical education. Understanding human error, the contributions of system design, and the need for human factors engineering should be as important in medical education as the Krebs cycle and the distribution of the coronary arteries. The University of South Florida is launching a broad-based program in patient safety for all residents and fellows; an innovative course in patient safety for fourth-year medical students, graduate nursing students, graduate public health students, and graduate engineering students; and a workshop on patient safety for residency program directors. Our masters-prepared graduate medical education librarian is creating a virtual library on patient safety immediately accessible to all of our faculty, residents, and students.

Once a beachhead has been established, the next steps might address the processes by which care is delivered and the processes by which professionals are educated and trained. The opportunities are limitless. But it will depend on the willingness of physicians and nurses to accept responsibility to fix the system, to roll up their sleeves, and to lead the march. In the words of George Bernard Shaw “Some men see things as they are and ask why. Others dream things that never were and ask why not.”

Note

1. Lean is a manufacturing tool that has the major benefit of minimizing inventory and waste. Six-Sigma is a system of measuring the number of defects per million operations in a statistical way and using that information to drive performance improvement. The popular combination of the programs is known as Lean-Six Sigma.

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MEDICAL HUMANITIES

Equity in Medical Care: An Aristotelian Defense of Imperfect Rules— and Bending Them

Geoffrey Rees, PhD

To the chagrin of some people, and the relief of most, doctors are not robots. As important as technological and bureaucratic systems have become for many aspects of contemporary medical practice, the bedrock of optimal care remains the clinical judgment of individual doctors. Good clinical judgment made possible by rigorous training and experience cannot be programmed. Instead, it constantly arises in an epistemological space between universals and particulars. On the one hand, rules and regulations, procedures, and technologies all provide the systematic structures that ensure stable medical practice. On the other hand, well-trained practitioners are constantly assessing the particular details that define any actual clinical situation. Clinical judgment is the cultivated capacity to work between these poles, to bring them together in the determination of appropriate decisions—appropriate because they join the general guidance of systems with the particulars of specific patients and clinical situations.

To ensure the justice of clinical judgment, and to make sure that systems do not harm people who need medical care, it is necessary to allow room to adjust the fit between universal and particular according to the judgment of the practitioner. The concept of “equity,” originally explicated by Aristotle in the *Nicomachean Ethics*, accounts for this adjustment [1]. Equity is especially important because it recognizes that the justice of systems of medical care depends, ultimately, on the individual moral agency of health care professionals.

When all goes well, medical care proceeds more or less seamlessly in the space between the general and the particular, so much so that doctors and other caregivers are not aware of the unifying activity of their practical judgment, nor do they question the justice of their activity. Tension is often present, however, and moments of crisis arise wherein a caregiver seems forced to choose between two conflicting courses of action, one defined by adherence to the strict requirements of a system, the other defined by the immediate and particular medical circumstances. In such conflicts adherence to an impersonal system often appears to entail unjust treatment of an actual person in need, so that the system itself appears unjust. Many worry, for instance, that strict enforcement of work hour rules requires residents to abandon their patients. The concept of equity helps to illuminate how even systems that are just nevertheless sometimes require correction to achieve equity. Aristotle explains: “What causes the problem is that the equitable is not just in the legal sense of ‘just’ but as a corrective of what is legally just. The reason is that all law is universal, but

there are some things about which it is not possible to speak correctly in universal terms” [2].

Aristotle’s basic point is that to function properly any system must generalize. But generalization entails the admission that systems cannot prescribe in advance a correct course of action for every possible contingency. A truly perfect system, in this sense, would be an absurdity, as it would require so much specification of possible contingencies that the system itself would become unwieldy and practically unthinkable. What Aristotle calls “legally just” can therefore be interpreted in contemporary terms as “procedurally just.” A health care system is procedurally just when it generally facilitates the provision of appropriate and fair medical care.

Following Aristotle’s account of equity, it is a mistake to assume that whenever a practitioner is caught between a general requirement and a particular circumstance, the system in question at the moment must, by definition, be unfair. Even the most “procedurally just” system sometimes will not fit an actual clinical situation. The requirement for informed consent, for example, sometimes seems to conflict with medical necessity, so that confusion ensues about how to proceed because it is not clear whether adherence to one guiding rule—act to save a person’s life—requires breaking a different rule—treatment without consent is battery. Equity in such situations does not require that an actor “break” a rule or act “against” a system. Instead Aristotle introduces the image of a special “rule” necessary to adjust the requirements of ordinary rules:

And this is the very nature of the equitable, a rectification of law where law falls short by reason of its universality. There are some things about which it is impossible to enact a law, so that a special decree is required. For where a thing is indefinite, the rule by which it is measured is also indefinite.... Just as this rule is not rigid but shifts with the contour of the stone, so a decree is adapted to a given situation [3].

Equity, in effect, improvises a rule so specific that it only holds for the particular instance of its application. Equity pushes a system forward where it otherwise falls short. Equitable action thus completes or perfects the application of general directives where they conflict or do not reach. In cases where a person who seems to lack decisional capacity refuses life-saving intervention, doctors typically improvise a way to construe consent that both facilitates good care and honors the requirement to obtain informed consent.

Distinguishing the Imperfect from the Unjust

A crucial benefit of Aristotle’s account for contemporary medical ethics is that it distinguishes procedurally just systems that are imperfectly able to guide decision making in a particular situation from systems that are in fact unjust. Put another way, Aristotle’s account of equity teaches that there is a profound difference between “shifting” a rule or working at the margins of a system and breaking a rule or acting against a system. To provide optimal medical care, doctors and other health care

providers therefore need to be able to wield the contemporary equivalent of an indefinite rule. They must retain the freedom to individualize the care they provide according to the unique details of each clinical situation.

This is not to say that *every* medical situation is so unique that it defies description within a system, nor is it to say that such situations are exceptional. Doctors therefore must reflect upon the difference between “shifting” a rule to achieve a good end that is not opposed to the system of general care and breaking a rule because the system itself cannot accommodate good care. In the former case the practitioner can claim in good conscience that her actions are equitable and ultimately conform to the system whose rules they shift. In the latter case, by contrast, the practitioner in good conscience must accept that she is breaking a rule and also accept responsibility for her actions accordingly. Many doctors, for example, choose to share medical information with immediate family members of persons receiving emergency medical care, in violation of HIPAA (Health Insurance Portability and Accountability Act) regulations. In doing so they break a federal law and must accept the unlikely but real possibility that when they breach the confidentiality of their patients they can face legal consequences.

A further implication of Aristotle’s description of equity is that, rather than attempt to determine the justice of a system based on whether it conflicts sometimes with the requirements of a particular circumstance, one should attempt to determine whether the system significantly impedes equitable improvisations. Applied in this way, the concept of equity helps define realistic expectations for what a system can justly accomplish and, at the same time, recognizes that health care professionals are empowered to exercise their own practical judgment in providing just and fair medical care. The imperfection of a system when rigidly applied to a particular case is therefore not a cause for distress, but rather celebration, since even the most just system possible depends for its perfection on the moral freedom of discerning individuals.

At their best, good systems allow space for the practical judgment of health care professionals to achieve a kind of perfection of justice in the particular actions of their daily practice. At their worst, they constrain persons from acting equitably. Conflict between the requirements of rules and particular situations is not itself an indication that a system has gone wrong. Instead, a truly “bad” system is one that does not allow practitioners to make adjustments—i.e., to shift rules—in order to attain equitable ends. To optimize medical care it is not necessary to seek to eliminate, in advance, the possibility of conflict between general and particular requirements. Such an attempt would itself be likely to institute a rigid general rule that would then generate further conflict. Rather than regard instances of apparent conflict between systematic and particular demands as failures of medical care, it makes sense to regard them as opportunities for equitable action.

When evidence accumulates that a system unduly constrains adjustments of equity, and so unduly constrains its own reformation, then there is reason to consider the

system as actually unjust. In those instances where equity is not possible, when the limits of a system obstruct good practice, then the responsibility of doctors is not to keep breaking the rules that define the system, but to seek to modify the system. If enough doctors repeatedly feel compelled to disregard certain aspects of HIPAA, then an appropriate implication is to explore whether the legislation itself is due for change.

Should it ever become possible to design and implement a perfectly just system of rules that comprehends every possible individual clinical occurrence, then indeed robots could become doctors, or doctors, robots. But in the meantime the possibility of optimal medical care will remain a work in progress, achieved in the equitable exercise of clinical judgment by well-trained and conscientious doctors.

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HISTORY OF MEDICINE

The U.S. Health Care Non-System, 1908-2008

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One hundred years ago, in 1908, health care was virtually unregulated and health insurance, nonexistent. Physicians practiced and treated patients in their homes. The few hospitals that existed provided minimal therapeutic care. Both physicians and hospitals were unregulated. When patients saw a physician, they paid their modest fees out-of-pocket; they were more concerned about the wages they would lose if illness kept them out of work than about the cost of their medical care.

Medical science and technology were primitive, and there was little that physicians could do to treat most illnesses. It had been only 40-50 years since the first understanding of bacteriology, antiseptics, and immunology; 21 years since the invention of a blood pressure measurement device; and 13 years since the discovery of X-ray technology. It would not be until 1910 that the first drug treatment to destroy disease—and not the patient—would emerge or that surgery would become common for conditions like tumors, infected tonsils, and appendicitis.

Commercial insurance companies did not write health insurance policies in 1908; they saw no way to avoid the risks of adverse selection (those who were sick would seek coverage, and those who were healthy would not) and moral hazard (coverage would encourage the insured to seek unnecessary services), and they lacked the means to calculate risks accurately and set appropriate premiums. Within the next 10 years, many European nations would adopt some form of compulsory national health insurance, but similar proposals in the U.S. were rejected because of lack of interest and resistance from physicians and commercial insurers [1].

Yet it was in the early 1900s that regulation and organization of health professions began to take hold. Membership in the American Medical Association (AMA) increased from 8,000 in 1900 to 70,000 in 1910 [2]. In 1904, the AMA formed the Council on Medical Education to establish physician licensure standards. The 1910 Flexner Report on medical education recommended stricter entrance requirements, better facilities, higher fees, and tougher standards for medical students [3]. By 1920, the cultural influence of the medical profession was growing as physicians' incomes and prestige increased.

During the 1920s, the cost of medical care rose due to growing demand and higher quality standards for physicians and hospitals. Families had more money to spend but less room in their homes to care for sick family members. Advances in medical technology, tougher licensing criteria, and the growing acceptance of medicine as a

science led to the emergence of hospitals as credible centers for treatment. They were now modern scientific institutions that valued antiseptics and cleanliness and used medications for the relief of pain. When the American College of Surgeons was founded in 1913, it was the first body to accredit hospitals [4]. Of the 692 hospitals examined in 1918, only 13 percent received accreditation. By 1932, the percentage had grown to 93 percent of the 1,600 hospitals surveyed [5]. In 1929, the average American family had medical expenses of about \$103—roughly 5 percent of the average annual income of \$1,916. Typically 14 percent of these expenses were for hospital care [6].

In 1929, a group of Dallas school teachers contracted with Baylor University Hospital to receive up to 21 days of inpatient care a year for regular monthly payments of 50 cents [7]. Similar prepaid service plans, many involving more than one hospital, were formed during the Depression years. While they gave consumers an affordable way to pay for inpatient care, their primary purpose was to assure hospitals a steady income stream during a period of declining revenues. By 1937, there were 26 such plans with more than 600,000 members total. These combined under the auspices of the American Hospital Association (AHA) to form the Blue Cross network of plans, the first of which had been established in 1932 in Sacramento. The creation of these plans was facilitated by state legislation that allowed them to organize as nonprofit corporations, enjoy tax-exempt status, and avoid the onerous insurance regulations (particularly financial reserve requirements) that applied to commercial insurers.

In the 1930s, physicians became concerned about proposals for compulsory national health insurance and the threat of insurance competition from Blue Cross [8]. Specifically, doctors worried that third-party payers would lower their incomes by restricting their ability to set their own fees. In response, physicians established a network of their own insurance plans covering physician services. These plans, known as Blue Shield, preempted the hospital-oriented Blue Cross plans from entering into the primary care sector. Meanwhile, in 1935, the Social Security Act was passed without a health insurance component.

The success of the Blue Cross and Blue Shield plans showed commercial insurers that adverse selection could be overcome by focusing on insuring groups of young, healthy, employed workers. The commercial plans also benefited from a legal advantage: as non-profit entities, the Blues had to “community rate” their policyholders, while the for-profit commercial plans (strictly regulated insurance companies) were free to engage in experience rating [9]. As a result the market for health insurance of all kinds increased dramatically during the 1940s, from a total enrollment of 20,662,000 in 1940 to 142,334,000 in 1950.

Another spur to health insurance sales came during World War II, when wage and price controls prevented employers from using higher salaries to attract workers. They were, however, allowed to offer fringe benefits like health insurance for up to 5 percent of a worker’s wages [10]. In addition, the National Labor Relations Board

ruled that health insurance benefits were a legitimate subject of labor-management negotiations. Lastly, the IRS determined that employers could deduct the cost of employee health benefits from taxable business income, and employees did not have to include the value of those benefits in calculating their taxable income. The role of employers as the primary source of health insurance coverage was now firmly entrenched [11].

A New Way to Pay for Health Care

The Blue Cross and Blue Shield plans used a reimbursement methodology called “cost plus.” In this payment scheme, physicians were compensated according to “reasonable and customary charges” that they themselves set, and hospitals were reimbursed on a percentage of their actual costs plus a percentage of their working and equity capital. This allowed doctors to charge whatever they wanted and encouraged hospitals to increase costs so their cost-based income would be greater. This methodology was replicated by commercial insurers and the subsequent government health insurance programs, Medicare and Medicaid.

As hospitals became the center of medical care delivery, it became apparent that many communities lacked adequate access to them. The Hill-Burton Act was passed in 1946 to provide loans and grants for the construction of new hospitals and improvements in the physical plants of existing ones [12].

Over the years many legislative proposals for different approaches to health insurance were introduced and failed. In 1944 President Roosevelt asked Congress for an “Economic Bill of Rights” that included a right to adequate medical care, but this request was never fulfilled. President Truman proposed a national health insurance program that would have created a system covering all Americans, but it was denounced by the AMA and called a “communist plot” by members of Congress [13]. By 1950, national health care expenditures equaled 4.5 percent of the GNP (gross national product) and were continuing to rise [14].

During the 1950s, the price of hospital care doubled, and medical breakthroughs were coming at a fast pace. Medications became available to treat infections and conditions like glaucoma and arthritis, and new vaccines were developed to prevent childhood diseases like polio. The first successful organ transplant was performed in 1954.

Entering the 1960s, the health care system was fiscally unrestrained. There were no external controls on the cost of medical therapies delivered or the resources consumed. There were, by then, more than 700 companies selling health insurance, yet people who were unemployed, like the elderly, were having difficulty paying for it. Realizing that proposals for total reform of the system were not working, advocates turned to a more incremental approach. In 1965, Congress created the Medicare and Medicaid programs to provide health care coverage to the elderly and poor [15]. Overnight the federal government became the largest single purchaser of health care services, but these two public programs adopted the same reimbursement

defects that were found in the private health insurance industry, accelerating the rate of health care price inflation.

During this same period, there was concern about a doctor shortage and the need for additional manpower in other health professions. One result was the enactment of the Health Professions Educational Assistance Act of 1963, which provided direct financial assistance to medical, dental, nursing, pharmacy, and other health professional schools and their students [16].

The Advent of HMOs and Other Payment Plans

In 1929, the Ross-Loos Medical Group had established a prepaid health plan that provided medical services to Los Angeles city and county employees for \$1.50 a month [17]. In retrospect, this is considered to be the first HMO (health maintenance organization). In 1945, the Kaiser Foundation Health Plan was founded to provide prepaid health benefits to workers in Kaiser shipyards; it has come to be viewed as a model for HMOs. Yet from 1945 until the 1970s, these plans, which combined the financing and delivery functions of health care, were idiosyncratic players in the health care market.

In 1970, Paul Elwood coined the phrase “health maintenance organization” to emphasize the clinical prevention role of plans like Kaiser’s [18]. At a time of soaring health care costs, it was noticed that HMOs were able to reduce resource utilization rates, particularly hospital admissions and lengths of stay. The Health Maintenance Organization Act of 1973 was passed to encourage HMO growth in the marketplace [19]. This law provided grants and loans to start or expand HMOs, removed state restrictions on federally certified HMOs, and required employers of 25 or more employees to offer this type of plan as a benefit option in addition to indemnity (or fee-for-service) plans. In the 1970s there were 26 plans with about 3 million subscribers nationwide; by 1991 the numbers had grown to 556 plans with 35 million enrollees.

In 1983, Medicare instituted a prospective payment system (PPS) for reimbursing hospitals [20]. It paid hospitals for services on the basis of 475 diagnosis-related groups (DRGs) of illnesses. Like most price control systems, the PPS caused hospitals to shift the patient cost burden to activities not covered by the controls. In 1992, the system for calculating reimbursements to physicians for services covered by Medicare was switched to one based on the cost of resources consumed in delivering a particular clinical service.

During the late 1980s and early 1990s, health spending increased at an even more rapid pace. This has been attributed to expensive new medical technologies (estimated to account for an average of one-third of annual cost increases) and the curtailing of the ambitious HMO-promoting programs of the 1970s. Another attempt at national health care reform was made in 1993 through the failed Clinton “managed competition” proposal.

Traditional HMO and fiscal management practices, such as gatekeeping, capitation reimbursement, utilization review, clinical practice guidelines, and selective physician contracting [21], lumped under the term “managed care,” strengthened the power of the health care organizations that used them. Under these constraints, the growth in health care spending slowed noticeably in the mid-1990s, but the constraints provoked resistance from patients and physicians, who saw treatment decisions being taken from their hands and their clinical judgment being second-guessed.

All payers, private and public, gradually backed away from some of their more severe managed care policies (like capitation and physician choice limits) but have not replaced them with anything more effective in controlling costs. Not surprisingly, health care cost inflation picked up again in the late 1990s.

Controlling Costs in the 21st Century

The current strategy for addressing the spending problems within the U.S. health care system is to introduce changes that will make it function more like a traditional “perfect market.” This is based on the assumption that health care should be treated as a private consumable product rather than a public good. These changes are wrapped up in the “consumer-driven health care” movement. All consumers, including those under employer-based health plans, will assume greater responsibility for making decisions about many aspects of their health care: how much of their own money to spend on it, the type of insurance protection to buy, which providers (physicians and hospitals) to use, and what specific clinical procedures to receive. This initiative should be combined with greater transparency about the cost, quality, and other features of health care providers and products, much of it gathered through comprehensive electronic medical record and information systems.

There are no active proposals at the federal level for resolving the lack of access to health care experienced by 45 million uninsured Americans, 15 percent of the population. Ambitious efforts at universal coverage have been launched by a few individual states, namely Massachusetts, Maine, Hawaii, and California. Time will show the success of their approaches. Encouragingly, physician attitudes towards national health insurance have evolved to the point that, in April 2008, 59 percent of them supported legislation to create such a program [23]. Certainly the next U.S. president and Congress will be under pressure to give greater attention to many aspects of the health care delivery and financing systems.

For the moment, the U.S. continues to spend 50 percent more on health care as measured by its share of the GDP (gross domestic product), than any other developed country. In 2006, health care spending accounted for over 16 percent of the U.S. GDP [22]. At the same time, life expectancies are lower and infant mortality rates higher in the U.S. than in most of those other developed countries. The success of various approaches to systemic health care reform thus remains to be established.

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Utilization review encompasses a variety of mechanisms designed to assure that the resources consumed in treating patients, primarily by physicians, are medically necessary. Under this scheme, physicians are required to get a health plan’s permission before admitting a patient to a hospital, and to obtain further permission to keep the patient in the hospital beyond a predetermined length of stay. In some cases, if the plan later concludes that a treatment or service was not warranted, it will deny reimbursement.

Capitation reimbursement was introduced in response to physician resentment at nonphysician micromanagement of clinical decision making. Physicians received advance payments of a fixed monthly amount per member under their ongoing care, whether a particular member was actually provided services in a given month or not. As long as the physician was responsible for a large enough pool of members, the total capitation payments (properly calculated) usually sufficed to cover the costs of treating the very few seriously ill and the modest number of more moderately ill among them. Proponents of capitation argue that it is an incentive for physicians to treat patients as efficiently as possible, using their own clinical judgment. Critics claim that it can result in the undertreatment of patients.

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Op-Ed

The Teaching of Law in Medical Education

Nirav D. Shah, JD

The influence of law on the practice of medicine in the United States has required physicians to become as skilled in understanding the regulatory nuances of Medicare as they are in treating diabetes. Today a physician must not only be able to communicate with patients and diagnose illness to be successful, he or she must also be well-versed at navigating the complex legal and regulatory systems that now govern what type of medical care will actually be delivered to a patient. Sadly, American medical education does an inadequate job of preparing physicians for these delivery system challenges.

Many of today's practicing physicians are ill-equipped to handle the legal, regulatory, and business realities of modern medical practice [1]. They struggle with complex reimbursement schemes and enter into contracts that are disadvantageous to their practice, at the least, and illegal at worst. Many report job dissatisfaction stemming from their confusion over Medicare statutes [2], and they frequently report feeling helpless when insurance companies deny payment for proposed care. Some surveys show that practicing physicians have a poor and often incomplete understanding of basic principles of malpractice law [3]. They often learn the bare necessities of managing a medical practice "on the job" or from colleagues who themselves have suffered first-hand from various pitfalls [4], and, as a result, they expose themselves to staggering liability. Physicians also report an inability to navigate the legal system and a persistent fear of lawsuits [5, 6]. Surveys show that physicians are ignorant of even basic risk-management principles such as when to disclose a patient's infectious disease status [7] and how to manage obligations to adolescent patients [8].

But physicians themselves are not solely to blame for this lack of knowledge. Much of the fault lies with the medical education system. Medical education in the United States does a poor job of training physicians about the legal realities of medical practice. Influenced by the bioethics movement of the last 3 decades, medical schools and residency programs have incorporated formal ethics education into the curriculum, but they have yet to formalize any instruction in the malpractice, business, and regulatory issues that dominate medicine. This tradeoff—emphasizing ethics rather than law—results in a system with precisely the wrong priorities. Few ethical dilemmas faced by physicians require specific ethics training to resolve, but every physician will face some legal dispute where an awareness of the issues and how to approach them would be invaluable.

Evidence that training in ethics changes medical students' behavior is weak [9, 10], whereas even a brief exposure to legal issues can improve physician compliance and, ultimately, professionalism. Medical schools and residency programs should consider law as the cornerstone for teaching ethics. To be sure, the goal is *not* to turn young doctors into amateur attorneys. Rather, it is to educate physicians about the legal backdrop of the regulatory, business, malpractice, and ethical questions they will surely face.

The Current State of Legal Education in Medical Curricula

Presently only 37 percent of U.S. medical schools offer formalized coursework dealing with the legal or regulatory issues in medicine [11]. Several schools incorporate “medical jurisprudence” into another course, typically the first-year ethics or a health economics course [11]. Yet even when law and legal issues are raised, the discussion focuses on malpractice as opposed to regulatory and enforcement issues.

Medical students are clamoring for more exposure to law and medicine [11]. The same survey that showed that less 37 percent of medical schools teach law and medicine in any formal way also found that 82 percent of medical students wished their medical school offered a class on “legal pitfalls in practice” [11]. Why the discrepancy between demand and supply? For one thing, it is difficult to find qualified health law professors to teach in medical schools. The field is highly specialized, and attorneys who possess the interest and professional qualifications are scarce. Further, it has been my experience that there is a reluctance within medicine to discuss practical legal and business realities of medicine—particularly when teaching medical students. For example, when the patient-physician relationship is discussed in ethics classes, the degree to which fear of malpractice might drive patient care is minimized.

Consequences

The lack of legal exposure in medical education carries consequences. For one, it leads to a deep suspicion and mistrust among physicians of the legal and regulatory systems. It has also been shown that physicians who don't understand the broad strokes of the legal landscape are prone to make risk-management decisions based on lore rather than fact—leading to the much-maligned practice of “defensive medicine” [12]. And defensive medicine carries its own costs, financial and otherwise. It leads to unnecessary testing, hospitalizations, and potentially harmful false-positives [13, 14]. In an era where evidence-based medicine is the basis for the standard of care, physicians who practice defensive medicine out of a misunderstanding of the law do a disservice to their patients.

Law, then, should form the framework for ethics education. Not everyone agrees. Sokol, for example, argues that “law often represents the lowest acceptable measure of morality” [15]. That is perhaps true, but it doesn't alter the argument for teaching law. If anything, the statement that law is the “lowest measure of morality” only means students should know about the law's contours so that they can strive for a

higher mark. Law sets the floor of acceptable behavior, so talking about ethical responsibilities without knowing that minimum standard is unhelpful. To be sure, physicians should not equate ethical behavior solely with what the law allows. Rather, they should base their behavior on an ethical code they feel comfortable with—whether personal or professional. But without first knowing what the low point of acceptable behavior is, it's impossible to aim higher.

Proposal

A medical school curriculum that addresses the legal context of medical practice should focus on raising awareness of a wide range of subjects and should train students to recognize areas where medical practice and law can come into conflict. Such a curriculum should aim to give medical students concrete tools with which to enter medical practice, with the hope that these tools will help them avoid common legal pitfalls [16].

A legal medicine curriculum should be broadly divided into three main areas of interest: laws pertaining to the practice of medicine, laws pertaining to ethical conduct, and regulation.

Laws pertaining to the practice of medicine. This area includes topics such as negligence, standards of care, malpractice, and HIPAA (the Health Information Portability and Accountability Act). These subjects are the most relevant to physicians' daily practice and are also the areas where myth often parades as fact. An examination of the laws that pertain to medical practice should begin by introducing basic concepts from tort law, such as duty to patients, breach of duty, causation of injury, and damages, and then move on to more detailed topics such as risk management and documentation. The legal aspects of the patient-physician relationship should also be covered. In particular, this curriculum should address questions about when a patient-physician relationship legally begins, how to "fire" patients, and how to manage and disclose medical errors. In my experience as a teaching assistant for first-year medical student ethics courses, the concerns that give the students the most distress are, not surprisingly, the questions that ethics teaching poorly equips them to handle [17].

Laws pertaining to ethical conduct. By "the law of ethics" I refer to the jurisprudence behind prominent ethical debates. For example, it's difficult to fully appreciate a physician's role in the debates surrounding end-of-life care without first understanding the legal definitions of death, brain death, assisted suicide, and futility. These areas are deeply rooted in law, and, if they are viewed as purely ethical decisions, the role that courts and legislatures have played in their evolution is overlooked.

Topics that have a clear ethics component are often informed by a wide body of law ranging from legislative statutes and agency regulations to judicial opinions. Though the law does not answer many thorny dilemmas such as how transplantable organs should be distributed, it does provide parameters within which the debate should take

place. For example, recent changes to the National Organ Transplant Act have legalized the previously contentious issue of “kidney swapping” [18]. While the legalization of such a swap doesn’t eliminate the ethical question of whether such the swap *should* be allowed, it does refocus the debate on how the procedure might be carried out.

Regulation. Regulation cuts the broadest swath in medical jurisprudence, encompassing all areas where the government interacts with and regulates the practice of medicine [19]. While physicians typically conceive of “the law” mostly in terms of malpractice, the law that they will interact with most during their careers is in the form of regulation. Regulatory agencies from the FDA to the Department of Justice exercise great power over the practice of medicine in the United States. Statutes like the False Claims Act and the Stark Laws control billing and referral matters, antitrust laws govern physician practices and investment ventures, federal prescribing guidelines govern how physicians can prescribe controlled substances. Yet health law courses seldom address these topics, even though they are arguably more important than malpractice.

Conclusions

The current system of medical education fails medical students and trainees by not providing any systematic approach to thinking about the legal issues they will face. Many curricula focus, instead, on ethics, which leaves students without clear guidance on the legal matters they will certainly encounter. While ethics education is important, it should be taught in concert with law. Students should leave medical school with an appreciation for how the legal system works and how to navigate it. Such awareness may lead to fewer decisions made on the basis of myth and greater comfort in practicing evidence-based medicine over defensive medicine.

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always disclose all errors, no matter how small” (not necessarily legally required and, today, a matter of risk management policy and professional consensus). See, for example, Nguyen AVT, Nguyen DA. *Learning from Medical Errors: Legal Issues*. Abingdon, UK: Radcliffe Publishing LTD; 2005.

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Virtual Mentor

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Suggested Readings and Resources

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