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Improving Allocation of Limited Resources

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FROM THE EDITOR
Accountability in Rationing

Ethical dilemmas in modern medical practice often arise from the tension between the noble position that physicians hold, in their own eyes and the eyes of society, and the realities of resource limitations, including physician time, available medical services, and especially money. However much we would like to extend to every patient the best and most comprehensive therapies known, the reality is that resource rationing is already in place in our health care system and is set to take an increasingly prominent and recognized role in medical practice as America attempts to control its debt. This issue of *Virtual Mentor* attempts to identify areas of medicine in which additional rationing of resources may be ethically tenable…and those in which it is not.

How is it that America's health care policies have come to be what they are? In this month's medicine and society section, Michael K. Gusmano, PhD, elucidates some of the ways in which national resources come to be disproportionately allocated to specific medical causes and patient populations. In the history of medicine section, Will Ross, MD, MPH, recounts the story of Medicare's End Stage Renal Disease program, one of the longest-running and most costly of our government's health care expenditures, and questions whether it is still a sensible program to fund—or indeed, whether it ever was. In the health law section, Valarie Blake, JD, MA, updates us on the Supreme Court's mixed ruling on the constitutionality of the Patient Protection and Affordable Care Act (ACA).

Our health care system's resource limitations pose dilemmas for individual physicians and other health care providers every day. Narayan Iyer, MD, and Sabine Iben, MD, confront the volatile situation that arises when practical and economic considerations clash with a family's wishes, and a life hangs in the balance. They untangle the snarl of idealism, practicality, hope, and justice that surround this sensitive decision. Katherine J. Mathews, MD, MPH, MBA, explores the consequences of patients' self-rationing that results from their economic constraints and advises physicians about how to help such patients access necessary treatment instead of forgoing care. Finally, Ronald MacKenzie, MD, Matthew Matava, MD, and Charles Carroll, IV, MD, consider the case of a patient who requests a costly procedure that may help him, but which evidence suggests may merely be an expensive placebo.

Two articles look at technical innovations that may have implications for efforts to balance our medical budget. In our state of the art and science section, Siddharth Devarakonda, MD, Ramaswamy Govindan, MD, and Peter S. Hammerman, MD,

PhD, explain what next-generation gene sequencing could do for cancer therapies, concluding that, as the cost of gene sequencing declines, effective targeted therapies personalized to each patient's tumor will be much more cost-efficient to develop than the standard selection of often-noxious chemotherapy agents. In their journal discussion article, David S. Gierada, MD, and Lawrence M. Kotner Jr., MD, consider the ethics of low-dose CT screening for lung cancer, including whether the costs and risks of the screening are appropriate for various patient populations. This issue also includes some suggestions for how medical resources might be more efficiently allocated in the future. In the medical education section, Betsy Goebel Jones, EdD, and Steven L. Berk, MD, provide a detailed account of Texas Tech's Family Medicine Accelerated Track program, a recently accredited 3-year medical school program that produces well-trained doctors in less time and with less debt. In our first policy piece, Kevin Frick, PhD, assesses the new National Quality Forum guidelines designed to improve cost-efficiency in health care. The second policy forum piece, by Todd Ferguson, PhD, reviews the ABIM Foundation's Choosing Wisely campaign, in which physicians and patients work together to develop treatment plans that are effective for the patient but are also efficient and promote the sustainable use of limited resources.

Finally, this issue considers the overall structure of our health care system. This month's excerpts from the *Code of Medical Ethics* survey the ethical landscape of various cost-containment schemes, including managed care, capitation, and physician pay-for-performance. In an op-ed, Ed Weisbart, MD, CPE, argues that some aspects of our health care system are fundamentally unsustainable even with the ACA's changes, and proposes that a single-payer system would do much to alleviate our budgetary crisis and improve care.

Adam Aronson
MS-2
Washington University School of Medicine
Saint Louis, Missouri

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ETHICS CASES
Surgery for Placebo Effect?
Commentary by C. Ronald MacKenzie, MD, Matthew J. Matava, MD, and Charles Carroll IV, MD

Dr. Janus is an orthopedic surgeon who specializes in arthroscopic surgery and keeps current with medical research in his area. His goal is not only to provide the best care but also the most effective treatment at the lowest cost for his patients. Lately, he has treated many elderly patients with osteoarthritis of the knee and has noticed that this type of surgery is often a financial burden for his patients. Although the surgery is quite expensive, at $4,500 per knee, patients continue to request it, hoping to improve their mobility. In reviewing the current literature, Dr. Janus learns that the type of arthroscopic knee surgery he has been performing routinely (arthroscopic lavage and debridement) was shown in two different studies to provide no benefit over placebo; in fact, a strong placebo effect has been suggested. Dr. Janus feels that the patients he operated upon usually did improve, but he cannot rule out the placebo effect.

Mr. Marcus is a 70-year-old retiree living on his limited pension. He suffers from advanced osteoarthritis in his knees and would do anything to be able to walk more easily on his own. He says to Dr. Janus, “My best friend had this surgery last month, and he’s already getting around the golf course great. He says this surgery was the best thing he ever did for himself. I sure would love to be able to keep up with him now. What do you say, Doc, can you do this surgery for me?”

Commentary 1
by C. Ronald MacKenzie, MD

This case involves the use of a highly popular, widely employed, and generally effective surgical technique—arthroscopy of the knee. First described in 1934, arthroscopic procedures have a number of advantages over alternative approaches; they are safe, are performed in the outpatient setting, and do not preclude the later performance of more definitive surgery, such as total knee replacement [1]. As a result they are favored by patients, physicians, and medical insurers (payers) alike.

Once one of the most commonly performed of orthopedic procedures, arthroscopic debridement of the knee has come under scrutiny in recent years with the publication of two major randomized controlled clinical trials that failed to demonstrate benefit to the enrolled patients [2, 3]. Even in the current environment, with its emphasis on evidence-based medicine, such level I clinical evidence is hard to come by, particularly in the context of surgery. Nonetheless, a clinical impression endures to support the use of this procedure for osteoarthritis (OA) of the knee, albeit in a more limited, defined subset of patients.

The budget deficits and rising health care spending that have been in the forefront of the national consciousness for many years figure into the broader discussion of this case. One of the goals of the Patient Protection and Affordable Care Act of 2010 was control of the skyrocketing costs of medical care, a goal that requires the participation of physicians. Although physicians may believe that the costs of health care are largely beyond their control, the literature pertaining to regional variation in health care-related expenditures argues otherwise [4].

The issue of cost containment can be viewed in a number of ways, influenced by one's vantage point in the system. For instance, the term "rationing" is often used by physicians who see cost-containment practices as anathema to their duty to their patients (regardless of costs); concerns relating to cost have no place at the bedside. Bioethicists have preferred the term "allocation of scarce resources," thus framing the debate in terms of distributive justice, a foundational principal of biomedical ethics [5]. Those with an interest in health care policy see the problems in terms of systems organization, structure, and information management [6].

Regardless of how one looks at these issues, when health care resources become truly depleted, patients will inevitably be deprived of care, leaving only fairness in the distribution of the limited services to contemplate. A (partial) way out may be evolving with a recent shift in the debate from an ethics of rationing to one of waste avoidance [7]. Stimulated by Howard Brody's "Top Five List," [8] numerous medical societies have taken up the task of identifying those diagnostic tests and treatments that are commonly ordered but offer limited benefit. The American Board of Internal Medicine (ABIM) Foundation's "Choosing Wisely" campaign is one example of this approach [9]. Although skepticism exists as to the long-term adequacy of this effort [10], attacking interventions of dubious benefit, estimated to account for 30 percent of the overall health care budget, appears to have caught on.

Is arthroscopic debridement of the knee one such procedure? From the standpoint of medical professionalism, we are told something of Dr. Janus's philosophy of care—"to provide the most effective treatment at the lowest cost for his patients." This view parallels the ethical principles emphasized by various professional societies, such as those promoted in the Ethics Manual of the American College of Physicians (ACP) [11]. This document stresses a number of professional duties among which is the physician's obligation to society, a role acknowledging the social context in which medical care is delivered. Within this framework, decisions concerning care at the level of individual patients must consider the allocation of resources writ large, an attention that, as mentioned earlier, challenges the physician's advocacy role. Advocacy for individual patients nonetheless has its limits, and physicians are not obligated to provide all treatments, particularly those of uncertain effectiveness.

This clinical scenario therefore provides an opportunity to marry both the application of current, evidence-based medical judgment with the need to recognize the larger imperatives currently impacting the health care system. With that said, Dr. Janus's

primary responsibility does remain his patient, in this case, to advise him about surgery.

Based on current standards of practice, he is obligated to first recommend a comprehensive program of nonsurgical management. Numerous nonoperative treatment options are available to treat patients with OA of the knee. These include activity modification, physical therapy, nonsteroidal anti-inflammatory agents, and intra-articular injections (corticosteroid or hyaluronate). All patients with symptomatic OA of the knee should be treated according to these tenets before more aggressive (surgical) methods are employed. Only for some of those who do not respond should the surgical option be considered: patients with radiographic mild arthritis or near-normal alignment but not patients with valgus configurations or arthritis in both knees [1]. So what should Dr. Janus recommend to Mr. Marcus and how should he convey it?

The case description gives limited clinical information from which to base a definitive recommendation. Nonetheless we are told that Mr. Marcus has "severe" disease in the knee(s), implying an advanced, bilateral process, clinical characteristics that are known to correlate with a poor surgical outcome. Hence, based on recent evidence, he does not appear to be a good candidate for arthroscopic surgery. Presenting this opinion to such a hopeful patient will challenge Dr. Janus's skills of care and communication.

Since the 1970s, the literature of medical ethics has been suffused by four major principles: respect for autonomy, nonmaleficence, beneficence, and justice, the first three of which have particular relevance to this case [12]. Respect for patient autonomy means that patients have a right to request the treatment of their choice, which in Mr. Marcus's case is to have surgery. Yet the work of caring for patients must simultaneously maximize benefit and minimize harm, goals that originate with the sometimes conflicting principles of beneficence and nonmaleficence. Dr. Janus must therefore ask himself, "Can the arthroscopy help this patient?"—a calculus that requires him to evaluate the potential benefits of the procedure in relation to the risks, while taking into account the wishes of the patient.

Although the risks of this surgery are typically small, available evidence suggests that the benefit of such surgery is likely to be low; indeed clinical experience suggests such intervention may in some instances exacerbate the symptoms and accelerate joint deterioration. Therefore, though for some patients (such as Mr. Marcus's friend) the procedure may prove beneficial, for Mr. Marcus himself this is unlikely to be the case. Given the low likelihood of success, indeed the potential for making his condition worse, Dr. Janus should advise against surgery and advocate for a more conservative therapeutic strategy. It is critical for Dr. Janus to explain the reasoning and justification for his advice and to ensure that Mr. Marcus comprehends the explanation and, ultimately, finds it satisfactory.

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C. Ronald MacKenzie, MD, is an associate professor of medicine at the Weill Cornell Medical College in New York City and an attending physician at Hospital for Special Surgery, where he holds the C. Ronald MacKenzie Chair in Ethics and Medicine. He is chairman of the American College of Rheumatology Ethics and Conflict of Interest Committee.

Commentary 2

by Matthew J. Matava, MD, and Charles Carroll IV, MD

The scenario described in this vignette is frequently seen by orthopedic surgeons. Arthroscopy of the knee is one of the most common orthopedic procedures performed in the United States [1-3] and has resulted in significant reduction in patient pain and improvement in function. However, some conditions and symptoms, such as pain osteoarthritis in the absence of mechanical symptoms such as locking, catching, and giving-way, have not been found to improve following arthroscopy [4-12]. Although roughly 650,000 arthroscopic procedures for osteoarthritis of the knee

at a cost of approximately $5000 each [1] are performed annually in the United States [13], evidence available on the efficacy of this procedure is inconclusive [4-6, 14]. Most clinical series [4-12, 15, 16] have shown success rates between 50 and 75 percent. It is this lack of success that prompted Moseley et al. [13] in 2002 to investigate the benefit of arthroscopic surgery in a group of older adults suffering from osteoarthritis of the knee.

The study included 180 patients from the Houston Veteran's Affairs Medical Center, 75 years of age and younger, with knee osteoarthritis who reported at least moderate pain despite maximal medical treatment for at least 6 months. They were randomized to three study arms: arthroscopic debridement, arthroscopic lavage, or a sham operation consisting of three 1-cm portal incisions without penetration of the joint capsule. The primary outcome measure was knee pain 2 years after surgery. The authors found no significant difference between treatment arms of the study, thus concluding that routine arthroscopic lavage, debridement, or both were no better than the sham procedure.

Critics of this study point out that flexion weight-bearing radiographs were apparently not done to fully discern the degree of cartilage wear, nor were X-rays taken of the entire lower extremity to assess the mechanical axis of the limb; the study population was largely male and may not be representative of the general population; the degree to which the patients experienced mechanical knee symptoms was not well-described; and the authors used the Knee-Specific Pain Scale as their primary end point even though this is a non-validated measurement that was "created for this study." Therefore, there was harsh criticism from many orthopedic surgeons following the publication of this controversial study.

This study, however, does not lead us to recommend a sham operation to persons suffering from osteoarthritis of the knee. Rather, it suggests that routine knee arthroscopy for osteoarthritis of the knee is not clinically beneficial to any significant degree in those patients who resemble those who participated in the Moseley trial. Considering the financial burden this procedure puts on an already stressed U.S. medical system, unless other studies offer a contrary conclusion, orthopedic surgeons should exhaust other, less expensive, less risky, and more effective treatment options for patients with osteoarthritis of the knee.

Use of Placebo in Clinical Trials

This case raises questions about the potential clinical benefit and ethical ramifications of placebo-controlled trials in surgery. "Equipoise" is considered a central ethical element to consideration of placebo controls. Equipoise refers to uncertainty about which arm of a trial may have greater benefits or harms. In its most basic form, equipoise represents a state of genuine and credible doubt among knowledgeable researchers about the relative therapeutic merits of some set of interventions that target a specific medical condition; to many it represents a necessary condition for ethically acceptable human-subjects research [17].

It is widely accepted that the purpose of evidence-based medicine is to implement medical therapies as "proven" by multicenter randomized controlled trials (RCTs). The current gold standard of evidence is the double-blind RCT, in which the therapy of interest is compared to the accepted treatment or to a placebo. The term "placebo" is commonly used to describe any substance or procedure that a patient accepts as therapy but that has no known mechanism of action other than a patient's belief in its value. Comparison against a placebo is considered the most powerful tool in evaluating the isolated effects of a procedure or treatment on a patient and his or her disease process. The use of a placebo as the control arm of a study is allowed under any of the following circumstances [18]:

- There is no standard treatment;
- New evidence has cast doubt on the standard treatment's benefits or definitively shown it to be no more beneficial than placebo;
- The standard treatment is unavailable due to high cost or short supply;
- The standard treatment has not worked well for a specific patient population;
- An add-on to the standard treatment is being considered; or
- Adequately informed patients have consented to forgo the standard therapy for a minor ailment, like the common cold.

Sham Surgery

The term "sham surgery" is often used when a placebo procedure is used in a surgical trial. "Sham" derives from a Middle English variant of "shame" [19]. As the word suggests, sham surgery has historically been ethically controversial. There is an essential ethical requirement that the sham surgery must pose less risk to subjects than the procedure being tested, which eliminates certain groups from participation in sham-controlled surgical studies, namely, the critically ill, the acutely traumatized, and patients whose conditions can be successfully resolved with a proven safe and effective procedure. Likewise, *sham surgery in clinical research should not be confused with sham surgery in clinical care, where it has no legitimate or ethically supportable role,* even when no effective therapeutic modality is available [19].

Sham surgery is considered acceptable in a clinical trial when:

- It is unclear whether a procedure offers benefits above the placebo effect, which includes benefits due to the "experience of surgery" and the postoperative care regimen;
- The risks are reduced as far as possible in the sham surgery arm without compromising trial design; or
- There is no treatment that has been shown to be better than the standard therapy.

Despite these accepted indications, there has been considerable debate in the literature about the ethical acceptability of using placebos in surgical research.

How can a sham operation bring about improvement in a patient's clinical condition that mimics a true therapeutic intervention? Patients may experience benefits from the hospitalization, better pain management, ancillary treatment, and the more active

sympathy that surgery elicits from all caregivers. These benefits have been shown to include improvement in pain and quality-of-life measurements [20]. These justifications are stronger when there is no clear physiological basis for why a given surgical procedure might work, as in the Mosely trial.

Sham surgery differs from use of medical placebos in several ways—the level of risk being the most obvious one. Subjects who receive placebo medications are receiving a substance with no known medical benefit, but also no risks or side effects. In contrast, sham surgeries involve risk, pain, and deception. Any sham surgery carries the risks—such as bleeding, infection, and anesthesia complications—present in every surgical intervention. They must also cause the subject some pain and appear something like the "real" operation, or subjects will know they did not have the experimental intervention and the placebo effect will be lost. The surgeon who participates in a placebo-controlled surgical trial must also actively strive to deceive the subject. This calculated deception is the basis for the potential power of the sham operation to influence the subject's condition [21].

Critics of sham procedures point out that the use of a procedure that could cause harm without offering a compensating physiologic benefit poses ethical problems and might violate the principle of nonmaleficence [22]. This has led renowned ethicist Ruth Macklin to conclude that "performing surgery in research subjects that has no potential of therapeutic benefit fails to minimize the risk of harm" [23]. Opponents of sham operations argue that, if an intervention of proven effectiveness already exists, and if there is genuine disagreement among medical experts as to whether the new intervention is equally or more effective, then the new intervention must be compared against the established treatment rather than a placebo. If no such established intervention exists, the study intervention may be compared only against a benign placebo [17].

Miller believes that the sham arthroscopic surgeries reported by Moseley and colleagues were warranted because the procedures were relatively innocuous and the research had such clear value for evaluating a common intervention used by over half a million patients a year with total health care costs of some $3 billion [24]. The osteoarthritis study appears to have been methodologically necessary to achieve valid results and was conducted in accordance with ethical guidelines.

An implicit assumption underlies much of the debate over sham surgery—that rational people would not want to have their symptoms relieved by a procedure that draws upon their state of mind instead of succeeding through some intrinsic physiologic effect of the intervention itself. One may ask why we shouldn't learn how to use or enhance these beneficial psychological effects rather than eliminate them. It is not surprising that half of patients reported that the intervention diminished their pain, because according to Moseley et al., "Postoperative care was delivered according to a protocol specifying that all patients should receive the same walking aids, graduated exercise program, and analgesics" [13].

Should our goal be to reduce or to stimulate placebo effects? One may argue that it is unethical *not* to use sham surgery to thoroughly evaluate a surgical procedure before it is introduced into clinical practice. Whatever we decide, it is at least clear that a variety of sham surgeries might be of significant value to both patients and medical science [25].

Case Summary and Ethical Considerations

What should the physician do if a patient in pain who is a good candidate for the intervention comes in and asks for the procedure, saying that he knows that the operation helps only about half the time? On the one hand, a formerly accepted but challenged article leads Dr. Janus to think that the surgery is not warranted or at best may be successful due to a placebo effect. On the other hand, he has provided arthroscopic surgical care to other patients whose conditions resemble Mr. Marcus's with apparent success. The patient has requested the treatment and the physician believes that it can be safely done with a beneficial outcome. What is the physician to do?

At the office visit, a careful history and examination with appropriate radiographic studies should be performed. After a diagnosis is made, the physician should consider both noninvasive and invasive options. Conservative (nonoperative) treatment should be considered initially, followed by more invasive options if they do not bring about improvement. The concerns and goals of the patient need to be explored in the context of current evidence and the ethical imperative to minimize harm. Although one can argue that performing the surgery to achieve the placebo effect places the patient at risk for questionable gains, one can also argue that the benefits outweigh the risks. In spite of this, the surgeon should not embark on a treatment that clearly could harm the patient. Open dialogue will be necessary between patients and physicians to ensure that cost considerations are balanced with safety, ethical principles, and the needs of the patient.

As we go forward, decisions like these will continue to be an issue for patients and physicians. Ethical decisions will be pressured by cost considerations and value-driven health care. In the end, physicians may not be allowed to perform certain procedures if treatment choices are dictated by third-party payers despite an ethically sound approach by the treating physician and an informed patient.

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Matthew J. Matava, MD, is a professor of orthopedic surgery and co-chief of the sports medicine section of the Washington University Department of Orthopedic Surgery in Saint Louis, Missouri. His clinical and research interests include sports-related injuries of the knee and shoulder, articular cartilage restoration, and multiligament knee reconstruction. He is the head team physician for the Saint Louis Rams football team and Washington University varsity athletics and assistant team physician for the Saint Louis Blues hockey team.

Charles Carroll IV, MD, is a hand and orthopedic surgeon at NOI NorthShore Orthopedics and an associate professor of clinical orthopedic surgery at the Feinberg School of Medicine of Northwestern University in Chicago. He is the chairman of the ethics committee for the American Academy of Orthopedic Surgery and the coordinator for ethics of practice for the *Journal of Bone and Joint Surgery*.

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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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ETHICS CASES
Patient Self-Rationing, a Health System Problem
Commentary by Katherine J. Mathews, MD, MPH, MBA

Dr. Jansen is an internist in a small town. He makes it his priority to get to know his patients individually and takes great pride in caring for them as if they were family. One of his regular patients is Mr. Smith, a soft-spoken 55-year-old cashier who has hypertension, type 2 diabetes, and gastroesophageal reflux disease. Throughout the years, Mr. Smith has been punctual and kept his appointments. In just a few months, however, he has canceled two appointments without explanation. Finally, he makes an appointment and keeps it. When he enters the office, Dr. Jansen notices that Mr. Smith looks less healthy than ever before.

"Glad to see you this time, Mr. Smith. Why did you cancel your other appointments?" Dr. Jansen asks, with growing concern about his patient's health.

Mr. Smith explains, "My health insurance has a very high deductible and copay, and I have been struggling so much to pay the bills recently that I just couldn't afford to come in. I figure it's not much use anyway, since I can't afford to pay for my prescriptions either. Just that Nexium you want me to take would bankrupt me. The only reason I'm here today is because I haven't been able to feel my feet since last week, and I'm really worried. But I still won't be able to pay for tests to find out what's wrong, expensive medications, or even a follow-up visit anytime soon. I just don't know what to do."

Commentary
The case of Dr. Jansen and Mr. Smith brings forth a jarring mix of emotions: a Norman Rockwell painting of the small-town doctor clashing with a call from a debt collection agency.
This story of patient self-rationing directs our attention on an interaction between two individuals and asks us to consider how shared decision making between patients and doctors can help improve the use of resources in our current health care environment.

At one level, the strategies are straightforward, falling within the increasingly popular domain of "health literacy." The health literacy perspective assesses what patients do and do not know and focuses on solutions that improve their abilities to grasp complex technical concepts and navigate convoluted and confusing systems of care and health insurance coverage.

As a health care consumer, Mr. Smith is already fairly savvy. He knows about deductibles, copays, and the ever-looming threat of medical debt that can lead to bankruptcy. He understands that brand-name medications can cost an arm and a leg. He is also sensitive to how Dr. Jansen's office works—he cancels his appointments as opposed to just not coming and getting labeled as "noncompliant" and a "no-show."

If we want to continue analyzing the case within the framework of individual decision making and invoke the tools of health literacy, we could advise Dr. Jansen to engage Mr. Smith in the following ways:

Review options, weighing both cost and effectiveness. Inform Mr. Smith of less expensive but equally effective options for diagnosing and treating his condition, if there are any. If there are none, talk with Mr. Smith about less-expensive options that are good enough if not the best. For example, he could take generic omeprazole rather than Nexium. He might even buy over-the-counter formulations, avoiding prescription drugs entirely.

Justify necessary work-up and eliminate unnecessary tests. Dr. Jansen should tell Mr. Smith which tests are necessary to diagnose the source of his loss of sensation in his feet. At the same time, Dr. Jansen must ask himself which test results would contribute to his decision making and which, though informative or confirmatory, would not alter his treatment plans. Is his reflux related to *H. pylori*? Could untreated *H. pylori* be worsening his insulin resistance? In other words, do we have the right mix of diagnoses and treatments?

Initiate conversations about payment plans. When Dr. Jansen has some idea of what testing must be done and what Mr. Smith's plan will cover, he can begin to collaborate with Mr. Smith about a payment schedule for the remainder of the charges. What amount does Mr. Smith think he can pay per month?

Negotiate the frequency and necessity of follow-up. Need for follow-up visits can only be determined after Mr. Smith's diagnosis is known and a treatment plan outlined. But, since Mr. Smith seems reliable and interested in his health, there may be a way to reduce the frequency of face-to-face visits in order to lower and spread out his overall out-of-pocket costs. What self-monitoring and measurements might he be able to track at home, e-mailing or calling in results to Dr. Jansen so as to minimize the number of visits he has to pay for?

With each of these strategies, some costs might be whittled away, enabling Mr. Smith to manage his cash flow a little better. Let's hope Dr. Jansen's office staff are as willing to help Mr. Smith as he is. Dr. Jansen might consider hiring a social worker to provide case management as a way to tackle this mix of medical and financial issues that are probably widespread in their small town.

To summarize this part of the discussion, if we wanted to stay in the framework of individual decision making, we could. But the question is, do we want to work only within this framework? Is the individual level of analysis the correct ethical framing for these issues?

I would argue that it is not and that to do so is risky and potentially harmful to Mr. Smith. Here's the point: if we believe that these problems can all be solved by Mr. Smith's individual decisions and actions, we set up a situation where he's considered solely at fault when things don't work. It's challenging for physicians to face situations that they cannot resolve easily or in which they may be helpless, and there's the horrible temptation to blame the patient by labeling him or her noncompliant or uneducated. But to blame is to cause harm. In the face of large and systemic issues that limit what individual doctors and patients can do, the ethical and therapeutic stance is compassion. Even if Mr. Smith has challenges that Dr. Jansen can't solve, at least he can be aware of everything that Mr. Smith is up against and support him in his efforts.

The major forces at work in this case come not from an interaction between two men but from the financial structure of our current health care system. How so? First, as much as we lament rising health care costs, every dollar spent is somebody else's dollar of revenue. When it comes to large for-profit sectors like the pharmaceutical industry or outpatient dialysis, our national spending translates into highly coveted profit margins.

Second, as many have observed, we don't run a health care system, we run a sick care system. We pay providers when people are sick and can get a medical diagnosis, and the sicker and more complicated the medical case, the higher the reimbursement, especially when a few procedures are included as part of the work-up.

Consider, by contrast—what might have happened to Dr. Jansen and Mr. Smith 10 or 20 years ago if economic incentives had focused on risk reduction? Would Mr. Smith even have type 2 diabetes now? Or perhaps if we more systematically integrated behavioral health into medical care, might we have realized that Mr. Smith suffered from chronic low-grade depression resulting from a series of traumatic events in his childhood? Might we have known that he uses food and alcohol to manage stress, and might we have planned a very different and much more comprehensive wellness plan for him years ago?

Finally, there is one more challenge in illustrating these macro issues with a story about two individuals. As much as stories help us connect to the human side of events, they can also distance us from those human costs if they allow us to think that the story is about other people. Perhaps many readers will identify with Dr. Jansen and the pressures on physicians to manage costs in this complicated health care environment. How many readers will identify with Mr. Smith?

A few years ago, it would not have occurred to me to identify personally with Mr. Smith, as much as I might have known patients in similar situations. Now it does. Because I work in a small, charitably focused not-for-profit clinic, I don't get benefits. I purchase health insurance for my family through a broker and pay rates based on our individual underwriting. I opted for a plan with a relatively low deductible (given my choices) of $5,000 per individual and $10,000 for the family—as long as we stay within network. Because my son has a number of medical conditions, I chose fixed copays for ambulatory care including specialty visits. But his physical therapy and unexpected hospitalization last summer hit against the deductible. I have negotiated the frequency of visits with the physical therapist, and, with the hospitalization, I was quick to invoke my right to a payment plan that spread costs out over 12 months. You might imagine that I'm as health literate as they come, but it has not done much to lower my costs.

In my own 1960s, small-town childhood, our country doctor, Dr. Hobbs, lived around the corner and saw patients in his home. His dark-paneled waiting room included a collection of children's magazines on a bookshelf in an alcove beneath the stairs. As is true of Dr. Jansen, Dr. Hobbs knew everyone in town personally and even made house calls. What is absent from those memories is strife over financial arrangements, the issue at the heart of the story about Dr. Jansen and Mr. Smith. But without understanding the financial arrangements at the macro and micro levels, who benefits and who does not from each cost, we will not have a clear picture of how to create a more effective and sustainable health care system. From an ethical point of view, we will have abandoned our social justice responsibilities.

Katherine J. Mathews, MD, MPH, MBA, is director of clinical services at Casa de Salud, a health care organization that serves low-income, Spanish-speaking people in Saint Louis, Missouri. Dr. Mathews has a long history of public health and health policy work to improve access to high-quality care for the medically underserved.

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ETHICS CASES
Is Understaffing a Unit a Form of Rationing Care?
Commentary by Narayan P. Iyer, MD, and Sabine Iben, MD

Dr. Johnson has been medical director at Saint Theresa Hospital for 6 years and has a reputation for his strong work ethic, highly satisfied patients, interpersonal skills, and decision-making ability. He is often called for guidance in very difficult cases. During his tenure, Saint Theresa Hospital has seen a large increase in patient visits, though the medical staff has not grown accordingly. Treatment costs, manpower, equipment, and other medical expenses have escalated greatly, while the hospital's income has remained fairly consistent. One of the most understaffed departments is neonatology. Last year, the department treated 20 patients with the help of other staff members. Only one of those patients survived past 1 month.

The attending neonatologist at the NICU, Dr. Smith, had just seen a 1-pound baby girl born at 26 weeks' gestation with semilobar holoprosencephaly, tetralogy of Fallot, and esophageal atresia. The baby's APGAR score was 2 at 1 minute and 5 minutes. Dr. Smith approached Dr. Johnson and explained, "We have a neonate who will require several major surgeries to have any chance of survival, and even then the level of function she might attain is uncertain due to her neural malformation. She may or may not ever be able to survive outside of the hospital. The parents are understandably frantic and want everything done to keep the baby alive, but I think it's futile—the last few preemies we saw with similar malformations all died within a month. We simply do not have enough staff on hand to treat the patient and would have to pull from other units. What do you suggest we do?"

Commentary
As soon as questions of will or decision or reason or choice of action arise, human science is at a loss.
A.N. Chomsky [1]

Physicians, in their capacity to provide or deny lifesaving treatment , can inadvertently become-the gatekeepers of medical care. With the spiraling cost of our health care system, doctors are more likely than ever to be asked to consider some form of health care "rationing" in their medical decision making.

Rationing can be defined as "the withholding of a medically beneficial service because of that service's cost to someone other than the patient" [2]. According to Ubel and Goold, in order to meet the criteria for bedside rationing,

> the physician must (1) withhold, withdraw, or fail to recommend a service that, in the physician's best clinical judgment, is in the patient's best medical interests; (2) act primarily to promote the financial interests of someone other than the patient (including an organization, society at large, and the physician himself or herself); and (3) have control over the use of the medically beneficial service [2].

Does our case fulfill the criteria for rationing? Yes, *if* Drs. Smith's and Johnson's reasons for withholding medical care are not primarily based on the infants best interest [2]. Let's analyze their predicament.

A preterm infant born at 26 weeks' gestation has, on average, an 84 percent chance of survival and a 34 percent chance of survival without morbidity [3]. However, the numbers look bleak when this specific infant's additional existing congenital anomalies are taken into consideration. Dr. Smith says that none of the infants treated at this particular hospital with similar congenital malformations survived. In order to have any chance of long-term survival the infant will require multiple major surgeries during a prolonged hospital stay. In the (unlikely) case of survival, major long-term morbidities and poor quality of life for the child and the family seem certain. In this setting, many would consider medical care futile. Finally, like many hospitals in the country, Saint Theresa Hospital is facing financial limitations, and managers and doctors have to decide how to allocate resources most effectively. Given these clinical and economic realities, should the parents' choice of "doing everything" to save the baby's life be honored? Which course of action is more justifiable ethically—aggressive medical treatment or comfort care? Assuming provision of medical care is not considered futile by the medical team, the significance of resource allocation becomes an important factor in determining the course of action in this case.

To help clarify this complex situation, we will consider it through the lens of the four principles of medical ethics popularized by Tom Beauchamp and James Childress: beneficence, nonmaleficence, respect for autonomy, and justice.

Beneficence means putting the patient's welfare at the heart of all decisions. It may be difficult to define which outcome is in the patient's best interest. Many argue that saving a person's life should always supersede concerns about prolonged suffering, pain, and long-term morbidity. Others consider "quality" to be more important than "quantity" of life. In the latter view, providing comfort care until the eventual death would be consistent with the principle of beneficence.

Nonmaleficence is doing no harm. Generally, the harms of such treatments as surgical procedures are accepted because they prevent a greater harm—death or increased disability. In the case at hand, the harm would be inflicted in the attempt to secure uncertain survival. According to this principle and considering the grim

prognosis, it may not be justifiable to put the infant through the traumatic intensive care.

The principle of respect for autonomy recognizes the right of an individual to self-determination. In the case of unemancipated minors this right is generally exercised by the parents, who are considered most able to act in their child's best interest. There may be a conflict between the recommendations of clinicians and the choices parents make. If the parents' preferences fall within the range of standard medical care, they have to be respected; otherwise relevant laws protect children from endangerment and physicians from liability. If the parents in our case continue to request full medical treatment and the infant is not resuscitated, their parental autonomy is violated.

Justice refers to fairness in access to care. At the core of rationing decisions lies a specific type of justice called distributive justice. Distributive justice involves equitable and appropriate distribution of limited resources [4]. It is important to recognize that the interpretation of distributive justice depends on the context [5]. In the libertarian framework, individuals are fully responsible for their own health. Each individual has the right to decide when and for what to seek treatment. In the communitarian concept, the criteria for justice is based on what the society considers is necessary health care. In the utilitarian concept, justice means improving the health of the society as a whole. The motive behind this concept is largely economic—available financial resources should be used in a way that achieves the greatest possible health gain for the whole population. Thus, in this concept, it is justifiable to withhold expensive and relatively ineffective treatments for rare conditions. Finally, the egalitarian principle of distributive justice holds that those with like needs get like care [5]. Because the U.S. health care system is both publicly and privately funded, it reflects many if not all of the views of justice explained here. Hence arguments can be and are made for both granting and withholding intensive care for our infant.

Armstrong and Whitlock describe six criteria that could be "weighed in the balance" to resolve allocation dilemmas like this one [6]. Specifically, the criteria that may be applied to our case are need and equality.

a) Need: Does the baby have a need for medical intervention? It is clear that the infant will die without intensive care. Other than elective procedures, most interventions in medicine are needed, although the degree of need may be perceived differently by the patient and the medical staff. Therefore, allocation of resources based on the "need criterion" alone is not practical or financially sustainable.
b) Equality: Equal distribution of health care resources is not a useful concept by itself. Under this standard, it would not be justified to spend excessive resources for intensive care for our infant while healthy persons use only minimal resources (say for preventive visits). Traditionally, the insurance model is based upon pooling of funds to allow distribution of resources from those using less to those needing more. Most people will agree that

c) Contribution: Contribution to the society cannot be used as the sole criterion for allocating of resources. In the case of newborns, it is impossible to project future contributions to society and it would clearly be unfair to deny care for that reason.
d) Ability to pay: To deny health care services because of one's inability to pay goes against the fundamental belief that every individual has the right to receive emergency medical care regardless of citizenship, legal status, or ability to pay, as specifically outlined in the Emergency Treatment And Labor Act (EMTALA) of 1986.
e) Effort: A person's effort to improve his or her own health has been used as a criterion for allocating resources. It is reasonable to make allocation decisions about limited resources based on the patient's effort to support the care they receive. This criterion has been used for organ allocation—patients who are not compliant with their pretransplant care regimens may not be transplant candidates for that reason—but in the case of children or mentally handicapped patients, or in a clinical situation like this one that is not dependent on patient effort, this criterion is obviously not applicable.
f) Merit: Allocation of resources can be judged on the potential that the investment will benefit the patient. Clinical research and experience are used to determine whether a particular intervention's likelihood of success warrants the treatment. The use of exceedingly costly medical therapies may not be questioned when there is a reasonable chance of cure; it is more likely to be questioned when there is a low likelihood of improving the life expectancy of a terminally ill patient. In our case the potential benefit would be a life saved, but the chance of success is very low. If she lives, the baby is likely to be severely disabled and need chronic care. Societal and parental values regarding what constitutes a reasonable quality of life modulate the standard of "potential benefit." The reason the physicians in the case are discussing not offering care is that the chance of success (life with reasonable quality) is exceedingly low.

The American Medical Association (AMA) *Code of Medical Ethics* provides guidance on resource allocation. According to the code, nonmedical criteria such as ability to pay, age, social worth, perceived obstacles to treatment, the patient's effort to improve his or her health, or past use of resources should not be considered while allocating limited resources [7].

Keeping the aforementioned ethical concepts in mind, doctors and hospital managers need to have a process in place for making resource allocation decisions preferably as soon as limitations of resources are recognized. The process should be fair, inclusive, and transparent [8]. A process that fulfills these criteria will provide procedural justice, according to the belief that "if the process is fair, the outcome will likely be fair as well" [9]. An example could be a meeting of hospital managers,

doctors, and nurses to understand and navigate through the diversity of positions, possibly with the input of an ethics committee or consultant.

Given that rationing decisions are made within the constraints of the institution's financial viability, is the team obligated to invite parents to these meetings? According to the AMA, "patients denied access to resources have the right to be informed of the reasoning behind the decision" [7]. Hospital staff may choose to follow through with the decision making first and involve parents after a consensus has been reached. As in other situations when the medical team is choosing to limit therapies, a parent's wish to contact other institutions, if available, should be facilitated.

Case Analysis

At the organizational level, when various goods are in competition, the first priority should be the patient's quality of care, followed by professional excellence, and finally the organization's financial stability [8].

The case presented here reveals rationing at the institutional level. By not adequately staffing the neonatal unit, the hospital administration is withholding optimal care from newborn infants. It is likely that the poor outcomes in the neonatal unit are related to this chronic understaffing. In the vignette described here, the grim prognosis means that instituting intensive care may very well be considered futile and not in the infant's best interest and should therefore not be instituted. Nevertheless, physicians should ensure that the principles of distributive justice are not violated—care should be continued or discontinued on the basis of medical benefit, not financial concerns. Parents should be involved in the decision-making process and their views respected. Frequently, parents realize the futility of care with appropriate counseling and support. The hospital administration should use this opportunity to create a system in which rationing decisions are made in consultation with all stakeholders (including patient representatives) in a transparent way.

In summary, rationing of care is increasingly becoming a reality, but it need not compromise ethics. Using sound principles, physicians will be able do justice to their patients, profession, organization, and society.

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Narayan P. Iyer, MD, is a fellow in neonatology in the Case Western Reserve University-Cleveland Clinic Foundation-MetroHealth Medical Center Neonatal-Perinatal Fellowship whose research interests include neonatal pulmonary mechanics and quality improvement.

Sabine Iben, MD, became interested in bioethics while dealing with complex ethical cases as a staff neonatologist and neonatal director of the Fetal Care Center at the Cleveland Clinic Foundation in Ohio. Dr. Iben has a certificate in pediatric bioethics from Children's Mercy Hospital in Kansas City.

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MEDICAL EDUCATION

The Family Medicine Accelerated Track Model: Producing More Family Doctors Faster

Betsy Goebel Jones, EdD, and Steven L. Berk, MD

In their 2010 book *Educating Physicians: A Call for Reform of Medical School and Residency* [1], timed to coincide with the centennial of Abraham Flexner's groundbreaking report, Molly Cooke, David Irby, and Bridget O'Brien posed the key question of resource use in medical education: *Can we produce competent and compassionate physicians more efficiently and effectively?* Indeed, that quest for efficiency and effectiveness demands an accounting of the costs and products of medical education, including high tuition and student debt and low numbers in the primary care physician workforce essential to meeting the nation's health care needs. In our current milieu, which stresses resource use that promotes *better care*, *better health,* and *lower cost*, the Texas Tech University Health Sciences Center School of Medicine (TTUSOM) is attempting a new path to all three goals: the Family Medicine Accelerated Track (FMAT). FMAT is a 3-year medical school curriculum that culminates in the MD degree and places students in one of our three family medicine residency programs.

Context

The U.S. primary care crisis has been well documented in lay, academic, and policy circles [2-5]. Expanded access to health care as part of the Affordable Care Act (ACA) will worsen this physician shortage, as millions more Americans enter a health care system that is ill equipped to handle them [6]. The Association of American Medical Colleges (AAMC) and U.S. medical schools have recognized this potential workforce crisis and have committed to increasing the number of graduating medical students by 15 to 30 percent [7].

The crisis will not be averted, moreover, unless the increasing imbalance of generalists to specialists is also addressed [8-10] apart from efforts to increase the number of medical school graduates. According to the Kaiser Family Foundation, 56 percent of U.S. patient visits are to primary care clinicians, but only 37 percent of physicians practice primary care medicine, leaving the nation's most vulnerable populations—the uninsured, low-income, those in rural or inner-city areas—without a usual source of care [11].

Rebalancing the Workforce

So how can we ameliorate the shortage? By turning out primary care doctors more quickly and by reducing the obstacles for students to pursue primary care. The Council on Graduate Medical Education (COGME) and others [12, 13] have

highlighted accelerated training as a means of promoting primary care. The 2010 COGME report, "Advancing Primary Care," noted that "workforce researchers have argued for years that one way to quickly increase the supply of physicians is to reduce the number of years of training," which has additional usefulness for students entering less-lucrative specialties, and they write approvingly of "primary care fast track programs where students are ensured of preferential admission to generalist residency programs" [14].

The financial benefits of condensed training may be linked to specialty choice. The cost of undergraduate medical education has, in recent years, risen at twice the rate of inflation [15]. U.S. medical school seniors responding to the AAMC Graduate Questionnaire revealed a debt increase of more than $18,000 between 2007 and 2011 [16]; median debt among U.S. seniors in 2011 was $162,000 [17]. The relationship between tuition debt and specialty choice is complicated [18-20], but the role of student debt and of the disparity in compensation between primary and subspecialty care cannot be discounted in explaining why only 8.4 percent of U.S. seniors in MD and DO programs matched into family medicine residences, filling only 48.2 percent of residency positions [21].

Reforming the cost of medical education, as a means of reducing the role that student debt plays, may be an important way of enabling students to feel comfortable pursuing primary care. Peter Bach and Robert Kocher, writing in the *New York Times*, proposed that predoctoral training should be free, but postdoctoral specialty training should bear a cost to the trainee, meaning that only those who are "virtually assured highly lucrative jobs" would accrue debt [22].

Accelerated training in primary care—as typified by FMAT—is another method of cost reform. Ray Dorsey, David Nincic, and Sanford Schwartz evaluated four methods to reduce the financial burden of medical education—reducing medical school tuition, decreasing medical school duration, increasing residency compensation, and decreasing residency duration [23]. Of those methods, decreasing medical school duration offered the greatest potential for reducing the financial burden. Even without financial incentives and scholarships, students in accelerated training tracks pay (and incur debt) for one fewer year of medical school, a benefit that also accrues to funders of medical education, including state and federal governments.

At TTUSOM, we calculate that FMAT decreases our students' debt load by about $86,800. This difference results partly from the institution's commitment of about $15,500 to cover tuition and fees for the second year, but mostly from eliminating the usual fourth-year tuition debt and replacing it with a resident's salary and benefits totaling about $52,800. As Dorsey et al. pointed out, this also reduces the burden on students of the "the high opportunity cost each year of training holds" [24].

The decision to cover at least one year of FMAT students' tuition and fees was integral to our commitment to reducing student debt. We chose the second year of medical school so that students would benefit from a reduced debt load early in their training. Funding sources include existing scholarship funds earmarked for FMAT as an institutional priority; we also have a Health Resources and Services Administration predoctoral primary care training grant through 2015.

Decreasing the duration of medical education—especially to encourage students to pursue primary care—is not a new idea. The accelerated residency program was piloted in the 1990s, and it proved successful in attracting U.S. graduates to primary care. Between 1989 and 2002, 15 medical schools participated in the pilot [25]. Among the findings from extensive evaluation of programs and learners: high performance on standardized exams, improved prestige and morale for those in primary care, and early recognition of leadership, as measured by graduates' career choices and subsequent positions [25-28]. Despite that success, these pilot programs were discontinued by 2002, primarily because their structure, which combined the fourth year of medical school with the first year of residency, conflicted with the guidelines of the Accrediting Council of Graduate Medical Education (ACGME), which requires that all residency trainees be graduates of accredited medical schools or already licensed to practice medicine [29].

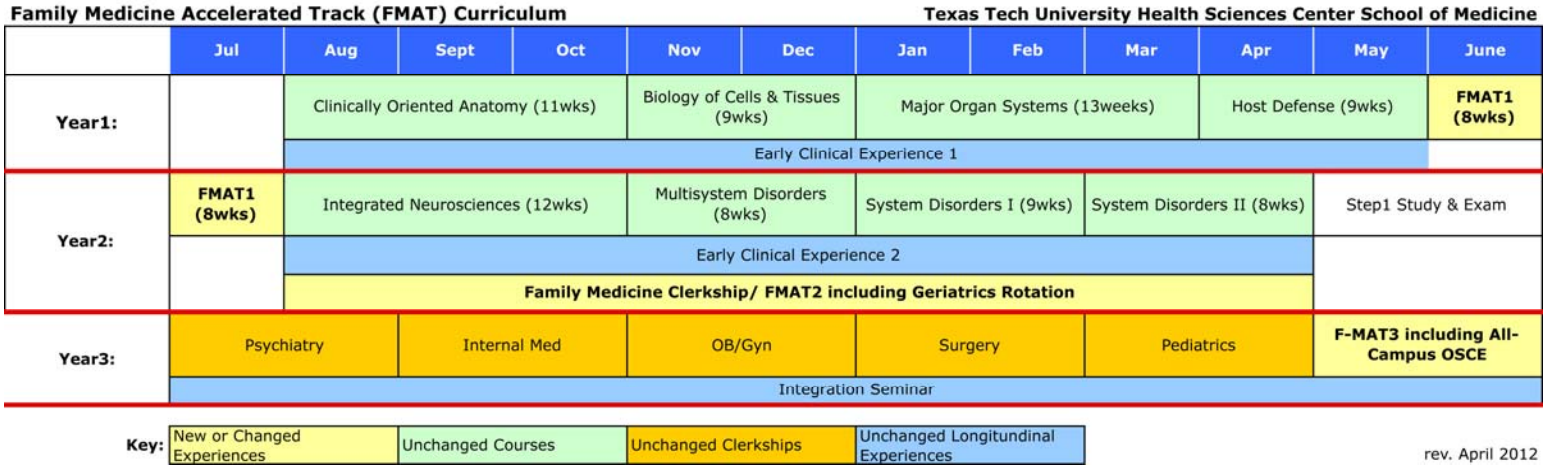
How FMAT Works

The FMAT program differs from the earlier pilot program models in that students receive the MD degree at the end of 3 years before entering a 3-year residency program. Currently, students may apply to the FMAT program at two points in time: when applying to TTUSOM and midway through their first year, following fall orientation sessions. Applicants in the former group who are invited for a campus visit meet with an FMAT faculty member in addition to their other interviews. Enrolled TTUSOM students who apply to the program also interview with the FMAT selection committee, whose members are faculty in the program. Of a class of 8-12 students, about half are selected from each of the two application methods. The entire class is in place by mid-spring, prior to the beginning of FMAT coursework in June.

All students at the Texas Tech School of Medicine complete the first 2 years of medical school in Lubbock, before they are distributed for clinical training among the regional campuses in Amarillo, Odessa, or Lubbock in the summer between their second and third years. FMAT students complete the standard first- and second-year basic sciences blocks and third-year clerkship rotations with very few alterations from the 4-year program. All clerkship rotations in TTUSOM's 4-year curriculum are 8 weeks long, including family medicine. Whereas the 4-year curriculum spans 160 weeks, FMAT covers 149 weeks; both curricula exceed the Liaison Committee on Medical Education's requirement that a "medical education program must include at least 130 weeks of instruction" [30]. The FMAT curriculum includes 3 courses distinct from the 4-year track's: an 8-week systems-based course taken in the summer between the first and second years, a longitudinal family medicine clerkship

in the second year (the equivalent of a 12-week experience), and a third-year capstone course that covers senior selective and critical care experiences (see figure 1). The capstone course is conducted on the distributed campuses where students will also complete their family medicine residency training [31, 32].

Figure 1. TTUSOM FMAT curriculum



Students may opt out of FMAT and return to the 4-year curriculum at any time. The accelerated nature of the program cannot accommodate time for remediation, so a student who encounters academic difficulty would be counseled to move to the traditional curriculum.

Significantly, the FMAT program at Texas Tech is limited to family medicine, as opposed to primary care more broadly. National and local data indicate that only 10 to 20 percent of internal medicine residency graduates choose primary care careers, down from 54 percent a decade ago [33], and only about 40 percent of pediatrics graduates remain in primary care [34]. In contrast, more than 90 percent of family medicine graduates make careers in primary care, and almost 40 percent do so in communities of fewer than 25,000 people or areas of the inner city that could be considered low-income [35]. The FMAT program is designed so that students transition to one of our family medicine residency programs in West Texas, all of which have a strong track record of placing graduates in rural and underserved communities where the lack of primary care physician workforce is most acute.

Evaluating the Program

Evaluation of the FMAT program will, by necessity, be a long-term process, especially if the ultimate goal is a net gain in the primary care physician workforce. Interim metrics include student interest and program completion, as well as performance in courses, clerkships and standardized exams. We anticipate following our graduates to assess satisfaction and competencies into residency and well beyond, especially as we seek to improve curriculum elements and student experiences.

As of the fall of 2012, the FMAT program includes 9 students in the class of 2013 who will go through the match and graduate in 2013, 7 students in the class of 2014 who are in the midst of the longitudinal family medicine clerkship, and 4 first-year students who will be joined by another 5-8 students to complete the class of 2015. All nine students in the FMAT class of 2013 passed Step 1 with scores at about the national average. These students performed better than their peers in the traditional program on an end-of-second-year objective structured clinical examination (89.12 vs. 88.35) but less well than their peers on an OSCE at the end of their third-year clerkship (92.38 vs. 95.03). One class of students, however, yields numbers too low to determine statistical significance.

Program improvements from our first to second years include adding procedures workshops and ultrasound training, allowing students more control over their schedules and improving patient and health care team continuity. Continuous feedback from students, faculty, and residents, as well as formal evaluations and focus groups, drove these changes, as well as other course corrections.

The 2-part application process outlined above was adopted to expand the FMAT applicant pool, beginning with the class of 2015. All students in the classes of 2013 and 2014 were chosen from among first-year TTUSOM students, which effectively limited the number of potential students to about 150.

It may well be asked whether the FMAT program's efficiencies resonate with its students. For a poster that they initiated and prepared for the 2011 AAMC Annual Conference Innovations in Medical Education session, one member of the FMAT class of 2013 reflected on personal experiences in allocating the limited personal resources required to succeed in an intensive accelerated program, saying: "Right now is the most stressful time I've experienced in medical school…. I have noticed a definite decrease in my test grades, but this might be due simply to the fact that neuro is a harder course. All of this being said, however, I would not trade the clinic time. Clinic is interesting [and] exciting and will be 100 percent relevant to my future as a family physician. The same cannot necessarily be said for neuro."

Future Directions for Accelerated Training

Without question, accelerated training is not for every medical student. The ideal FMAT candidate is perhaps that student who is strong enough academically to withstand a rigorous schedule and sure enough of his or her career goals to select family medicine in the first year of medical school. Indeed, it is that early decision—both specialty choice and residency location—that obviates the need for much of the elective and try-out rotations that often comprise the fourth year of medical school [13].

By the same token, accelerated training programs that promote primary care are not for every medical school. Such programs require faculty time, clinic space, and administrative advocates at the highest level. A September 9, 2012, article in the *New York Times*, "Luring Students Into Primary Care," noted that TTUSOM's

"mind-set around primary care" is perhaps more positive than all schools enjoy [36]. Even so, a number of other schools—Mercer University, Louisiana State University, and the Medical College of Wisconsin, to name three—are developing their own accelerated models, and we anticipate that a growing cohort of schools will lead to shared curricula, evaluation strategies, and recommendations for best practices. At TTUSOM, we posit that accelerated training is a dramatic strategy to expand the primary care physician workforce, and we are privileged to engage that "mind-set" toward our shared goals of better care, better health and lower cost.

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Betsy Goebel Jones, EdD, is a professor and vice chair of the Department of Family and Community Medicine at the Texas Tech University Health Sciences Center School of Medicine in Lubbock. She is a member of the Family Medicine Accelerated Track leadership team and regional director of the Laura W. Bush Institute for Women's Health.

Steven L. Berk, MD, is executive vice president and provost of Texas Tech University Health Sciences Center and a professor of internal medicine and dean of the TTUHSC's School of Medicine in Lubbock. He is board certified in infectious diseases and geriatric medicine. Dr. Berk served as chairperson of the Department of Internal Medicine at East Tennessee State University's Quillen College of Medicine during the time of its accelerated residency program.

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American Medical Association Journal of Ethics
November 2012, Volume 14, Number 11: 854-860.

THE CODE SAYS
The AMA *Code of Medical Ethics*' Opinions on Cost Containment, Payment Structures, and Financial Incentives

Opinion 8.054 - Financial Incentives and the Practice of Medicine
In order to achieve the necessary goals of patient care and to protect the role of physicians as advocates for individual patients, the following statement is offered for the guidance of physicians:

(1) Although physicians have an obligation to consider the needs of broader patient populations within the context of the patient-physician relationship, their first duty must be to the individual patient. This obligation must override considerations of the reimbursement mechanism or specific financial incentives applied to a physician's clinical practice.

(2) Physicians, individually or through their representatives, should evaluate the financial incentives associated with participation in a health plan before contracting with that plan. The purpose of the evaluation is to ensure that the quality of patient care is not compromised by unrealistic expectations for utilization or by placing that physician's payments for care at excessive risk. In the process of making judgments about the ethical propriety of such reimbursement systems, physicians should refer to the following general guidelines:

(a) Monetary incentives may be judged in part on the basis of their size. Large incentives may create conflicts of interest that can in turn compromise clinical objectivity. While an obligation has been established to resolve financial conflicts of interest to the benefit of patients, it is important to recognize that sufficiently large incentives can create an untenable position for physicians,

(b) The proximity of large financial incentives to individual treatment decisions should be limited in order to prevent physicians' personal financial concerns from creating a conflict with their role as individual patient advocates. When the proximity of incentives cannot be mitigated, as in the case of fee-for-service payments, physicians must behave in accordance with prior Council recommendations limiting the potential for abuse. This includes the Council's prohibitions on fee-splitting arrangements, the provision of unnecessary services, unreasonable fees, and self-referral. For incentives that can be distanced from clinical decisions, physicians should consider the following factors in order to evaluate the correlation between individual act and monetary reward or penalty:

(i) In general, physicians should favor incentives that are applied across broad physician groups. This dilutes the effect any one physician can have on his or her financial situation through clinical recommendations, thus allowing physicians to provide those services they feel are necessary in each case. Simultaneously, however, physicians are encouraged by the incentive to practice efficiently.

(ii) The size of the patient pool considered in calculations of incentive payments will affect the proximity of financial motivations to individual treatment decisions. The laws of probability dictate that in large populations of patients, the overall level of utilization remains relatively stable and predictable. Physicians practicing in plans with large numbers of patients in a risk pool therefore have greater freedom to provide the care they feel is necessary based on the likelihood that the needs of other plan patients will balance out decisions to provide extensive care.

(iii) Physicians should advocate for the time period over which incentives are determined to be long enough to accommodate fluctuations in utilization resulting from the random distribution of patients and illnesses. For example, basing incentive payments on an annual analysis of resource utilization is preferable to basing them on monthly review.

(iv) Financial rewards or penalties that are triggered by specific points of utilization may create enormous incentives as a physician's practice approaches the established level. Therefore, physicians should advocate that incentives be calculated on a continuum of utilization rather than a bracketed system with tiers of widely varied bonuses or penalties.

(v) Physicians should ascertain that a stop-loss plan is in place to prevent the costs associated with unusual outliers from significantly impacting the reward or penalty offered to a physician.

(3) Physicians also should advocate for incentives that promote efficient practice, but are not be designed to realize cost savings beyond those attainable through efficiency. As a counterbalance to the focus on utilization reduction, physicians also should advocate for incentives based on quality of care and patient satisfaction.

(4) Patients must be informed of financial incentives that could impact the level or type of care they receive. Although this responsibility should be assumed by the health plan, physicians, individually or through their representatives, must be prepared to discuss with patients any financial arrangements that could impact patient care. Physicians should avoid reimbursement systems that, if disclosed to patients, could negatively affect the patient-physician relationship.

Issued June 1998 based on the report "Financial Incentives and the Practice of Medicine," adopted December 1997; updated June 2002.

Opinion 8.13 - Managed Care

The expansion of managed care has brought a variety of changes to medicine including new and different reimbursement systems for physicians with complex referral restrictions and benefits packages for patients. Some of these changes have raised concerns that a physician's ability to practice ethical medicine will be adversely affected by the modifications in the system. In response to these concerns, the following points were developed to provide physicians with general guidelines that will assist them in fulfilling their ethical responsibilities to patients given the changes heralded by managed care.

(1) The duty of patient advocacy is a fundamental element of the patient-physician relationship that should not be altered by the system of health care delivery. Physicians must continue to place the interests of their patients first.

(2) When health care plans place restrictions on the care that physicians in the plan may provide to their patients, physicians should insist that the following principles be followed:

(a) Any broad allocation guidelines that restrict care and choices--which go beyond the cost/benefit judgments made by physicians as a part of their normal professional responsibilities--should be established at a policy-making level so that individual physicians are not asked to engage in bedside rationing.

(b) Regardless of any allocation guidelines or gatekeeper directives, physicians must advocate for any care they believe will materially benefit their patients.

(c) Physicians should be given an active role in contributing their expertise to any allocation process and should advocate for guidelines that are sensitive to differences among patients. Health care plans should create structures similar to hospital medical staffs that allow physicians to have meaningful input into the plan's development of allocation guidelines. Guidelines for allocating health care should be reviewed on a regular basis and updated to reflect advances in medical knowledge and changes in relative costs.

(d) Adequate appellate mechanisms for both patients and physicians should be in place to address disputes regarding medically necessary care. In some circumstances, physicians have an obligation to initiate appeals on behalf of their patients. Cases may arise in which a health plan has an allocation guideline that is generally fair but in particular circumstances results in unfair denials of care, i.e., denial of care that, in the physician's judgment, would materially benefit the patient. In such cases, the physician's duty as patient advocate requires that the physician challenge the denial and argue for the provision of treatment in the specific case. Cases may also arise when a health plan has an allocation guideline that is generally unfair in its operations. In such cases, the physician's duty as patient advocate requires not only a challenge to any denials of treatment from the guideline but also advocacy at the health plan's policy-making level to seek an elimination or modification of the

guideline. Physicians should assist patients who wish to seek additional, appropriate care outside the plan when the physician believes the care is in the patient's best interests.

(e) Health care plans must adhere to the requirement of informed consent that patients be given full disclosure of material information. Full disclosure requires that health care plans inform potential subscribers of limitations or restrictions on the benefits package when they are considering entering the plan.

(f) Physicians also should continue to promote full disclosure to patients enrolled in health care plans. The physician's obligation to disclose treatment alternatives to patients is not altered by any limitations in the coverage provided by the patient's health care plan. Full disclosure includes informing patients of all of their treatment options, even those that may not be covered under the terms of the health care plan. Patients may then determine whether an appeal is appropriate, or whether they wish to seek care outside the plan for treatment alternatives that are not covered.

(g) Physicians should not participate in any plan that encourages or requires care below minimum professional standards.

(3) When physicians are employed or reimbursed by health care plans that offer financial incentives to limit care, serious potential conflicts are created between the physicians' personal financial interests and the needs of their patients. Efforts to contain health care costs should not place patient welfare at risk. Thus, physicians should accept only those financial incentives that promote the cost-effective delivery of health care and not the withholding of medically necessary care.

(a) Physicians should insist that any incentives to limit care must be disclosed fully to patients by plan administrators upon enrollment and at least annually thereafter.

(b) Physicians should advocate that limits be placed on the magnitude of fee withholds, bonuses, and other financial incentives to limit care and that incentive payments be calculated according to the performance of a sizable group of physicians rather than on an individual basis.

(c) Physicians should advocate that health care plans or other groups develop financial incentives based on quality of care. Such incentives should complement those based on the quantity of services used.

(4) Physicians should encourage both that patients be aware of the benefits and limitations of their health care coverage and that they exercise their autonomy by public participation in the formulation of benefits packages and by prudent selection of health care coverage that best suits their needs.

Issued June 1996 based on the report "Ethical Issues in Managed Care," adopted June 1994; updated June 2002.

Opinion 8.051 - Conflicts of Interest under Capitation
The application of capitation to physicians' practices can result in the provision of cost-effective, quality medical care. It is important to note, however, that the potential for conflict exists under such systems. Physicians who contract with health care plans should attempt to minimize these conflicts and to ensure that capitation is applied in a manner consistent patients' interests.

(1) Physicians have an obligation to evaluate a health plan's capitation payments prior to contracting with that plan to ensure that the quality of patient care is not threatened by inadequate rates of capitation. Physicians should advocate that capitation payments be calculated primarily on the basis of relevant medical factors, available outcomes data, the costs associated with involved providers, and consensus-oriented standards of necessary care. Furthermore, the predictable costs resulting from existing conditions of enrolled patients should be considered when determining the rate of capitation. Different populations of patients have different medical needs and the costs associated with those needs should be reflected in the per member per month payment. Physicians should seek agreements with plans that provide sufficient financial resources for all care that is the physician's obligations to deliver and should refuse to sign agreements that fail in this regard.

(2) Physicians must not assume inordinate levels of financial risk and should therefore consider a number of factors when deciding whether or not to sign a provider agreement. The size of the plan and the time period over which the rate is figured should be considered by physicians evaluating a plan as well as in determinations of the per member per month payment. The capitation rate for large plans can be calculated more accurately than for smaller plans because of the mitigating influence of probability and the behavior of large systems. Similarly, length of time will influence the predictability of the cost of care. Therefore, physicians should advocate for capitation rates calculated for large plans over an extended period of time.

(3) Stop-loss plans can prevent the potential of catastrophic expenses from influencing physician behavior. Physicians should ensure that such arrangements are finalized prior to signing an agreement to provide services in a health plan.

(4) Physicians must be prepared to discuss with patients any financial arrangements which could impact patient care. Physicians should avoid reimbursement systems that, if disclosed to patients, could negatively affect the patient-physician relationship.

Issued December 1997 based on the report "The Ethical Implications of Capitation," adopted June 1997; updated June 2002.

Opinion 8.056 - Physician Pay-for-Performance Programs
Physician pay-for-performance (PFP) compensation arrangements should be designed to improve health care quality and patient safety by linking remuneration to measures of individual, group, or organizational performance. To uphold their ethical obligations, physicians who are involved with PFP programs must take appropriate measures to promote patients' well-being.

(1) Physicians who are involved in the design or implementation of PFP programs should advocate for:

(a) incentives that are intended to promote health care quality and patient safety, and are not primarily intended to contain costs;

(b) program flexibility that allows physicians to accommodate the varying needs of individual patients;

(c) adjustment of performance measures by risk and case-mix in order to avoid discouraging the treatment of high-risk individuals and populations;

(d) processes to make practice guidelines and explanations of their intended purposes and the clinical findings upon which they are based available to participating physicians.

(2) Practicing physicians who participate in PFP programs while providing medical services to patients should:

(a) maintain primary responsibility to their patients and provide competent medical care, regardless of financial incentives;

(b) support access to care for all people and avoid selectively treating healthier patients for the purpose of bolstering their individual or group performance outcomes;.

(c) be aware of evidence-based practice guidelines and the findings upon which they are based;

(d) always provide care that considers patients' individual needs and preferences, even if that care conflicts with applicable practice guidelines;

(e) not participate in PFP programs that incorporate incentives that conflict with physicians' professional values or otherwise compromise physicians' abilities to advocate for the interests of individual patients.

Issued June 2006 based on the report "Physician Pay-for-Performance Programs," adopted November 2005.

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Virtual Mentor
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JOURNAL DISCUSSION
The Inconclusive Evidence on CT Screening for Lung Cancer
David S. Gierada, MD, and Lawrence M. Kotner, Jr., MD

Lee CI, Forman HP. CT screening for lung cancer: implications on social responsibility. *AJR Am J Roentgenol*. 2007;188(2):297-298.

Mortality rates due to lung cancer are truly staggering. It is estimated that, in 2012 as in previous years, there will be more than 220,000 new lung cancer cases and more than 160,000 deaths due to lung cancer in the United States [1]. This is far more than the number of deaths from breast, colon, and prostate cancer, the next three most common causes of cancer death, combined. Most patients with lung cancer are diagnosed at an advanced stage of the disease, and 5-year survival rates have remained near 15 percent for many decades [2]. Past attempts to detect and treat lung cancer before symptoms occur, by screening with chest radiography (CXR) and sputum cytology, did not reduce mortality [3]. About 40 percent of the U.S. population are smokers or former smokers [4], and, after a period of declining, smoking rates have leveled off at around 20 percent [5]. Without improvement in prevention, detection, and treatment, high lung cancer mortality rates are all but guaranteed to continue.

The ability to detect small lung cancers at an early stage using low-radiation-dose CT has been the most promising such improvement since its potential was first demonstrated in the late 1990s [6-8]. The initial and numerous subsequent studies reported 0.5-2.7 percent of persons screened were diagnosed with cancer, the majority of which were early-stage and treatable by surgery [9]. Far greater long-term survival was predicted for these CT screen-detected cancers than is typical for non-screen-detected cancers [10]. But due to inadequate statistical power in some studies, lack of control groups in others, possible lead-time bias (the possibility that earlier diagnosis extends not survival but merely the length of time a person lives with the knowledge of having the disease), and overdiagnosis, the true mortality benefit of CT screening has remained uncertain.

In this context, Lee and Forman [11] noted an increase in enthusiasm for lung cancer screening in 2007, despite a lack of endorsement by any major medical organizations. Stressing the importance of an approach to screening that is sensitive to the well-being of patients and socially responsible, the authors pointed out the inconclusive evidence of benefit, uncertainty regarding risks and economic costs, and the potential for diversion of resources away from other health care initiatives. They advocated patient education regarding potential benefits and risks, a uniform

approach to informed consent, and continued research to define properly the benefits, risks, costs, and alternatives.

Following the completion of the National Lung Screening Trial (NLST) in late 2010, the benefits and risks have become much better defined. The NLST recruited more than 50,000 smokers and former smokers between the ages of 55 and 74, with at least a 30-pack-year (year of pack-per-day smoking) history of smoking, to be screened annually for 3 years by either low-dose chest CT or posteroanterior chest x-ray [12]. After a median 6.5 years of follow-up, the lung cancer mortality rate was 20 percent lower in the CT screening group [13]. This translated to the prevention of one lung cancer death for every 320 people screened, a frequency even more favorable than estimates for screening mammography [14]. Viewed from the perspective of the individual, the benefit seems more modest; the chance of an individual dying from lung cancer in the CT arm was 1.33 percent compared to 1.66 percent in the CXR arm. However, more than a third of the lung cancers in the CT arm were diagnosed during follow-up after screening had ceased or after a missed screen. The actual benefit of CT screening therefore may be even greater if, as with mammography [15], annual screening continues and the impact of screening increases with greater follow-up time. In addition, screening may be of greater benefit to those at greatest risk based on their age and smoking history [16].

More than 25 percent of all CT screening examinations were classified as positive due to the presence of at least one noncalcified pulmonary nodule 4 mm or larger in diameter, but more than 95 percent of these positive examinations were falsely positive, requiring additional diagnostic evaluation. Death occurred within 60 days of a screen-prompted invasive diagnostic or therapeutic procedure following 0.1 percent of all positive screens, including 1.5 percent of those diagnosed with lung cancer and 0.1 percent of those not diagnosed with lung cancer. These rates are well below the 1.33 percent rate of lung cancer death among all trial participants and the 34 percent death rate of all those with lung cancer, respectively, in the CT arm of the trial.

Ethical Considerations

In deciding whether CT screening is prudent routine clinical practice, the potential harms must be considered in addition to the benefits. Whether the outcomes of the NLST can be duplicated in the general medical community without increasing the use and risks of invasive testing will need to be considered in decisions related to promoting the use of CT screening as part of health care policy. Development of professional guidelines and accreditation for the workup of positive screens could be a means of ensuring the quality of care necessary for a positive impact.

Another important concern in CT screening is reader variability, which can be substantial; radiologists vary in their ability to detect small nodules, in the measurement of the nodules detected, and even in whether they classify a visible abnormality as suspicious for cancer [17, 18]. Computer programs that help detect and measure lung nodules appear promising as a means of reducing this variability

[19]. Better standardization of interpretation will be an important aspect of insuring the consistency of screening results and evaluating the effectiveness of screening across different populations and over time.

The low-dose CT scans performed for screening and surveillance of detected nodules entail a potential individual and societal burden of future radiation-induced cancer. The CT screening technique in the NLST delivered a mean effective dose of 1.4 mSv per scan [20], less than the approximate average annual exposure from natural environmental radiation sources in the U. S. of 3.1 mSv [21]. While the risks of a single screening examination are exceedingly low, the risks of repeated exposures over years of screening and follow-up are less certain. Recent estimates suggest that the number of lives saved by screening those at high risk would be far greater than the mortality due to radiation-induced cancers, but also that this may not hold for those at low risk such as younger people and nonsmokers [22-24]. This underscores the need to define carefully the appropriate population to be screened, again to avoid doing more harm than good.

Given the relatively high rate of false positive examinations leading to further follow-up of abnormalities eventually found to be benign, CT screening may have adverse effects on quality of life. The limited studies to date confirmed that those screened experience psychological distress while waiting for screening test results [25] and found that individuals with abnormal results perceived an increased risk of lung cancer and increased anxiety that diminished over time [26]. These findings suggest that patient education regarding the actual risk of lung cancer, known false positive rates, and expected benefits may help mitigate adverse psychological effects. The best methods of education have yet to be determined but, because many patients seek such information from their primary care doctor, physician education also may be needed.

Implementation of widespread CT screening raises many economic concerns. The expense includes not only the screening test but also the subsequent costs of imaging follow-up, other diagnostic procedures, and treatment. Note that because of the high false positive rate, the vast majority of people undergoing additional imaging and other diagnostic testing will not have lung cancer. Estimates of the cost-effectiveness of CT screening depend on assumptions such as the cost of the screening CT, the false-positive rate, the number and type of diagnostic tests and procedures and their costs, the stage distribution of cancers detected, treatment methods and costs, and mortality rates. Whereas previous studies found that the cost per quality-adjusted life year saved would be less than $50,000 (the amount at present generally accepted as the upper limit for being cost-effective) [27, 28], studies using NLST data estimate substantially higher costs [29, 30]. A pending cost-effectiveness analysis from the NLST, based on cost data collected from actual screening, should provide even more realistic estimates. Ultimately, policy makers must weigh the value of screening against the expected burden of the cost to the rest of society.

Lee and Forman noted that, regardless of its return on the dollar, CT screening would be an additional expense to the health care system that would reduce resources available for other societal goals. While a dramatic solution is needed to reduce significantly the deadly effects of lung cancer, the value of screening may seem less impressive when one considers that overall mortality from any cause in the NLST was only 6.7 percent lower in the CT arm. This most likely reflects, in part, the lack of an effect of CT screening on the high mortality resulting from other smoking-related diseases such as atherosclerosis, chronic obstructive lung disease, and other malignancies. Would the financial resources needed for widespread CT screening be of better use in large-scale, intensive smoking prevention and cessation efforts that might reduce all smoking-related morbidity and mortality over the long term?

Conclusion

Since the publication of the NLST results, CT screening has been endorsed by several major medical organizations. The American College of Chest Physicians, the American Society of Clinical Oncology [31], and the American Lung Association [32], now recommend screening for persons who meet NLST eligibility criteria. The National Comprehensive Cancer Network [33] and the American Association of Thoracic Surgeons (AATS) [34] made a broader recommendation to include those as young as 50 and those who have as few as 20 pack-years of smoking, if they have other risk factors such as asbestos exposure, chronic obstructive pulmonary disease, or a family history of lung cancer. The AATS guideline extends the upper age limit to 79 years and includes annual screening for individuals who have been treated for primary lung cancer and have had 4 years of radiographic surveillance without evidence of recurrence. An update to the lung cancer screening guidelines of the U.S. Preventive Services Task Force, which influences Medicare coverage decisions in addition to providing guidance, is pending. All groups emphasize that screening should be conducted with multisubspecialty teams that include radiologists, pulmonologists/internists, thoracic oncologists, and thoracic surgeons, and all highlight the importance of including smoking cessation efforts.

The role that CT screening will play in our health care system is unclear. In contrast to 2007, when Lee and Forman observed increasing momentum for screening despite scientific uncertainty and a lack of official endorsement, there is now strong supportive evidence and professional society endorsement, but minimal demand from patients or their physicians. There are several possible reasons for this: primary care physicians may be inadequately informed, they may be unconvinced of the benefit to their eligible patients, and only a limited number of insurers now cover the screening test. Whether screening for lung cancer will become routine for millions of at-risk individuals will depend on careful assessment of mortality benefit, risks, and costs by makers of public policy.

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David S. Gierada, MD, is a professor of radiology in the Cardiothoracic Imaging Section of the Mallinckrodt Institute of Radiology at Washington University School of Medicine in Saint Louis, Missouri. He was a Washington University site co-principal investigator of the National Lung Screening Trial.

Lawrence M. Kotner, Jr., MD, is an associate professor of radiology in the Abdominal Imaging Section of the Mallinckrodt Institute of Radiology at Washington University School of Medicine in Saint Louis, Missouri. Dr. Kotner has a special interest in the historical and ethical issues of medicine.

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STATE OF THE ART AND SCIENCE

Cancer Gene Sequencing: Ethical Challenges and Promises

Siddhartha Devarakonda, MD, Ramaswamy Govindan, MD, and
Peter S. Hammerman, MD, PhD

The availability of massive parallel sequencing technology (MPS) and advanced computing has made it possible to sequence genomes faster and more accurately than ever [1]. The overall cost of sequencing is also continuing to decrease. Because cancer results from genomic alterations, identification of clinically relevant molecular alterations and the use of effective targeted therapies has been shown to dramatically improve responses to cancer treatment. In spite of these achievements, our understanding of the genomic alterations that drive cancer is still limited. Thus, it will be necessary to sequence a large number of genomes in which cancer genes are present to discover novel targets and identify pathway aberrations that are critical for cancer initiation and progression. Such an approach will make it possible to identify subsets of patients most likely to respond to particular therapeutic agents and to design the most efficient clinical trials.

While next-generation sequencing technology carries great potential to aid cancer research, there are several challenges ahead. This essay addresses some of these challenges including those concerning patient privacy and confidentiality, disclosure of genetic information, and the ownership of inventions.

Ethical Challenges in Genomic Cancer Research

Genomic cancer research involves collecting biological specimens from a large number of volunteers. For the sake of ensuring patient privacy, collected samples are de-identified. Despite de-identifying patient data, the possibility of linking genomic data to a specific individual is still possible, as was demonstrated in a recent study [2]. Since genomic data are often accessible via public databases and are unique to a given individual, the process of de-identifying such data is crucial to safeguarding patient privacy. While there is no easy solution to this problem, several interesting possibilities have been put forth [3]. Regulation enforced by the government that would make it illegal for an unauthorized party to attempt to establish the identity of an individual from publicly accessible de-identified data is a possibility. Nonetheless, it would also be crucial to ensure that would-be participants are aware of the risks before they decide whether to participate.

Tissue specimens banked under a “generic” tumor bank consent form that did not have any information regarding large-scale genomic studies should be used only after seeking separate consent from the tissue donor, including information about the privacy and confidentiality risks associated with genomic studies. It is unclear what

the optimal strategy ought to be with the stored specimens from patients who cannot be reached [4].

Whether study participants or their family members should be informed of incidental genotype findings is an important concern—especially if such findings have the potential to bear adversely on health. Existing guidelines recommend such genotypic findings be communicated to the participant [5, 6]. Since such a situation inevitably brings up the issue of patient privacy, adopting a "movable firewall" strategy can ensure that patient anonymity is not compromised [7]. In this approach, only the "honest broker"—an independent third party entrusted with the "identified" data in the tissue repository who is not involved in primary research—is capable of linking genetic changes to specific individuals, should such a need arise [8]. This model facilitates constant updating of research data without compromising patient identity and reduces the risk of conflict of interest.

A few other challenges are worth discussing in the context of disclosure. Disclosing all variations to the participant can lead to unnecessary testing and its attendant financial, physical, and mental stress. There can be legal and ethical ramifications if the patient develops a clinical condition due to any genetic variations that were previously classified "nonsignificant" [9]. Patients who are aware of a family history of certain diseases might not be comfortable learning about their individual risk incidentally, when their DNA is sequenced for a different reason. Finally, expecting patients to pick a list of changes they might be interested in learning about is not reasonable, given the possibility that multiple combinations of genetic variations will be uncovered as a result of sequencing studies. Unfortunately, existing recommendations do not address providing a participant or his family members (in the case of deceased participants) access to complete genomic data.

Ethical Challenges in the Legal and Financial Context

One can anticipate that the volume of patent applications will rise exponentially as sequencing machines continue to generate large volumes of data and *in silico* methods for pathway analysis and drug discovery increase the rate at which new targets are identified and molecules targeting them are screened. Genomic data carries great market potential for drug discovery, diagnosis, and prognostication. Gene patenting laws, which are still a matter of great debate, will have to be redrafted appropriately to deal with legal and ethical challenges that can arise from these advancements [10]. While intellectual property rights are necessary to safeguard and ensure innovation, they come with their fair share of ethical challenges.

The patenting of genomic data can pose several roadblocks to cancer research. Scientists have to expend valuable resources to identify existing patents and negotiate them [11], and uncertainty associated with the scope of a patent can discourage potential investors from funding related research [12]. Because patents on lifesaving interventions can make them less affordable and accessible, laws governing the exclusivity of such molecules have been a subject of controversy,

especially in resource-limited developing countries [13]. Because the interpretation of patent laws can vary from country to country, there is a need to establish an international court where such issues can be represented and addressed appropriately [14].

Future Directions

Despite the obvious ethical and social challenges, next generation sequencing will be an indispensable technological resource for many reasons. It is estimated that approximately 95 percent of candidate anticancer drugs entering clinical development fail [15], which imposes a major economic burden on society. It has been argued that testing targeted agents in nonselect patient populations is partially to blame for this failure. Genome sequencing will definitely help make it possible to test therapies on the relevant populations; biomarker-based patient selection for several targeted therapies has already proven successful [16-18].

Genome sequencing can also lead to the identification of treatable mutations in rare tumors, offering hope to patients with otherwise untreatable cancers. The ability to treat cancers with targeted agents would also mean moving away from standardized multi-agent chemotherapy regimens that are associated with severe toxicity. The ability to triage and screen patients based on their genetic predisposition to certain cancers can improve the effectiveness of screening policy. Given the high expenditure associated with cancer screening and failed therapy, one can only predict that, with progressively declining sequencing costs, next-generation sequencing would be highly cost-efficient.

Modern medicine has continually moved away from the empiric "one-size-fits-all" approach and will continue to do so. The blinding pace at which genomic technology and bioinformatics is evolving will only accelerate over the years to come.

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Siddhartha Devarakonda, MD, is a second-year resident in internal medicine at Saint Luke's Hospital in Chesterfield, Missouri, whose research and educational interests include the molecular biology of cancer and lung cancer.

Ramaswamy Govindan, MD, is a professor in the oncology division of the Department of Medicine at Washington University School of Medicine in Saint Louis, Missouri. His research interests include lung and esophageal cancer.

Peter S. Hammerman, MD, PhD, is an instructor in medical oncology at the Dana-Farber Cancer Institute and Harvard Medical School in Boston, an affiliated researcher at the Broad Institute, and a clinician in the Lowe Center for Thoracic Oncology. His research interests are lung cancer genomics and development of novel targeted therapeutics.

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HEALTH LAW

The Constitutionality of the Affordable Care Act: An Update

Valarie Blake, JD, MA

On June 28, 2012, the U.S. Supreme Court upheld key provisions of the Patient Protection and Affordable Care Act (ACA) after 26 states had challenged its constitutionality in lower courts. In last November's *Virtual Mentor* health law column, we summarized some of the key legal issues the court would consider in the ACA case, and now we examine their ruling, including the basis for the court's decision and relevant legal considerations as the ACA is implemented [1].

The Court's Holding

The Supreme Court's 5-4 decision determined the constitutionality of two key substantive provisions in the ACA: the individual mandate and a requirement that states expand eligibility criteria for Medicaid coverage [2].

Individual mandate. The most legally and politically controversial aspect of the ACA, the individual mandate requires Americans to purchase health insurance or face a government penalty, with some exceptions—particularly for low-income individuals who cannot afford to buy insurance [3]. The individual mandate has been considered necessary to cover the cost of U.S. health care. Without a mandate, fewer healthy people would pay into the system to counterbalance the cost associated with care for the sick. The healthy, mostly younger people would be able to "free ride," purchasing health insurance only when they got sick, after paying little or nothing up front when their use of services was lower [4, 5].

States that challenged the ACA argued that the individual mandate was an overreach of Congress's commerce clause powers, the government's well-recognized (but not limitless) power to regulate certain economic activity that either occurs between states or substantially affects the states in the aggregate [6, 7]. The court reasoned that the commerce clause allows the government to regulate actions of those who participate in a market but not the inactions of those who choose *not* to participate in that market [8]. Without this distinction, the government could regulate practically anything. Justices analogized that, for example, persons with poor diets are pervasive and more costly to the health care system than the uninsured, yet it would be seen as a strong liberty breach for the government to mandate that citizens purchase only health food [8].

While the court rejected the claim that the individual mandate was within Congress's commerce power, the mandate was found to be constitutional as a tax [9]. The penalty, though not labeled a tax in the ACA, is similar in several ways to other

taxes. Its amount is determined by income, number of dependents, and filing status, and it is paid into the treasury when filing income tax. It is not a punishment for an illegal action: failure to purchase health insurance is not illegal, the penalty for refusing to purchase health insurance is less than the cost of paying for actual insurance, and there are no criminal sanctions attached. (The Congressional Budget Office has predicted that approximately 4 million people will opt to pay the IRS instead of an insurance company [10].) Moreover, while the individual mandate is clearly intended as an incentive to purchase health insurance, many other taxes are also in place to promote certain behaviors—for example, the government taxes cigarettes to reduce nicotine consumption. Thus the Court found the mandate well within Congress's power to tax. While Congress doesn't have the power to require individuals to purchase health insurance, it *does* have the power to tax those individuals who do not.

Medicaid expansion. The second provision challenged by the states required them to expand their Medicaid programs to cover adults with incomes up to 33 percent above the poverty level by 2014 or to face a penalty (including withdrawal of all federal Medicaid funds) [11]. Most states only cover much poorer individuals and sometimes only low-income families with children [11]. The intended goal of the Medicaid expansion was to increase the pool of people covered under state and federal health insurance programs to include those who would have difficulty affording insurance under the individual mandate.

Striking down as unconstitutional a penalty on nonparticipating states, the court reasoned that Medicaid originally intended to cover four types of needy persons: the blind, the disabled, the elderly, and families with children [11]. It argued that, while Congress has the right to redefine who may fall into the categories of those covered and to provide monetary incentives to states to cover certain populations of persons, the Medicaid expansion changed the original goal of the program itself—making it a not just a program to cover needy persons, but a national health care plan intended to provide universal coverage that, moreover, uses penalties rather than incentives to encourage compliance [11]. Deeming the provision too coercive, the court held instead that the government cannot penalize those states that choose not to expand Medicaid in this way [11].

The Aftermath of the Ruling

Politicians, journalists, and academics alike have speculated about the ramifications of the court's mixed ruling on the constitutionality of the ACA.

The ACA's timeline of implementation continues into 2014, but certain provisions have already begun or will begin soon. For example, in October 2012, the value-based purchasing program began to give hospitals financial incentives to improve their quality of care and to implement electronic health records [12]. The federal government bolstered state-run health coverage in 2012, allocating funds to the states to cover more preventive medicine, increasing payments for family practitioners, and increasing the resources of the Children's Health Insurance Program [12]. And in

2014, insurance overhauls will roll out: insurers will be prohibited from discriminating on the basis of preexisting conditions, annual limits on insurance coverage will no longer be permitted, insurers will be required to cover people participating in clinical trials, and tax credits to help individuals and small businesses afford insurance will begin [12]. Most importantly, the individual mandates and the optional Medicaid expansion will begin on January 1, 2014 [12].

In the meantime, the ACA remains a politically controversial law, and some states still seek to oppose or avoid certain requirements. Five states (Missouri, Montana, New Hampshire, Utah, and Wyoming) have passed restrictions on compliance with the ACA until the state legislature approves its implementation [13]. Sixteen states have provisions that say the state government will not enforce the individual mandate [13]. However, because federal law trumps state law and the individual mandate mainly governs the conduct of individuals and their employers, not the states, these laws will have little impact on how the ACA is enforced [13].

Georgia, Indiana, Missouri, Oklahoma, South Carolina, Utah, and Texas have all enacted interstate health compacts that seek to allow them to join together in an effort to establish broad health care programs for their citizens independent of federal control [13]. Interstate compacts have been used in the past when states agree to improve or work together on a shared resource, often such things as responsibility for roadways or bodies of water or land, the collecting of taxes by companies that do business between states, or, sometimes, interstate law enforcement efforts [14]. Such compacts require Congress's approval to prevent states from overstepping federal authority [15]. Health compacts have been a vehicle for politicians to show their disapproval of the ACA, but some commentators think it unlikely that Congress would approve a compact that so significantly shielded the states from federal law [16].

While the headlines and the excitement over the Supreme Court's ruling has begun to diminish, the central controversies of the ACA, including the proper role of federal and state government in matters of health and the challenges of covering the uninsured, will remain at the forefront during the 2012 election and well into 2014.

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Valarie Blake, JD, MA, is a senior research associate for the American Medical Association Council on Ethical and Judicial Affairs in Chicago. Ms. Blake completed the Cleveland Fellowship in Advanced Bioethics, received her law degree with a certificate in health law and concentrations in bioethics and global health from the University of Pittsburgh School of Law, and obtained a master's degree in bioethics from Case Western Reserve University. Her research focuses on ethical and legal issues in assisted reproductive technology and reproductive tissue transplants, as well as regulatory issues in research ethics.

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POLICY FORUM

National Quality Forum Guidelines for Comparing Outcomes and Resource Use

Kevin D. Frick, PhD

The health care system may move toward applying value-based purchasing more broadly. If this occurs, those making value-based decisions will need measures of efficiency to provide guidance. Measuring efficiency, whether in health care or elsewhere, involves a comparison of inputs into a process with the outputs of that process. A wide variety of metrics has been used in the academic literature to assess the efficiency of medical care, including but not limited to return on investment, cost-benefit, and cost-effectiveness. In each type of evaluation, analysts make a structured comparison of inputs into the process of providing medical care and improving health (with the resources used often valued in dollars) with the health, productivity, or quality-of-life outcomes of that care.

One difficulty with trying to design a useful measure of efficiency is that there are numerous stakeholders—patients, families, insurers, employers, the government, and the health care providers. Each of these stakeholders may have a different perception of how much it is justifiable or worthwhile to spend on a visit or episode of care. For example, insurers, who pay a large portion of the cost for many services, may be more motivated to reduce costs than patients. Additionally, each stakeholder may prioritize the outcomes of care differently, e.g., the employer may view making the patient more productive as more important than saving medical care costs at present or in the future. In short, considerations of which outcomes are important or which expenses worthwhile are likely to lead to value-laden disputes.

In 2012, the National Quality Forum (NQF) promulgated a set of measures of efficiency [1] that take a different approach than cost-effectiveness measures that might be reported in the academic literature as dollars spent per quality-adjusted life-year gained. From available descriptions [2, 3], it appears the NQF measures are designed to (1) include data on the quantities of various resources used, (2) risk-adjust the resource use for the severity of the condition, (3) apply a standard price so that providers in more expensive areas who use the same resources as providers in less expensive areas would not be considered inefficient simply because their inputs' prices are higher, and (4) compare the quality of outcomes with the resources used.

The focus on resource use means that the measurement begins by counting numbers of visits, hospitalizations, and laboratory tests or imaging studies. A visit that involves only evaluation and management with no imaging and no labs is counted differently than a visit that entails labs and other procedures. This is the first step in making sure that the comparison is as logical and as meaningful as possible, focusing

on whether there is waste rather than other variations in the price of resources for care.

The process of risk adjustment is necessary because variation in disease severity is associated with appropriate variation in resource utilization. Physicians who treat patients who are more severely ill should not be penalized for this. The process of risk adjustment modifies the quantities of resources to make the comparison fairer.

The application of standard prices is another step in the effort to assure that the comparisons being made are fair and meaningful. Consider the fact that even Medicare has different reimbursement rates in different regions. One simple approach would be to use Medicare national average reimbursement levels. Other reimbursement systems could be employed as well, although many are similar to Medicare. Without a standardized value applied to each resource being measured, different practices could not be compared.

Finally, the combination of quality and resource-use measures allows for the assessment of efficiency. This is the final step in the process of making certain that the use of resources for generating similar outputs is being compared. The objective appears to be to compare the costs of providing the same level of quality. This is a simpler, less value-laden question than comparing the costs of a given treatment with its effects and asking whether it is worth spending a certain amount more to achieve greater health. Instead, when resource-use and quality measures are juxtaposed, the resources used to provide the same level of quality can be compared. The question of what level of quality is appropriate is then separate.

Sometimes when the desire to drive the health care system toward greater efficiency is discussed, there is a concern that the focus is exclusively on costs and that providers (both physicians and hospitals) will have an incentive simply to minimize costs at the expense of outcomes. This is unlikely to be the case when the cost metrics are used in conjunction with quality metrics. It is likely that some costs can be cut by providing care more efficiently, with little impact on outcomes. Cutting costs by reducing the use of *needed* resources will eventually lead to worse health outcomes. If the quality, as measured by health outcomes, is diminished, the contracting and reimbursement system between insurers and providers will likely penalize the provider—either with reduced levels of reimbursement or with fewer contracts going forward.

Ideas about what levels of quality are acceptable and what is worth paying for can vary among stakeholders. Each stakeholder will have to determine how to incorporate quality into the decision making process. The aspect of the NQF measures that makes them widely useful is the focus on comparing like with like: risk adjusting, standardizing input prices, and comparing only clinicians whose services result in the same outcome ensure that it is not making value judgments.

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Kevin D. Frick, PhD, is a health economist and professor in the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health in Baltimore. He has conducted cost-effectiveness research on a variety of topics and served on the National Institute for Nursing Research's Advisory Council.

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POLICY FORUM

Improving Health Outcomes and Promoting Stewardship of Resources: ABIM Foundation's Choosing Wisely Campaign

Todd Ferguson, PhD

More than any other feature, the physician's fiduciary duty to patients defines medicine as a profession. It is this duty that binds patient and physician together in the moral activity that characterizes the patient-physician relationship. This duty also demands that the physician set aside his or her own beliefs and advancement in order to do what is in the patient's best interest while upholding the patient's confidentiality.

As Edmund Pellegrino and David Thomasma [1] explain, this duty—imposed by a patient's trust that the physician will act on his behalf to improve his welfare—is the "moral center of medicine":

> The physician is understood to have special skills which he promises to use in the interests of the patient when that patient presents himself for care. The prime focus of the physician's intention, therefore, is the good of the patient who presents himself here now—and not some distant patient, not even the good of society or the greatest good for the greatest number [2].

Without this duty of fidelity that binds the physician's decisions and actions to the welfare of the patient, the patient is unable to trust the physician, the patient-physician relationship disintegrates, and the practice of medicine ceases to be a profession. This relationship does not take place in a hermetically sealed office, however, but in a larger social framework in which the physician has multiple, if not conflicting, obligations and responsibilities in addition to the primary role as healer [1].

Today, as the practice of medicine rapidly evolves, physicians face the difficult task of "making fair, prudent, cost-conscious decisions for care that meet the needs of individual patients and help to ensure the availability of health care to others" [3]. One fundamental challenge confronts every practicing physician in America today: providing safe, effective, high-quality care to patients while also limiting the rising cost of health care and the use of limited resources.

Believing that unnecessary use of resources was a significant contributor to rising health care costs, the American Board of Internal Medicine (ABIM) Foundation launched a national multiyear initiative, Choosing Wisely, in 2012, to bring attention

to the increasing waste of resources in the United States, "help physicians and patients engage in conversations about the overuse of tests and procedures and support physician efforts to help patients make smart and effective care choices" [4]. The unique aspect of this campaign is that physicians and patients work together to develop treatment plans that are effective for the patients but are also efficient and promote the sustainable use of limited resources.

In particular, the Choosing Wisely initiative strives to promote conversations between physicians and patients that help "patients choose care that is: supported by evidence; not duplicative of other tests or procedures already received; free from harm; [and] truly necessary" [5]. By conversing openly with patients, physicians avoid acting paternalistically or withholding diagnostic procedures or treatments. Thus, they avoid even the perception that they are trying to restrict care. They also work with patients to eliminate or limit costly interventions that might have little or no benefit for them [3].

The Choosing Wisely campaign is a component of the ABIM Foundation's larger goal of promoting wise choices by clinicians that will "improve health care outcomes, provide patient-centered care that avoids unnecessary and even harmful interventions, and reduce the rapidly-expanding costs of the health care system" [6].

To help make the Choosing Wisely campaign as practical and widespread as possible, ABIM has partnered with specialty and consumer groups to provide resources to both practicing physicians and patients. Currently, close to 20 specialty societies have signed on to the campaign, including:

The American Academy of Allergy, Asthma, and Immunology
The American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine
The American College of Physicians
American College of Radiology
The American Geriatrics Society
The American Society for Clinical Pathology
The Society of Hospital Medicine

The fundamental component of the campaign is that each participating specialty society has identified its own list of "'Five Things Physicians and Patients Should Question' that provide specific, evidence-based recommendations physicians and patients should discuss to help make wise decisions about the most appropriate care based on their individual situation" [5]. Every item on each list of five is a common procedure or treatment that is overused and thus can lead to waste of health care resources (and a higher cost of treatments and shortage of resources for others). Each recommendation is accompanied by a short explanation of why the specific diagnostic test or procedure should be "questioned" by the physician and patient; some provide ideas for possible alternative procedures. The overall goal for the lists is to encourage "physicians, patients and other health care stakeholders to think and

talk about medical tests and procedures that may be unnecessary, and in some instances can cause harm" [5].

In the list of "Five Things Physicians and Patients Should Question" compiled by the American Academy of Family Physicians, for example, one recommendation suggests not performing Pap smears on women younger than 21 or those who have had a noncancer-related hysterectomy because (a) "most observed abnormalities in adolescents regress spontaneously, therefore Pap smears for this age group can lead to unnecessary anxiety, additional testing and cost," and (b) "Pap smears are not helpful in women after hysterectomy (for non-cancer disease) and there is little evidence for improved outcomes" [7].

In addition to the lists developed by the specialty societies, Consumer Reports has worked with the societies to develop consumer-friendly summaries of the lists that can help patients better understand some of the basic tests and procedures that are commonly overused by physicians. These lists include: "Allergy tests: When you need them and when you don't" [8], "How should you treat heartburn and GERD?" [9], and "When do you need antibiotics for sinusitis?" [10]. Such lists not only help patients stay informed about common diagnostic procedures, they also encourage them to engage in dialogues with their physicians about their health concerns and devise "wise treatment decisions" that work for patients like them, aren't duplicative or harmful, and are "truly necessary" [4]. Above all, the more that patients and physicians work together to discuss effective and responsible treatment decisions, the more they can build trusting, deliberative relationships—which ideally result in improved health outcomes for patients and more responsible use of limited health care resources.

While the ABIM Foundation's Choosing Wisely campaign provides a useful way for physicians to engage their patients in open dialogues about their health and the most effective and efficient treatment options for their unique medical needs and goals, it is only the first step in the delicate balance all physicians must maintain between their fiduciary duty to their patients and their duty to be responsible stewards of limited health care resources.

It is imperative for today's physicians to find an "equilibration" among their various professional loyalties and commitments so they can fulfill their primary obligation as healers while also being stewards, patient advocates, and scientists. Every physician's "efforts in individual and personal medical transactions must be reinforced by a context of moral policy decisions which also attempts to reach some equilibrium between the inherent tensions of the canons of morality and economics" [11]. As it expands and becomes more widely adopted and implemented, the ABIM Foundation's Choosing Wisely campaign serves as a vital resource for physicians in meeting the challenge of providing safe, effective, high-quality, and sustainable care.

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Todd Ferguson, PhD, is a research associate for the American Medical Association's Ethics Resource Center in Chicago. His research interests include social justice issues and the value of decency in the design, development, and implementation of health care services. He earned his PhD from Purdue University and is coeditor of *Restoring Hope: Decent Care in the Midst of HIV/AIDS* (2008).

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MEDICINE AND SOCIETY

Power, Politics, and Health Spending Priorities

Michael K. Gusmano, PhD

The United States spends nearly $2.7 trillion on health care annually, and its major public health insurance programs, Medicare and Medicaid, represent about 20 percent of the federal budget. The amount of money is not necessarily a problem, but there are reasons to believe that this money is not spent wisely. International comparisons suggest that the U.S. does not get a good return on its health care spending. If we focus only on measures of health that can be influenced by health care, like mortality that medical attention may have prevented, the U.S. does far worse than countries that spend less on health [1-3]. Domestically, analysis from the Dartmouth Atlas Project also raises questions about the effectiveness of our health care spending [4]. There are enormous geographic variations in spending that do not correlate with the needs of patients in those areas or with outcomes. Although many expensive medical technologies represent good "value for money" [5], others, it seems, do not.

Beyond efforts to calculate the return on investment associated with particular technologies is the question of how to set priorities. Even if we limit spending to interventions for which there is a strong evidence base, this does not address the question of whether we are directing our resources toward diseases, conditions, or determinants of health where they would have the greatest effect. In terms of research, many studies claim that the NIH may not target diseases and conditions that represent the greatest burden to society, whether burden is measured in terms of mortality, disability-adjusted life-years, or cost [6]. One study found that some cancers, like breast and prostate cancer, receive a share of research funding that exceeds the burden they impose on society, while other forms of cancer, like bladder cancer, receive a far lower share of funding in relation to their societal burden [7].

The mismatch articulated by the study above between where spending goes and where it is most needed is not limited to research. Many argue that our health care delivery and finance systems place too much emphasis on specialty care and not enough on primary care. Advocates who argue for increased spending on prevention often point out that "only" 5 percent of the money spent on health care is devoted to population-wide approaches to health improvement [8]. The U.S. health care system provides far greater financial rewards for treating illness than it does for keeping people healthy. The makeup of the health care workforce and the methods we use to pay physicians reflect these priorities. In every other developed nation, about half of all physicians work in primary care; in the U.S. only one-third do [9]. The lack in primary care workforce is perpetuated by reimbursement policies that reward

specialty care services at a higher rate than primary care, discouraging medical students from pursuing primary care as a career [10].

Why is there such an apparent mismatch between what our spending priorities ought to be and the actual allocation of funds? Differences in wealth, which often translate into greater political power, offer a partial explanation. Some public health advocates expressed with alarm [11] the fear that the *Citizens United* decision, in which the Supreme Court ruled that the government cannot limit corporate independent expenditures for advocacy advertising during election campaigns [11], could doom public health policies that conflict with corporate interests. Consistent with this view, one study found that disease groups with sufficient resources to lobby Congress are able to affect NIH funding priorities by influencing congressional earmarks [12].

There are times when groups without a great financial advantage organize effectively and increase the treatment available for a particular condition or set of patients. HIV/AIDS activists forced the FDA to adopt major changes in the drug approval process. Breast cancer advocates changed the research priorities of the federal government and forced the health care system to change the way it treated patients with this disease [13, 14].

But the patient-activism model is limited because not all patients are equally likely to participate in the health policy process [14]. Furthermore, the success of patient groups that do participate in the process may have little to do with the merits of their demands or efforts of their members. The personal experiences of celebrities or policy makers may lead them to champion the cause of certain patient groups and increase the probability of success [15]. When a member of Congress has a personal experience with a disease or set of diseases, he or she is more likely to support spending on these conditions.

The degree to which patients suffering from the disease are viewed as "deserving" can also influence public support and spending patterns. Support for patients living with HIV/AIDS, a disease that was originally associated exclusively with gay men, increased significantly thanks to media coverage of Ryan White, a teenager who contracted HIV after receiving infected blood to treat his hemophilia in the mid-1980s. The perception of deservingness, reasonable or not, is a powerful force in the political process and shapes who gets what from government.

How should we set priorities for health care spending? More than a decade ago, Daniel Callahan reviewed competing ethical principles, as well as efforts by health policy researchers to create formulas that could be used to set priorities for health care spending [16]. He found objections to all of the above. Measures of burden that emphasize mortality may lead us to invest too little in chronic diseases that reduce the quality of our lives but not always their length. Measures of burden that emphasize health expenditure may lead us to ignore diseases that lead to rapid death and, as a result, cost very little. Instead, he advocated using "the political method of setting priorities." He argued that, "it is familiar, messy, and yet comparatively

simple in its operation: people argue, struggle, and lobby to get what they want, and there are winners and losers—but also another chance on another day for the losers to turn the tables" [16].

Callahan's claim that no formulas or broad principles can substitute for a political process when determining priorities in health care is compelling. The question is whether it is possible to construct a political process that is less likely to be unfairly dominated by those with greater wealth, those who happen to share a disease with someone in a position of power, or those who are simply considered more attractive than other sick people. Is it possible to create a process that is fair? Given the history of health policy in the U.S., this is no easy task.

Advocates of deliberative democracy hope to create forums in which participants make decisions on the basis of reasons "that can be accepted by those who are bound by it" [17]. These advocates reason that when more people are involved in the decision making process there is a greater chance that those affected by a decision have an opportunity to influence it [18]. Creating a more participatory, more deliberative process is challenging, but not impossible. Identifying strategies for creating a deliberative process is important because our best hope to improve the allocation of health care resources is to improve the political system that shapes these decisions.

Several federal agencies, including the Agency for Healthcare Quality and Research, the Institute of Medicine, and the U.S. Food and Drug Administration are exploring more deliberative processes for shaping health policy decisions. None of these agencies, nor the academic researchers who focus on deliberative democracy, have identified an ideal process. There are, however, questions that all efforts at deliberation must address to be successful. Who are the relevant stakeholders? How representative are participants in the deliberative process? What decision rules will govern the deliberative process? Will the deliberation be moderated by a "neutral" party? Who will be responsible for vetting the background material that the group will use in their deliberations? Will the process be a one-time interaction or will participants have a chance to meet with each other over a period of time?

One-time interactions in the form of polling a representative sample of the public may be valuable, but these efforts cannot substitute for regular meetings among stakeholders. Doing this, however, requires a substantial commitment of time and other resources and may exclude some people from the process. How to balance the desire for inclusivity with the value of frequent meetings can have a profound effect on the outcome of the deliberation—but it is a question without an obvious answer. The answers to all of the questions listed above can shape outcome of these deliberations and their perceived legitimacy. Calls for deliberation are ubiquitous, but unless we work to reach consensus on what constitutes a fair process, efforts to use a deliberative process will be met with disappointment [17].

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Michael K. Gusmano, PhD, is an associate professor of health policy and management at New York Medical College in Valhalla and a research scholar at The Hastings Center. Dr. Gusmano's research interests include the politics of health care reform, comparative health systems, aging, health and health care inequalities, and normative theories of policy analysis. His most recent book, *Health Care in World Cities* (Johns Hopkins University Press, 2010), documents the implications of national and local health care policies for access to care in New York, London, and Paris.

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HISTORY OF MEDICINE

God Panels and the History of Hemodialysis in America: A Cautionary Tale

Will Ross, MD, MPH

In the words of economist Herbert Stein, "unsustainable trends cannot be sustained." [1] We are currently spending $2.7 trillion annually, or 18 percent of our GDP on health care in the United States. Conservative estimates indicate that the passage of the Patient Protection and Affordable Care Act (ACA) will save over $200 billion by the end of 2016 [2], making the bold assumption that we can bend the cost curve downwards through a blend of preventive health care measures and new forms of capitated (non-fee-for-service) payments for heath care services. Economists and policy makers will find that much can be learned about cost containment and its challenges from the Medicare-funded End Stage Renal Disease Program.

Recently the ACA established the Patient-Centered Outcomes Research Institute (PCORI) [3], which funds research designed to improve the quality of our health care delivery system, particularly identifying best-practice approaches that are evidence-based and applicable across economically and ethnically diverse populations. As it establishes policies to encourage the equitable dispensation of this country's limited health care resources, PCORI's experts will be able to evaluate the outcomes of the nation's longest-standing entitlement program, the End Stage Renal Disease (ESRD) Program.

The ESRD Program's Origins and Where It Stands Today

Established in 1972, the ESRD program proposed to cover treatment for end-stage kidney disease for all Americans eligible for Social Security [4]. The program was initiated in response to a Seattle policy during the 1960s that allocated access to hemodialysis, an effective but expensive treatment, on the basis of a patient's social worth. At the time, James Shannon, director of the National Institutes of Health (NIH), wrote to the surgeon general about the "difficulties" created by innovations that delivered dialysis to patients with end-stage kidney disease: lives could be saved, but at a high cost to individuals and the country [5].

In 1962 the Seattle Artificial Kidney Center charged a committee of physicians, nurses, and community and civic leaders to develop an allocation system for dialysis treatments [6]. The committee agreed that "social worth," an assessment of the patient's anticipated contribution to society, would be the primary criterion for determining who would receive the life-sustaining treatment. Those individuals deemed highly valuable to society would receive dialysis, ostensibly to facilitate their physical rehabilitation and return to their jobs, families, and civic duties. Social worth, however, turned out to be just as subjective as it sounds, and bioethicists

immediately condemned the practice as highly discriminatory and derided the committee as a "God panel" [7, 8].

In response, a Committee on Chronic Kidney Disease, chaired by the renowned nephrologist Carl Gottschalk, convened in 1967 [4] and recommended federal funding for treatment of all patients with ESRD, assuming that most patients found medically suitable for dialysis would be under age 54 with few if any comorbidities. Rather optimistically, the committee estimated that approximately one in five ESRD patients would fall into the category of medically suitable. In light of escalating rates of renal failure affecting a broader economic swath of the electorate, Congress codified the lifelong subsidization of eligible patients with ESRD in 1972, through Public Law 92-603, signed by President Richard Nixon [5].

The fiscal implications of the Congressional decision were grossly underestimated. When the legislation was enacted, there were only 10,000 patients receiving dialysis, with an annual cost of $280 million, but by 2008, there were 382,000 patients receiving dialysis, for a total cost of $39.5 billion, accounting for 8 percent of Medicare costs [9].

The Gottschalk committee was wrong about much. Those on dialysis are not very likely to regain productivity and contribute civically. Dialysis does not necessarily result in workforce participation: a recent review of the United States Renal Data System database indicated there was a 71 percent unemployment rate *even among individuals aged 18-64* on dialysis. Additionally, non-Hispanic white men aged 30 to 49 years were significantly more likely to have the same level of employment after the initiation of dialysis as they did 6 months previously [10].

Furthermore, the elderly are now the largest and fastest-growing group with ESRD [11]. According to a cross-sectional study of the most recent National Health and Nutrition Examination Survey (NHANES), more than one-third of people aged 70 years and older have moderate chronic kidney disease, and the overall incidence of established ESRD in those aged 75 years or older has increased 67 percent since 1994 [12]. These older patients have more comorbidities and an increased risk of death from cardiovascular disease.

Despite decades of optimizing dialysis practices—more biocompatible membranes, refining dosage of dialysis, technological innovation in dialysis monitoring, and medical breakthroughs such as improved anemia control with erythropoietin stimulating agents—it has been difficult to document any improvements in patient survival [13]. The standardized mortality rate among those on dialysis has remained stubbornly unchanged at 20 percent for the past 20 years: 15 percent higher than in Europe even when controlling for the patient's age and the presence of diabetes [14]. Moreover, the increased financial outlay for dialysis services and the remarkable technological innovations over half a century have not translated into improved quality of life on dialysis. Using a well-validated instrument to measure quality of life (Medical Outcomes Study Short Form 36 Item Health Survey), Gabbay and

colleagues found that between 1997 and 2006 there was no significant improvement in health-related quality of life among dialysis patients in the United States [15]. The elderly on dialysis have a greater threat of accidental falls than their age peers who are not on dialysis, experience a loss of independent functioning, and may develop progressive cognitive impairment [16].

Introduced with the noble intentions of restoring patient dignity and autonomy, the ESRD program has mushroomed into an unsustainable behemoth. Given the extensive evidence demonstrating unchanged quality of life and increased life-threatening complications for elderly dialysis patients, it is ethically justifiable to consider limiting access to hemodialysis and advocating nonaggressive renal care for the more frail elderly population. This was supported in a study by Chanda et al. [17], who found, that among patients older than 75 years with severe extrarenal comorbidities, dialysis did not confer a statistically significant survival advantage over nonaggressive, conservative renal care.

The quintessential questions in the rationing decision are:

1. What protocols guide the rationing of dialysis services?
2. Who makes the final decision to ration care?
3. How do we determine the level of disability and infirmity when assigning patients to treatment or nonaggressive care?

The tacit assumption has always been that the Centers for Medicare and Medicaid Services (CMS) would assume responsibility for making the guidelines that inform the rationing of any health care services. A 15-member Independent Payment Advisory Board [18] made up of doctors and medical professionals, economists and health care management experts, and consumers has been charged with finding ways to reduce the growth in Medicare spending. Paradoxically, that board is restricted by law from making any recommendations that involve rationing of health care [19]. It is possible that CMS's more cautious approach may in part be a response to the nefarious "death panel" rumor first espoused by former Alaska governor Sarah Palin, who opined that "the newly created health care legislation would create a death panel of bureaucrats who would decide whether Americans were worthy of medical care" [20].

So, for now, no one expects any serious health care rationing policy to emerge from the current combative climate on Capitol Hill. The answer may actually come from the community of renal specialists themselves. In a bold and responsible manner, the Renal Physicians Association and the American Society of Nephrology recently issued clinical practice guidelines on appropriate shared decision-making in the initiation and withdrawal of dialysis [21]. While these guidelines do not currently consider cost and do not explicitly endorse rationing, they are logical approaches in deciding how to ration health care.

Rationing need not be associated with the draconian image of patients dying in the streets for lack of care, but should be a highly reasoned and openly discussed

practice that assesses the risks of treatment for certain patient subgroups alongside the quality-adjusted life-year (QALY)—that is, the number of years of improved quality of life they stand to gain from medical interventions [22]. This utilitarian approach to optimizing resource allocation was embraced by the U.S. Panel on Cost-Effectiveness in Health and Medicine, composed of physicians, health economists, ethicists, and other health policy experts, who concluded that "QALYs provide a convenient yardstick for measuring and comparing health effects of varied interventions across diverse diseases and conditions" [23]. Stefanos Zenios and colleagues at the Stanford Graduate School of Business applied the QALY principle to dialysis patients. Their study showed that, for the sickest patients, the average cost of an additional quality-adjusted year of life was quite high—$488,000 [24].

Although placing a cost on human life is a value judgment, the use of QALYs offers the advantage of standardization and fairness in deciding how to obtain the greatest health gains from our dwindling resources [25]. Perhaps to allay baseless fears of "death panels," the Affordable Care Act precludes the use of QALYs in making recommendations based on benefit-per-intervention thresholds. It will take further courage from physician leaders and policymakers to adopt QALYs for measuring the cost effectiveness of medical interventions such as dialysis.

Without abrogating ethical principles, we can move forward with reasoned, evidence-based approaches to constrain health care spending. Reining in the cost of the ESRD program by providing nonaggressive care to patients with the highest morbidity would go far in proving to conservatives and liberals alike that reducing health care spending need not compromise the quality of health care. At the root of this argument is the inflated political rhetoric about rationing.

To be honest, rationing is already occurring in the care of dialysis patients. It occurs through the process of "cherry picking" [26], or dismissing from medical practices those patients who are chronically late for appointments, disruptive to staff or other patients, or nonadherent with their medical regimen. Payment systems that reward outcomes-based quality of care (pay-for-performance) and the bundling of formerly billable payments for ESRD services [27] could exacerbate the adverse selection or cherry picking in the health care market. However, when provider payments are adjusted for variations in the clinical complexity of cases (case-mix adjustment), pay-for-performance systems are steps in the right direction.

Renal care will continue to benefit from the widespread adoption of policies that identify individuals with multiple comorbidities, especially those older than 75, who could be assigned to nonaggressive medical management. In that context, QALYs are useful tools in cost-consequence approaches to medical decision making. While QALYs should not be the sole basis of medical decisions [28], they should be embraced as a fair method of curbing health care spending.

Perhaps most controversially, the government must decide whether it is now time to phase out the subsidization of care to all patients with ESRD and let patients under

age 65 seek insurance coverage from third-party payers. If the Medicare ESRD Program were restricted to patients 65 and older, shifting the insurance burden to third-party payers could save the program up to $13.5 billion annually [29, 30]. The long-term fiscal benefit would be amplified if the ESRD Program adopted a mechanism to prevent or delay progression of disease, particularly diabetes and hypertension, in those under age 65.

We are already in the era of health care rationing, and the specter of "God panels" should no longer thwart our efforts to make prudent, ethical, and equitable decisions that are in the best interest of our patients and our country's long-term fiscal health.

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Will Ross, MD, MPH, is associate dean for diversity and associate professor of medicine in the Renal Division at Washington University School of Medicine in Saint Louis, Missouri. A senior fellow at the Center for Health Policy, Dr. Ross focuses on minority health care workforce development, knowledge mapping, and construction of conceptual frameworks to reduce health care inequities.

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OP-ED

A Single-Payer System Would Reduce U.S. Health Care Costs

Ed Weisbart, MD, CPE

We Have Not Yet Solved the Health Care Crisis

The Affordable Care Act (ACA) is introducing insurance reforms that will improve the lives of millions of Americans, but we need to go much further to solve the crisis in health care.

Without correcting the fundamental structural flaws in health care financing, overall health care costs will remain poorly controlled. Though our clinical outcomes are mediocre by comparison [1], the average per capita cost of health care in the United States is twice that of other modern nations [2]. Increasingly, these costs are being borne by patients and government, driving personal bankruptcies and ever more austere public policies [3, 4]. Under the ACA, 30 million people will still have no coverage [5], and countless more will have inadequate coverage [1].

For most Americans, the glory days of "Cadillac health plans" are over, if they ever existed. The declining actuarial value of plans offered by employers means that the ACA will still leave those who need health care with financial hardships and high rates of bankruptcy, in spite of the subsidies for premiums and out-of-pocket expenses. (The actuarial value of a plan is the percentage of a patient's predictable costs within the covered list of services that would generally be paid by the insurance company.) In order to participate in one of the ACA's new health insurance exchanges, insurance companies are required to offer at least one "silver" and one "gold" plan, with 70 percent or 80 percent actuarial value, respectively. An insurance policy with a 70 percent actuarial value would, by definition, leave patients responsible for 30 percent of the overall cost of the care on the list of covered services. Many other medically necessary services, such as home and long-term care, dental treatment, hearing aids, and basic vision care, will not be covered and are therefore not captured in out-of-pocket maximums.

Health insurance exchanges are envisioned to function like many familiar online marketplaces, such as Travelocity or Amazon. The fate of the ACA's health insurance exchanges may not be determined entirely until after the upcoming elections. At the moment, only a handful of states have fully committed to implementing exchanges [6]. States that do not implement an exchange will have an exchange implemented for them by the federal government, assuming Congress allocates the appropriate resources. They will be available on January 1, 2014, for uninsured individuals and small groups to compare insurance plans.

Comparison shopping makes sense when buying a product like an automobile, about which individual preferences vary widely. With health insurance, however, we all need the same thing: affordable access to high-quality health care. We need to be able to select our own physicians, but the complexities of selecting an insurance company distract us from genuinely beneficial health care activities. Given the currently dominant role of insurers in our health care, the exchanges are a step forward. But what we need is a leap forward, changing the insurance companies' role and allowing us to focus on our health, not our insurance.

In the 6 years since Massachusetts adopted legislation very similar to the ACA, the cost of health care has continued to drive patients into financial ruin [7]. The state has achieved nearly universal coverage, but, like the ACA, its legislation has yet to effectively address cost and sustainability. Its newly enacted cost-containment law relies heavily on unproven measures such as capitated payments and wellness programs, offering little promise of success [8].

We will not solve our health care crisis as long as private insurance plays a dominant role. We should correct the flaws of the current Medicare program and extend this coverage to all age groups. This approach was well described in 2003 in the Physicians for a National Health Program's "Proposal of the Physicians' Working Group for Single-Payer National Health Insurance" [9].

Major Deficiencies Remain

The Dartmouth Atlas of Health Care has repeatedly documented "glaring variations in how medical resources are distributed and used in the United States" [10]. They attribute much of this variation to supply-sensitive care, that is, care determined by resources and capacity rather than by medical need, and conclude that supply-sensitive care "accounts for more than half of all Medicare spending" [11], some of which is of no medical value and a waste of resources.

A second problem is that the uniquely American plethora of private insurance companies drives a squandering of resources. Legions of staff manage independent computer systems. Each insurance company devotes an enormous number of personnel to responding to emerging regulations from a variety of disparate governmental programs. The expense of this redundancy is considered "overhead" and passed along to the consumer. The intent behind those regulations could instead be implemented once, in a single system servicing the entire country.

Each insurance company develops its own programs for utilization management, prior authorizations, and evidence-based drug formularies to compel the use of that plan's preferred vendors and pharmaceuticals, consuming resources but adding little proven value to health outcomes. No two "evidence-based" formularies have the same drugs on their lists. It's virtually impossible for a physician to remember which low-molecular-weight heparin is preferred by which insurer. Medical groups and hospitals all dedicate staff to managing within this environment, eroding their profits and contributing to a demand for higher reimbursement.

Cost-containment efforts today are focused on the back end of delivery, placing economic pressures on individual physicians and patients who cannot realistically be expected to pursue systemwide solutions [12]. This is the illogic behind "pay for performance" and "consumer engagement."

In a cynical denial of the responsibility for national planning, patients and physicians are expected to be able to control costs today. Information about the prices of treatment regimens is seldom available at the point of health care delivery, especially not for the complex needs of the desperately ill who consume the lion's share of resources. It is inhumane to ask someone dealing with the most dangerous phase of a major illness to attempt a cost-benefit comparison of a variety of therapies and health care providers.

Furthermore, pretending that health care is a commodity does not make it easier to reduce it to something simplistic like a spreadsheet comparing airline tickets. Neither the full cost nor the relevant quality is readily available for comparison-shopping.

The ACA began an important discussion of cost containment through the modernization of broad systems such as electronic health records, prevention, and accountable care organizations. While these may hold promise, there is little reason to anticipate their leading to the savings necessary to reverse the crisis [13, 14].

A Single-Payer System Would Improve Resource Allocation

A single-payer system offers several strategies that have succeeded in other countries. As Marmor and Oberlander have written, "they may not be modern, exciting, or 'transformational.' But they do have the advantage of working" [15].

Consolidate fragmented finances. It's been said that when you are trapped in a hole, the first rule is to stop digging. Certainly don't dig faster.

Profound administrative excesses divert resources into activities that do not improve health outcomes. They often represent the entire careers of countless highly skilled and compassionate people who could be spending their time delivering health care rather than impeding it.

Insurance companies have balked at the ACA's requiring them to spend at least 80-85 percent of their revenue on delivery of health care. (In contrast, more than 98 percent of Medicare's expenditures are clinical [16].) Estimates vary, but one-quarter to one-third of our current costs are driven by insurance company overhead, profits, and the administrative costs embedded in clinical settings. Roughly half of these costs would be recovered under single-payer and could be reallocated to the delivery of meaningful health care services [17, 18].

A single-payer model would eliminate the inefficiencies of fragmentation by converting public programs such as Medicare, Medicaid, and CHIP into a single

administratively efficient financing system. Streamlined billing under single payer would save physicians vast amounts in overhead [19].

In addition to reduced billing expenses, physicians would also enjoy a meaningful drop in their malpractice premiums. Roughly half of all malpractice awards are for present and future medical costs [20], so if malpractice settlements no longer need to include them, premiums would fall dramatically.

Use bulk purchasing to negotiate lower costs. We spend more but use less of most services [21] than other member nations of the Organization for Economic Cooperation and Development. In other words, our prices are much higher [22]. As health care economist Uwe Reinhardt noted,

> prices for identical products or services in the U.S. tend to be, on average, twice or more than the prices of the same products and services paid in other countries…. Prices are high here because the payment side of the health system is so fragmented that few payers have sufficient market power to bargain for lower prices from an increasingly consolidated supply side [23].

Drug formularies vary widely among health plans. The medical evidence behind the formulary selections is the same in Florida and Alaska, yet the drug lists are sometimes as different as the geography. Although pharmacy benefit managers work within the boundaries of medical evidence, they also consider the prices they have negotiated and the local drug market shares on their formulary selections. Any industry's power to negotiate prices depends upon its purchasing volume.

Only a single-payer system enables the kind of bulk purchasing of drugs and medical devices that would give the buyer power. A model for this structure exists today in the United States: the Department of Veterans Affairs. Due to governmental authority to negotiate drug prices for the VA, it pays roughly half of the retail price of drugs [24].

Negotiations with clinicians should ensure adequate reimbursement of expenses plus fair profits, while ensuring value for taxpayers. A recent careful analysis found that this model is effective and does not lead to a loss in physician income [25].

Adopt responsible, rather than profit-driven, strategies. The United States has little national planning of health care resource allocation. Uncontrolled costs consuming an ever-increasing percentage of the GDP create the appearance of inadequate resources, but the experience of other nations [20] belies this. Under a single-payer system, regional planning of resource allocation would be aligned with public health needs rather than duplicating services and driving up medically questionable utilization. Investing in health care buildings and equipment for reasons other than anticipated need duplicates services and drives up utilization. Intelligently planning

capital investments to match community health care needs is the key to aligning utilization of services with public health priorities.

According to the Physicians' Working Group for Single-Payer National Health Insurance, "Capital spending drives operating costs and determines the geographic distribution of resources. When operating and capital payments are combined, as they currently are, prosperous hospitals can expand and modernize while impoverished ones cannot" [9], threatening the viability of safety-net institutions that serve vulnerable populations. This self-stimulating relationship is dependent upon market opportunities, often not the same as public health priorities. Regions with excess capacity inevitably have excess utilization [10]; better planning could also ensure adequate capacity in underserved areas. Divorcing capital from operating budgets eliminates the ongoing pressure to reap future capital growth by limiting reimbursement to clinicians. Capital, operating, and educational budgets would be nationally funded, regionally administered, and nonfungible. Applying national planning to regional budgeting would right-size capacity.

Today's fragmented system is akin to requiring each household in a community to anticipate their needs for the coming year and negotiate their own fees and scope of services with the local police and fire departments. Imagine instead how much of their budgets these life-saving community services would be obliged to devote to marketing to and negotiating with each household and the rampant disparities in service that would result. That is precisely what is happening today in health care, and it is absurdly wasteful. For police and fire departments, we have recognized that it is significantly less wasteful to give all citizens the same "coverage" for set prices and to administer it with regional coordination. Global budgeting is the only sensible strategy for such unpredictable yet universally needed services.

Conclusion

The ACA has begun the process of much needed change. Now we need to go further in reforming health care finance to enable all Americans to achieve their fundamental human right to comprehensive coverage. The rest of the modern world has run the laboratory studies for us; now is the time for us to adopt this well proven solution.

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Ed Weisbart, MD, CPE, is a founding member of the Saint Louis chapter of Physicians for a National Health Program, a single-issue organization advocating a universal, comprehensive single-payer national health program; a faculty member at Washington University of Saint Louis; chief medical officer at Rx Outreach, a nonprofit mail-order pharmacy providing affordable medications for people in need; and a volunteer in a variety of safety-net clinics across the country. Formerly, he was a family medicine practitioner and then the chief medical officer of Express Scripts.

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About the Contributors

Theme Issue Editor

Adam Aronson is a second-year medical student at Washington University School of Medicine in Saint Louis, Missouri. His research interests include cancer, Alzheimer disease, and other diseases of aging. He is considering a career in oncology.

Contributors

Steven L. Berk, MD, is executive vice president and provost of Texas Tech University Health Sciences Center and a professor of internal medicine and dean of the TTUHSC's School of Medicine in Lubbock. He is board certified in infectious diseases and geriatric medicine. Dr. Berk served as chairperson of the Department of Internal Medicine at East Tennessee State University's Quillen College of Medicine during the time of its accelerated residency program.

Valarie Blake, JD, MA, is a senior research associate for the American Medical Association Council on Ethical and Judicial Affairs in Chicago. Ms. Blake completed the Cleveland Fellowship in Advanced Bioethics, received her law degree with a certificate in health law and concentrations in bioethics and global health from the University of Pittsburgh School of Law, and obtained a master's degree in bioethics from Case Western Reserve University. Her research focuses on ethical and legal issues in assisted reproductive technology and reproductive tissue transplants, as well as regulatory issues in research ethics.

Charles Carroll IV, MD, is a hand and orthopedic surgeon at NOI NorthShore Orthopedics and an associate professor of clinical orthopedic surgery at the Feinberg School of Medicine of Northwestern University in Chicago. He is the chairman of the ethics committee for the American Academy of Orthopedic Surgery and the coordinator for ethics of practice for the *Journal of Bone and Joint Surgery*.

Siddhartha Devarakonda, MD, is a second-year resident in internal medicine at Saint Luke's Hospital in Chesterfield, Missouri, whose research and educational interests include the molecular biology of cancer and lung cancer.

Todd Ferguson, PhD, is a research associate for the American Medical Association's Ethics Resource Center in Chicago. His research interests include social justice issues and the value of decency in the design, development, and implementation of health care services. He earned his PhD from Purdue University and is coeditor of *Restoring Hope: Decent Care in the Midst of HIV/AIDS* (2008).

Kevin D. Frick, PhD, is a health economist and professor in the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health in Baltimore. He has conducted cost-effectiveness research on a variety of topics and served on the National Institute for Nursing Research's Advisory Council.

David S. Gierada, MD, is a professor of radiology in the Cardiothoracic Imaging Section of the Mallinckrodt Institute of Radiology at Washington University School of Medicine in Saint Louis, Missouri. He was a Washington University site co-principal investigator of the National Lung Screening Trial.

Ramaswamy Govindan, MD, is a professor in the oncology division of the Department of Medicine at Washington University School of Medicine in Saint Louis, Missouri. His research interests include lung and esophageal cancer.

Michael K. Gusmano, PhD, is an associate professor of health policy and management at New York Medical College in Valhalla and a research scholar at The Hastings Center. Dr. Gusmano's research interests include the politics of health care reform, comparative health systems, aging, health and health care inequalities, and normative theories of policy analysis. His most recent book, *Health Care in World Cities* (Johns Hopkins University Press, 2010), documents the implications of national and local health care policies for access to care in New York, London, and Paris.

Peter S. Hammerman, MD, PhD, is an instructor in medical oncology at the Dana-Farber Cancer Institute and Harvard Medical School in Boston, an affiliated researcher at the Broad Institute, and a clinician in the Lowe Center for Thoracic Oncology. His research interests are lung cancer genomics and development of novel targeted therapeutics.

Sabine Iben, MD, became interested in bioethics while dealing with complex ethical cases as a staff neonatologist and neonatal director of the Fetal Care Center at the Cleveland Clinic Foundation in Ohio. Dr. Iben has a certificate in pediatric bioethics from Children's Mercy Hospital in Kansas City.

Narayan P. Iyer, MD, is a fellow in neonatology in the Case Western Reserve University-Cleveland Clinic Foundation-MetroHealth Medical Center Neonatal-Perinatal Fellowship whose research interests include neonatal pulmonary mechanics and quality improvement.

Betsy Goebel Jones, EdD, is a professor and vice chair of the Department of Family and Community Medicine at the Texas Tech University Health Sciences Center School of Medicine in Lubbock. She is a member of the Family Medicine Accelerated Track leadership team and regional director of the Laura W. Bush Institute for Women's Health.

Lawrence M. Kotner, Jr., MD, is an associate professor of radiology in the Abdominal Imaging Section of the Mallinckrodt Institute of Radiology at Washington University School of Medicine in Saint Louis, Missouri. Dr. Kotner has a special interest in the historical and ethical issues of medicine.

C. Ronald MacKenzie, MD, is an associate professor of medicine at the Weill Cornell Medical College in New York City and an attending physician at Hospital for Special Surgery, where he holds the C. Ronald MacKenzie Chair in Ethics and Medicine. He is chairman of the American College of Rheumatology Ethics and Conflict of Interest Committee.

Matthew J. Matava, MD, is a professor of orthopedic surgery and co-chief of the sports medicine section of the Washington University Department of Orthopedic Surgery in Saint Louis, Missouri. His clinical and research interests include sports-related injuries of the knee and shoulder, articular cartilage restoration, and multiligament knee reconstruction. He is the head team physician for the Saint Louis Rams football team and Washington University varsity athletics and assistant team physician for the Saint Louis Blues hockey team.

Katherine J. Mathews, MD, MPH, MBA, is director of clinical services at Casa de Salud, a health care organization that serves low-income, Spanish-speaking people in Saint Louis, Missouri. Dr. Mathews has a long history of public health and health policy work to improve access to high-quality care for the medically underserved.

Will Ross, MD, MPH, is associate dean for diversity and associate professor of medicine in the Renal Division at Washington University School of Medicine in Saint Louis, Missouri. A senior fellow at the Center for Health Policy, Dr. Ross focuses on minority health care workforce development, knowledge mapping, and construction of conceptual frameworks to reduce health care inequities.

Ed Weisbart, MD, CPE, is a founding member of the Saint Louis chapter of Physicians for a National Health Program, a single-issue organization advocating a universal, comprehensive single-payer national health program; a faculty member at Washington University of Saint Louis; chief medical officer at Rx Outreach, a nonprofit mail-order pharmacy providing affordable medications for people in need; and a volunteer in a variety of safety-net clinics across the country. Formerly, he was a family medicine practitioner and then the chief medical officer of Express Scripts.