

Virtual Mentor
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The “R” Word—Ethical Allocation of Medicine’s Resource

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FROM THE EDITOR Confronting the “R” Word

As it has become more and more obvious, over the last several decades, that we cannot continue to afford our current medical care delivery system, the “r” word—rationing—has elicited extreme rhetoric and aroused much concern. Rationing is the controlled distribution of resources, goods, or services that are in short supply. In the United States, health care, much of which is privately financed, is one of our scarcest resources. In the private sector, health care is limited—which is to say, rationed—in free-market fashion: you get what you, or your employer, can afford. In the public sector, health care is rationed by long waits in emergency rooms and high patient copays coupled with low payments to physicians that discourage some from accepting Medicare and Medicaid patients.

In July 2009, Peter Singer wrote that the case for explicit health care rationing in the United States starts with the difficulty of thinking of any other way in which we can continue to provide adequate health care to people on Medicaid and Medicare, let alone extend coverage to those who do not now have it. Health-insurance premiums have more than doubled in a decade, rising four times faster than wages. Health care now absorbs about one dollar in every six the nation spends, a figure that far exceeds the share spent by any other nation. According to the Congressional Budget Office, it is on track to double by 2035 [1].

Rationing health care means getting better value for the billions we spend by limiting which treatments are paid for with public money. No one wants to be the one who is denied health care, an expensive pharmaceutical, or a physician’s time and focus. But when public funds subsidize or pay fully for health care, we have to try to get the best possible value for our money. Some form of health care rationing is both desirable and inescapable. How do we change our thinking and practice to both protect patients from falling by the wayside, of having their care “rationed,” as they fear, and continue to provide them with care?

In this issue, we examine a number of different ways to understand and implement rationing in our health care system. The clinical cases deal with issues that arise when patients’ perception of what constitutes necessary care is at odds with what is medically indicated for management, when changes in evidence-based medicine alter our ideas about providing cost-effective care, and when we try to assign a price to human life and health. We also look at how physicians have dealt with the rising

costs of running a practice in the face of decreasing payments by rationing their time with patients—and ultimately, spending less time at home.

What all this comes down to is that we as a society are at a crossroads. As President Obama has said, the health care system is broken. We have to change how we think, how we spend, and what we expect. As physicians, we have to help our patients understand that the era of offering tests and services “because they are covered” is over. The new era will be one of relying on comparative effectiveness (and perhaps even cost-effectiveness) analysis and being called upon to justify services that are not recommended by the results of those studies. In the end, rationing is not about taking away from our patients something they truly need, but being able to give more of what we have to more people.

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CLINICAL CASE

Cost Effectiveness in Clinical Screening

Commentary by Robert J. Karp, MD, and Yuriy Shepelyak

Dr. Jorgensen is a family practice doctor with a steady, yet varied, patient population. Practicing medicine in a small suburban community, he sees whole families ranging from newborn babies to adults well into their 80s. He prides himself on his practice of preventive medicine in particular, and, because he has such a longstanding rapport with his patients, they adhere to his counseling on healthy living and follow up regularly for annual physicals and appropriate screening tests.

Among other things, Dr. Jorgensen is particularly diligent in his screening for, and treatment of, diabetes mellitus; he tests all of his patients over age 45 for diabetes and refers all of his diagnosed diabetic patients for annual ophthalmologic exams.

Recently, Dr. Jorgensen began mentoring a new family practice physician, Dr. Sandkey. Dr. Sandkey completed her residency in family practice at a large, inner-city academic hospital, where she attended a number of lectures on cost-effective treatment. Like Dr. Jorgensen, Dr. Sandkey has a special interest in preventive medicine and is well-versed in the current recommendations regarding diabetes screening and treatment.

Because Dr. Sandkey is looking to model her practice after Dr. Jorgensen's, she has been going through old patient charts to see how Dr. Jorgensen tracks his patients' health maintenance. One day she approaches Dr. Jorgensen to discuss his screening practices: "Dr. Jorgensen, I have to ask you about how you choose your medical interventions and screenings. I read a study that indicated screening everyone age 45 and older for diabetes had minimal benefit but cost more than \$500 per person on average. Why have you decided to screen this entire group of patients?"

Commentary

"The human condition is such that...there are many possible courses of actions and forms of life worth living, and therefore to choose between them is part of being rational or capable of moral judgment; [we] cannot avoid choice for one central reason...namely that ends collide; that one cannot have everything....The very concept of an ideal life...is not merely utopian, but incoherent."

Isaiah Berlin [1]

Dr. Jorgenson is imbued with a sense of obligation to his patients that transcends matters of cost. He wants to serve them well within a society that can seem frivolous

in its willingness to indulge the “haves” and penurious when it comes to the health and well-being of the “have nots.”

Let’s say that Dr. Jorgensen graduated in the 1960s from an institution known for its difficulty and its superb reputation for training clinicians. In Dr. Jorgensen’s day, students spent the first 2 years deeply engaged in the fundamentals of biochemistry, physiology, and other building blocks needed to undergird the practice of clinical medicine, which were the emphasis of the third and fourth years.

If the word “ethics” was spoken in a class or clinical setting, Dr. Jorgensen does not remember. But to him, ethical practice means providing the same care for rich and poor, powerful, and disenfranchised alike. In the current American health context, in which diabetes is a real risk for many, including or especially the poor, Dr. Jorgensen understands equal care to mean putting a particular emphasis on diabetes screening, as recommended by the American Diabetic Association [2].

Fresh from her much more recent education and residency in family medicine at Dr. Jorgensen’s alma mater, Dr. Sandkey’s training very likely included an emphasis on cost effectiveness—overtly, in the form of lectures and seminars, and more subtly, in the culture of her educational institutions. The difference in their perspectives may be due more to the evolving priorities of medical education than to a lack of concern for patients on her part. But Dr. Sandkey could put Dr. Jorgenson off by broaching this topic as though cost effectiveness is the primary concern. If anything, even if she came with the highest levels of recommendation for her engagement, understanding, and skills, it could make Dr. Jorgenson question his judgment in choosing her as a mentee. “What a mistake,” he might think. “The product of an enlightened education comes out worshipping the almighty dollar rather than caring about the essential needs of patients. I’m ashamed.”

Dr. Sandkey might foster a more productive conversation if she takes a respectful, evidence-based approach and reassures Dr. Jorgenson of her commitment to the patients’ interests. Supposing Dr. Sandkey said the following: “Preventive medicine is one of my highest priorities. What I’m suggesting is only that there may be an alternative way to provide optimal service at the lowest cost and danger. The ‘population strategy’ you suggest for screening, in which we screen everyone, is best when there is a diagnosable and treatable problem with few signs or symptoms spread though the community which we have a low-cost, low-pain method of identifying. As Caroline Wright has written, ‘organized population screening programs [must be] designed to ensure that the benefits of screening outweigh the harms’ [3]. Screening babies for hearing loss and infants for lead poisoning meets those standards [4]. I’m not sure that a population strategy serves our older patients who might have diabetes.”

Dr. Sandkey is in favor of an “at-risk” strategy, one in which clinicians identify the presence of “biologic or environmental factors that predispose...[and] easily recognizable early warning signs that [it] is impending,” and screen only the

patients who are subject to those factors [5]. She suggests, “An ‘at-risk’ strategy would work better, especially if combined with guidance given to everyone—a ‘public health’ strategy” [6]. This last approach, often used in childhood, is not to screen at all because the risks of screening are too high. Instead, everyone receives recommendations for healthy living [7].

Dr. Sandkey might support her argument by respectfully mentioning that her ideas are in agreement with evidence-based guidelines made to further the interests of patients. The United States Preventive Services Task Force, for example, recommends an “at-risk” group approach for diabetes screening [8]. Though the ADA takes a population approach [1], it adds “*particularly those with a body mass index of 25 kilograms per meter squared or greater.*” Emphasis is added to show that the ADA leaves discretion for use of an “at-risk” approach to the clinician. As its data show, there was moderate evidence of effectiveness only for screening adults with hypertension.

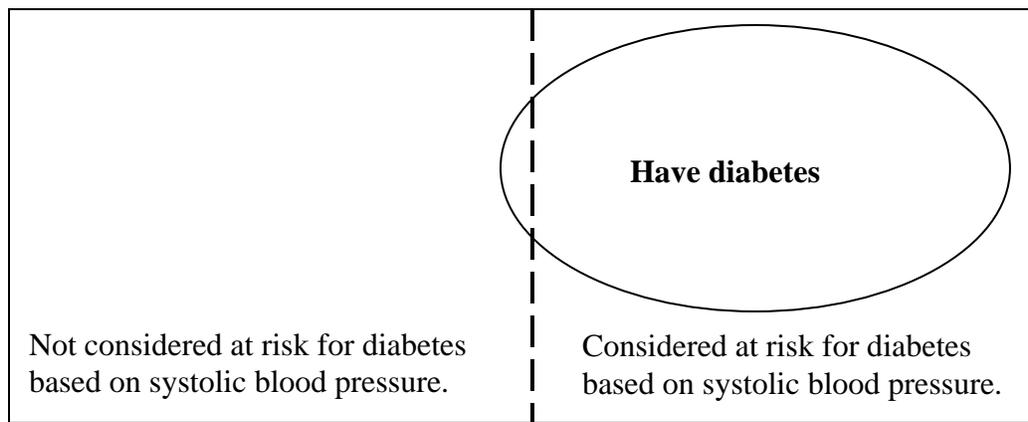
Dr. Sandkey could say, “Both the American Academy of Family Physicians [9] and the Canadian Task Force on Preventive Health Care [10] found insufficient evidence to recommend screening adults who are at low risk for coronary vascular disease. This seems like a good way of removing patients who are very unlikely to have a positive result from the screening pool.”

Dr. Sandkey might go on to argue that screening should be limited to conditions that meet the following five criteria [11]:

1. It is an important public health concern;
2. there is an asymptomatic period;
3. an effective screening test exists;
4. there is a treatment for the disorder; and
5. treating the asymptomatic stage is proven to provide long-term benefit.

Screening an undifferentiated population leads to an increase in the number of patients with false positive test results and a decrease in the positive predictive value of your testing [12]. According to Bayes’ Theorem, the predictive value (PV) of a test is proportional to the prevalence of the problem in the population surveyed. Thus, the goal of a screening process is to create the smallest possible pool of patients containing all or almost all affected individuals (the true positives, or TPs). An ideal—and ideally cost-effective—screening test has maximal sensitivity with least loss of specificity: the number of false positives (FPs) is kept at a minimum and the PV ($TP / [TP + FP]$) is at its maximum. An appreciation of Bayes’ Theorem, often difficult for the clinician, is critical to the use of evidence-based medicine [13].

“Our goal,” she could declare, “is to create the smallest pool containing all or almost all who are affected, leaving out those we are sure are not.” And then she could show him this figure:



**Population screening:
screen all regardless of SBP.**

**At-risk screening:
screen all with SBP above 135.**

Fig. 1. Screening everyone (the entire rectangle) is a “population” strategy. Screening to the right of the dotted line would be taking an “at-risk” strategy.

“So,” she would continue, “an ‘at-risk’ approach is most efficacious and has the lowest human, as well as economic, cost. Of course, I do propose implementing a public health strategy: Though different treatments would be provided for those patients who tested positive and those who did not; preventive guidance is appropriate for everyone.”

By making clear her shared commitment to benefiting patients, Dr. Sandkey can show Dr. Jorgenson that she is interested in preventive medicine and well-versed in the recommendations for screening strategies, and he may be more willing to consider an alternative plan. They will do regular risk assessment interviews for all patients using a behavior modification approach that encourages healthful diet and habits. They will focus on obesity, smoking, and preventing hypertension. When, however, patients show identifiable risk for diabetes, they will perform formal testing.

Now they will be satisfied. Why? Because they were able to listen to each other’s concerns, communicate effectively, and find a common path that allows them both to maintain their ethical standards, and, finally, they can feel confident that they are doing right by their patients.

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Robert J. Karp, MD, has been a professor of pediatrics at the Children’s Hospital at SUNY Downstate in Brooklyn, New York, for 24 years. During the early 1970s in Philadelphia, he worked in an inner-city school health and nutrition project, which was outside the ethos of medical practice at the time. His current project is *A Teacher’s Guide to Pediatric Nutrition*.

Yuriy Shepelyak is a third-year medical student at SUNY Downstate Medical Center in Brooklyn, New York. He was born in Ukraine, grew up in Brooklyn, and will probably spend the rest of his life in New York City. He is strongly considering going into pediatrics or physical medicine and rehabilitation.

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CLINICAL CASE

Patient Requests for Nonindicated Care

Commentary by Zachary Ginsberg, MD, MPP, and Erica Kreismann, MD

Dr. Michaels was an experienced ER attending physician in a major level 1 trauma center working the night shift. It had been a relatively slow shift so far, so he had spent a lot of time teaching his new intern, Jay. Just after 11 p.m., Jay came to present a 53-year-old patient, Mr. Brower, who was experiencing sudden-onset back pain with numbness and tingling down his leg after having lifted a heavy box. Jay had conducted a thorough history and physical, and Dr. Michaels agreed with his assessment that Mr. Brower had a herniated disc in his lumbosacral spine.

Dr. Michaels asked Mr. Brower to repeat the events surrounding the onset of his back pain, reviewed Mr. Brower's physical findings, and gave Jay the signal to explain the diagnosis. After explaining the anatomy of the spine and how the herniated disk could cause Mr. Brower's leg symptoms, Jay recommended 2 days of limited activity and treatment with a nonsteroidal anti-inflammatory drug followed by a return to normal activities. He then added that if Mr. Brower's symptoms did not improve, he could come back for further testing, including an MRI to confirm the diagnosis. Confused, Mr. Brower asked why they did not want to perform an MRI now.

Dr. Michaels stepped in to explain that, given Mr. Brower's history and physical, there was little doubt that the cause of his discomfort was a herniated disc. "We are confident of the diagnosis, Mr. Brower, having often seen the symptoms you report following an event like you describe—lifting the heavy box. We always recommend conservative management first. If your symptoms improve, which they most likely will, there's no reason to be concerned. Further imaging and testing is really only necessary when our 'tried and true' methods of treatment don't work. We'll follow you closely to see how you do."

"But Doc," Mr. Brower protested, "why not just do the MRI now? I'm here already and I want to be sure it's just this disc thing you're talking about. My insurance will pay for it, so I don't understand what the big deal is. Is this a cost-cutting thing? I don't want my health to suffer just to help your hospital's bottom line!"

Commentary

It is difficult to find oneself in disagreement with the wishes or desires of a patient. We live in a society that values patient autonomy highly. Patients are often in role of consumers and have expectations about the service they are receiving. Yet

physicians must also keep in mind the overriding context of care while working to benefit their patients' health.

Health care resources are not without limit, which the national debate is making increasingly clear. And allowing unlimited access to certain resources sometimes renders them unavailable to other patients. One way to frame the tension in this scenario is to look at it as a conflict between two basic tenets: autonomy and distributive justice. How can we best balance our stewardship of limited resources with patients' desire to direct their own care?

With regard to a resource such as MRI access, which is limited because of its cost, the wishes of an individual patient may be overridden by the ethical principle of distributive justice: making scarce resources available to those who need them. A just distribution of resources allocates preferentially to those who need rather than want the MRI. Concern for justice should prompt the clinician—and patient—to assess whether the premature use, as defined by medical indication, of a scarce resource is appropriate given that it may not be available when it is needed for another patient. In a just health care system, does the patient's right to make autonomous decisions about health care entitle him or her to make requests that limit resource availability for other patients?

Another way to frame the tension is to see it as a conflict between respect for patient autonomy and physicians' clinical judgment. When a patient in a tertiary or quaternary care center requests a test or therapy that we would not recommend or that is not medically indicated, what obligation do we have to acquiesce? The physician in this case must balance respect for the patient's autonomy with his or her own judgment to uphold both the principle of nonmaleficence—exposing the patient only to the risks of therapies that are indicated and necessary—and distributive justice.

Do we treat patients like customers in a department store? Or can we—must we—temper their autonomy with the paternalistic goal of doing what is in the patient's best interest while also distributing resources to those who need them most? Unlike a department store, which encourages consumers to purchase whatever they want and can afford in accordance with the business's goal of selling as much inventory as possible, the health care setting has limited resources and the interventions available are not without risk to the patient or patient pool. Physicians avoid harm where possible, yet we would posit that a patient's right to an autonomous decision does not compel physicians to perform tests or treatments they believe to be outside the realm of indicated practice.

Patients seek doctors not only for the access they provide to therapeutic and diagnostic interventions; they seek the counsel of physicians because of their years of study and insight. Acquiescing in the moment could compromise the care of the next patient without providing clear benefit (and, sometimes causing harm) to the present patient. Thus, a physician whose patient requests a nonindicated test is not

ethically bound to fulfill it. While this view might be unpopular with those patients who view health care as a consumer good, it is not unethical to withhold *nonindicated* treatment in the name of distributive justice.

In response to the patient's question whether this is a cost-cutting measure to save the hospital money, all communication should be honest and start with reassurance that patient need, as opposed to finances or convenience, drives clinical-decision-making. Furthermore, the physician should explain that a 2-day delay is not withholding care, but giving the patient time to recover so that he will only be exposed to the risks of testing if it is absolutely necessary. Not only is no test benign, but false positives have risen as nonindicated testing increases, and an MRI might expose him to further unnecessary risk if a false positive prompted unnecessary intervention. If he waits the 2 days, these risks will be minimized—and the cost of testing will only be incurred if needed.

In our current context of care, as we strive to improve health outcomes while containing costs through conscientious stewardship of our health care resources, it is essential to identify the limits of what is possible ethically. From this discussion, we contend that whether one views health care as a market commodity or public good, there should be ethical limits on requests for interventions, tests, and therapies that are not medically indicated. Physicians are ethically justified by the principle of distributive justice to decline this request if and when the resource is scarce, and deny a service that is not medically indicated.

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CLINICAL CASE

Rationing Treatments Based on Their Cost per QALY

Commentary by David A. Wong, MD, MSc, FRCS(C)

Dr. Jackson is an orthopedic surgeon with an excellent record for good medical care and patient satisfaction. Over the last 5 years, her hospital's financial security has declined and administrators have been looking at various options for reducing the cost of care. They have tentatively decided to phase out treatments and services that cost more than a certain amount per quality-adjusted life year (QALY). This will enable them, they feel, to provide the most health for their dollar, so to speak.

Dr. Jackson receives a letter from the hospital stating that she will no longer be able to offer treatments deemed insufficiently cost-effective. This includes the injection of epidural steroids for sciatica, a treatment that has resulted in crucial relief in the short term (about a month) for Dr. Jackson's patients but, due to the need for repeat injections and the absolute expense of the treatment, has a high cost per QALY.

In disbelief, Dr. Jackson calls her friend Dr. Stein, one of the hospital administrators. She explains to Dr. Stein her view that patient care should not be affected by the cost of the services she uses, especially when the treatments have worked well for her patients; if treatments are *clinically* effective, they should be offered. Dr. Stein, himself a clinician, agrees personally with this view and knows of Dr. Jackson's excellent record for patient satisfaction, but he says, "The hospital is going to go under: we simply can't afford to spend the way we've been spending. You know as well as I do that if we close, many of our patients will have nowhere to go. We have to cut back somewhere; what do you suggest?"

Commentary

Ethical challenges are an inherent component of medical practice. Examples of these dilemmas have appeared in medical treatises as far back as Hippocrates' exhortation to first do no harm. As we move into a new era of health care reform, ethical allocation of limited medical resources will become a more pressing challenge for the medical profession in the United States. Essentially, the quandary boils down to the conflict between society's need to limit health care spending and medicine's promise to provide effective care for individual patients.

American society's discomfort with cost-effectiveness research and putting a price on human life and health (e.g., the debate over "death panels") has kept the government from directly basing its coverage and payment decisions on this type of research. Instead, the 2009 Stimulus Bill HR-1 provided \$1.1 billion for comparative effectiveness research (CER), comparing the effectiveness of two or more

interventions, to the National Institutes of Health (NIH), the Center for Medicare and Medicaid Services (CMS), and the Agency for Healthcare Research and Quality (AHRQ) [1]. In addition, the United States Institute of Medicine (IOM) was charged with determining the top 100 priorities for CER [2].

Attention to basic health care economic analysis has been sadly lacking in medical curricula in the United States. Physicians must quickly educate themselves on both comparative effectiveness research and cost-effectiveness research. Otherwise, we will abdicate major medical treatment decisions to health economists, politicians, and government policymakers.

Rationing using the principle of cost effectiveness has been a cornerstone of health care delivery in many countries, most notably the United Kingdom (U.K.). Cost-effectiveness research generally compares the cost of a medical intervention or technology to a measure of the outcome's value [3], often the quality-adjusted life year (QALY). The effectiveness of a procedure is thus generally reported as a dollar amount per quality-adjusted life year gained. The QALY measurement incorporates both the quality of health (as measured by a utility score) and the length of time (benchmark one year) over which the health state exists.

The ethical questions raised by rationing health services according to their cost effectiveness begin with setting the cost per QALY for which a medical treatment will be approved and reimbursed. The National Institute for Health and Clinical Excellence (NICE) in the U.K. has used a cost per QALY of £30,000 (approximately \$48,000) as the threshold [4]. Thus, a treatment or technology costing less than this limit will generally be approved and an intervention costing more will be refused. By this criterion, even treatments with a definite positive clinical outcome will be unavailable from the National Health Service if their cost per QALY exceeds the threshold.

An example of a procedure that is limited in the U.K. and used frequently in the U.S. is the lumbar epidural steroid injection (ESI) for a herniated lumbar disc. Based on the findings of a randomized controlled trial by Price et al. [5], NICE eliminated epidural steroids as a reimbursed treatment for sciatica in the NHS because the authors calculated that the cost to improve a patient's health status for a year (cost per QALY) was £354,171 (approximately \$571,335). This figure far exceeds the £30,000 threshold that NICE uses to approve reimbursement.

Consider the ethical issues raised by this one example:

- Should coverage decisions be made solely using class I [6] data, i.e., a single RCT, or should level II data such as large case series—which do not entail the expense and clinical difficulties of an RCT—be included in the decision-making process? I believe they should be, especially if outcomes for a particular treatment or technology can be reproduced and level-II conclusions become more reliable.

- Ethically, what is a reasonable threshold to set the cost per QALY gained? There have been suggestions that \$100,000 might be a figure that U.S. society would be willing to pay [7]. Of course, some people will consider it rationing to set *any* cost-per-QALY limit.
- Should the benchmark for cost effectiveness be a year, or should we fund treatments with shorter periods of improvement? I do think there is a role for treatments such as ESI that result in shorter periods of improvement and thus are expensive when considered in isolation in a cost per QALY analysis. But if an ESI gives relief in the short term that, when combined with other treatments like medications and physiotherapy, can be part of a good outcome overall, one could argue that the combined-treatment approach (not just the ESI) should be considered in a cost analysis.
- Is it ethical to withhold treatment based primarily on cost? My personal view is that cost is only one factor in clinical decision making and should not be made the sole determinant. Outcomes—prognosis for recovery of functional status—and other clinical factors—such as whether a condition is acute or chronic—should be major considerations in comparing treatments, not just cost effectiveness.

Clearly, the adoption of cost-effectiveness concerns into the United States health care system raises a number of ethical issues. To be active participants in formulating policy decisions which will impact day-to-day patient care, physicians must become familiar with the principles, methodology, and limitations of CER and cost comparisons and the associated ethical issues.

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MEDICAL EDUCATION

Teaching Resource Allocation—And Why It Matters

Meina Lee, LLB, and Elizabeth Geelhoed, PhD

Health care rationing—whether to do it, how to do it—is a highly debated topic, especially in light of health care reforms currently being pursued. The unavoidable truth is that society’s resources are limited even in the United States and we can no longer pretend that we can offer every patient every medical treatment. Health systems around the world face the same predicament, and difficult choices have to be made to ensure that money spent on health care is used to best effect.

Much news coverage is given to often-political “big-ticket” resource allocation decisions made by governments. There is a disconnect between the decision makers at the system level and those at the bedside. But the high-level decisions ultimately influence the day-to-day decisions made by physicians, nurses, and other health professionals.

The statistics are well publicized: the United States spends two and a half times the average on health care [1] and is predicted to spend 25 percent of its GDP on health care by 2025 [2]. Last year a Gallup-Healthways poll found that 1 in 6 adults in the U.S. did not have health insurance [3]. How are these figures relevant to medical students when they graduate and begin to practice? For a number of reasons, it is important for future medical decision makers to understand how resource allocation decisions further up the chain of command are being made. Medical decision making does not exist in a vacuum. It affects—and is affected by—the economic and social environment of the health system.

In this article, we describe the experience of teaching health economics to students at the School of Population Health at the University of Western Australia. In particular, we discuss how an understanding of ethics can inform resource allocation decisions.

Health Systems and Economics

The study of health economics is well established in Australia. A health economics course that focuses on issues relating to scarcity in the allocation of health resources has been taught at the School of Population Health since the 1990s. The course is compulsory for undergraduate health science students, master of public health students, and nursing and pharmacy students. It is not, however, compulsory for medical students, even though doctors have the greatest influence on how health dollars are spent.

Students are taught basic theoretical and conceptual frameworks from economics and other disciplines that enable them to analyze the functioning of a health system critically. Importantly, they learn how to apply economic theories of demand, supply, and markets. They are taught methods and techniques to evaluate the cost effectiveness of health care programs. The aim is practical: rather than being an academic exploration of the topic, students are expected to be able to integrate these evaluations into resource allocation decision making. They are also taught how to compare international health systems, specifically in terms of efficiency and equity. Such comparisons explore the extent to which additional resources can improve overall health under different scenarios and the importance of the distributional effects.

The Roles of Ethics in Resource Allocation

Health economics provides a range of measures to help in deciding whether to allocate resources to a particular area or another. Cost-benefit analyses distill the “cost” and the “benefit” into purely dollar terms. However, students are introduced to other concepts such as cost effectiveness, in which the value of a particular program is expressed not in dollar terms, but rather in terms of health outcomes such as life years gained.

One reason for using a cost-effectiveness approach is that we value health so highly and hesitate to view it in purely dollar terms. Good resource allocation decisions must involve more than a money-based analysis; they must reflect what society thinks is worth investing in.

This is where ethics can contribute. Ethics provides a framework for examining and ordering our values. We can value things such as respect for personal autonomy, doing no harm, value for money, or privacy. If enough individuals value the same things in the same way, we can determine a general set and ranking of community values. (At the same time, ethical values are not universal and what is considered highly important, e.g., respect for autonomy, will depend on culture, time, and place.)

Almost all health resource allocation decisions have ethical consequences because they promote particular values while minimizing others. Indeed, ethical norms are so embedded in resource allocation decisions that we can take them for granted. For example, will we prefer to fund preventive measures or cures? Will we prefer to put more resources into fighting diseases that affect the young or those that affect the elderly? Is “life years gained” the most important outcome? Knowing how well a particular resource allocation aligns with a society’s priorities can help decision makers gauge how acceptable it is going to be to that community.

Therefore students are also taught ethics, in particular the trade-off between ethics and efficiency when making resource allocation decisions. Although we value efficiency, sometimes we might prefer to fund a program that is less efficient

because it reflects something more important to us. Ethics sets out a systematic way to tease out these elements.

Once students are introduced to the fundamentals of common (Western) ethical theories, they apply them to examples taken from health systems around the world. Consider, for example, co-payments. Western cultures generally place great value on individual rights and self-determination (autonomy). Understanding this, private health insurers often allow subscribers more choice of treatments or physicians in return for higher co-payments. It is thought that, by making individuals responsible for a share of their health costs, they will more thoroughly investigate all possible treatment options and prices. In this way, patients enjoy more choice while being delegated more responsibility for their health care. Conversely, there is the risk of “moral hazard” if there are no co-payments. In essence, if individuals don’t have to pay for their own health care they’re more likely to have treatments they don’t really need.

Another example of resource allocation decisions studied in the health care economics course is the public and private insurance arrangements in Canada and Australia. Both countries provide universal health coverage, but their structures reveal different approaches to defining “universal.” In Canada, the law establishes a universal maximum on coverage. Private insurers are generally prohibited from covering any services that are also publicly covered. In other words, if procedure A is publicly covered then there is only one waiting line—and everyone who wants that procedure joins that line. Regardless of wealth, people can’t buy their way to the front through private insurance.

By contrast, the Australian Medicare system provides a universal minimum. There is a uniform floor of publicly covered services. However, individuals have the freedom to supplement with private insurance and join a different, shorter line for that service—provided they are willing to pay for it.

Both Canada’s and Australia’s systems reflect a societal preference for equality. Nevertheless, health and income disparities worldwide continue to increase, as seen in the United States. Health inequality could theoretically save money because of lower life expectancy, but it can cause greater disability in marginalized socioeconomic groups and also cost the nation through productivity losses and possibly political unrest. Because current reforms designed to ensure minimum health coverage for all depend on increased taxes for higher wage earners, such changes have been contentious.

Other Observations

The course curriculum continues to evolve over time. An important challenge is thinking of ways to better engage students on the topic. Students tend to think that learning about the economic aspects of supply and demand and strategic expenditure decisions are far less important than their clinical coursework.

The recent global financial crisis has put additional pressure on health systems around the world. More than ever, we need to make sure that money spent on health care is used to best possible effect. This will require effort on the part of everyone in the health system—from the government down to the patients and doctors. An understanding of how their actions affect the wider context of the health system will provide future doctors with the grounding to make the health system they inherit better.

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THE CODE SAYS

AMA Code of Medical Ethics' Opinions on Allocating Medical Resources

Opinion 2.03 - Allocation of Limited Medical Resources

A physician has a duty to do all that he or she can for the benefit of the individual patient. Policies for allocating limited resources have the potential to limit the ability of physicians to fulfill this obligation to patients. Physicians have a responsibility to participate and to contribute their professional expertise in order to safeguard the interests of patients in decisions made at the societal level regarding the allocation or rationing of health resources.

Decisions regarding the allocation of limited medical resources among patients should consider only ethically appropriate criteria relating to medical need. These criteria include likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in some cases, the amount of resources required for successful treatment. In general, only very substantial differences among patients are ethically relevant; the greater the disparities, the more justified the use of these criteria becomes. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients. Non-medical criteria, such as ability to pay, age, social worth, perceived obstacles to treatment, patient contribution to illness, or past use of resources should not be considered.

Allocation decisions should respect the individuality of patients and the particulars of individual cases as much as possible. When very substantial differences do not exist among potential recipients of treatment on the basis of the appropriate criteria defined above, a "first-come-first-served" approach or some other equal opportunity mechanism should be employed to make final allocation decisions. Though there are several ethically acceptable strategies for implementing these criteria, no single strategy is ethically mandated. Acceptable approaches include a three-tiered system, a minimal threshold approach, and a weighted formula. Decision-making mechanisms should be objective, flexible, and consistent to ensure that all patients are treated equally.

The treating physician must remain a patient advocate and therefore should not make allocation decisions. Patients denied access to resources have the right to be informed of the reasoning behind the decision. The allocation procedures of institutions controlling scarce resources should be disclosed to the public as well as subject to regular peer review from the medical profession.

Issued March 1981, updated June 1994, based on the report "[Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients.](#)"

Opinion 2.095 - The Provision of Adequate Health Care

Because society has an obligation to make access to an adequate level of health care available to all of its members regardless of ability to pay, physicians should contribute their expertise at a policy-making level to help achieve this goal. In determining whether particular procedures or treatments should be included in the adequate level of health care, the following ethical principles should be considered:

- (1) degree of benefit (the difference in outcome between treatment and no treatment),
- (2) likelihood of benefit,
- (3) duration of benefit,
- (4) cost, and
- (5) number of people who will benefit (referring to the fact that a treatment may benefit the patient and others who come into contact with the patient, as with a vaccination or antimicrobial drug).

Ethical principles require that a just process be used to determine the adequate level of health care. To ensure justice, the process for determining the adequate level of health care should include the following considerations:

- (1) democratic decision making with broad public input at both the developmental and final approval stages,
- (2) monitoring for variations in care that cannot be explained on medical grounds with special attention to evidence of discriminatory impact on historically disadvantaged groups, and
- (3) adjustment of the adequate level over time to ensure continued and broad public acceptance.

Because of the risk that inappropriate biases will influence the content of the basic benefits package, it may be desirable to avoid rigid or precise formulas to define the specific components of the basic benefits package. After applying the five ethical values listed above, it will be possible to designate some kinds of care as either clearly basic or clearly discretionary. However, for care that is not clearly basic or discretionary, seemingly objective formulas may result in choices that are inappropriately biased. For that care, therefore, it may be desirable to give equal consideration (e.g., through a process of random selection) to the different kinds of care when deciding which will be included in the basic benefits package. The mechanism for providing an adequate level of health care should ensure that the health care benefits for the poor will not be eroded over time.

Issued June 1994, based on the report “[Ethical Issues in Health System Reform: The Provision of Adequate Health Care.](#)”

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JOURNAL DISCUSSION

Identifying Bedside Rationing

Taeho (Greg) Rhee

Ubel PA, Goold S. Recognizing bedside rationing: Clear cases and tough calls. *Ann Intern Med.* 1997;126(1):74-80.

In “Recognizing Bedside Rationing: Clear Cases and Tough Calls” [1], Ubel and Goold define bedside rationing as “the withholding by a physician of a medically beneficial service because of that service’s cost to someone other than the patient” [2]. The practice is often controversial. As they write elsewhere, most cases of health care rationing are “morally charged” and entail “difficult decisions with potentially tragic consequences” [3]. It is critical for physicians to be able to understand bedside rationing and be able to recognize it in their own practices.

Ubel and Goold put forth three conditions that make withholding a service 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]. They provide an example in which bedside rationing was clearly occurring in 1997, when the article was written.

A patient arrives at his local emergency department with the classic signs and symptoms of acute myocardial infarction. The emergency department physician decides to administer thrombolysis with streptokinase rather than tissue plasminogen activator even though the latter is slightly better for this type of heart attack. Tissue plasminogen activator costs 10 times as much as streptokinase, and the physician thinks that the benefits of this therapy are not worth the additional costs [2].

The example meets all three necessary conditions for bedside rationing. There are, however, many other cases in which bedside rationing is more difficult to identify. The authors give a more ambiguous example:

A neurologist works at a county hospital that does not have a magnetic resonance image (MRI) scanner. The hospital puts money aside each year so that six patients can receive an MRI at a nearby hospital. A physician evaluates a patient who has a “soft indication”

for an MRI. The physician could order an MRI for the patient. However, he knows that if he requests an MRI for this patient, he denies an MRI to another patient, who may need it more. Thus, he tells the patient that an MRI is unnecessary [4].

At first glance, this case may not seem to be an example of bedside rationing, since the scarcity of time slots and the hospital's limitation on the number of MRIs available each year is not the physician's doing [2]. But the physician does decide when and to whom to grant MRI access. From an economic standpoint, it may be justified to deny the MRI; yet the physician must still recognize this as a form of rationing. Furthermore, the physician has an ethical responsibility to inform the patient that the MRI is, above all, unavailable, not strictly useless.

Ubel and Goold suggest that physicians ask themselves three basic questions to identify whether their actions qualify as bedside rationing [2]. The first question is whether the service that is being withheld is in the patient's best medical interests. If not, then no rationing has occurred. If the answer is yes or unclear, the case involves some form of health care rationing and physicians should ask themselves the next question: is the service being withheld primarily to save money for someone other than the patient? If not, physicians are not engaged in bedside rationing. As Ubel and Goold point out, if the patient chooses a less expensive option due to the cost to him- or herself, the physician is not rationing care. If it is or may be, then they could be engaging in bedside rationing and they should consider the final question.

The last question is whether the service in question is under the physician's control. If the answer is yes, then the decision counts as bedside rationing. Otherwise, it could be another form of health care rationing based on the availability or choice of insurance plans, for example. It is often unclear when physicians truly have complete control over use of a given resource—due to structural administrative mechanisms, for example.

The authors believe that there are many types of health care rationing, all of them difficult to define due to the variety of causes of resource scarcity. Understanding how to identify bedside rationing practices has important implications for physicians' patient-centered, ethical practice behaviors. A more comprehensive understanding of bedside rationing will enable physicians to better explain why patients do not receive care that is either inappropriate or not under the physician's control. Ubel and Goold conclude that when physicians are able to use a standardized set of questions to determine if bedside rationing is *appropriate*, they will be able to make more informed and consistent decisions about the best care services available for their patients.

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CLINICAL PEARL

Diagnosing Acute Low Back Pain

Robin Polansky, MD, MPH

Low back pain is one of the leading causes of primary care and emergency room visits and job-related disability in the United States [1]. Back pain is sorted into three categories, differentiated by the duration of symptoms. Acute back pain, which is the focus of this article, is classified as pain lasting 6 weeks or less, subacute back pain is pain that has been present between 6 and 12 weeks, and chronic back pain is pain that persists longer than 12 weeks [2].

Etiologies of low back pain include (but are certainly not limited to) mechanical injury (e.g., muscle sprain or spasm, ligament strain, facet joint disruption), arthritis, sciatica (lumbar radiculopathy), spinal fracture, malignancy, connective tissue disease, infection (e.g., vertebral osteomyelitis, epidural abscess), cauda equina syndrome, metabolic causes (e.g., hyperparathyroidism), abdominal or retroperitoneal visceral or vascular processes, psychogenic pain, and malingering. Careful history-taking and physical examination are crucial to diagnosing the etiology of back pain.

The patient in [this case](#) is experiencing sciatica, pain that originates in the lower back and radiates down the lateral or posterior thigh and occasionally to the ankle or foot. It may be associated with weakness, numbness and/or tingling in the affected leg. It is caused by injury to or compression of the sciatic nerve, which is formed by the nerve roots of L4, L5, S1, S2, and S3 [3-7]. It is important to understand that sciatica is a symptom, not a medical condition in its own right. Common causes of sciatica include herniated discs, degenerative disc disease, spinal stenosis, piriformis syndrome, pelvic injury or fracture, and tumors.

During history taking and physical examination for lower back pain and particularly sciatica, it is important to look for clues to the cause. Red flags in the patient's history include past cancer, fever, unexplained weight loss, immunosuppression, extended use of steroids, intravenous drug use, urinary tract symptoms, trauma, and bowel or bladder incontinence or retention. Physical findings that are cause for concern include decreased or loss of anal sphincter tone, saddle anesthesia, significant motor weakness, vertebral tenderness, and persistent or worsening neurological symptoms [8]. The presence or absence of these red flags dictate whether further workup is warranted.

Three types of imaging modalities can be used to further elucidate the diagnosis of back pain: plain radiographs (x-rays), computed tomography (CT), and magnetic

resonance imaging (MRI). Plain radiographs consist of anteroposterior and lateral lumbosacral spine views. Pelvic and hip x-rays may be considered if it is felt the pain may be referred from the hip or pelvis. Plain films can show evidence of fracture, malignancy, spondylolisthesis, degenerative changes, disc space narrowing, infection, and prior surgery. They do not assess discs, ligaments, nerve roots, epidural fat, or the spinal canal. Also, the sensitivity of plain films for detecting malignancies and infections is subpar [9]. Use of plain films is generally limited to cases of recent significant trauma, recent mild trauma in a patient over age 50, a history of prolonged glucocorticoid use or osteoporosis, or cases in which the patient is more than 70 years old.

CT and MRI scans of the lumbosacral spine are more sensitive than plain films but are only indicated for patients with acute back pain if clinical findings suggest possible emergent conditions affecting the spine, including cauda equina syndrome, infection, fracture with neurologic compression, acute radiculopathy with progressive neurologic deficits, and tumors. CT is superior to MRI for revealing bony abnormalities (e.g., sacroiliac joint disease, fractures) and may be particularly useful for further elucidation when plain films are abnormal or inconclusive in the setting of recent trauma. However, MRI is preferred to CT because it provides better visualization of nonbony structures (e.g., discs, nerves) and does not subject patients to radiation (the radiation exposure from a lumbosacral CT can be more than 10 times as high as that from a plain film) [10]. Choice of imaging modality may also be affected by contraindications to MRI (e.g., metal implants) and MRI availability.

There are reasons to think twice before performing any imaging on a patient who has acute low back pain and no red flags. First, and most importantly, the vast majority of cases of acute low back pain are mechanical or nonpathological; less than 5 percent of acute low back pain cases are due to serious systemic pathology [11]. Secondly, up to 90 percent of patients with acute lower back pain recover within 2 weeks [12]. Given the rapid resolution of most back pain cases, early imaging may expose patients to unwarranted radiation and risk of malignancy.

Thirdly, radiographic findings do not necessarily correlate with patients' symptoms or presentation. Treating patients based on the radiographic findings alone may lead to unnecessary interventions, health care expenses, and patient anxiety. For example, research has shown that as many as 60 percent of people without back symptoms have disk bulges and protrusions on MRI [13].

Lastly, early imaging in cases of acute low back pain where no sign of serious etiology is present has not been shown to improve outcome or patient satisfaction. One study showed that depiction of stenosis, nerve root compression, or both on MRI in the first 48 hours after onset of acute radicular back pain did not affect the outcome after 6 weeks of conservative management [14]. Other research has shown that MRI evaluation to provide reassurance does not lead to better prognosis [15] and that patient awareness of imaging findings does not affect the outcome and is associated with a reduced sense of well-being for the patient [16]. A review of

predictive studies of acute low back pain revealed that psychosocial variables (e.g., coping behaviors, psychiatric comorbidities) are much stronger predictors of long-term disability than radiographic findings [17].

The bottom line is that 80 percent of adults seek care at some point for acute low back pain [18] and, in the large majority of cases, the pain typically resolves with conservative management. To order MRIs (or other imaging) for every patient who comes in with acute back pain is a superfluous use of precious health care resources and dollars. The most reasonable approach, in the absence of red flags, is conservative management; imaging should only be considered if the patient does not improve as expected or if red flags subsequently appear. It is also extremely important to take the time to explain the diagnosis, treatment, and expected management plan to patients. Studies have shown that patients who feel that they have been given a sufficient explanation for the etiology of their problem are less likely to request diagnostic tests and more likely to be satisfied with the visit [19, 20]. Reassurance is key.

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HEALTH LAW

ERISA's Effect on Claims of Injury due to Denial of Coverage

Ilene C. Albala, MBe, JD

But whatever the HMO, there must be rationing and inducement to ration [1].

Rationing has become a dirty word, though many argue that rationing is necessary if we wish to improve the American health care system [2]. Supporters of the new health care act, the Patient Protection and Affordable Care Act (ACA), are resolute in their stance that the act does not promote rationing [3]. Yet the Supreme Court already recognizes that rationing plays a crucial part in the health care system [4]. In the famous United States Supreme Court case *Pegram v. Herdrich*, Justice David Souter wrote about the pivotal role of rationing in managed care organizations, contending that “no HMO organization could survive without some incentive connecting physician reward with treatment rationing” [5].

While it has described the critical role of rationing in managed care organizations, the Supreme Court remains unwilling to condemn or condone the practice. In the past 11 years, the Court has heard three cases related to health care rationing—*Pegram v. Herdrich*; *Rush Prudential HMO, Inc. v. Moran*; and *Aetna Health Inc. v. Davila* [5-7]. These three cases focus on the liability of managed care organizations for refusal to cover or reimburse certain medical procedures. In each case plaintiffs sought redress for injuries allegedly caused by HMOs' delay or denial of medical services. While these cases are seemingly straightforward claims of negligence due to HMOs rationing coverage, they have been anything but.

Complicating these claims of liability for managed care organizations that deny reimbursement or coverage of medical services is the ever-perplexing ERISA legislation. The Employee Retirement Income and Security Act (ERISA), enacted to protect employee pension plans and retirement benefits, also encompasses employee “welfare benefit plans,” their medical and disability benefits [8, 9]. Because ERISA is a federal regulation, including “welfare benefit plans” meant that the legislation could preempt certain aspects of state laws that govern medical insurance. With little guidance from legislators as to which areas of state insurance laws ERISA can supersede, courts have been left with the task of interpreting ERISA preemption.

In *Pegram v. Herdrich*, the plaintiff sued her HMO for medical malpractice after she suffered from peritonitis allegedly caused by her physician's delay in ordering an ultrasound to determine the cause of her stomach pain. Ms. Herdrich alleged that the physician's delay was due to the HMO's practice of reducing costs by creating incentives for physicians to limit medical treatment—in other words, rationing.

While the issue for the plaintiff was one of negligence due to rationing, the question of law before the Supreme Court was *not* whether the delay in medical services was negligent, but rather whether an HMO, acting through its physician employees, qualifies as a fiduciary under ERISA [10].

The unanimous Court, though, did not ignore the issue of rationing completely. Justice Souter commented on rationing, describing it as a necessity:

Since inducement to ration care goes to the very point of any HMO scheme, and rationing necessarily raises some risks while reducing others (ruptured appendixes are more likely; unnecessary appendectomies are less so), any legal principle purporting to draw a line between good and bad HMOs would embody, in effect, a judgment about socially acceptable medical risk [11].

However, he went on to say that this was not a judgment that the Court was willing to make. Instead, Justice Souter wrote that the judiciary should avoid deciding issues of acceptable levels of rationing in the health care context. The Court instead stated that, if anyone should determine this threshold, it should be the legislative branch, with its “preferable forum for comprehensive investigations and judgments of social value” [12].

Two years following *Pegram*, the Court decided *Rush Prudential HMO, Inc. v. Moran*, in which Justice Souter again delivered the majority opinion (this time 5-4). Here again, the Court deferred to the physician’s judgment, once again confounded by ERISA preemption law.

The Supreme Court addressed the issue for a third time in 2004, when the nine Justices unanimously decided *Aetna Health Inc. v. Davila*. The Court held that a patient-employee, who was allegedly injured after a denial of coverage for medical services, had no claim for damages because the claim was preempted by ERISA. There were two companion cases in *Davila* brought by respondents Juan Davila and Ruby Calad. Both respondents allegedly suffered from injuries arising from their HMOs’ decisions not to cover their medical treatments, contradicting their physician’s recommendations.

Juan Davila suffered from arthritis, and, when his physician prescribed Vioxx, Davila’s HMO refused to cover the expense, offering instead to pay for a cheaper drug. Davila subsequently had a severe reaction to the drug and sued the HMO, Aetna, under a Texas statute that held HMOs to an “ordinary” standard of care. Once again, the question became not whether rationing of medical services that allegedly created injuries was lawful, but rather whether or not ERISA preempted state law. The holding indicated that future patients who bring legal actions against their managed care organizations will be limited to a recovery in the amount of the reimbursement of the unjustly denied payment [13].

Conclusion

While ERISA was designed to protect employee retirement and pension plans, the effect on patients has been anything but protective. Applied in the health care context, ERISA has created a loophole through which managed care organizations can escape liability for full compensatory damages solely because the patient is insured by his or her employer. Yet hope is not lost. Justices Ruth Ginsburg and Stephen Breyer recognized this “regulatory vacuum” in their concurrence in *Davila* as they joined the “rising judicial chorus urging that Congress and [this] Court revisit what is an unjust and increasingly tangled ERISA regime” [14].

The day that the Supreme Court announced its decision in *Davila*, Congress reacted. Representative John Dingell (D-MI) reintroduced a patients’ bill of rights that would attempt to fix this gap in patient protection [15]. Since then however, little progress has been made and the loophole remains.

Physicians are seemingly left out. A real consequence of ERISA is that physicians could be exposed to malpractice claims, since the act shields MCOs while leaving physicians to bear responsibility for these negligence claims.

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POLICY FORUM

Oregon's Experiment with Prioritizing Public Health Care Services

Philip A. Perry, MSJ, and Timothy Hotze

On May 2, 1990, Oregonians woke up to the headline, “State to Unveil Health Care Priorities for the Poor.” And so began the public phase of the great health care rationing debate [1]. Rationing is a problematic concept in medical ethics; it’s also a reality in the lives of many Americans. And that is why the Oregon Health Plan (OHP) has become a perennial in the world of health care reform controversies. That morning in 1990, many Oregonians got their first look at a priorities list of about 2,000 procedures, also known as the “first list” (or later as “the first list, quickly dumped” [2]). Other lists followed. The state was attempting to decide which procedures its Medicaid program should cover. To most people, that spelled rationing. The most current list is *Prioritization of Health Services, a Report to the Governor and the 75th Oregon Legislative Assembly* [3]. The health services commission refers proudly to it as “the world’s first prioritized list of health services” [4]. A history of the health plan is also on the state’s web site, and is a good introduction to the subject [5].

The importance of the list in the annals of American health policy is that Oregon tried to develop a transparent process for prioritizing medical services through its laws and regulations. That’s the real impact. Rather than relying on undisclosed private decisions by individuals or insurers, Oregon developed a public process. A look back at the impetus for the state’s rationing experiment is helpful.

In 1987, Coby Howard’s case shocked the state. He was a 7-year-old boy on Medicaid who needed a bone marrow transplant, which was no longer covered under the state’s Medicaid plans. The news reports of the boy’s illness and death in December of that year drove home the reality of the legislature’s ongoing debate over what could be done when a needed procedure was denied [6, 7]. As one policy scholar has described it, these debates raised “unanswerable questions of equity” and inequity [8]. Then-governor Neil Goldschmidt initiated a workgroup to reform the state’s Medicaid system. Coby’s illness was also one of the factors that spurred John Kitzhaber—a former ER physician and a state legislator—to act [9].

In the legislature’s deliberations in 1987-1990, rather than championing transplants, then-state senator Kitzhaber argued persuasively that thousands of low-income Oregonians lacked access to even basic health services, much less access to transplants. It was the genesis of an idea to expand basic health care coverage within the state to as many needy people as possible [10]. Kitzhaber later became governor (1995-2003; 2010-present).

The workgroup that was formed came up with several guiding principles that led to the list, among them the following:

- Access to a basic level of care must be universal;
- Society is responsible for financing care for poor people;
- A “basic” level of care must be defined through a public process [11].

As originally envisioned, the health plan (Oregon Medicaid Priority-Setting Project) work group wanted the state’s citizens to have “universal access to a basic level of care” [11]. A panel of experts, the Health Services Commission, was to develop the prioritized list of covered items, and it would be the legislature that would have to “draw the line” at covered and uncovered services [9].

How does it work? The state’s regulations explain how physicians and others should work with the list:

The Prioritized List of Health Services determines which services the OHP may cover. Once a patient’s condition has been diagnosed, providers must use the list to find out whether the condition and treatment fall between Line 1 and the currently funded line number [12].

The Health Services Commission has eleven people on it: five physicians (four MDs and one DO), four consumer members, a public health nurse, and a social worker. Many others worked on the list too. Complex cost-benefit formulae were brought to bear, including an early form of QALYs (quality-adjusted life years), referred to in current documents as Healthy Life Years [13].

The initial list, based on a methodology of cost-benefit analysis yielded some peculiarities, such as possibly covering tooth caps, but not surgery for emergent appendicitis [14]; so techniques that incorporated net-cost components were later used to refine the list, and a set of overarching categories derived from the workgroup’s guiding principles ruled the decision-making process [15]. Analytical approaches to prioritizing health services proved necessary but insufficient for determining covered treatments in the charged political atmosphere, as well as in the judgment of the Health Services Commission, so the commission used its authority to alter or to “move by hand” the procedures or treatments that seemed to be obvious, common-sense priorities based on the commissioners’ judgment, and, in this way, most problems were ironed out. A biennial review of the list was instituted [13].

At the outset, federal waivers were needed to allow a state Medicaid program to operate in such a fashion. The rationing debate shifted to Washington in 1990, and Congress took up the question of whether to allow Oregon to proceed with this kind of extensive Medicaid demonstration project, via congressionally granted waivers. Al Gore contributed an article to *Academic Medicine* titled “Oregon’s Bold Mistake.” Oregon’s Senators, Ron Wyden, a Democrat, and Robert Packer, a

Republican, both favored the plan and helped. In the end, federal waivers were approved and have been periodically altered or renewed.

Throughout its 20 years of use, “the line” between covered and uncovered services moved many times, (as documented in the “Historical Overview” of the list online) when the legislature saw fit, based on recommendations from the Health Services Commission and budget constraints. In 1995, for instance, the line was moved up 27 spaces to line 581 out of 745 total procedures, with the concomitant reduction in coverage.

As an example of the commission’s work to balance competing claims, the highest-priority categories 1 through 6 currently encompass things like the “birth of a child and maternal care” (category 1); “preventive care;” and “life-threatening diseases,” each with many line items in the category, whereas lower-ranked categories include nonfatal, self-limiting, elective, or inconsequential conditions and interventions [15]. This list reinforces the traditional Medicaid priorities of guaranteeing care for mothers and children.

Under Oregon’s model, many people who had been doing without health care could now get basic services. It was hailed by some for this achievement. But others said the real keys to its success were not the list, but a cigarette tax that helped to fund it and the use of managed-care techniques for almost all the recipients, which may have controlled costs [16].

Studying Oregon’s health plan at a Brookings conference in 1992, ethicists split on the consequences of rationing. Some, such as Henry J. Aaron of the Brookings Institution, supported the ideals and encouraged the openness of the experiment. But he cautioned about the likely negative public reaction. Robert Veatch worried that the physician-dominated Health Services Commission would err on the side of strict utilitarianism. Norman Daniels pointed out serious justice issues. Sara Rosenbaum of the Children’s Defense Fund aimed sharp criticism at the plan’s treatment of women and children [17]. A doctor and ethicist, John La Puma (of New York) wrote, “As a practicing internist and clinical ethicist, I would simply like to add some practical medical limitations of the Oregon Plan’s methodology.” He pointed out that the plan would ratify “a new financial ethos in medical care.” and that “the physician should not be placed in the position of defending a public policy that is more interested in saving money than in providing medically necessary services” [18].

What about fairness? Some procedures under the state’s old Medicaid program were covered while others, such as substance abuse programs and, as Coby’s case so emotionally showed, organ transplants, were not. There had never been “universal” coverage of all procedures under Medicaid. The Oregon plan represented a shift from one kind of rationing to another; it shifted responsibility from obscure Medicaid bureaucrats squarely to the shoulders of the state legislators. When the next life-or-death case came around, legislators would be held accountable for not covering specific diseases or treatments.

It was clear that initially (1990), some who already had Medicaid would have to sacrifice some benefits, and, while many low-income citizens would gain coverage, others might lose some coverage [19]. Successive administrations pushed for more health reforms to iron out these disparities and searched for more funding. Governor Barbara K. Roberts (1991-1995) advocated a state sales tax for health care. This proved unpopular with voters [20], who denied her a second term. In 1995, Kitzhaber was elected governor, with health reform as part of his mandate. After his 8-year tenure ended, in 2004, new governor Ted Kulongoski launched a “Future of the OHP” workgroup, to make recommendations on sustainability for the health care budget. In 2007, he signed the Healthy Oregon Act, a roadmap for reform, to cover children and the uninsured—still about 615,000 Oregonians, a frustratingly high number [21].

When an economic downturn hit the Pacific Northwest in the early 2000s, it tested the health system severely. Health policy makers had hoped to include more people. Yet, instead of expanding to cover the “next Coby,” legislators realized they might be making “more Cobys” by covering fewer services. They hoped to reduce coverage but still expand the number of people covered for a minimum or basic level of health care. Ultimately cuts were made, but, in a bow to conservative principles of personal responsibility, co-pays were instituted and, mainly, premiums were charged or raised. This was the price in changing political times for funding from the state legislature and the federal government.

OHP 2

This second phase of the Oregon Health Plan, OHP2 for short, began in 2003. The program divided the plan into two: OHP Plus for those who would have been automatically Medicare eligible, and OHP Standard for those “expansion” populations not generally covered under traditional programs. Uninsured individuals and families who relied on state Medicaid were given a choice of reenrolling, and many chose not to. Enrollments dropped steeply, crashing from 104,000 in 2002 to 49,000 in the “Medicaid expansion program,” which aimed to cover the poorest. Rather than share the cost, people were willing to do without health care at all. Few policymakers were expecting this result. They did not realize how price-sensitive purchasing health care could be for a family living close to the bone. Or how many families would choose to go without and spend their money on other needs or wants. All told, by 2007 the OHP had lost 75 percent of its enrollment [22]. It was time for new reforms.

Oregon’s plan had changed significantly from inception to practice, reducing the scope from covering all low-income Oregonians to only those at or near the federal poverty line and dividing those in the plan into two groups. It is likely that those who conceived of the plan did not anticipate how readily future legislators would cut back on services during a budget crunch.

Prior to his comeback campaign for governor in 2010, Kitzhaber’s health policy group, Archimedes Movement, articulated its ongoing concern about fair resource

allocation: “All medical interventions are not of equal value and effectiveness in producing health, and therefore a prioritization process must be established to decide what will be financed with the public resources” [23]. Now back in the governor’s office, he says “the main goal is not to ration people, but to change the way care is organized and delivered to reduce costs” [24].

That goal of universal coverage at a basic level, though elusive for Oregon, is certainly consistent with the current push for health reform in the Affordable Care Act of 2010 and with the ethically oriented ideals expressed worldwide in aspirational ethics codes such as the UN’s basic human rights statements [25, 26]. Can rationing be a bridge to such an ideal future?

In a free society, news coverage will focus on rationing decisions because of the human drama. In Oregon, media certainly played a role in forming public opinion, perhaps prolonging the superheated rhetoric. For this reason alone, one group of health scholars actually advocated physician-based bedside rationing, rather than public rationing in the U.S., with its acrimonious debate in the news and in state assemblies [27]. Oregon continues to evaluate health reform ideas at a trendsetting pace. The true test of a statewide policy’s success in politics is perhaps more practical: can it be sustained through the economic and political ups and downs of the years?

Though it may not be the purest example of rationing, Oregon with its list is still the bellwether for the U.S. on the problem of prioritization of health care services, and it deserves further attention. As far as we know, no other states have adopted the list. In health care, the state motto applies: “Alis propriis volat.” She flies with her own wings.

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POLICY FORUM

How Comparative Effectiveness Research Feeds into Cost-Benefit Analyses

Kevin D. Frick, PhD

The Patient Protection and Affordable Care Act emphasized comparative effectiveness rather than cost effectiveness or cost-benefit analysis. To understand both the distinction and the influence comparative effectiveness research (CER) may have on cost-benefit analysis, it is critical to recognize how comparative effectiveness is defined by the United States Department of Health and Human Services. Here are the definition and the statement of purpose from the Federal Coordinating Council for Comparative Effectiveness Research:

Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

- To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and sub-groups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.
- This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the result [1].

Several aspects of this definition and statement of purpose make comparative effectiveness research more adaptable to cost-benefit analysis than typical randomized controlled trials (RCTs). First, the definition emphasizes that the results should be applicable in “real world settings.” Randomized trials don’t simulate real world settings. The degree to which RCTs follow protocol distinguishes them from typical clinical practice, and the inclusion and exclusion criteria for trials are often quite stringent—particularly with respect to comorbidities—so that patients in a randomized trial are often not representative of clinical patients, many of whom have comorbidities that make the treatment of the condition more complex. Often,

randomized trial costs that are associated with strict adherence to protocols can be difficult to separate from the costs of the treatment or intervention itself. So the CER's conduct of research in real world settings means that its findings will be more applicable to cost-effectiveness or cost-benefit studies than RCT results and of greater use to insurers, employers, governments, and individuals who pay for treatment in clinical settings.

The CER statement of purpose emphasizes that the results are intended to help patients, clinicians, and others make better decisions by knowing which interventions and treatments are most effective for whom. "For whom" refers to diverse patient populations who will be included in the research. This information will provide insights about incentives, resources, and response to incentives that pertain to specific demographic subgroups.

While effectiveness is important, decision makers realize that the resources (both time and money) to engage in a treatment regimen or intervention have to come from somewhere and are ultimately limited. There are some interventions and treatments that may be efficacious but that are just too expensive to obtain.

Finally, the CER definition states that research will draw upon multiple sources of data, e.g., claims, surveys, and studies with different designs, to inform end users about a range of outcomes. These results will also provide data for economic evaluation. In some cases, RCTs focus on a single outcome, which may be of interest to clinicians but which does not necessarily reflect the patients' interests in an ideal manner or allow them to decide whether a proposed treatment is "worth it."

Thus, the methods and outcomes of comparative effectiveness research seem to feed quite well into economic evaluations that other parties might find useful, even though the CER definition itself makes no mention of cost or cost effectiveness.

The omission appears to have been driven by the politics surrounding health reform. This policy was made after a flurry of accusations that health reform would spawn "death panels" whose members would decide whether patients received life-sustaining care. This was not a particularly accurate interpretation of end-of-life counseling, but it did publicize the fact that choices have to be made about the costs at which it makes sense to continue to provide care to a variety of patients.

It is important to acknowledge not only that "rationing" is necessary—there may be costs at which it is not economically warranted or, more crucially, feasible to continue to provide care—but also that we must determine who decides what funding is warranted for different patients in different situations. What those who use the term "death panel" failed to acknowledge is that the allocation of (scarce) resources occurs all the time—at the moment, it just happens in an ad-hoc manner, without transparency, based mainly on the doctor's knowledge of the patient's prognosis and ability to pay (that is, in most cases, the patient's insurance coverage).

Ultimately we have to face the question of whether to leave the decisions about resource allocation to the market or to regulators or to some combination of the two.

By avoiding mention of costs, the CER definition allowed legislators and regulators to sidestep the issue and escape immediate criticism from those who think a different distribution of authority between the market and regulation would be more appropriate. Unfortunately, the choice left decision makers without structure that could have been useful for all concerned. Moreover, failing to require comparative effectiveness research to include costs allows researchers to avoid collecting data for and analyzing what is, often, the most challenging aspect of the research. And it enables researchers to present outcomes that may not actually be useful to end users who (whether they would like to admit it or not) need to know how to prioritize the many possible uses of limited health care resources.

Fortunately, many researchers who are proposing or conducting comparative effectiveness research have recognized this shortcoming in the definition and have planned to collect and present cost or at least resource use data alongside the comparative effectiveness data. In some cases, there is a choice to omit cost-effectiveness results and instead just present cost or resource utilization information alongside effectiveness data, but even that will make the results more useful.

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MEDICINE AND SOCIETY

What Is a Life Worth?

Leonard M. Fleck, PhD

Death panels do not fit anyone's conception of health reform. Yet this is what the Obama administration was accused of endorsing when it proposed paying physicians to talk about advance care planning with their older patients. The rhetorical implication of the charge was that physicians were being paid to counsel terminally ill patients to refuse life-prolonging care in order to save Medicare money. The painful clinical reality often enough is a minimally conscious moribund patient whose family demands that "everything be done," despite the obvious and pointless prolongation of terminal suffering that entails.

Medicine today is suffused with the need to control costs. How can that be done ethically? What does it mean to be a "just" and "caring" society (or physician) when we have only limited resources to meet virtually unlimited health care needs? The "limited resources" are money, taxes, or insurance premiums that we (collectively) are willing to pay to meet our health care needs. Our health needs are "unlimited"; the last 40 years have seen a proliferation of new and expensive medical technologies that effectively create needs, driving health costs skyward [1]. In 2009 the United States spent \$2.5 trillion on health care, about 17.6 percent of our GDP [2]. It is predicted that by 2019, this figure will have risen to \$4.5 trillion, or about 20 percent of the likely GDP [3]. Medicare expenditures were about \$500 billion in 2009; in 2019, they could be as high as \$1 trillion [3].

Some researchers believe that cost control can be achieved "painlessly," without violating moral norms or deep political values [4]. This is supposed to be achieved by getting rid of "waste and inefficiency." Unfortunately, one person's waste and inefficiency is often another person's life-sustaining care. How much life-sustaining care are we morally obligated to provide to patients in a persistent vegetative state (PVS)? Think of Terri Schiavo and the moral and political controversy that case generated. There may be 25,000 such patients in the U.S. whose care costs more than \$2.5 billion annually. We might be tempted to regard this expenditure as being merely "imprudent," not unjust. But the Urban Institute estimates that 22,000 Americans die prematurely each year as a result of being uninsured and unable to afford timely primary care that might have addressed a curable cancer before it became incurable [5]. These are patients who clearly could have benefited substantially from timely medical care, unlike PVS patients. This should nudge us out of any moral complacency about "imprudence."

Renal dialysis was perfected in the late 1960s. Very few Americans in end-stage kidney failure could afford the annual cost (\$90,000 in 2010 dollars) of dialysis at that time, which meant they would die prematurely. Advocates were outraged that we would allow these individuals to die when we had an effective technology that could prolong their lives indefinitely, and only money stood in the way of saving them. The rallying cry of some was that human life was priceless. Congress responded by creating the 1972 ESRD amendments to Medicare, which paid the full costs of dialysis or kidney transplants for all patients in end-stage renal failure, no matter what their employment or insurance status might be. The belief at the time was that this was a unique technology and that the cost of the program would top out at \$500 million 20 years out. The actual cost of the program in 2009 was about \$31 billion, and it was sustaining about 480,000 lives. This was national health insurance for end-stage kidney disease [6].

The obvious moral question today, a question of justice, is why patients who need equally expensive care for their heart disease or cancer or liver disease do not also have national health insurance coverage. What became apparent by the late 1970s was that dialysis was not a morally unique life-prolonging intervention; rather, it was the beginning of a torrent of such technologies.

Today we have dozens of extraordinarily expensive cancer drugs that cost \$50,000 to \$130,000 for a course of treatment and yield median survival gains measurable in weeks or months [7]. More than 600,000 cancer patients each year are candidates for these drugs. We have dozens of drugs to manage heart disease. None are as expensive as the cancer drugs, but with 5.5 million Americans in various stages of heart failure and about 70 million Americans with some form of heart disease [8], costs add up quickly.

In 2010 we did more than 1.2 million coronary angioplasties at \$40,000 each and almost 500,000 coronary bypass surgeries at \$65,000 each. We implanted almost 200,000 cardiac defibrillators (ICDs) at \$40,000 each with the intention of preventing fatal cardiac arrhythmias. Does it matter that 81 percent of them never fired over a 5-year period, at which time a battery would have to be replaced for \$20,000 [9]? Does that represent a wasteful use of health resources? We have a test that can identify with 98.7 percent accuracy who among these potential ICD recipients will not have a fatal arrhythmia over the next 2 years. We could save \$2 billion per year by using that test. But getting it wrong 1.3 percent of the time represents 800 lives that would be lost each year. How should we assess that outcome, morally speaking? Does that represent a morally objectionable “pricing of human life”?

We have about 4.5 million Alzheimer patients in the U.S. At least 500,000 of them in any given year will be in the end stages of that disease. If physicians caring for those patients detected a heart irregularity suggestive of a potentially fatal arrhythmic event, would it be unjust if they failed to offer the option of an ICD to those patients? Would this be a morally objectionable “pricing of human life”?

More than one million Americans are HIV-positive. Today the vast majority of those individuals have their lives sustained by three or four drug combinations that cost \$35,000 per person per year. Each year in the U.S. 550,000 individuals are in end-stage heart failure. Dick Cheney, our former vice president, is one such individual. But he is having his life prolonged for an extra year or two because he received a left-ventricular assist device (LVAD) at a cost of \$200,000. Does every one of those 550,000 individuals have a right to one of these devices for an extra year or two of life? That would represent an extra \$100 billion in health care costs. If we failed to provide that option to all those individuals for financial reasons, would that represent a morally objectionable pricing of human life?

If we have only limited resources to meet virtually unlimited health care needs, at what social cost might a just and caring society limit access to LVADs to relatively younger individuals (70 or fewer years of age) in order to provide access to needed and effective health care for the 50 million uninsured in the U.S.? Or to assure sufficient resources for meeting the life-prolonging needs of HIV-positive patients? About 1.3 million Americans have rheumatoid arthritis. Roughly 20 percent of them will have the most serious form of that disease, requiring treatment with infliximab at a cost of \$25,000 per person per year. Infliximab does not save or prolong the lives of these patients; it “only” improves the quality of their lives. Does this mean that if we are concerned about “pricing human life” that we are morally obligated to fund LVADs for all patients in end-stage heart failure who want one along with any cancer drug that offers only very small gains in life expectancy before we would consider funding the costs of infliximab for patients with rheumatoid arthritis?

My point is that the rhetoric of “pricing human life” badly distorts our moral judgment when we must set health care priorities and control health care costs. We cannot avoid the need to make rationing decisions; we have only limited resources and the domain of what we call health care “needs” expands with each new medical technology [10].

The fundamental moral challenge is this: should we allow the nonrational and nonmoral forces of the market and the relative power of conflicting political interest groups to determine who is denied access to needed health care (which is how rationing now occurs in the U.S.)? Or should rationing decisions come about through a rational, respectful, inclusive, democratic deliberative process that allows us to decide together what expensive, marginally beneficial, life-prolonging health care we would be willing to deny to our future possible selves [11]? The virtue of such a process is that it is open and transparent, unlike the hidden, unaccountable workings of markets and interest groups that allow us to accept with equanimity and moral indifference the premature deaths annually of 22,000 uninsured Americans. Such a process also has the virtue of sparing physicians primary moral responsibility for making these rationing decisions.

If I am unwilling to pay additional taxes or insurance premiums for an LVAD for an 85-year old stranger in end-stage heart failure because I believe it is “not worth it,”

then I am morally obligated to say the same holds true for a future possible version of me in those same circumstances. We have the moral right to judge for our future possible selves that there are many other health care interventions that I might need that yield much more benefit at a much lower cost than that LVAD. Such a public choice for our future possible selves is neither unjust nor uncaring.

The same cannot be said for the life-threatening rationing decisions imposed by the Arizona governor and legislature upon 100 Medicaid recipients needing various transplants [12]. Their claim was that this was not a cost-effective use of taxpayer money. If this was an honest assessment, then such transplants ought to also be excluded from the health plans of these government officials. This is what it means to make rationing decisions that are just and caring and responsible.

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MEDICAL NARRATIVE

The Other Limited Resource—Time with Patients

Douglas Jay Mund, MD

As Charles Dickens might say about the practice of medicine in the twenty-first century: it is the best of times, it is the worst of times. We live in an age of astounding technological and pharmacological innovation and discovery. Our ability to diagnose and treat disease has never been better. We are on the threshold of being able to diagnose cancer from a single abnormal cell and have transformed life-threatening and life-altering diseases to chronic disorders with minimal morbidity. The introduction of biologic drugs has dramatically changed the expression and progression of disease.

As a rheumatologist with more than 30 years of clinical experience, I have witnessed these dramatic changes. Rheumatoid arthritis, a potentially devastating and crippling disease, has become, in many instances, a disease devoid of significant morbidity. The introduction of biologic therapies can greatly reduce and often halt joint destruction and deformity. Indeed, the incidence of joint replacement surgery due to rheumatoid arthritis has been greatly reduced. But we have paid dearly for these advancements, and the cost has been the time, effort, and expense needed to obtain authorization for their use. That time often comes at the expense of time spent with patients.

N.B. is a patient with rheumatoid arthritis whom I have been treating for more than 20 years. In our early encounters, I was able to spend as much time with her as I needed in each interaction, getting to know her as a whole person, including the emotional factors that could impact her disease. We developed a successful therapeutic relationship partly because I had the time to spend. I attended her surprise eightieth birthday party and helped her face the devastating and depression-inducing death of her husband. I played the role of psychiatrist as much as that of rheumatologist. But, in more recent years, our interactions have become shorter. More and more time has to be spent dealing with insurance companies, pharmacy benefit management and other third-party institutions to obtain required medications and get approval for imaging studies and even for the office visits themselves. I have been forced to ration time with her.

This has become a defining aspect in the practice of medicine today. Medicine is a business with significant fixed and ever-rising expenses, coupled with fixed and rarely rising insurance payments. More and more time is allocated to obtaining prior authorizations for tests, imaging, and procedures, justifying our medical decisions, and fighting insurance company and pharmacy benefits denials. By detracting from

the time we have to spend with our patients, these administrative tasks can decrease our overall knowledge of them and can have a significant impact on the satisfaction both patient and physician get from their relationship. A physician who chooses to continue to practice as he or she did years ago finds that he or she has very little “away” time, time outside of the practice setting, time to spend with family and personal relationships. This, too, can cause the physician great anxiety and dissatisfaction.

My need to ration time with patients has forced me to make several changes. All patient encounters occur in the examination room only. It reduces the time spent moving from room to room and therefore the overall appointment time, but patients are denied the comfort and sense of ownership that sitting in my consultation room engenders. While I attempt to spend as much time with patients as needed, there is always a strong urge to move on to the next patient. Most of the time, however, I find myself working longer hours rather than deny patients needed access to care. Due to the amount of time it takes to obtain prior authorizations, I rely on my patients to take the lead in these endeavors, further imposing time limits on direct and indirect patient care. Lastly, it has forced me increasingly to consider early retirement or restriction of practice activities as the level of satisfaction with my professional life wanes.

I, like most of my colleagues, love practicing medicine but detest the myriad extraneous, nonessential busywork tasks forced on us by the insurance industry, government regulations, and patient expectations. I often reflect on the fact that, despite the high level of dissatisfaction, anxiety, and depression in the medical community, we continue to deliver the best care in the world. I fervently hope that future generations of physicians will have a greater satisfaction in their work and will not be forced to further ration their time in pursuing this most noble profession.

Douglas Jay Mund, MD, is a clinical rheumatologist who has been in solo practice for 30 years. He is a founding member of the American College of Rheumatology, a member of the board of the Nassau County Medical Society in New York, and a member of the board of managers of the SUNY Downstate Medical Center alumni association. Dr. Mund has particular interests in rheumatoid arthritis and osteoporosis.

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