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FROM THE EDITOR

The Many Uses of Legitimacy in Medical Ethics

Many scholars, including Norman Daniels, James E. Sabin, Leonard M. Fleck, Amy Gutmann, and Dennis Thompson [1-5], have inquired about the legitimacy of certain resource distributions in health care. Roughly, the consensus is that, because they are legitimate, decision-making bodies such as governments, insurers, accountable care organizations (ACOs), and others have the authority to make allocation decisions despite disagreement about how to allocate resources. Legitimacy is thus a fruitful concept for addressing several questions about such allocations because there is often vast, yet reasonable, disagreement about which distributions are best or most just. For example, there is disagreement about what a state or private health insurer must provide to those whose health care they are responsible for. Likewise, there is disagreement about what allocative decisions physicians should make at the bedside. Important work has applied the concept of legitimacy to these questions [1-6].

This issue of the *AMA Journal of Ethics*® considers questions about legitimacy and authority in health care, including but not limited to questions about allocation. Three papers consider several traditional questions about the legitimacy of allocation mechanisms, allocative bodies, and specific allocations. Fleck and Marion Danis consider a case in which a physician serving on the board of an accountable care organization must make decisions about whether an [expensive cancer drug](#) should be covered. The prices of such drugs and the allocative questions that their high prices raise have been growing concerns [7, 8]. Fleck and Danis emphasize that these decisions must be made under nonideal conditions and reflect on how these decisions can be legitimately made. Michael A. Rubin and Robert D. Truog address another case in which questions arise about the processes of decision making that clinicians should use in [rationing in the pediatric intensive care unit](#). They argue that failing to keep distinct the concepts of rationing and futile or inappropriate treatments, which may be conflated in such cases, can lead to confusion that may prove problematic in the allocation process. Finally, while many believe that bedside rationing is morally required [6, 9, 10], Philip M. Rosoff argues that there are perils to physicians' [rationing at the bedside](#). He notes that when judgments other than those about clinical criteria color such rationing, patients can be deprived of their rights to equal medical treatment. In particular, Rosoff is interested in the influence of implicit biases—features of our cognitive and conative systems that may be unconscious and may include judgments about race, age, social class, gender, and the like [11-14]. On his view, the role of such bedside rationing ought to be minimal while that of public deliberation in rationing ought to be vast.

This first set of questions about the authority to allocate resources in the face of disagreement about what counts as good, just, or fair allocations parallels a second set addressed in this issue—that of questions about the authority of science in the face of disagreement about the quality of evidence. What counts as such sound medical judgment when experts' assessments of the evidence diverge? What grounds of legitimacy do such controversial evidence and consensus have?

Such types of disagreement about the evidence are rife in the medical literature. Examples include the clinical controversies about the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* revision process [15], the new cholesterol guidelines [16], and the guidelines on prostate and breast cancer screening [17-19]. Yet, despite the prevalence of questions about legitimacy in the rationing literature, only with rare exceptions [20] have scholars attended to which features, if any, make it the case that physicians have obligations to follow controversial guidelines in the face of reasonable disagreement and whether such guidelines can be enforced. One of the novelties of this issue is that several scholars address questions like these.

Two papers confront questions of how the mechanisms of generating and assessing evidence may be relevant to the legitimacy of that evidence. Govind Persad asks how frameworks for legitimacy that emphasize [fair procedures](#), such as those of Sabin and Daniels [2], might be extended from the process of decision making about resource allocation to the process of generating and assessing evidence. Persad draws on philosophical work on epistemic injustice (roughly, the injustice done in virtue of failing to give someone his or her standing as an epistemic agent [21]) and consensus-based theory justification in science. He considers how such injustice may arise in the process of gathering medical evidence, how procedures should preclude it, and how questions about consensus might apply to questions about how to gather or assess clinical evidence.

Likewise, Mary Jean Walker and Wendy A. Rogers consider issues of legitimacy that arise in assessing medical evidence. They contrast the seemingly reasonable disagreement about medical evidence over the effectiveness of vertebroplasty for acute osteoporotic vertebral fracture with the seemingly unreasonable disagreement over denial of the safety of vaccines. They argue that assessments of evidence must rely on "reflective awareness" because, while we need to rely on [heuristics](#) and testimony, these mechanisms can misfire, leading to mistaken beliefs about the evidence.

In addition to questions about the processes that may grant legitimacy to scientific evidence generally, we can ask about the legitimacy of specific scientific evidence or consensus. For instance, one might ask about the legitimacy of the controversial recommendations of the *DSM-5* Task Force to remove the "bereavement exclusion" for

the diagnosis of major depressive disorder. *DSM-IV TR* had attributed a bereaved person's depressive symptoms of less than two months that did not cause "marked functional impairment" or consist in "morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation" to grief rather than major depressive disorder [22]. However, many found this exception unwarranted [23], ultimately leading to the elimination of this exclusion from *DSM-5* [24]. Yet, critics saw this move as welcoming further medicalization of normal stressors, thereby inviting further problems into psychiatric practice, such as unnecessarily medicating normal patients and subjecting them to unnecessary side effects [15]. Two papers in this issue deal with this controversy.

Sabin and Daniels, two of those most responsible for drawing the attention of medical ethicists to the importance of legitimacy, discuss the question of the legitimate authority of policy-relevant scientific bodies. Specifically, they argue that the American Psychiatric Association (APA) has authority in addressing scientific questions but not questions of ethics and public policy. They suggest that had the [DSM-5 Task Force](#) provided reasonable justifications for its proposed revisions to the *DSM* as understood by their "accountability for reasonableness" framework [2], the outcome of the disagreement over the bereavement exclusion would have been more accommodating and *DSM-5* would not have lost the degree of legitimacy it did in the process.

John Z. Sadler examines a case of a primary care clinician considering [referral](#) to one of two psychiatrists for a widower with possible major depressive disorder. The physician is convinced the two psychiatrists would treat the patient quite differently, given their beliefs about the bereavement exclusion. Thus she feels that, in choosing whom to refer this patient to, she will make a determination outside her area of expertise that will affect his care. Sadler encourages patience in assessing the case and emphasizes that the physician seeing the patient is the expert with authority on the patient's care needs rather than consultants who have not yet seen the patient or independent panels working with broad population data.

This issue also addresses questions concerning the legitimacy of sanctions for those who flout (seemingly) legitimate evidence—those who are often called quacks. In this issue's podcast, I interview medical historian James Mohr on the various mechanisms through which such [self-regulation](#) has been deployed and the effectiveness of each as well as his thoughts about the implications of these mechanisms for the future of medical self-regulation. Jon C. Tilburt, Megan Allyse, and Frederic W. Hafferty consider the case of [Dr. Mehmet Oz](#), who has fallen under increasing criticism for his popularization of health products that lack evidence by the standards of academic medicine [25-27]. As they see the situation, Oz's case is alarming, first, because, if the medical profession cannot effectively regulate his disregard for evidence, what or whom can it regulate? Second, it is alarming because there are many other forms of medical

practice that fail to meet such standards to which the profession has turned a blind eye.

Finally, there are questions about the meaning of legitimacy itself and how a better understanding of it might inform our investigations. Although there are accounts of the conditions of legitimacy in recent bioethical thought [1-3, 28], little attention has been given to its meaning. In his contribution to this issue, Arthur Isak Applbaum argues that [legitimate authority](#) is a normative power to govern others, corresponding to a liability of those others to be so governed. He then offers an account of its conditions, such that an authority is legitimate only when it is itself a free agent and exercises authority over subjects (or members) who themselves also remain free. He argues that the medical profession is not such an agent and hence does not have authority over its members but that various groups, such as professional organizations and hospitals, might meet this condition and so have authority over their clinicians.

Collectively, these papers show that we continue to have a great deal to learn about legitimacy in bioethics. Many now believe appeals to legitimacy are somehow relevant to questions about resource allocation, although there is still disagreement over the grounds and implications of legitimacy in the domain of resource allocation. But, as we have seen, legitimacy is also relevant to questions about self-regulation, medical professionalism, and the status of evidence in medicine. The lesson of this issue is that the concept of legitimacy does more work in bioethics than it is frequently taken to and that examination of the concept could pay dividends for policy and practice.

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ETHICS CASE

Polarities in Clinical Thinking and Practice

Commentary by John Z. Sadler, MD

Abstract

This analysis of a case of a bereaved patient that poses two treatment options—watchful waiting or medication—focuses on five “polarities” in clinical practice: (1) the normal and the pathological, (2) the individual and the diagnostic collective, (3) the primary care physician and the consultant, (4) the expert and nonexpert, and (5) the moment and the process. These polarities can accentuate ethical problems posed by this case, for example, by creating stark contrasts that mask the complex contexts of care and characteristics of patients. These stark contrasts can create false dilemmas that may obscure simpler, shared decision-making solutions. Alternatives to conceiving cases in terms of polarities are discussed.

Case

Dr. Jones sees a new patient, Mr. Thompson, a 68-year-old man in her outpatient, primary care clinic today. In reviewing his intake forms, Dr. Jones sees that Mr. Thompson scored 18 points on the Patient Health Questionnaire (PHQ-9), suggesting “moderately severe depression.” When she asks Mr. Thompson about how he is feeling, he tells her that his wife died three weeks ago but that he did not want to tell Dr. Jones about this because he did not want to trouble her.

In further talking to Mr. Thompson, Dr. Jones discovers that he has lost appetite, interest in his activities, and the ability to concentrate at work. He feels tired yet has had trouble falling and staying asleep. Finally, family and friends tell him that he seems a little “distracted” or slower lately. Dr. Jones asks whether Mr. Thompson has thought of hurting himself, and Mr. Thompson says no. She also asks if he owns a gun, and he says no.

Dr. Jones begins to consider how to diagnose and treat Mr. Thompson. She knows that recent changes to the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* regarding bereavement have caused significant debate among her psychiatric colleagues. She often refers psychiatric patients to either Dr. Taylor or Dr. Martinez, who seem to have very different stances on the issue as she learned on discussions during recent consults. Dr. Taylor worries that the *DSM-5* is medicalizing normal grief even more

than previous editions had: "Researchers find that grieving people typically yearn for their loved ones roughly every other day at one year after losing them, but the new *DSM* will lead many to label such people diseased." He prefers to attentively watch such patients to see how their symptoms progress over time. Dr. Martinez shares Dr. Taylor's worry about overmedicalization and "false positive" diagnoses but believes that, generally, clinicians should initiate treatment of possible depression if the symptoms are severe enough: "It's entirely normal for one's connective tissue to sever under blunt force trauma and for one's body to react with fever and other symptoms to a viral invasion. It is easier to distinguish such dysfunction with 'normal compensation' in physical medicine from 'normal function.' Yet, in psychiatry, it is difficult to distinguish dysfunction with normal compensation from a 'problem of living.'"

On the one hand, Dr. Jones feels that if she refers to Dr. Taylor, Mr. Thompson will receive watchful waiting, but she is concerned that his insurer will fight against reimbursement without a diagnosis. On the other hand, she is worried that a referral to Dr. Martinez will result in treatment with selective serotonin reuptake inhibitors (SSRIs) that is unnecessary and that Mr. Thompson may come to see himself as diseased rather than normal. Hence, she feels that her choice will ultimately determine Mr. Thompson's diagnosis and treatment. She is unsure of what to do.

Commentary

If I were Mr. Thompson and knew about Dr. Jones's deliberations, I would want to stick with Dr. Jones, knowing that I was in good hands with such an insightful, knowledgeable, and thoughtful clinician. The following describes why.

This case poses what might be considered practice "polarities"—false dilemmas presented as either/or decision points to clinicians. These polarities could include (1) the normal and the pathological, (2) the individual and the diagnostic collective, (3) the primary care physician and the consultant, (4) the expert and nonexpert, and (5) the moment and the process. Each of these polarities play into the clinical problem posed here. One of the key points of this essay is that clinicians should be wary of such polarities because they oversimplify the complexities of clinical judgments and clinical relationships. The discussion that follows illustrates these points.

Five Practice Polarities and the Making of False Dilemmas

The normal and the pathological. The authors of the *Diagnostic and Statistical Manual of Mental Disorders (DSM) IV-TR* and *DSM-5* are careful to note that the manuals are "not meant to be used in a cookbook fashion" [1] and should be used with practical judgment sensitive to the clinical context [2]. They recognize with humility that most of the *DSM* disorders are without a specified pathoetiology, and *DSM* disorders remain works-in-progress in understanding mental illnesses, perhaps the most complex of conditions faced by clinicians. While the aspirations of the *DSM* are to provide empirically based,

rigorous constructs for clinical, administrative, and research use, clinicians should know that ambiguous *DSM* cases are common, as is the one faced by Dr. Jones. Fortunately, Dr. Jones does not need to declare normality or disorder, other than as a diagnostic preliminary for a medical record. She can make her best estimate at Mr. Thompson's initial visit and revise her assessments through clinical observations and responses to treatments, if any, in later visits. Indeed, she needn't make a decision to refer in this clinical moment, but rather, can reserve some time to discuss options with Mr. Thompson in this and a prompt follow-up visit.

The individual and the diagnostic collective. As clinicians trained in the methods of science, we often forget that a patient with a disease or a disorder is a unique individual whom we encounter in his or her wholeness, while our knowledge of diseases and disorders is based on collections of people thought to resemble each other in specific ways—what might be called “diagnostic collectives” or groupings, which are abstract categories, remote from the complexity of the singular person. Those who define such diagnostic groupings—the World Health Organization, publishers of the *International Statistical Classification of Diseases and Related Health Problems (ICD)*, and the American Psychiatric Association (APA), publishers of the *DSM*—wield considerable practical power and exert diagnostic authority no matter how conscientiously the authors of the diagnostic manuals may wish to constrain their authority. While Mr. Thompson might meet *DSM-5* criteria for a major depressive episode, clinicians should keep in mind that the *DSM-5* criteria are based upon shared characteristics of large groups of people, some of whom exhibit some, all, or none of the *DSM* criteria. How representative a diagnosis is and how much clinical utility it has are ongoing questions for psychiatric researchers and *DSM* committees. Thus, in clinical practice, making a diagnosis is just the beginning in finding out “what is going on with the patient” [3]. The clinician working with the unique patient adds living flesh to the bare-bones diagnostic category or categories that the patient seems to fit. Other considerations, of course, apply to “what is going on with the patient,” from the patient's personal values, to his sociocultural context, to how his medical care is paid for, to name a few. These limitations of *DSM* categories are why the *DSM* authors advise the *DSM* to be used with an eye towards its clinical utility (or not) [4]. While the *DSM* categories have the authority of the APA and teams of experts, the clinician is the ultimate arbiter in diagnosing her patient, and responsible clinicians will consider conventions as well as [controversies](#) in applying *DSM* categories, just as Dr. Jones does here.

The primary care physician and the consultant. Primary care physicians can use consultants in different ways. One way is to transfer total care for a particular condition to the consultant. In Dr. Jones's case, she might want to let one of the psychiatrists simply manage Mr. Thompson's depression. Alternatively, Dr. Jones might want a second opinion from one or more of the psychiatrists in deciding Mr. Thompson's care, with advice in management or additional referral (to a psychotherapist or minister, for

example). The sketchy details in the case make choosing any of these options difficult to substantiate. What's clear is that Dr. Jones seems to be confident in predicting each of her consultants' therapeutic leanings. Assuming her judgments are valid, what seems indicated to me is for Dr. Jones to discuss these possibilities with the patient and solicit the patient's input in [shared decision making](#) [5, 6]. From this discussion, what the patient wants may become obvious, and in such an ambiguous treatment selection situation, Dr. Jones would have a poor justification to refuse Mr. Thompson's preferred direction. In any case, she should monitor Mr. Thompson herself to address the excesses or neglect of one of the psychiatrists, if that were to happen. That, among other things, is what primary care is for.

The expert and nonexpert. This polarity is most closely attuned to the theme of [legitimacy/authority](#). The *DSM* authors are experts in their field and experts in the diagnostic collectives they are dedicated to constructing. But, as noted in discussion of the individual and the diagnostic collective above, the physicians' expertise stops at the patient they have not seen, whom they don't know, and whom they have no relationship with. The "expert" may be a specialist as described above. However, the expert about Mr. Thompson, at least from the medical point of view, is certainly Dr. Jones. This medical expertise is complemented by Mr. Thompson himself as an expert "by experience" [7-9]. In the conclusion, I discuss how clinical decisions should emerge from this dual expertise of patient and clinician.

The moment and the process. Polarities of practice tend to prompt us to make quick decisions. But with the exception of the medical/surgical emergency or intensive care, quick decisions are not required and may represent unreflective, impulsive practice. Insurance company billing requirements and managed care also (seem to) demand quick decisions. But patients and their diagnoses change as their illnesses and lives change, regardless of how industry or experts describe patients' maladies. In the case here, Dr. Jones does not have an urgent-care decision to make; provisional diagnoses and choices can be discussed with Mr. Thompson and can be made, tested, and revised over a series of brief outpatient encounters and ultimately submitted to an insurance company. Ethical dilemmas that seem so urgent in the moment melt away in the face of actual ongoing relationships, particularly ones that are ongoing in a primary care setting. While "the system" urges us to make quick decisions, they are rarely required even by the system. Although I do not think diagnosis based upon reimbursement rates is an honest way to practice medicine, the case here presents a genuine ambiguity that deserves a provisional, and only provisional, diagnosis. A relevant consideration in choosing a provisional diagnosis is whether the diagnosis permits (e.g., funds) the patient's proper monitoring, but the clinician's first obligation is ensuring that the patient, not the insurance company, receives proper care.

Conclusion

My comments about medical polarities have much to do with habits of thinking that are perpetuated by social and academic conventions. The case presented here is cast in a classical medical literature genre wherein the terms of the case are framed from the clinician's—Dr. Jones's—point of view. The case poses questions for Dr. Jones, and for Dr. Jones only. Dr. Jones has a clinical problem—referring a bereaved patient for treatment with either medications or psychotherapy—which seems to be solely hers. The problem with this genre convention is that the dialogical, interpersonal, intersubjective nature of the patient-clinician relationship is lost. The case presented here omits almost any salient information about Mr. Thompson's values, psychosocial circumstances, personal preferences, ways of thinking, patterns of participating in health care, economic and insurance circumstances, and so on. Thus, the case seems highly problematic because a key portion of the patient-clinician relationship (that is, the patient) is missing from the case. In a more elaborated context and dialogue, Dr. Jones may find Mr. Thompson to be an individual who inhabits one or more of these contexts and has one or more of these characteristics:

1. Doesn't like to take medications, especially psychiatric medications
2. Is already in grief counseling with his minister, and the minister recommended medication for him, as he is struggling more than most.
3. Doesn't like to go to consultants, because he thinks they are only in it for the money.
4. Is a loner who would rather take a pill to ease his pain.
5. Has great faith in Dr. Jones and would prefer her to make a treatment decision.

These, of course, are only five of the countless contexts and characteristics that arise in the patient-clinician relationship and, indeed, in shared decision making generally. Each of these in isolation suggests a relatively obvious course of action, once the patient's perspective is understood. Unfortunately, our genre conventions of medical ethics cases often do not respect the patient's standpoint, and patients can be presented, as here, as generic stand-ins for real people. What we need are ethics cases and pedagogies that embrace stakeholder voices and that support shared decision making, thereby avoiding polarization, false dilemmas, and oversimplifications. *The Virtuous Psychiatrist: Character Ethics in Psychiatric Practice* [10] and *Narrative Psychiatry: How Stories Can Shape Clinical Practice* [11] are examples of two books that demonstrate new genre forms of ethics cases as multistakeholder, dramaturgical processes that avoid false dilemmas and promote nuanced, collaborative practices with patients.

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

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ETHICS CASE

How Should Therapeutic Decisions about Expensive Drugs Be Made in Imperfect Environments?

Commentary by Leonard M. Fleck, PhD, and Marion Danis, MD

Abstract

Clinicians must inevitably make therapeutic decisions under nonideal conditions. They practice in circumstances that involve incomplete evidence. They deliver care in health care systems that are complex and poorly coordinated. Each of the patients that they take care of is unique while research offers evidence regarding relatively homogeneous populations of patients. Under these circumstances, many parties—medical scientists, reviewing agencies, insurers, and accountable care organizations—can and should contribute to optimizing the development, approval, funding, and prescription of therapies—particularly expensive and marginally beneficial therapies. In aggregate, they should aspire to achieve a pattern of fair, cost-effective therapeutic decisions to ensure a sustainable health care system. Here we offer some suggestions regarding decisions that physicians might pursue to facilitate fair and cost-effective patient care.

Case

Dr. C sits on a committee as part of his tertiary care center's accountable care organization (ACO) that is considering whether a new biologic, Expensivimab, should be included in the organization's bundled treatment plan for its patients. Expensivimab is a new humanized antibody that targets an apoptotic receptor. One study suggests that it increases tumor-free survival in late stage non-small cell lung cancer (NSCLC) by a median of six months relative to a drug approved several years ago. Another suggests that it increases overall survival by a month-and-a half relative to the same drug. Yet no research on the comparative effectiveness of Expensivimab relative to other interventions for NSCLC exists, and even data on the risks of Expensivimab relative to the older drug is scant.

Furthermore, assessing Expensivimab's cost-benefit ratio is difficult. Although Expensivimab costs \$750,000 per patient, the United States Food and Drug Administration (FDA) did not request any data on trial participants' perceptions of their quality of life. Hence, no assessment of quality-adjusted life years (QALYs) or disability-

adjusted life years (DALYs) is available to assess the cost-benefit ratio of Expensivimab—either on its own or relative to other interventions.

Dr. C has grown worried about the increasing costs of drug coverage—especially relative to the potential benefits. Containing such costs is especially difficult because the Centers for Medicare and Medicaid Services (CMS), which determine whether Medicare will cover a drug and whose decisions many other insurers follow, are legally prohibited from negotiating the prices of such drugs. He worries that unless providers and insurers start to demand evidence regarding quality of life and benefits relative to other available drugs, pharmaceutical companies will have no incentive to investigate Expensivimab. In consequence, assessments of benefit will be only informed by standard clinical parameters such as time-to-mortality and tumor-free survival.

A similar committee at a nearby tertiary center's ACO decided that the drug was not part of its coverage. Dr. C fears that this only makes his ACO's decision more politically controversial. A decision to cover the drug would be seen as a disagreement with fellow experts, a message that may be particularly problematic when the precedent for covering oncologic agents has been to cover agents with similar benefits.

While considering how to vote, Dr. C's thoughts turn to two patients that he recently met. Ms. G is a 68-year-old woman who was just diagnosed with NSCLC. She could benefit from Expensivimab. Mr. J is 71-year-old patient with colorectal cancer who recently started a similar agent that has recently been approved for colorectal cancer and has a benefit profile similar to that of Expensivimab. Mr. J's drug is very expensive but costs slightly less than Expensivimab. Dr. C worries how he might feel the next time he sees Ms. G or Mr. J, knowing how his vote might affect patients like them. Dr. C considers what to say and how to vote at the upcoming meeting.

Commentary

As this case illustrates, clinicians must inevitably make therapeutic decisions under nonideal conditions. The health care systems they work in are administratively and economically fractured. Each of their patients is unique and incommensurable while clinical research offers evidence and guidelines based on relatively homogeneous populations. In commenting on this case, we will focus on policies that might facilitate cost-effective and fair therapeutic decisions for cancer patients generally.

The core ethical challenge for Dr. C is to be both a loyal advocate for the best interests of his cancer patients and a prudent [steward](#) of social resources with which he is entrusted. Ethicists disagree about the extent to which a physician must be an uncompromising advocate for the best interests of her patients [1-3]. In this essay, we argue that there are ethically acceptable ways of meeting this challenge, either by working through professional organizations to effect policy changes more protective of patient financial

interests related to cancer care or by holding sensitive conversations with individual patients aimed at helping them make more prudent financial choices regarding their own cancer care.

Patient-Centered Drug Coverage Policies

Physicians are responsible for a substantial fraction of health care expenditures. They authorize prescription drugs, surgery, home health care, diagnostic tests, and so on. They ultimately play an inescapable role in the distribution of medical resources. In the United States, for example, they are responsible for 60–70 percent of health care expenditures [4], which reached \$3.2 trillion in 2015 [5]. Physicians would be ethically irresponsible if they simply acquiesced to cost restraints imposed by policymakers (in organizations or governments, for example), which means physicians are professionally obligated to engage with those policymakers, perhaps by questioning application of guidelines in particular cases. What policies, then, should Dr. C endorse?

First, whatever policies are endorsed ought to be [patient-centered](#). That is, physicians must take account of the best interests of their patients as determined in part by the values of those patients. This does not mean that patients have a moral right to commandeer unlimited social resources. Given limited budgets, considerations of fairness and justice will limit what any patient can demand in the way of cancer care, especially with metastatic disease and a predictable terminal outcome. Hence, patient-centered care must be fair and cost effective.

Patient-centeredness is challenged by demands for evidence-based medical practice in accord with clinical guidelines generated with [cost effectiveness](#) in mind. Care that yields too little benefit at too high a cost is not cost effective. This is usually described as “low-value” care. Clinical guidelines are always based on patient populations and thus may poorly fit individual cancer patients with their unique medical histories, comorbidities, and genetic vulnerabilities. Still, ignoring such guidelines would often be medically, ethically, and economically irresponsible. So what should complex patient-centered care look like?

Given et al. [6] suggest a strategy of dynamic assessment of value in the context of high-cost cancer treatment. In particular, they discuss oral molecular agents similar to Expensivimab in the context of metastatic disease. They start by following the recommendations of the American Society of Clinical Oncology (ASCO) [7] to calculate the net health benefit (NHB) for a patient using these molecular agents. Their working assumption is that value for that individual patient changes as treatment unfolds. They write: “The value of treatment may hang on modest reductions in progression, tolerable adverse effects, and out-of-pocket costs that are not ruinous. Each dimension can change quickly as treatment progresses” [8]. In other words, the NHB can change significantly from the patient’s perspective—for better or worse, depending on the

patient's values—as treatment proceeds. Patient-centeredness means that such changes will be looked for and responded to appropriately.

Perhaps there should be minimal concerns about costs for those oral molecular agents that yield years of gain in overall survival with tolerable side effects. Imatinib for chronic myeloid leukemia (CML) would be a good example, certainly for patients with minimal comorbid conditions. But imatinib is not curative and would need to be taken for years (at least eight years for first-line treatment to prevent disease progression), and it is very expensive. More precisely, the current list price of imatinib is over \$120,000 per year, although its list price had been only \$26,400 per year when it was introduced in 2001 [9]. Nothing has changed about that drug since 2001 to justify that price increase [10]. What does this mean from a patient-centered perspective?

Trade-Offs: Policies for Drug Coverage in the Real World

As reported in the *Washington Post*, Dianne Dale Watson, 77 years old, has been on imatinib for nine years watching her savings erode at the rate of \$500 per month for that drug [9]. Research by Dusetzina et al. found that monthly copayments for imatinib ranged from \$0 to \$4,792 from plan-to-plan [11]. Obviously, such differences in cost have variable consequences for individual patients. Dusetzina et al. also found a 70 percent increase in the risk of discontinuing imatinib (or other tyrosine kinase inhibitors) for patients whose copayments were in the upper 75th percentile [11]. Surely these findings should be regarded as ethically problematic, given the sustained effectiveness of this drug for CML patients.

Accordingly, we suggest removing economic barriers—such as copayments and deductibles imposed by insurers or ACOs with an insurance role—for very effective cancer drugs. Individual physicians may have little ability to effect changes such as these, but physician professional organizations may have that ability if sufficient political courage can be mustered. What individual physicians can do is have conversations with their patients about costs that are aimed at helping patients make decisions that better accord with their values [12]. We also suggest that pharmaceutical manufacturers be held responsible for what is justly regarded as [price gouging](#), as illustrated by media coverage of Valeant [13]. Many other pharmaceutical companies are open to the same criticism. For example, ARIAD Pharmaceuticals was challenged by lawmakers for raising the price of its leukemia drug, ponatinib, in one year from \$114,960 to \$198,732 [14]. We agree with lawmakers that such price increases are unconscionable.

If Dr. C endorsed the strategy of ignoring costs in the care of cancer patients, it would spare the consciences of physicians caring for individual patients with otherwise different capacities to pay, but it would be ethically and economically irresponsible since those costs would still be passed on either to taxpayers or to other insured individuals. To emphasize that point, ipilimumab, another drug that has proven quite effective in

treating advanced melanoma, in combination with nivolumab, costs about \$300,000 for a course of treatment [15]. Saltz [15] proposes this mental experiment: in the United States, 589,430 cancer deaths were expected to occur in 2015 [16], presumably all from metastatic disease. If all these patients had available to them an ipilimumab-like drug (or drug combination) for their specific cancer, it would add \$174 billion per year to health care budgets in the United States. Given limits on health budgets (established by willingness to pay taxes and insurance premiums), increased expenditures of this magnitude would likely prohibit the feasibility of addressing other health needs that lack the political visibility and social anxiety associated with cancer. That would not be an ethically defensible position.

Returning to the real world, the vast majority of new targeted cancer therapies have nothing like the efficacy hypothesized in that mental experiment. As Saltz [15] and others [17] have concluded, there is no rational relationship between the price of these drugs and their actual efficacy. Further, the efficacy of the vast majority of these cancer drugs is far below that of imatinib. Fojo and colleagues [18] examined 71 cancer drugs approved by the FDA for solid tumors between 2002 and 2014 and found that the median gains in progression-free survival and overall survival were respectively a very modest 2.5 months and 2.1 months. These drugs cost \$100,000 or more per year. This is the world in which Dr. C must make some decisions.

Some Policy Options, Some Practice Options

Both of Dr. C's patients have Medicare coverage; the price of these drugs is the core problem. Medicare, with its more than 55 million covered lives in 2015 [19], should be able to extract large discounts from pharmaceutical companies. However, both Medicare and the FDA are forbidden by law from considering the price of these drugs in making coverage decisions [20]. Congress put these laws in place in 2004 as a result of heavy lobbying by Big Pharma that was aimed at preventing Medicare from bargaining for large discounts, as most European countries have been able to do [20]. No doubt those laws should be repealed, but Dr. C must make his decisions under current law.

The ACO and Dr. C do have options. Considerations of fairness (i.e., all patients with CML should have equal access to drugs like imatinib), just allocation, and maximizing patient welfare all speak in favor of making cost-effective decisions regarding these cancer drugs. The ACO should insist on adequate scientific evidence of a certain level of cost-effective benefit. For example, the ACO board could require a six-month median gain in life expectancy for a \$100,000 drug for a certain indication. In our opinion, this might be regarded as a minimum benchmark for high-value care regarding these cancer drugs. It would send a signal to drug developers regarding what is acceptable. Few such signals exist now.

The ACO board members are few in number, which is to say, only minimally representative of a diversity of perspectives. Perhaps the necessary choices should be the focus of well-informed rational democratic deliberation [21], in this case, by all ACO members willing to invest the time. If a majority of members are willing to pay the additional costs associated with reducing the survival norm for coverage to four months and to accept the trade-off in either reduced benefits or higher costs that would be required, then few obvious ethical considerations would speak against such a choice. Likewise, while ethical norms advise treating like cases equally, there may be reasons to approve Expensivimab for some indications and not others. If adequate evidence suggests greater than a six-month median overall survival for colorectal cancer but only six-week median survival for NSCLC, then approving coverage for one indication but not the other would be ethically permissible. Note that the range around that median will also make things more ethically complicated. If the range of overall survival is two to eight months around a five-month median, not very much is ethically at stake. But if the range is from two months to four years around a five-month median, the ethical stakes are significant. Achieving sufficient agreement on some uniform policy for all these indications through a democratic deliberative process in these latter circumstances might be virtually impossible. What, then, might be ethically acceptable options for that ACO and Dr. C?

American political culture is highly individualistic. Ethically acceptable options can be constructed congruent with that cultural background. For all those \$100,000 cancer drugs that yield only very marginal benefits in terms of progression-free survival or overall survival, one option, in our opinion, would be an add-on insurance rider. Individuals would have to purchase such riders while disease-free with a disease-free family history, and insurance companies or ACOs could accept or reject individuals as they wished and price accordingly. These riders could be very expensive, which would underscore that this option was not cost effective, both for individuals and society. Financially well-off individuals could afford such riders. This outcome is not unjust since the likely benefits are marginal and uncertain. The riders could be embraced by individual ACOs and provide a competitive advantage if presented effectively and honestly (“working to save you money”).

Alternatively, financial risk and responsibility could be shifted to drug companies in the form of value-based pricing or performance-based reimbursement [22-25]. As a hypothetical example, if a drug company’s research showed a six-month median gain in overall survival for its drug, then it would receive only 10 percent of the drug price for patients whose survival gain was less than three months, 20 percent for less than six months, and full price for those who exceeded that six-month gain. The same percentages would apply if patients experienced intolerable toxicities within that six-month window and withdrew from using the drug. This approach is congruent with the dynamic value, patient-centered approach discussed earlier [8]. That is, patients would

be at dramatically reduced risk of financial toxicity if the drugs were too medically toxic or failed to yield predicted gains in life expectancy. Furthermore, these same value-based pricing rules would apply for all cancer drugs. Such a policy would not be disadvantageous to either Mr. J or Ms. G. Dr. C would be fulfilling his responsibilities as a physician, both as a patient advocate (or patient educator) and as a prudent user of social resources. This approach is essentially a form of consumer protectionism by government, which physicians can embrace in good conscience.

Finally, Dr. C should not endorse a policy that put in place high copays or coinsurance for targeted cancer therapies that are very costly and yield only marginal gains in life expectancy. Assume a required 30 percent copay by patients that would be affordable by the financially well-off exclusively. Further assume the benefits of the drug are marginal, so it might not seem to be unjust. However, it *is* unjust because the other 70 percent of those costs are being financed through a common insurance pool financed in part by the less well-off. Some drug companies provide coupons to the relatively poor to cover that copay. However, that practice only encourages the costly over-consumption of these marginally beneficial targeted therapies to the benefit of the bottom line of these drug companies but to the detriment of the just and cost-effective allocation of social resources.

Conclusion

In summary, we have argued that physicians have moral obligations to protect their patients from both unnecessary medical harms as well as financial harms associated with very expensive drugs that are likely to provide little benefit. At times, fulfilling this obligation will require that physicians work through professional organizations to effect policy changes at the state or national level that will provide necessary patient protections as well as a more just and prudent allocation of social resources. At other times, their obligations in this regard will require that physicians spend time with individual patients to help them make more informed choices regarding worthwhile care, as judged from both a social perspective and the perspective of that individual patient.

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ETHICS CASE

What to Do When There Aren't Enough Beds in the PICU

Commentary by Michael A. Rubin, MD, MA, and Robert D. Truog, MD

Abstract

The concepts of medical futility and rationing are often misunderstood and lead to significant consternation when resources are stretched and pediatric intensive care unit (PICU) beds are unavailable. While the two concepts overlap, each has its own distinct application and moral justification. Most importantly, we should avoid using one to justify the other. Bioethics professionals should assist critical care clinicians in clarifying when each rubric should be applied as well as how to develop policies to standardize the approach.

Case

Dr. A, the attending physician on the pediatric surgical team, calls the pediatric intensive care unit (PICU) to schedule a patient with mitral valve stenosis for admission to the pediatric intensive care unit for monitoring during the surgical stay. The director of the PICU, Dr. L, tells Dr. A that she will have to get back to him about availability because beds are fully occupied.

Dr. L and Dr. A admit to each other being greatly frustrated that this problem has arisen multiple times in the past few years. Dr. L tells Dr. A that a number of patients have been in PICU beds for exceptionally long periods with little chance of recovery and that this has meant that a number of surgeries have been delayed and that a number of nonsurgical cases have been transferred to other facilities. They agree to request an ethics consultation.

At the time of the request, Dr. L expressed her concerns to an ethics consultant that care being provided to long-time PICU patients was often futile, constituted inappropriate uses of clinical resources, and violated clinicians' professional autonomy. The ethics consultant wondered what constitutes futility and how many PICU patients' care was futile, and suggested that some of these cases were ones in which "bedside rationing" might be appropriate. At this point, Dr. L became concerned that if long-term care was not futile—if some patients might still benefit from intensive care—then if the hospital and its staff did not provide such care they would be failing to do their best for the patients and might be failing in their professional obligations. However, Dr. L was not sure she felt comfortable creating a rule that forced her PICU staff to withhold potential

benefits from particular patients—even if those benefits were slight. Although she thought this was generally sensible, she was not sure that her role was to make other clinicians act this way in all cases.

The consultant suggested that deliberation upon these cases could be helpful and suggested that a larger group of stakeholders from the hospital be convened with the full ethics committee to draft a PICU policy that would address two elements: (1) guidelines regarding PICU admissions decision making and for establishing a PICU care discontinuation protocol; and (2) guidelines for how such decisions would be made and implemented, who would be involved in such decisions, and how those affected by the decisions—including caregivers, patients, and their families—would be notified. A time for deliberation on these two issues was scheduled.

Dr. A now plans to call his patient and family to deliver the news that they will have to wait until a bed is available. She worries about how she can justify the delay to them and wonders what to say.

Commentary

Recently, a multisociety task force published a landmark position paper on potentially inappropriate treatments and medical futility [1]. The task force achieved many goals, including a consensus definition of futility, a demonstration of the need for hospitals to develop processes to address cases of potentially inappropriate treatments, and a call for clinicians to take a leadership position in continuing the discourse. The position paper proposed restricting the term “futility” to its physiological meaning: the inability to achieve the intended biologic goal of a treatment. For example, cardiopulmonary resuscitation of a patient is “futile” when it is physiologically impossible for the procedure to restore a spontaneous perfusing rhythm, as in a patient with a ruptured ventricle. Disputes about treatments that are not futile in this physiological sense are considered “potentially inappropriate treatments.” When treatments are not physiologically futile, clinicians and patients or their families might disagree about whether the goals of treatment are appropriate or whether the chances of success are sufficient to justify the attempt. In these cases, the treatment is considered potentially inappropriate, and a multistep process involving the family, ethics consultants, and others is invoked to help resolve the quandary.

The position paper does not, however, address how treatments denied on the basis of being futile or inappropriate compare with treatments denied on the basis of rationing. As we will show below, rationing, futility, and inappropriate treatments are often interwoven, obscuring an understanding of each. As our ability to prolong life with increasingly sophisticated devices and methodologies improves, and as the cost of these technologies escalates, questions like the ones raised by this case will become more

pressing, making it necessary for us to understand the distinctions among these concepts as well as their correct application.

Unraveling the Concepts

The concept of futility—defined in the multisociety document as treatments that cannot achieve their physiological goals—is perhaps the easiest to address. Unfortunately, a decision about whether to use physiologically futile treatments is rarely of any practical significance; patients quickly die regardless of whether these treatments are used because, by definition, the treatments do not work. Futile treatments thus should never be provided, regardless of the availability of the resources or the values of the clinicians, patient, or family.

More difficult is untangling the concepts of rationing and inappropriate treatments. Treatments deemed to be inappropriate may work in the physiological sense but are judged to be inappropriate either because the goal of treatment is considered unreasonable (e.g., the continued vital existence of a patient diagnosed as brain dead) or the goal is reasonable but the chance of achieving that goal is unreasonably small [1]. Since what is considered “reasonable” in these circumstances is not a question that can be answered by medical expertise alone, we need a dispute resolution process (such as the one described in the multisociety guidelines [1]) for making this determination. In the following discussion, we will lump together treatments judged to be physiologically futile with those that have been determined to be inappropriate, since (according to the guidelines) in neither case should the treatment be initiated or continued.

In the case described, Dr. L and Dr. A are arguing that a significant number of PICU beds are occupied by patients who are receiving treatment that is either physiologically futile or inappropriate. Since there are not enough PICU beds to perform necessary and clearly beneficial surgical cases, they believe a policy should be developed to permit withdrawal of treatment from the former patients to make enough beds for the latter patients.

On the other hand, the ethics consultant seems to be suggesting that it is unlikely that a significant number of beds could be made available by this approach, since continued treatment for most of the patients would not be inappropriate by the standard described in the multisociety document. Therefore, the consultant suggests that more beds could be made available if resources were rationed.

In order to understand how rationing and futile or inappropriate treatments are related, we can analyze the difference in reasoning as follows.

Argument for futile or inappropriate treatments:

- *A treatment is futile or inappropriate.*
- *We have an obligation not to provide futile or inappropriate treatments.*

- *Therefore, we should not offer this treatment.*

Argument for rationing:

- *Multiple patients need a treatment that is beneficial and desired.*
- *We have a limited amount of resources to provide this treatment.*
- *Therefore, we will have to decide between patients so that we make best use of our resources. This necessarily means that some patients will not receive treatment that is both desired and potentially beneficial.*

Note that while these are separate concepts with distinct justifications, we do not mean to imply that they *both* cannot be true in the same situation; it may be true that there is both a need to ration *and* one option that is futile or inappropriate. We are not claiming that they are mutually exclusive, rather, that they are not mutually necessary.

Comparisons of the Two Concepts

The fundamental difference between rationing and inappropriate treatments is *to what a particular treatment is being compared*. Rationing requires a selection of the best distribution of limited resources based on a comparison of the needs of two or more patients or populations of patients, in situations in which all of the treatments are desired and may have some value in improving the health of the patients involved. In contrast, considerations of inappropriate treatment are not comparisons to another patient but to a complex and continually evolving standard that is based on accepted medical practice and on cultural, religious, legal, political, and socioeconomic perspectives regarding the appropriate goals of medical care and the corresponding obligations of the medical profession [2]. For example, a rationing decision might involve which patients in an ICU are most likely to benefit when only one unit of blood is available and multiple patients are in need of a transfusion, while a futile or inappropriate treatment decision might involve considering if a particular patient should be receiving *any* blood—not because another patient in the PICU needs it, but because it might not provide any benefit to that patient.

Moral Justification of Withholding or Withdrawing Futile or Inappropriate Treatments

Withdrawing or withholding futile or inappropriate treatments has a strong foundation in bioethics. Self-determination (autonomy) allows patients to make an informed decision among all medically feasible options. Additionally, beneficence requires physicians to advocate for a care path that they believe is most likely to improve the well-being of a patient. Our need to balance these goals is incorporated into the process of shared medical decision making, in which the patient and physician participate in a multistep, cooperative process [3]. Physicians are not obligated to offer every possible option, however—only those that have some prospect of benefit. If a requested treatment is unable to achieve its physiologic goal, it is futile, and should not be offered. If a treatment

is not physiologically futile but potentially inappropriate, then we should follow a dispute-resolution process to achieve a resolution of the conflict between the patient and the physician.

Moral Justification of Rationing

Dr. L and her fellow physician are resistant to the role rationing might play in this case scenario. While many PICU clinicians believe that they should never be involved in rationing decisions, reflection shows that clinicians are continually involved in the process of rationing. Every time we decide to prioritize our time for one patient rather than another, accept the limitations in drug choices that the hospital formulary has made based on the cost effectiveness of the alternatives, or decide where to build a new hospital, we have rationed. The ethical hazard lies not in our decision to ration; as long as the world has finite resources *we will ration*. Rather, the concern resides in the fact that the criteria for rationing are not solely determined by medical facts or judgments; rationing involves a complex calculus that includes not only medical criteria but also societal decisions about how health care resources should be allocated, including the overall financial resources that should be devoted to this purpose as well as rules about which patients should have priority over others. Unfortunately, given a general reluctance in our society to face up to the reality of the need to ration, these criteria are rarely discussed and hence tend to be poorly defined, vague, and inchoate.

Is It Rationing or Futile/Inappropriate Treatment?

A useful way to distinguish if a question is that of rationing or futile or inappropriate treatment is to analyze what happens when moving from the granular to the global. Rationing considerations scale up differently depending on the level investigated. For example, as we move from deciding which patients get a particular treatment, to how to distribute beds in an ICU, to where to build hospitals with large-capacity ICUs, and, finally, to how many hospitals should our society invest in to support our population, the nature of the rationing decision changes in that the options being compared are different in scale and consequence. In contrast, questions of futile and inappropriate treatments do not change when examined on a larger scale—if a particular treatment is futile or inappropriate for one patient, then the same should be true for all patients with the same medical condition in that hospital, region, or political jurisdiction. This is the very reason that landmark legal cases regarding medical ethics have so much influence: when a court rules that a hospital may refuse to provide a treatment to a patient with a particular medical condition because it is ineffective, for the argument to be valid, it would have to apply to all patients with that condition.

Who Are the Decision Makers?

The final factor separating futile or inappropriate treatments and rationing concerns who is authorized to make the decision in resolving the dispute. As rationing decisions are a comparison of the needs of two or more patients, each of whom may benefit from the

treatment in question, the patients themselves should not be part of the decision. Each would likely advocate for receiving the needed resource. Rather, rationing decisions ought to be made by those who are most likely able to make an objective, well-informed decision. In emergent [bedside rationing](#), that expert may be the nurse or the physician, while in decisions about pharmacy spending or the location of new hospitals health care economists, hospital administrators, and public health professionals are important stakeholders. In contrast, patients and their surrogates are party to discussions of potentially inappropriate treatments, as value-laden decision making requires a personal knowledge of preferences and culture that only the patient can provide. As we will show below, the relevant stakeholders will affect the [development of policy](#) designed to assist the PICU in managing these quandaries.

Development of Policy

As our case scenario suggests, two separate policies should be developed based on which rubric is most appropriate for a particular situation: futile/potentially inappropriate treatments or rationing, with the first being based on the multisociety position paper. Each case in question should be evaluated based on its own, without the influence of the available resources driving the decision-making process. Stakeholders would include a multidisciplinary medical team in addition to ethics consultants and the patient or his or her surrogate decision makers [1]. A policy regarding who is admitted to the PICU and how to allocate resources should include a wider group of stakeholders, including representation from the medical profession and from the larger society through the involvement of elected leaders and the political process [1]. As stated previously, however, patients and families would not contribute to these deliberations, since one would not expect them to be able to take a neutral position regarding the decision given their justified self-interest. Ideally, rationing decisions should be as objective as possible, based on maximizing medical benefit within the limitations of resource constraints and following agreed-upon principles of allocation.

Conclusion

A most fulfilling aspect of being a physician or surgeon is being able to offer an intervention that might improve the health of a patient. Although we wish to both affect a positive change in patients and provide a sense of satisfaction for them and their families, we often have to communicate that we cannot improve their health or offer a therapy that they are requesting. This can be a grueling process for both patient and clinician and must be done on the basis of sound ethical reasoning and accurate medical knowledge. While we might prefer to turn a blind eye to such quandaries until resource scarcity makes it necessary, we need to be prepared to manage such situations, as they will come to us and decisions must be made.

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ETHICS CASE

Who Should Ration?

Case and Commentary by Philip M. Rosoff, MD, MA

Abstract

A principal component of physician decision making is judging what interventions are clinically appropriate. Due to the inexorable and steady increase of health care costs in the US, physicians are constantly being urged to exercise judicious financial stewardship with due regard for the financial implications of what they prescribe. When applied on a case-by-case basis, this otherwise reasonable approach can lead to either inadvertent or overt and arbitrary restriction of interventions for some patients rather than others on the basis of clinically irrelevant characteristics such as ethnicity, gender, age, or skin color. In the absence of systemwide reform in which the resources saved from one patient or group of patients are reallocated for the benefit of others, prudence is urged in the application of “bedside rationing.”

Case

Mr. J is a 58-year-old black man who has been mostly homeless for the past eight years. He has a number of chronic medical conditions of which end-stage renal failure is his most critical. He has been receiving hemodialysis for six years. Because he does not have health insurance and is not eligible for Medicaid in the state in which he resides, Medicare covers many of the costs associated with care for his kidney disease under the end-stage renal disease benefit. Mr. J is not a known substance abuser but does have significant mental health issues and has preferred to live on the streets rather than in the shelters and the halfway houses to which he has been assigned. He has also proved to be unable to maintain a relationship with outpatient dialysis centers, despite multiple attempts and interventions by social services. He is an ultra-frequent visitor to the university hospital emergency department (ED), with up to ten visits a week in the cold winter months. Most of his dialysis is administered there or at the hospital’s inpatient dialysis facility. Not surprisingly, his erratic care and his lifestyle have contributed to a slow deterioration in his overall condition. The physicians who see him most often—ED physicians and hospitalists—believe that further provision of dialysis is a waste of hospital and national resources (and their time); they believe that Mr. J is incorrigible and is “using” them and the system for his own purposes. They wish to unilaterally stop treatment and switch him to hospice care, even though Mr. J retains decision-making capacity and expresses a desire to continue living as he has been doing. Should the

physicians be able to limit his access to specific kinds of care by appeals to his excess consumption of resources they believe to be in short supply?

Commentary

The example of Mr. J—and many thousands of similar cases that occur regularly in emergency departments, hospital wards, and clinics throughout the country—raises significant questions about how we prescribe and dispense interventions and care to patients and the reasons we give for both largesse and parsimony. Are the resources Mr. J's physicians are so concerned about conserving really scarce in the same way that we think about the absolute shortage of livers, hearts, and kidneys used for organ transplantation? It is not simply tangible resources that are subject to our scrutiny, as physicians also might differentially allocate the time they devote to particular patients or make recommendations based partly upon whether the patient is likeable, more or less similar to them, and so on [1]. Is it a fundamental part of a physician's professional duty to both patients and society to act as a representative and responsible [steward](#) of these resources? Or are these decisions simply a convenient justification employed to limit access for a particular patient? After all, one wonders how the ED physicians would view Mr. J's frequent visits and consumption of their valuable time and supplies if he were white and wealthy, even if he did have similar apparently self-destructive and imprudent unhealthy behaviors. (While they very well might feel the same way, they probably wouldn't express it so openly.) This is not to say that many (perhaps most) physicians who are susceptible to these sorts of hidden or implicit biases might not be acting in good faith and honestly believe they are safeguarding either society's or their institution's valuable and possibly limited goods. However, the problem with individualized or [bedside rationing](#) (as opposed to systematic, systemwide rationing that applies similarly to similarly situated patients), is that it can fall prey to deep-seated prejudices about certain kinds of people and even certain kinds of diseases especially when it uses "rules" that might be idiosyncratic and arbitrary. Alcoholic liver disease—which might require liver transplantation—is one example of a disease that many believe to be more representative of a personal moral failing than an illness deserving of compassion, sympathy, and care [2].

In the remainder of this essay, I will discuss so-called bedside rationing under the control of individual physicians and compare it to rationing that applies to an entire health care system, even though both have the laudable goal of conserving scarce resources and apportioning them to those who need them the most and can presumably benefit the most from receiving them. I will argue that there are moral hazards associated with the former that can (mostly) be avoided with the latter.

Problems of Bedside Rationing

All physicians ration. An inherent part of the practice of medicine is the creation of "menus" of reasonable options of diagnostic and therapeutic interventions that are

tailored to the patient's clinical needs, tempered with deference to her desires and life goals. Ideally, the list should be reasonably similar for patients similarly (clinically) situated, with modifications suited to the specific circumstances in which the patient (and often her family) find themselves. In the United States, more so than in most other wealthy industrialized nations, a key component in this calculus is the patient's ability to afford what is on the list, and one should not underestimate the impact affordability can have on patient care [3]. In a more quotidian manner, we also constantly make decisions about who is more clinically deserving of what—presumably meaning who can benefit most when there are not sufficient resources (like ICU beds, ED triage, and even our time) for all who could conceivably benefit—and these decisions are an essential constituent of doctoring. However, there are important differences between resources that are in [short supply](#) relative to demand, such as livers and hearts, and those that are relatively scarce or fungible, such as money [4, 5]. While both could (and surely have) certainly fallen prey to discriminatory and biased allocation methods, the former are less likely to suffer from willful bigotry and favoritism, especially if the supply is centrally controlled and organized in an open manner and is dependent upon public cooperation (i.e., for donation). Because the latter resources are so contingent upon the personal views of the dispensing agent (a physician or member of the legislature controlling a health care budget, for example), they might be more open to individual assessments and opinions about what should be the case and for whom. While these less-than-salutary facets of how many people view the world can affect actions such as willingness to donate organs [6-8], it is notable that an important feature of most organ allocation rules is their disregard of personal features unless they could have a direct impact on clinical outcomes (such as graft survival) [9].

It is important to note that rationing only makes sense—indeed, this is true of health care in general—when it pertains to interventions that can help people, such as relieving their suffering [10]. If we do it right by ignoring features about people that are usually (but not always) clinically irrelevant, such as their skin color, gender identity, sexual orientation, immigration status, and the like, we can act as good stewards of the local resources at our disposal and serve our patients well by offering them choices that could conceivably help them and limiting options either that they do not reasonably need [5] or from which they can have little-to-no chance of benefiting [11, 12].

If, however, we physicians assume a role that is not necessarily ours to take—that of stewards of nationwide, potentially commonly held, resources and attempt to solve systemic resource constraint issues on an individual patient basis—we run a great risk of making arbitrary, capricious, and biased decisions that fail both the patient and the profession. Of course, in a disjointed, decentralized health care system such as exists in the US, the notion of communal resources is generally limited to such things as organs for transplantation, even though a more circumspect analysis would also recognize that more might be shared than is commonly recognized, such as money (meaning that all of

us are affected in numerous ways by how health care dollars are spent). Nevertheless, it is common to conflate bedside and system-based rationing when there is a motivation to act as responsible guardians of the nation's (or hospitals', insurance companies' or even individual patients') goods. More frequently than we would like to admit, some physicians justify withholding treatments from patients by claiming good stewardship when in reality it is prejudice masquerading as rationing [13, 14]. This is not to say that physicians engage in widespread and overtly prejudicial practices in the manner in which they care for their patients, simply that rationing of the sort that takes place at the bedside—that involves often on-the-spot decisions about what is reasonable to offer a specific patient—could be vulnerable to a rationing rationalization in which some clinically similar patients are treated differently for ethically (and possibly medically) indefensible reasons. This is the essence of what I see as the structural problem with this form of decision making.

Can Bedside Rationing Coexist with Systemwide Rationing?

How do we reconcile the daily allocation decisions made by physicians—we might call this “micro-rationing”—with more systemic distributions that have a much wider scope—we might call this “macro-rationing”? The former is generally focused on particular, individual patients and what they might want, need, or are thought to deserve by their physicians (or whoever is paying for their health care), while the latter more generally applies to the allocation of larger quantities of goods to groups of patients. Examples of the latter might include the national organ transplant system or the plans that were developed to distribute the influenza vaccine in the event of a pandemic several years ago [15-17]. Renal dialysis falls somewhere in the middle between the two. Since it is a socialized program available to all US citizens and permanent residents as a defined Medicare benefit (irrespective of age), it is not a prime illustration of a scarce resource (although some might view the money funding the program as such). However, physicians have some discretionary power in deciding to whom to offer this therapy [18, 19]. (This form of discretionary choice is more of an open issue in the United Kingdom and its National Health Service [20].) Examples of micro-allocations permeate clinical practice, the most common perhaps being the rationing of time. While it might be true that some concierge physicians are able to devote virtually unlimited amounts of time to their privileged clientele, most of the rest of us must carefully parcel out our face-to-face (and other) time, presumably based upon what a patient needs in the moment. Undoubtedly this time pressure contributes to the frequent delays in seeing physicians, as the careful planning of 15 minutes per visit (or whatever the allotment might be) quickly goes awry when a complicated or challenging situation presents itself.

Moreover, physicians are only human and hence susceptible to the implicit biases that almost all of us possess to a greater or lesser extent, as could appear to be the situation in the case presented here. Not only can these covert (and sometimes not-so-covert) prejudices lead to substantial and measureable differences in clinical outcomes for

identifiable groups such as members of ethnic minority groups [1, 21], they can also profoundly affect other areas of medical practice based upon something as simple as whether a patient is likeable or not [22, 23]. In the case of Mr. J, it might be tempting to assume that the emergency department staff's treatment of him was value neutral, meaning that their concern for the conservation of resources (their time, hemodialysis "chair time," supplies, and so on) was similar to what it would have been for any other patient similarly clinically situated. But there could be reason to suspect that this might not be the case. We naturally wish to spend more time with people who are friendly and respectful and whom we identify as trustworthy. Conversely, while we might feel a duty to care for all patients, we hasten out of the exam or hospital room of those who are surly, belligerent, or demanding. Not surprisingly, patients we might view negatively in the moment might also have characteristics (such as skin color) that trigger implicit negative biases we might hold, thus producing a double whammy of aversion and animating our judgments about personal desert, worthiness, and other clinically irrelevant inferences about specific patients. These responses could lead to narrowing the "menu" of available options for some but not all patients.

The dangers of micro-allocations of this very personalized type—in which physicians take it upon themselves to serve as arbiters of who should get what for perhaps the wrong (i.e., unjust) reasons—are that patients might not receive the care or interventions that they by rights should have (meaning the care that would be offered to clinically similar patients who differ from them in some other, clinically irrelevant manner) [24]. In addition, physicians might be singularly unsuited by temperament, training, and knowledge to understand and hence implement rationing decisions for patients on the basis of larger resource supplies and demands. For example, prior to the implementation of the model for end-stage liver disease (MELD) score for determining priority for eligibility listing for liver transplantation, there were significant racial and ethnic disparities between organ recipients. The practice had been for transplant physicians to advocate individually for the gravity of their patients' condition and hence the urgency of their need. This relatively simple, numerical score—composed of the total bilirubin, creatinine, serum sodium, and the international normalized ratio—virtually eliminated the discretionary ability of physicians to argue more persuasively for some patients than others, resulting in a near elimination of subjective forms of discrimination [25].

To be sure, physicians have an integral role to play in deciding who gets what (and why) on a population basis, as exemplified in the leadership responsibility they have in formulating organ transplant allocation rules. But these activities are at the level of policymaking for all patients of a given category (e.g., liver failure, advanced heart failure) rather than at the level of a single physician making allocation decisions for a single patient at the bedside and appealing to scarcity of resources (which might or might not be the actual case) as a reason for her chosen course of action. On the other hand, there

could be advantages to encouraging physicians to make these kinds of decisions in that they support and enhance the sort of individualized attention that physicians are educated to deliver so as to tailor any treatments specifically for the improvement of a patient's welfare. Yet to make these decisions in an ethically defensible manner by minimizing the influence of both implicit and explicit biases would require some form of oversight—either prospective or retrospective—as well as efforts like the MELD system to assist physicians in treating their patients as equally as possible. But attempting to distinguish “bad” micro-rationing from customized therapy can be tricky. Moreover, imposition of a structured and monitored framework for controlling these kinds of decisions might be cumbersome and generate even more bureaucratic headaches for physicians who are already overburdened with paperwork, external oversight, and the like [26].

In Mr. J's case, there is little doubt that his clinical situation, his frequent visits to the emergency department, and his inability to take advantage of more efficient outpatient dialysis, clinic visits, and so on, not only is detrimental to his overall health, but also arguably consumes resources that he wouldn't need if he were able to adhere to a more standard clinical course. But is his case substantively different from legions of other patients on whom we lavish as much if not more medical effort—think of patients with advanced cancer receiving extremely expensive novel medications to extend their lives for a few months—except for the fact that he is homeless, a member of an ethnic minority group, and does not heed medical advice?

Finally—and this might be the most significant flaw in bedside rationing—there is no way to ensure that the resources conserved by not providing them to one patient would be put to better use for another patient. Since these resources are not kept in a central pool to be allocated to a perhaps more deserving patient (or at least one whom the physician believes would benefit more from access to them), all that results from a bedside decision of this type—even a well-intentioned one—is that a patient doesn't receive something to which she might be entitled under different circumstances in which she has a physician who either doesn't hold or express personal biases. Unlike the organ transplant system, in which the decision to not offer a liver to patient A means that patient B will receive it, not giving dialysis to Mr. J has no effect whatsoever on the availability of dialysis to anyone else. Conservation of resources that relies on bedside rationing, or rationing on this micro level, does nothing to help others and does much to potentially harm individual patients.

Conclusion

Can “unauthorized” or unregulated bedside rationing be prevented or minimized? Physicians not only have to deal with their own implicit biases, but also are continually bombarded with the dual—and competing—demands to generate more income and spend less or cut costs. The general news media as well as publications from

professional organizations are rife with discussions of runaway health care costs, waste, and so on [27–29]. Meanwhile, insurance companies do their best to limit payments for expensive interventions and the words “prior approval” (the time-consuming mechanism by which insurers demand clinical justification before approving payment for a procedure or treatment) often strike dread into the hearts and minds of physicians throughout the land. Health care disparities thus might result from clinicians’ rationing care to particular patients—or particular kinds of patients, like Mr. J—out of their general concern about the inexorable rise in the nation’s health care budget. But the alternative—a top-heavy, management-level imposition of rules and regulations to limit costs that relies on systematic micromanaging of single patient-physician encounters, similar to that used in managed care in the 1990s when physicians were often rightly viewed as making decisions corrupted by personal financial conflicts of interest—is a nonstarter [30].

I do not wish to convey the impression that physicians should be profligate with either their patients’ or society’s resources, and I have argued for prudence elsewhere [4, 31]. The hazards of giving physicians uncontrolled discretionary power to be solo gatekeepers of what their patients have access to can lead to abuses that might conserve resources—but at a price. Few would argue that the escalating costs of the US health care system are not financially ruinous (or will be if unchecked). But unless there is a systemic and systematic mechanism in place that can ensure that the resources that are “saved” would be put to equal or better use elsewhere, there can be little warrant for permitting physicians (relatively) unfettered authority to make these sorts of *ex ante* decisions. Personally, I believe that proper health care resource rationing can only be accomplished within a framework of a wholesale remaking of the US health care system that emphasizes fairness of allocation based upon individual and group medical needs. However, this is an argument for another time and place. In whatever manner the distribution of shared or common resources is achieved, in a democracy, it should be a matter for public debate and deliberation, and not take place solely within the privacy of the hospital or office examination room [4, 5].

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THE CODE SAYS

AMA Code of Ethics' Opinions on Continued Knowledge Acquisition, Judgment, and Commitment to Innovation

Danielle Hahn Chaet, MSB

AMA Code of Medical Ethics' Opinion 1.1.6, "Quality," states quite clearly that "physicians individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable" [1]. The very first piece of guidance that this opinion gives to physicians in this area is that they should engage in efforts to improve the quality of health care by keeping current with best care practices and maintaining professional competence. Principle V reads in whole that "A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated" [2]. [Professional judgment](#) is based on experience as well as learned knowledge and skills. Relying on one's own professional judgment, sharing that judgment with others, and seeking consultation when necessary are foundational elements of practicing medicine [3].

Occasionally, however, physicians will find it necessary or beneficial to deviate from standards of care by improving on an existing intervention or using an existing intervention in a novel way. This type of innovative practice is discussed in Opinion 1.2.11, "Ethically Sound Innovation in Medical Practice" [4]. When deviating from the standard of care in a particular situation, physicians are still responsible for [innovating](#) on the basis of sound scientific evidence and clinical expertise. The opinion sets guidance for patient safety in these situations, such as specific elements to address when obtaining informed consent, including disclosure of the physician's experience with this innovative therapy, any known or anticipated risks and benefits, burdens of the recommended therapy, and why this particular route is being recommended. Physicians should also be transparent and share findings (positive, negative, or neutral) from their use of innovative therapies in some manner, so that the greater profession can benefit from this knowledge.

Medicine is largely a self-regulating profession, and Opinion 1.2.11 acknowledges this by providing guidance to all physicians. To promote responsible innovation, the medical profession should

require that physicians who adopt innovative treatment or diagnostic techniques into their practice have appropriate knowledge and skills.... Provide meaningful professional oversight of innovation in patient care; and ... encourage physician-innovators to collect and share information about the resources needed to implement their innovative therapies effectively [4].

By cultivating these conditions, the medical profession can help create an environment in which physicians are able to successfully draw upon their expertise, experience, skills, and knowledge in order to practice innovative medicine when appropriate.

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STATE OF THE ART AND SCIENCE

Reasonableness, Credibility, and Clinical Disagreement

Mary Jean Walker, PhD, and Wendy A. Rogers, BMBS, PhD

Abstract

Evidence in medicine can come from more or less trustworthy sources and be produced by more or less reliable methods, and its interpretation can be disputed. As such, it can be unclear when disagreements in medicine result from different, but reasonable, interpretations of the available evidence and when they result from unreasonable refusals to consider legitimate evidence. In this article, we seek to show how assessments of the relevance and implications of evidence are typically affected by factors beyond that evidence itself, such as our beliefs about the credibility of the speaker or source of the evidence. In evaluating evidence, there is thus a need for reflective awareness about why we accept or dismiss particular claims.

Introduction

Medical practitioners rely on evidence, but evidence can come from more or less trustworthy sources, be produced by more or less reliable methods, and its interpretation can be disputed. It can be difficult to tell when disagreements about the appropriateness of medical interventions result from different, but reasonable, interpretations of the evidence and when they result from unreasonable dismissal of legitimate evidence. Here, we draw on scholarship about judging the credibility of claims developed by the epistemologist Miranda Fricker. We provide a brief outline of her analysis of credibility judgments and apply it to two disputes—over vertebroplasty and vaccination—showing how assessments of evidence can be affected by background beliefs about the credibility of speakers or methods based on implicitly held “credibility” heuristics. We argue that clinicians need to exercise reflective awareness about why they accept some claims and dismiss others in order to properly assess whether these judgments are justified.

Judging Credibility

Fricker provides a detailed discussion of how we apportion credibility to the claims made by those around us in the course of everyday life [1]. Her approach is apt for thinking about how medical practitioners may assess claims, since busy clinicians are unlikely to have the time to engage in in-depth assessments of evidence for many particular treatments, much as they might like to do so. She notes that while we can sometimes

assess claims directly, by looking at whether they plausibly fit available evidence, most of our knowledge comes from other people. We could not obtain all the knowledge we need without utilizing such knowledge. Thus instead of directly assessing every claim, we often rely on judging whether particular speakers are credible—whether they are (likely to be) competent and sincere. For example, I believe my clinician over my hairdresser on matters of health (given her training) but my hairdresser over my clinician about day-to-day life in the Philippines (since she grew up there).

Often, however, we need to assess claims without having any knowledge about the speaker relevant to assessing his or her credibility. This can be addressed in some cases by relying on reputation or professional position as proxies for relevant personal information, but often even this will be unavailable. Thus, in many cases, we assess credibility by categorizing speakers and drawing on background knowledge about that category [1]. Thus I am likely to believe not just my clinician, but anyone in the category “clinician” on health matters, given my background knowledge about this category. That is, in assessing credibility we rely on heuristics: rough-and-ready rules about what categories of people are likely to be reliable sources about particular matters. My implicit heuristic in this example is that “clinicians are reliable sources about health matters.” Heuristics can attach to any category, not only professions: I would believe a Parisian over a tourist about directions from the Eiffel Tower to the Louvre, parents over those without children on statements about parenting, and so on.

Problems arise if credibility heuristics are themselves incorrect. Fricker argues that we sometimes adopt incorrect heuristics due to social prejudices. Credibility may be apportioned on the basis of potentially irrelevant features of speakers such their sex, race, class, and so on. If a racist society encourages a racist heuristic, such as “people with black skin often lie,” judgments of credibility accordingly become biased [2]. Heuristics can also cause problems because they are generally but not invariably true. My “clinician heuristic,” for instance, is likely to be reliable overall but could occasionally fail if a particular clinician is misinformed or biased. Despite their potential to mislead those who use them, rough, implicitly held credibility heuristics are relied on because they are quick and easy to use.

The Dispute over Vertebroplasty

Vertebroplasty is the injection of bone cement into a fractured vertebral body to treat pain following acute osteoporotic fracture. Vertebroplasty achieved positive results in clinical practice and in retrospective and nonrandomized studies published in the early 2000s [3]. Following dissemination of this evidence, it became a standard treatment. (Surgical procedures do not require regulatory approval and can be widely adopted without “high-level” evidence.) In 2009, two randomized controlled trials (RCTs), which are usually considered the gold standard in medical research, showed vertebroplasty to be no better than placebo [4].

Some researchers—who had extensive clinical experience with vertebroplasty—disputed the RCT results, claiming the research was conducted on the wrong population [5]. The majority of the participants in the two RCTs had experienced pain for more than six weeks. The disputants claimed that vertebroplasty is most efficacious for patients with pain of less than six weeks' duration. They argued that initial pain following vertebral fracture is caused by movement of the fracture fragments and may be present until the fracture heals, while pain of longer duration has a different cause, e.g., biomechanical strain. Vertebroplasty cements fracture fragments together, so it works only for unhealed fractures [5].

In response, those who favored accepting the RCT results provided reasons for preferring RCT evidence over that deriving from other experimental designs, clinical experience, or mechanistic reasoning [4]. RCTs include a control as well as a treatment arm, allowing researchers to identify whether outcomes can be attributed to the intervention. Blinding participants and researchers prevents biases arising from placebo effects or clinicians' expectations from affecting the study outcomes. Moreover, randomization prevents bias in the allocation of research participants and controls for the influence of unknown confounders [6-7]. Other experimental designs, clinical experience, and mechanistic reasoning do not control for these potential biases. Indeed, some proponents of the RCT results claimed that disputing those results was merely a reflection of the "strength of clinicians' placebo reactions" [8]—i.e., that the dispute was unreasonable, itself motivated by bias.

Is the Dispute Reasonable?

In this case, assessment of the evidence involves a heuristic concerning the reliability, not of speakers, but of [methods of evidence generation](#) [1]. The considerations above provide reason to accept the heuristic that "evidence generated using RCTs is more likely to be reliable than evidence from clinical experience, mechanistic reasoning or other experimental designs." Having made the heuristic and the reasoning behind it explicit, we can see that it is well supported. Yet it is a general, not an absolute, rule. One can consistently accept this heuristic and recognize that some RCT results will be incorrect. RCTs can be fraudulent or badly conducted, use inappropriate endpoints, or test nonoptimal versions of a technique or inappropriate populations. Indeed, the limitations of RCTs are well-known. For instance, they provide no information about how correlated variables are causally related and require a methodological rigor that makes generalizing their results to diverse populations problematic [6-7, 9].

By identifying and examining the heuristic underlying the claim that disputing the RCT results was unreasonable, we can see that this claim must be tempered. Although the RCT heuristic is rationally based, it is a general rather than an absolute rule. Thus, recognizing the robustness of RCT evidence does not imply that it is unreasonable to

question whether patients' symptom duration makes a difference to the efficacy of vertebroplasty.

Disputes about Vaccination

This complex set of disputes can be loosely framed as disagreement between a "mainstream" medical establishment (composed of health professionals, researchers, and government health officials) and [vaccine critics](#). The former group claims that vaccines that are in use are safe and effective. The latter hold various views, ranging from concerns about safety issues related to manufacturing processes, to belief in a right to refuse medical treatment, to claims that the medical establishment has been either deceived or corrupted by pharmaceutical companies with financial interests in widespread vaccination [10-11].

The hope that disputes about vaccination can be settled by evidence is complicated by the existence of different bodies of research evidence. The disputants can each cite evidence supporting their view while dismissing conflicting evidence, and they do not always agree on standards for judging evidence [10-11]. It is common for disputants to cast doubt on the reliability of the researchers who conducted particular studies by accusing them of bias related to research funding sources. Mainstream researchers are often government or industry-funded, while vaccine-critical researchers are sometimes funded by vaccine-critical groups [12-13].

Credibility and Categorization

One particular thread of this dispute illustrates the extent to which a dispute can be influenced by how a speaker is categorized and how a category of speakers is perceived. Some vaccine critics hold extreme views about vaccination itself (e.g., that it is a conspiracy to poison our children), or about other matters (e.g., that the government manipulates people and the environment by releasing various chemicals through airplanes) [14]. Holding extreme views tends to lower the speaker's overall credibility [12]. In Fricker's terminology, we place speakers in a category, "the vaccine-critical," and adopt a heuristic that "vaccine critics are not reliable sources." The reasoning implicit behind this heuristic seems to be that people who accept unlikely or odd claims are not reliable sources.

But that a claim seems unlikely or odd is not always a good indication that it is incorrect. Claims that were in the past considered "crazy conspiracy theories" have turned out to be true (e.g., Watergate [15]). The view that the medical establishment is deceived or corrupt does seem unlikely, since it would involve so many people being significantly influenced. Yet it is uncontroversial that available medical evidence is affected by funding mechanisms, conflicts of interest, and publication biases [16]. There is at least some reason to think that mainstream medical knowledge could be distorted. The heuristic at work in the vaccination dispute—namely, "vaccine critics are not reliable sources"—may

turn out to be difficult to rationally support.

A further problem with the heuristic is the breadth of the category. Some “vaccine critics” hold more moderate views, and some are hesitant about vaccines due to uncertainty. These people may be unfairly dismissed due to being placed in this category, leading to potential harms. For instance, if a clinician responds to parental hesitancy about vaccines with anger instead of information because she interprets uncertainty as an “antivaccine” stance, this could lessen parents’ trust in her and even contribute to their developing such a stance [11].

Of course, these problems with the heuristic do not imply that the vaccine critics’ claims should be accepted. They show only that one reason that vaccine critics’ claims are often judged to lack credibility does not have strong rational support. This case further shows that categorizations can sometimes lead to unfairly dismissing or misinterpreting the claims of others in ways that are unhelpful.

Conclusion

Assessments of clinical evidence can be strongly influenced by rough and largely implicit heuristics about those making the claims, the groups to which they belong, or methods of evidence gathering. For these reasons, in assessing medical disagreements, it is helpful for people to reflect on and critically evaluate the heuristics that underlie their judgments of credibility and what those heuristics really justify.

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POLICY FORUM

What Is the Relevance of Procedural Fairness to Making Determinations about Medical Evidence?

Govind Persad, JD, PhD

Abstract

Approaches relying on fair procedures rather than substantive principles have been proposed for answering dilemmas in medical ethics and health policy. These dilemmas generally involve two questions: the epistemological (factual) question of which benefits an intervention will have, and the ethical (value) question of how to distribute those benefits. This article focuses on the potential of fair procedures to help address epistemological and factual questions in medicine, using the debate over antidepressant efficacy as a test case. In doing so, it employs concepts from social epistemology such as *testimonial injustice* (bias resulting from the exclusion of evidence) and *hermeneutical injustice* (bias resulting from a prevailing discussion framework's conceptual limitations). This article also explores the relevance of scientific consensus to determinations regarding medical evidence.

Introduction

Debates in health care ethics and health policy frequently entangle questions of fact with questions of value. For instance, determining who should receive priority for scarce vaccines in a pandemic involves answering two questions: the descriptive (factual) question of which benefits these vaccines are expected to have for their recipients and the normative (value) question of how those prospective benefits should be distributed. More mundane health policy debates—for instance, over which medications to include in a formulary—similarly involve questions of both clinical efficacy and distributive fairness.

Many theoretical approaches have been proposed for resolving debates regarding distributive fairness in medicine. Employing approaches used in other areas of moral philosophy, such as utilitarian or Kantian ethics, represents one option [1]. Others propose borrowing from other areas of social policy, such as decision analysis [2]. Still others defend allocative principles that can be weighed and balanced against one another [3]. In this article, I discuss a different approach, which focuses on the establishment of fair *procedures* for choosing principles rather than the promulgation of specific *principles*. Rather than considering the application of fair procedures to the

development of ethical principles, I consider how fair procedures have been and can be used to develop and weigh factual evidence in medicine. Debates over the validity and weight of medical evidence are likely to become more significant and more frequent. Among the drivers of these debates are the large amounts of evidence being developed every day, a trend only accelerated by the expansion of clinical data collection and analysis; the growing relevance of scientific evidence to medical practice, exemplified by the increased emphasis on evidence-based medicine; and the use of evidence to support payment and insurance coverage decisions that have financial implications for patients and providers [4].

I first review the use of fair procedures in the more familiar territory of ethics and distributive justice. I then consider how fair procedures might be applied to the development and weighing of evidence. While some procedures for developing and weighing evidence are already in use, their fairness remains to be examined. In doing so, I introduce readers to the concept of epistemic injustice, which has recently been popular in social epistemology (the study of the social dimensions of knowledge). I also discuss the relevance of consensus to the legitimacy of evidence and the use of fair procedures in assessing cost-effectiveness.

Procedural Approaches to Ethical Questions

Before discussing the use of fair procedures in the development and weighing of factual evidence, I will briefly review their use in answering value questions. The most prominent procedural approach is the accountability for reasonableness framework developed by Norman Daniels and James E. Sabin [5]. Rather than proposing specific principles, Daniels and Sabin argue that normative questions, such as how the benefits of scarce medical interventions should be distributed, can be addressed through the development and operation of fair procedures. They propose four conditions that fair procedures must meet (see table 1).

Table 1. Conditions of accountability for reasonableness in decision making [5, 6]

Condition	Requirement
Publicity condition	Decisions be publicly accessible.
Relevance condition	Decisions be justified by “appeals to evidence, reasons, and principles that are accepted as relevant by fair-minded people who are disposed to finding mutually justifiable terms of cooperation” [7].
Revision and appeals condition	Process exists to appeal decisions and to revise policies.
Regulative condition/ enforcement condition	Decision-making process is regulated to ensure that publicity, relevance, and revision and appeals conditions are met.

Daniels and Sabin believe that decisions made using procedures that meet these conditions are ethically correct regardless of the substance of the decisions themselves. Similar procedure-based approaches have been advocated by Amy Gutmann and Dennis Thompson [8] and by Leonard M. Fleck [9]. These approaches have been extremely influential in health policy, to the point that even a critic of the accountability for reasonableness approach describes it as “to the point of becoming the dominant paradigm in the field of health policy” [7].

Procedural Approaches to Factual Questions in Medicine

I will discuss the use of procedural approaches to medical evidence via a real-world example: the debate over the efficacy of antidepressant medications. Recent studies have differed regarding whether antidepressant medications are more effective than a placebo at combating depression, with some studies concluding that their efficacy is only slightly greater than that of a placebo, and others concluding that they are substantially more effective [10]. The debate over the factual evidence for antidepressant efficacy has implications for physicians, formulary administrators, and public and private health insurers. Does factual evidence support prescribing a medication for a given patient with depression? Which antidepressant medications, if any, are high priority interventions that must be included in formularies? Which should be covered by insurance? I will consider how procedural approaches to the epistemology of medical evidence might help to address these questions.

Avoiding epistemic injustice. While physicians and scientists have no special expertise in answering purely normative questions, they do have special expertise in answering factual questions about the effects of medical interventions on different patients. This

bolsters the attractiveness of a procedural approach in which the only participants are expert scientists and physicians who reach a consensus and then explain that consensus to the public.

However, work on *epistemic injustice*—injustice with respect to knowledge—by the epistemologist Miranda Fricker [11] provides a basis for considering the perspectives of nonexperts in decision making as well (see table 2). Fricker classifies epistemic injustices into two categories: testimonial and hermeneutical. *Testimonial injustice* is the discounting of someone’s testimony on the basis of unjustifiable biases. If scientific studies were to discount women’s reports regarding antidepressant side effects on the basis that women are unreliable reporters, this would constitute testimonial injustice. In contrast, *hermeneutical injustice* involves testimony being ignored because it cannot be conceptualized or expressed within the prevailing framework for discussion. For instance, if participants in a clinical study reported that an antidepressant had the side effect of making it more difficult for them to form nurturing relationships, but these responses were ignored because nurturing relationships could not be categorized as a value within the study’s framework, this would be a form of hermeneutical injustice.

Table 2. Categories of epistemic injustice [11]

Type of epistemic injustice	Definition	Example
Testimonial injustice	Discounting someone's testimony on the basis of unjustifiable biases	Discounting women's reports regarding antidepressant side effects on the basis that women are unreliable reporters
Hermeneutical injustice	Ignoring testimony that cannot be conceptualized or expressed within the prevailing framework for discussion	Ignoring reports that antidepressants affect the formation of nurturing relationships because the framework does not discuss nurturing relationships
Epistemic objectification	Treating others as passive states of affairs from which information can be gleaned, rather than as agents who convey information	Failing to attend to research participants' feedback about their experience of antidepressant treatment
Exclusion	Using methods for collecting information that exclude relevant individuals or relevant information	Excluding relevant research participants from an antidepressant trial or using a trial design that provides no scope for patients to share relevant information they have about their experience of antidepressant efficacy and side effects

Concerns about epistemic injustice are particularly salient in medicine as opposed to biology or chemistry, because the goal of clinical practice is not to understand the chemical or biological effects of an intervention but instead to understand whether providing that intervention improves the life of its recipient. Assessing the capacity of an

intervention to improve patients' lives frequently requires attending closely to the details of their reports of their own experiences. Some approaches to medical research, however, might fail to attend sufficiently to others' testimony. Fricker discusses one form of such failure when she observes that someone who regards others not as "epistemic agents who convey information" but instead as "states of affairs from which the inquirer may be in a position to glean information"—that is, as passive objects to be observed—engages in what she calls "epistemic objectification" [12]. Similarly, a recent review of antidepressant efficacy complains that some studies of efficacy ignore "the patient's point of view" on whether antidepressants are preferable to a placebo [13]. Concerns about epistemic objectification suggest the importance of including narrative and ethnographic detail about patient experiences and assessing patient self-reports rather than relying solely on observational data or biomarkers [14].

Epistemic injustice can also occur when methods for collecting information exclude certain groups or types of information. Bina Agarwal has examined this form of exclusion in her research on community forestry groups whose deliberative practices exclude women and thereby overlook women's relevant knowledge about effective and sustainable forestry practices [15]. A similar injustice would occur if an antidepressant trial were organized in a way that gave participants insufficient opportunity to share relevant knowledge or excluded some groups of prospective participants. Even when exclusion reflects concerns about participants' capacity to consent, it nonetheless lowers the epistemic reliability of the information collected.

Evidence, replication, and scientific consensus. Elizabeth Anderson has suggested that evidence becomes more epistemically justified when it represents a consensus of scientists in different laboratories and institutions [16]. On this view, a scientific claim becomes epistemically justified not through the work of a single investigator or researcher but through the developing consensus of a community of inquirers. The importance of replication and verification of factual evidence by other inquirers is analogous to the appeal and revision condition Daniels and Sabin adopt: both require a proposal to be confirmed or revised by others.

Anderson's consensus view, although developed using examples from the laboratory sciences, is also applicable to the epistemic issues raised by medical science. As an example, the consensus view would give greater evidentiary weight to a finding regarding antidepressant efficacy that has been replicated several times by different investigators and received consensus among the relevant scientific community than one that is supported by a single trial.

Evidence about cost effectiveness. Decisions in health policy, and to a lesser extent in medicine, are often based on judgments about cost effectiveness as well as clinical effectiveness. Cost effectiveness is generally expressed as a ratio of the cost of an

intervention to the quality of life improvement that the intervention produces [17]. Some have worried that evidence regarding cost effectiveness is epistemically dubious for procedural reasons because determinations regarding quality of life rely on the judgments of individuals, such as medical professionals or healthy trial participants, who may not be representative of the broader population [17]. Additionally, cost effectiveness approaches are based on a population average (e.g., the average effectiveness of an antidepressant) and thus are insensitive to the distinctive ways in which particular individuals may benefit from or be harmed by an intervention [18]. Approaches emphasizing procedural fairness, particularly those concerned with epistemic injustice, will give greater weight to cost-effectiveness evidence when that evidence is collected via fair procedures.

Limitations of Procedural Approaches

Alexander Friedman and Annette Rid have charged that procedural approaches cannot resolve substantive disagreements regarding normative questions on their own and that the task of determining which considerations are relevant must therefore be solved by appeal to some strategy other than the use of fair procedures [6, 19]. These criticisms may also apply to the use of procedural approaches to factual questions. For instance, procedural approaches may not be able to answer the question of which scientists' views should prevail in the face of a disagreement about which kinds of evidence are relevant—for instance, a disagreement regarding whether to give any weight to anecdotal patient reports regarding antidepressant efficacy. However, fair procedures may be more effective at settling factual questions when considering the weight of evidence that has been established as relevant for some nonprocedural reason.

Conclusion

Procedural approaches, more frequently used to resolve disagreements over values in health care, also represent one framework for engaging debates regarding factual evidence in medicine. One procedural framework for weighing factual evidence focuses on avoiding epistemic injustice by making procedures for collecting factual evidence fairer and thereby more epistemically reliable. Procedural approaches can also be applied to factual determinations regarding cost effectiveness. While procedural approaches have limitations in their capacity to resolve debates over factual evidence, they represent an approach that warrants more attention.

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POLICY FORUM

Seeking Legitimacy for *DSM-5*: The Bereavement Exception as an Example of Failed Process

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Abstract

In 2013 the American Psychiatric Association (APA) published the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*. Even before publication, *DSM-5* received a torrent of criticism, most prominently over removal of the “bereavement exclusion” for the diagnosis of major depression. We argue that while the APA can claim legitimate authority for deciding scientific questions, it does not have legitimacy for resolving what is ultimately a question of ethics and public policy. We show how the “accountability for reasonableness” framework for seeking legitimacy in health policy could have been used to achieve a better resolution of the conflict than actually occurred.

Introduction

In 2013 the American Psychiatric Association (APA) published the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*. The manual sets the global standard for psychiatric diagnosis and shapes how psychiatry is understood and practiced worldwide. But even before publication, *DSM-5* received a torrent of criticism—most prominently over removal of the “bereavement exclusion” for the diagnosis of major depression—from psychiatrists and other mental health clinicians, researchers, and commentators who felt that US health care too frequently medicalized normal conditions.

We believe that the rancorous debate about the bereavement exclusion exemplifies an important issue about achieving legitimacy in health policy. We argue that while the APA can claim legitimate authority for deciding *scientific* questions, it does not have legitimacy for resolving what is ultimately a question of *ethics* and *public policy*. The APA’s scientific and clinical expertise is necessary but not sufficient for resolving the debate. To achieve a legitimate outcome and one potentially more acceptable to the clinical community and concerned members of the public, a more inclusive form of public deliberative process is required.

History of the Bereavement Exception in the *DSM*

The bereavement exception only became an issue with the publication of *DSM-III*. *DSM-I* (published in 1952) and *DSM-II* (published in 1968) based diagnoses on the hypothetical etiologies believed in at the time [1]. But when researchers demonstrated that American and British psychiatrists shown videotapes of the same patients made very different diagnoses [2], and that sham-patients who claimed to hear voices saying “empty,” “hollow,” or “thud” but then acted entirely normal were diagnosed with schizophrenia and hospitalized [3], it became clear that a new approach to diagnosis was needed.

DSM-III (published in 1980) sought to bring reliability to this chaotic situation by basing diagnoses on explicit checklists of symptoms. If a patient displayed a specified number of well-defined symptoms, the diagnosis was made [4]. But for the diagnosis of major depression, *DSM-III* and *DSM-IV* made an exception for patients whose symptoms could warrant the diagnosis if they occurred in the context of bereavement.

After the loss of a loved one, the symptoms [do not] persist for longer than 2 months or are [not] characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation [5].

The *DSM-5* Task Force chose to eliminate the bereavement exclusion for three main reasons. First, depressive illnesses that follow bereavement are clinically similar to depressive illnesses that occur in nonbereavement contexts [6]. Second, it seemed arbitrary to single out bereavement as the only exception to stress-induced conditions. What about divorce, loss of employment, or diagnosis of a serious illness [7]? Finally, since depressive illness includes the risk of suicide, missing the diagnosis because of the bereavement exclusion could cause serious consequences [8].

The two “sides” in the debate have published more in professional journals and popular media and on social media sites than we can summarize in detail in this brief article. But our reading of *DSM-5* [9] and the major arguments for retaining [10, 11] or eliminating [12, 13] the exclusion suggest that although the distinction between severe “normal” grief and depressive illness can be fuzzy, the two “sides” would actually treat patients in a very similar manner. Patients seen as experiencing [normal grief](#) might be treated for symptoms like insomnia but would be given reassurance that their painful state was “normal” and would resolve over time, while patients seen as suffering from depressive illness would be treated with psychotherapy, medication, or a combination thereof.

Where the “sides” differ is in their trust of the medical profession and their view of risk of “medicalizing” normal human phenomena like grief. Kendler pictures a clinically careful response to the bereaved person:

As with the psychiatric response to the ... major stressors to which we humans are all too frequently exposed, good clinical care involves first doing no harm, and second intervening only when both our clinical experience and good scientific evidence suggests that treatment is needed [12].

Frances, chair of the *DSM-IV* Task Force, does not share Kendler's optimistic view of psychiatric practice:

Medicalizing normal grief ... reduces the normalcy and dignity of the pain, short circuits the expected existential processing of the loss, reduces reliance on the many well established cultural rituals for consoling grief, and would subject many people to unnecessary and potentially harmful medication treatment [14].

After weighing the pros and cons, Pies concludes: "Given the serious risks of unrecognized major depression—including suicide—eliminating the bereavement exclusion from *DSM-5* was, *on balance, a reasonable decision*" (emphasis added) [15].

In the remainder of this essay we ask: Who has [legitimate authority](#) to do the balancing?

Legitimate Authority in the *DSM-5* Process

The APA tried valiantly to make the *DSM-5* process trustworthy, by such means as a strong conflict of interest policy that sharply limited commercial ties, substantial work group participation by nonmedical experts, international participation, and extensive opportunity for online comments on drafts (well over 10,000 comments from clinicians, researchers, and the public were received and reviewed) [16, 17]. And with regard to the dispute over whether to drop or retain the bereavement exclusion, the work group on mood disorders responded thoughtfully to those who favored keeping it, citing the research evidence that led to its conclusion [18].

But the equally expert group that favored retaining the bereavement exclusion was not persuaded [18]. And in the stalemate, each "side" leveled *ad hominem* attacks against the other.

We believe that the "accountability for reasonableness" framework we developed in *Setting Limits Fairly: Learning to Share Resources for Health* [19] to explain how private health plans and public programs like Medicare and Medicaid can achieve fairness and legitimacy for their limit-setting policies sheds light on the stalemated argument over the bereavement exclusion. The framework specifies that to claim fairness and legitimacy, three substantive conditions must be met: *publicity* (the rationales for policies must be publicly accessible); *relevance* (the rationales must provide a reasonable

justification for the policies), with “reasonable” being defined as considerations fair-minded people (those committed to seeking mutual justification for their views) see as relevant; and *revision and appeal* (dispute resolution mechanisms allowing challenge to policy and, more broadly, opportunity for revision in light of new evidence and arguments).

The *DSM-5* process met the publicity condition by explicating in great detail the rationale for dropping the bereavement exclusion. But it did not respond to its critics with adequately relevant reasons. The two “sides” agreed that bereaved persons who were suffering from depressive illness should be treated for the illness and that bereaved persons whose symptoms mimicked the symptoms of depression but who did not have depressive illness should be regarded as normal grieving persons [7, 11]. The disagreement was about whether the potential harms caused by dropping the exclusion outweighed the potential benefits from dropping it.

In clinical care it is well established that the role of the physician is to present the *facts* about a potential intervention, but the *values* of the patient should ultimately determine whether or not the intervention is undertaken. If physicians disagree with their patients’ choices, they should elicit the *reasons* for the choices and, if they wish, try to persuade the patient to a different conclusion.

In similar fashion, the *DSM-5* process needed to engage more fully with the reasons that motivated opponents of the proposed change. We would have recommended convening a deliberation that included stakeholders in addition to the dueling experts—individuals and families with experience of bereavement, grief counselors, clergy, and others. That process would have demonstrated that the dispute was primarily about values, not about the validity of research findings, and values provide reasons within the deliberative process.

The APA placed greatest weight on the risk that the bereavement exclusion would lead to misdiagnosing depressive illness as normal grief. The other “side” would have countered that the risk of misdiagnosing grief as depressive illness was worse and that the pharmaceutical industry would seduce grieving persons and physicians into prescribing unneeded medication. This dispute over how to “weigh” competing values is a disagreement over ethics and policy, not over a matter of scientific fact.

Even if the *DSM-5* leaders held to their view that the bereavement exception should be eliminated, if a deliberative process like the one we would have recommended had occurred, the stakeholders’ sense of legitimacy and fairness would probably have been different. The “opponents” would have known that their concerns about medicalizing normal grief and the ensuing prescription of unneeded medication had been heard, understood, and responded to, even if not agreed with. And the APA would have had a

better understanding of the fears that motivated the opponents of elimination. A skillful facilitator would have clarified the degree to which the disagreement was about the different weights the APA and the critics gave to the *risks* entailed by keeping or eliminating the exception, not primarily about the *facts* about bereavement and depression.

Our guess is that if a deliberative process of this kind had been convened, the distance between the contending perspectives would have been reduced, and the “sides” would have ended agreeing to disagree. The APA could then have invoked the revision and appeal condition and said—“we will go ahead with the plan to drop the bereavement exclusion, but let’s specify how to evaluate the impact over the next two years. But if it turns out that your concerns were correct, we will reinstate it...”

Although the APA made reasonable arguments for its view of the bereavement exception, it did not engage adequately with the concerns of those who argued for retention. As a result, the opponents—including the *DSM-III* and *DSM-IV* leaders—lost trust in the *DSM-5* decision-making process and saw it as an assertion of power, perhaps motivated by the pharmaceutical industry [11]. This was an avoidable outcome in an area of deep concern. Sadly, by a failure of process, it was not avoided!

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Chance to Choice: Genetics and Justice (Cambridge University Press, 2000); and *Is Inequality Bad for Our Health?* (Beacon Press, 2000). His current research is on justice and health policy, including priority setting in health systems, fairness and health systems reform, health inequalities, and intergenerational justice.

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MEDICINE AND SOCIETY

The Case of Dr. Oz: Ethics, Evidence, and Does Professional Self-Regulation Work?

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Abstract

Dr. Mehmet Oz is widely known not just as a successful media personality donning the title “America’s Doctor®,” but, we suggest, also as a physician visibly out of step with his profession. A recent, unsuccessful attempt to censure Dr. Oz raises the issue of whether the medical profession can effectively self-regulate at all. It also raises concern that the medical profession’s self-regulation might be selectively activated, perhaps only when the subject of professional censure has achieved a level of public visibility. We argue here that the medical profession must look at itself with a healthy dose of self-doubt about whether it has sufficient knowledge of or handle on the less visible Dr. “Ozes” quietly operating under the profession’s presumptive endorsement.

Introduction

Dr. Mehmet Oz’s surgical credentials including expertise in minimally invasive, heart transplant, and heart valve surgery are impeccable [1]. But when Dr. Oz walks onto the stage of *The Dr. Oz Show*, he’s not just a well-trained heart surgeon, he becomes “America’s Doctor®.” *The Dr. Oz Show* averages nearly four million daily viewers and has won two Emmys [2]. His guest list has included First Lady Michelle Obama [2]. Recently, Donald Trump brought a few medical records and discussed his physical fitness to be president [3]. Dr. Oz has the ear of the public, encouraging Americans to lose weight, eat more fruits and vegetables, sleep, and get their flu vaccinations; he credits his show for three million pounds a year of weight loss in the US [4].

To those “exercising power and influence over matters of policy, opinion, or taste” [5]—that is, the medical and political establishment—Dr. Oz is a dangerous rogue unfit for the office of America’s doctor. He has told mothers that there were dangerous levels of arsenic in their child’s apple juice (there weren’t) [6, 7] and suggested that green coffee is a “miracle” cure for obesity [8]. Federal regulators discovered altered data in hyped

coffee bean evidence [8]. The Food and Drug Administration tested for arsenic in apple juice and found the “vast majority of apple juice tested to contain low levels of arsenic” and given these levels was “confident in the overall safety of apple juice consumed in this country” [7]. Dr. Oz also featured two guests on his show who claimed that genetically modified foods were cancer causing [9] (despite repeated safety reports that found no adverse effects [10]).

For his misrepresentation of weight loss interventions, Dr. Oz got an establishment scolding in a 2014 congressional hearing. “I don’t get why you have to say this stuff because you know it’s not true,” Senator Claire McCaskill told him. “So why, when you have this amazing megaphone and this amazing ability to communicate, why would you cheapen your show by saying things like that?” [11]. Dr. Oz promised he had learned and hired a scientific fact checker to verify the scientific rigor of his claims [12]. Ten physicians wrote to the medical school dean at Columbia claiming that he was endangering public health, had demonstrated contempt for medical and scientific evidence, and was ineligible to sit on the faculty of a prestigious medical institution [13]. Medical and scientific professionals applauded, claiming Dr. Oz “undermines the trust that is essential to physician-patient relationships” [14]. No academic action was taken by the university, citing its commitment “to the principle of academic freedom and to upholding faculty members’ freedom of expression for statements they make in public discussion” [15]. Dr. Oz retains both his faculty position and his board certification. Here we explore some of the ironies and challenges posed by the attempted sanctioning of Dr. Oz and their implications for professional self-regulation as well as the boundaries of legitimate medical claims in the twenty-first century.

Dr. Oz and the Problems of Self-Regulation

The profession of medicine in its modern conceptualization includes [self-regulation](#). By upholding quality of care and dealing proactively with those who are dangerously out of step with their colleagues, self-regulation in turn gives medicine a degree of protection and autonomy from government procedural rule [16]. Self-regulation is a hallmark of implied and explicit norms that bind physicians as a group to one another and to society. The capacity to maintain some standard of quality and to respond when boundaries of what is considered legitimate practice are crossed, is sanctioned by society and implied in the privileges society bestows on the medical profession [16, 17, 18].

The Dr. Oz case raises two related but different issues about the ideal of self-regulation in the medical profession that mirror our contemporary moment. The first relates to Dr. Oz himself. Should a physician be allowed to say anything—however inaccurate and potentially harmful—so long as that individual commands market share? In a professional sector whose history and growth is marked by the sustained and rightful denouncement of quacks and quackery [19], an inability to define and fence the epistemic boundaries of scientific medicine from apparent quackery on such a visible scale becomes something

akin to a full-scale identity crisis for medicine. This impotence could be a function of either an unwillingness to undertake or inefficacy in self-regulation on the part of the profession or a perceived or actual possibility that even if physicians strongly sanctioned Dr. Oz, that sanctioning would not ring true for his audience. This situation raises important ethical questions. What standards of certainty should we hold so resolutely that when violated we say “enough!” and thus move to sanction? Dr. Oz certainly appears to be someone peddling unproven and ineffective remedies for personal gain. It would seem like his is a paradigmatic test case for professional self-regulation in medicine. Yet, he remains immensely popular, prompting us to wonder, if we can't effectively sanction Dr. Oz, whom can we sanction?

Implied in the capacity to discipline one of its own is the profession's warrant for doing so. This warrant hinges on our ability to detect and then respond to quackery in the service of public trust. What constitutes quackery deserves scrutiny. Dr. Oz claims he is all about trust. “The currency that I deal in is trust ... and it is trust that has been given to me ... by an audience that has watched over six hundred shows” [13]. This quotation suggests that Dr. Oz, as a TV personality, seems to feel that he responds to the longings of health care consumers who feel alienated from the markets and bureaucracies we call modern health care. Unlike their experience with a hurried, burned-out primary care doctor, health care consumers get from Dr. Oz a healthy dose of undistracted eye contact, a leisurely entertaining hour, and common sense advice about all the things they don't really teach doctors about in medical school—diet, supplements, and health habits. Not all Americans experience a trusting, empathic interaction with their clinicians. Yet millions seem to feel known and heard after a screen-based virtual visit with “America's Doctor®.”

And when it comes to epistemic boundaries, Dr. Oz admits he applies different standards of [evidence](#) compared to those accepted in the medical establishment. When challenged by a reporter for the *New Yorker* about his questionable evidentiary standards, he replied that all data could be differentially interpreted. “‘You find the arguments that support your data,’ he said, ‘and it's my fact versus your fact’” [2]. It's not that he doesn't offer data. It's common for Dr. Oz to offer some plausible mechanism from test tube experiments conducted by manufacturers, combined with personal anecdotes from his own or consumers' experience, to support the products he's promoting. A study of 80 recommendations made on *The Dr. Oz Show* in early 2013 found that published evidence supported 46 percent of recommendations, contradicted 15 percent, and did not support 39 percent [20]. Yet, his visible display of inconclusive evidence merely highlights questions about the boundaries of what counts as legitimate evidence in modern medicine. Those standards are fluid and evolving. We settle for incomplete, selectively published data in journals heavily subsidized by pharmaceutical companies and for outcomes that don't give firm answers [21]. While not on par with offering anecdotes as evidence, the fact that debates persist about what constitutes sufficiently high,

unbiased, quality evidence to support decisions in the profession as a whole [22] creates a wedge that Dr. Oz seems to exploit. In this context, Dr. Oz's reliance on incomplete or distorted data looks less exceptional, less worthy of sanction, and more fashionably lax than wrong.

The Boundaries of Legitimacy

The second and perhaps more perplexing irony of the Dr. Oz case turns the spotlight of attention back on the profession itself. That Dr. Oz has been singled out as the target of professional angst to the exclusion of other questionable "professionals" also deserves our reflection. There have always been disreputable physicians on the fringe of medical practice [23], but few with the combination of both media reach and the gloss of academic credentials. At our moment in history, the boundaries of legitimacy appear to be stretched not only by the reach of the media but also by the media's capacity to drive consumption. In a world with such overreach in health claims by a whole range of conventional and alternative actors, [legitimacy](#) seems very much a contested category; the possibility of policing excess consistently and fairly seems too overwhelming to contemplate seriously. Should we bring professional self-regulation SWAT teams to bust shady practices? Should we, as the medical establishment, seeking to self-regulate, troll for ads in the *New York Times Magazine* that bait patients to clinical centers to get the next robotic whatever [24] and publicly call into question the claims of esteemed organizations or their practitioners? We have not. And it is the selectivity this case expresses about the epistemic boundaries of medicine that, upon reflection, ought to raise our eyebrows.

Dual narratives of trying and failing to sanction Dr. Oz contrasted with rare attempts to sanction other physicians and their institutions with questionable practices expose a rich heterogeneous subtext of self-regulating impotence, incommensurable values, and commercial distraction for the profession as a whole. We fail to respond to threats that we are in bed with, and we only contemplate policing the "other" when the fame and consumer attention reach a fevered pitch or some economic interest is at stake. Some have speculated that the scientists, whose backgrounds were in areas other than medicine, who wrote the Columbia letter did so only after Dr. Oz came out against genetically modified food—an industry tied to his accusers [25]. In our selective injunctions, arguably we in the medical establishment make gestalt assessments of what is legitimate, barely stopping to question if we've gotten it right. If our gut instincts resonate with sanctioning Dr. Oz, the selection bias of failing to do so in other cases should haunt us. What we try to sanction and what escapes policing notice altogether implicitly define the functional boundaries of the work and in turn what constitutes legitimate and illegitimate bedfellows in it. The medical profession's inefficacy in actually sanctioning our most rogue members, combined with our self-regulating apathy toward more common and less egregious offenders of rigorous medical standards, suggests

that professionalism based on self-regulation might be empirically suspect in the early twenty-first century.

Conclusion

The case of Dr. Oz forces us to own our own contemporary moment, rebooting doubt on how we know what we know and whose opinion counts. In this sense, Dr. Oz and all that he represents is a mirror on the medical profession in late modernity. While medical boards and licensing persist, they arguably persist as weak vestiges of a robust ideal that seems unachievable at this contemporary moment. Here, we've tried to amplify medicine's need to redirect professional consciousness to rebuild the profession's identity, such that more patients will connect with and trust their physician rather than the image of one on TV.

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SECOND THOUGHTS

The Idea of Legitimate Authority in the Practice of Medicine

Arthur Isak Applbaum, MPP, PhD

Abstract

Legitimate authority is the normative power to govern, where a normative power is the ability to change the normative situation of others. Correlatively, when one has the normative power to govern others, these others face a normative liability to be governed. So understood, physicians do not have legitimate authority over their patients, and patients do not have legitimate authority over their physicians. An authority is legitimate only when it is a free group agent constituted by its free members. On this conception, associations of physicians sometimes have legitimate authority over individual physicians, and physicians sometimes count as members subject to the legitimate authority of these associations. This might be so even when they have not consented to membership.

Introduction

Disagreement over the proper practice of medicine is an enduring feature of contemporary health care: patients might disagree with their physicians about the suitability of resuscitation in end-of-life care; individual physicians might reject the guidance of medical associations over the off-label use of atypical antipsychotics; or employers might challenge a legal requirement to provide their employees insurance coverage for contraception. Sometimes the question of who should decide in the face of such dissension is posed as a question of who has legitimate authority over whom. As we shall see, this only sometimes is the most perspicuous way to understand the challenge of resolving disagreements in medicine.

Health care ethics largely is a subfield of political philosophy, and the idea and conditions of legitimate authority are a central concern of political philosophers. So we should expect discussions of legitimate authority in medicine to be as vigorous and varied as discussions of the concept in political philosophy itself. Here, then, is one brief account. If you don't accept it, substitute your own, but all views of legitimate authority in medicine presuppose, explicitly or not, views about legitimate authority simply.

What is Legitimate Authority? The Power-Liability Account

Legitimate authority, as I shall use the notion, is the normative power to govern, where a normative power is the ability, in some context, to change the normative situation of others—their rights and duties, permissions, and restrictions. Repurposing the well-known analytic jurisprudence of Wesley Hohfeld to moral concepts, when one has the normative power to govern others, these others face a correlative normative liability to be governed, in that they are subject to changes in their normative situation [1]. Just as one who is legally liable is not immune from being subject to certain costs or penalties at the discretion of another who has the power to invoke these legal liabilities, so one who is normatively liable is not immune from being subject to changes in what one morally owes or is owed at the discretion of another who has the power to invoke these normative liabilities. Normative powers are varied: they could be powers to create or dissolve moral rights and duties; they could be powers to enact legal or institutional rights and duties and to enforce them; and they could be powers to change the social facts that shape the possibilities and meanings of one's actions, such as what counts as a marriage or who counts as a physician.

Some writers hold that the normative power of legitimate authority necessarily is the power to morally obligate and that anything short of this collapses into a mere liberty to affect others [2]. The difference between the legitimacy-entails-duty view and the legitimacy-as-mere-liberty view of legitimate authority is this: if legitimate authority merely is the liberty (or, synonymously, the permission or option or prerogative) to govern others, we do not yet know whether these others have a moral duty to obey. But if legitimate authority is a claim-right to govern, then those subject to that authority do have a correlative moral duty to obey. I have argued that there is a stable view in between the legitimacy-entails-duty view and the legitimacy-as-mere-liberty view, which I have called the power-liability view [3]. Think of it as the Goldilocks account of legitimacy: legitimacy as a claim-right that entails moral duty is too hard; legitimacy as mere liberty is too soft; legitimacy as a normative power that entails normative liability is just right. On the power-liability account, one who is subject to the legitimate authority of another is liable to certain changes in institutional rules and liable to certain burdens that the application and enforcement of such rules might impose; one is precluded from resisting in certain ways; and one may not have justified grounds for complaint. But it still might be the case that one does not have a moral obligation to obey those rules.

The Legitimate Authority of Physicians over Patients and of Patients over Physicians

Do physicians have legitimate authority over their patients, or do patients have legitimate authority over their physicians? It is not helpful to think of the physician-patient relationship as an authority relationship in either direction. Each has normative control over certain decisions and resources, and therefore each has certain rights and duties, but to have a right against another is not yet to have authority over another. On

the power-liability account, a legitimate authority does not merely have certain rights and duties; that authority has the power to change certain rights and duties of others.

Physicians of course are *epistemic* authorities, in that they possess superior knowledge and judgment about diagnosis, prognosis, and the medical consequences of treatment. Epistemic authorities give us content-independent reasons to *believe* that some proposition is true and, insofar as the correct action to take depends on our beliefs, an indirect reason to act. If a physician is an [expert authority](#), a patient who is unable to assess the truth of the content of a scientific proposition nonetheless has reason to believe that the proposition is true merely because the physician says it is true. Our question is whether physicians are *normative* authorities, in that the directive of a physician imposes upon the patient a moral duty to comply or some other moral liability. If you ignore the expert instructions of the weather forecaster on the radio to carry an umbrella, you are likely to get wet, but you suffer no *normative* liability: you haven't violated a duty owed to the meteorologist, you cannot be stripped of some entitlement you would otherwise have, and you cannot be forced to carry an umbrella under pain of punishment by the radio station. Similarly, if you ignore the expert instructions of your physician to take your medications, you are unlikely to be cured, but you haven't violated a duty owed to your physician, you do not lose your entitlement not to be paternalized by her, and you cannot be forced to take your medicine under pain of punishment by the hospital. Although they are expert authorities with respect to you, neither your weather forecaster nor your physician has normative authority over you. Though their judgment be superior to yours, their instructions do not alter your normative rights and duties, permissions, and restrictions. Physicians care for their patients, but physicians do not govern their patients.

Nor do patients have normative authority over their physicians. Yes, physicians have a range of common and fiduciary duties towards their patients: to aid and not to harm; to conscientiously inform about diagnosis, prognosis, and choices and not to treat without genuine consent; to keep confidences and not to exploit. But not every claim-right against another is an exercise of authority over another in any illuminating sense. Insofar as we are self-governing, we have authority over ourselves, and when we consent to be treated, we create both a permission to treat where there wasn't yet such permission and a defeasible obligation to treat where there wasn't yet such an obligation. So we are exercising normative power, but it is the kind of power involved in ordinary consenting and promising. It is not the normative power to govern. Patients do not have normative power to command any treatment they fancy, creating in the physician a correlative liability to comply or to be sanctioned, let alone a duty to comply. The physician also is self-governing and is entitled to maintain the integrity of her calling, as she (or perhaps her colleagues, as we will see soon) understands it. She need not provide futile care and must not provide harmful care or disproportionately risky care [4]. Most important, whether she should provide beneficial but disproportionately expensive care depends in

part on who properly controls the resources to pay for it, for the patient has no content-independent authority to command the resources of the public or of third parties. Patients do not govern their physicians.

Who Has Legitimate Authority? The Free Group Agency Conditions

Does the medical profession have normative authority over individual physicians? For example, the American Medical Association's *Code of Medical Ethics* prohibits physicians from participating in legally authorized executions [5]. Is a physician who disagrees with this collective moral judgment nonetheless properly governed by the ruling, and so either has a moral duty to comply or at least has no justified complaint if professionally sanctioned? The American Academy of Family Physicians has recommended against routine prostate-specific antigen (PSA) screening for prostate cancer [6]. Is a physician who disagrees with this collective clinical judgment nonetheless properly governed by the recommendation and so has a duty, or at least a moral reason, to discontinue routine PSA screening? Whether the profession has this sort of normative power over physicians, I think, is the most interesting question about authority in medicine. To answer it, we need more than an account of what legitimate authority is, which I have argued is the normative power to govern entailing the normative liability of the governed. We need an account of the necessary conditions for having legitimate authority. I shall offer one. If you don't agree, substitute your own, but, once again, the question cannot be answered well without offering criteria.

If competent adults are entitled to be self-governing, how can this be reconciled with being governed by others? My answer is that authorities are legitimate only when they preserve the external and internal freedom of those they govern, and that in turn is the case only when the authority is a free group agent constituted by free members.

Consider an argument for a free group agency conception of legitimate authority:

- *A legitimately governs B only if B remains a free moral agent over time.*
- *B remains a free moral agent over time only if A's governance of B realizes and protects B's external and internal freedom over time.*
- *A's governance of B realizes and protects B's freedom over time only if A is a free group agent that counts a free B as a member.*
- *Therefore, A legitimately governs B only if A is a free group agent that counts a free B as a member.*

By group agent, I mean nothing metaphysically spooky, like the existence of some ghostly intelligent being. An agent is an entity that has the capacity to consider reasons for action, the capacity to choose an action responsive to those reasons, and the capacity to act in response to this choice. Since these three capacities are not necessarily mental states residing in one wet brain, it is possible that a collection of natural agents can coordinate in such a way that these three capacities are competently performed only by combining individual efforts, and, when this is so, a group agent capable of action exists.

Group agents are constituted in three distinct ways: through the shared and mutually adjusting aims and plans of several individual agents (as in a string quartet) [7]; through the establishment of one representative to act on behalf of one or more individual agents (for example, a labor union) [8]; and through procedures that gather judgments and distribute tasks in such a way that the three capacities of considering, choosing in response to considerations, and acting in response to choice are competently executed (think of a corporation) [9].

These three routes explain how a group agent might be constituted but not how a particular person is conscripted as a member of that group and so why that particular person is legitimately governed by it. I say “conscripted” to not prejudice whether the only way to count as a member is through consent. Consent indeed is one way, but there are two others. One also can be conscripted as a member of a group agent by way of fair play: if others have joined together to create mutual advantages, and you voluntarily seek out these advantages when you could have costlessly refused them, your voluntary action enlists you as a member, even though you have not consented to be a member [10]. For example, if your neighbors have joined together to dig and maintain a new well, if you voluntarily draw water from the well, you ought to do your fair share of maintenance. A third way to be conscripted as a member of a group agent is by practical necessity: insofar as you are governed by reason, if you will an end, you must will the necessary means to that end [11]. If membership in a group agent is a necessary means to an end, and, knowing that, you still will the end, then your commitment to instrumental rationality conscripts you into this necessary membership. If shipwreck survivors in a lifeboat must cooperate to survive, and your intention is to survive, then, if you are rational, your intention is to cooperate.

Do Physicians Have Legitimate Authority over Each Other?

Is the medical profession a group agent that legitimately governs the physicians that constitute it? If it were, then the profession would have normative powers whose exercise would change the normative situation of its member physicians. The directives of the profession would give physicians content-independent reasons either to comply or to accept the liability of noncompliance, and this would be so even when individual physicians disagree with the clinical or moral guidance of the profession. So the stakes are high. Fortunately for dissenting physicians, the “medical profession” as such does not constitute a group agent, for it does not have the three capacities of considering, choosing, and acting. “The profession” is not capable of action. Unfortunately for dissenting physicians, various and overlapping organized subsets of the medical profession might very well constitute group agents: practice groups, hospitals, medical schools, specialty boards, and associations. These are collectivities that are capable, through some mixture of shared aims, representation, and procedures, of achieving the unity of will necessary for group agency, for they typically have formal and informal mechanisms of [deliberation](#), decision, and execution. If I am right about how individuals

are conscripted as members of group agents, physicians do not necessarily have to consent and accept medical associations and organizations as legitimate authorities that govern them for these group agents to be legitimate authorities that govern them. Only about a quarter of physicians in the United States are dues-paying members of the American Medical Association [12], but it does not follow that the opinions of the AMA Council on Ethical and Judicial Affairs govern only dues-paying members. It may be sufficient that physicians voluntarily accept the benefits of the organizations of the practice of medicine or that the professional ends to which they are committed would be impossible to attain without these organizations.

Consider an example of conscription by free play. Suppose that physicians in a rural hospital serving an inadequately insured population cooperate to provide medical care for the community. They charge high fees to those with good insurance and provide free care to those who cannot afford to pay. The medical director of the hospital sees to it that free-care patients are evenly distributed among the house staff and the attending physicians. A new specialist joins the hospital in order to benefit from the prevailing high fees but refuses to provide free care, claiming, correctly, that he never agreed to do so. Still, we might conclude that he is governed by the cooperative venture that fairly spreads the burden of providing free care, even though he didn't voluntarily join the venture.

Next, consider an example of conscription by practical necessity. Suppose a transplant surgeon is committed to the effective allocation of scarce organs, that the only way to achieve the effective allocation of scarce organs is if all transplant surgeons participate in one nationwide matching program, that a matching program works only if it is supervised by a governing board, and that an adequate but not perfect matching program supervised by a governing board is in place. Then a rational surgeon is committed to be governed by the matching program's board, even though she could have devised a more effective matching program.

If—and it is a big if—the decision-making mechanisms of these group agents combine the reasons for action of its members in ways that preserve their freedom as self-governing agents, then these members have no justified complaint when their individual views or preferences do not prevail. Recall, however, that on the power-liability view, to be governed by a legitimate authority does not necessarily entail that one has a moral duty to obey. It might be that dissenting physicians merely are morally liable, and so cannot justifiably complain, when the rules of these professional organizations are enforced to their detriment.

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