AMA Journal of Ethics®

February 2017, Volume 19, Number 2: 183-191

POLICY FORUM

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

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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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ISSN 2376-6980