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Are clinical practice guidelines impartial?

Joshua Cohen
Erasmus University
Tufts University

In *A Theory of Justice*, John Rawls demands from citizens who decide upon principles of justice and the rules derived from such principles that they abstract from all particularities that constitute their identity as unique individuals. This demand is unrealistic in policy settings where actual policy-makers convene to provide guidance, establish rules regarding public good, and enact legislation. In practice, I argue, policy-makers, legislators, and others involved in developing social rules that pertain to distributive justice formulate such rules as reasonably partial spectators. To illustrate, I show how clinical practice guidelines are established and mediated by a reasonably partial expert panel whose partial action is publicly justifiable, yet whose claims to impartiality are not.

Keywords: Clinical practice guideline, Rationing, Distributive justice, Public justification

In the popular press, we get our daily reminders about the exponential rise in the cost of health care (15). Measures aimed at explicitly rationing health-care resources, using budget ceilings and/or cuts, capitation, and reimbursement denials, have met with considerable opposition (9;22;24). Increasingly, policy-makers have opted for implicit forms of rationing health-care resources, including market-oriented mechanisms such as higher deductibles and multi-tier co-payments for prescription drugs, as well as clinically oriented mechanisms such as the increased use of nurse care practitioners and the creation of clinical practice guidelines (23).

Although guidelines published by medical specialty associations are a relatively recent phenomenon, guidelines have been around since the establishment of professional medical education. What is new, and to some ethically problematic, is that issues other than quality of care have concurrently become driving forces motivating guideline development (17). One issue, rising cost, has directly contributed to changes in health-care policy; particularly with respect to systems of insurance, which in turn have promoted guideline development.

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WHAT ARE CLINICAL PRACTICE GUIDELINES?

Clinical practice guidelines are "systematically defined statements to assist practitioner and patient decisions about appropriate health care for specific (usually disease-specific) clinical circumstances" (13). Multidisciplinary expert panels composed of clinicians, other health-care practitioners, and a variety of stakeholders produce clinical practice guidelines that furnish clinical and organizational advice in the form of prevention, diagnosis, treatment, and palliation algorithms. Persons acting on behalf of patient, physician, caregiver, health insurer, and on occasion pharmaceutical industry representatives, may register as stakeholders to audit and provide input during the guideline development phase. Typically, the main criteria used when prioritizing guideline topics are prevalence of disease, practice variation, emergence of new technologies, and existence of evidence demonstrating potential to improve health outcomes and/or lower costs (14;19). Besides enabling informed decision making, another purpose of guidelines is to improve allocation of health-care resources. In so doing, guideline developers acknowledge a physician's primary responsibility to her own patient, while pointing out the need under certain circumstances to balance this duty against the needs of society.

Clinical practice guidelines have been developed nationally and internationally by a wide variety of (quasi)-governmental agencies, among which are the World Health Organization (5), the British National Institute for Clinical Excellence (18), the American Agency for Healthcare Research and Quality (25), and the Dutch Institute for Quality Healthcare (6). In addition, guidelines have been written and disseminated by private entities, such as disease managers and other managed-care organizations in the United States, as well as medical specialty organizations in both Europe and North America.

The guideline development process differs across settings. Nonetheless, we can shed some light on the general development process by presenting the contours of the evolution of a typical guideline. Guideline developers and stakeholders convene regularly in a series of town hall-style meetings in which a guideline advisory committee serves as executive body. The committee advises and assists in the guideline work program. Its members provide external validation by overseeing the development process and monitoring quality. An expert panel is formed for each guideline. The panel is composed of a chair, vice-chair, designated committee members who are specialists in the clinical area covered by the guideline, person(s) with patient/caregiver expertise, and sometimes an economic adviser. The committee either appoints or elects the guideline chair- and vice chairperson who play the role of moderator of the plenary sessions as well as working group meetings, umpire, manager, person who delegates tasks and responsibilities, and issuer of final approval to the guideline document in consultation with the expert panel. During this phase, (public) meetings are held to discuss and (re)-write drafts based on a professional consensus of what constitutes the best available evidence. Subsequently, the guideline advisory committee validates the evidence and positions taken, leading to revision and final approval by the chairperson in consultation with the expert panel. After dissemination and clinical implementation, guidelines are reviewed and updated when necessary.

Guidelines advise health-care practitioners on how to identify and stratify at-risk patients, as well as the care and maintenance of high-risk patients. For example, a guideline on high blood pressure describes the condition and indicates which patients are at risk to develop the disease. Subsequently, it suggests what to do when a patient presents with acute hypertension, and how to follow-up and control that patient's hypertension, according to evidence-based best practices.

A few zealous guideline advocates would like to introduce financial incentives as a stimulus to guideline compliance, akin to copay arrangements and capitation that are now part and parcel of managed care. In the United States, courts in the early 1990s began to ask physicians to justify individual medical decisions against guidelines (1). More often than not, however, guidelines are construed of as social rules that are not (yet) legally enforceable.

VALUE JUDGMENTS UNDERLYING GUIDELINE DEVELOPMENT

Guideline advocates assert that guidelines are impartial, and that they, therefore, introduce objective standards in a profession fraught with unwarranted practice and outcome variation (3). In a narrowly rational, disinterested world, clinical practice guidelines would be developed on the basis of uncontroversial supporting evidence and applicability to clinical practice. The goal would be to maximize some well-defined objective subject to resource constraints and calculation of opportunity costs. But, a narrowly rational, disinterested world does not surround clinical guideline development. We can presume that guideline developers are rational decision-makers but not with the axiomatic precision demanded by rational choice theory. Guideline decisions are made on grounds not merely related to reason and logic but also involve perspectives (16). Perspectives introduce partiality at the bricks and mortar level of guideline development. For example, cardiologist guideline developers are apt to be partial to the diseases they deal with on a day-to-day basis (coronary artery disease, hypertension, myocardial infarction). As they devise their guidelines, they cannot be expected to take into account the resource needs of unrelated conditions such as asthma, allergies, and gastrointestinal disease. Similarly, heart patient advocates participating in devising a heart disease guideline will be partial to their constituents.

Clinical experts may not agree on which course of action to take. This finding happens because each expert examines the evidence from her own perspective, drawing from her own experiences, and attitude shaped in part by the social organization to which she belongs (7). Differences in perspective, background, and interests lead to differences in interpretation, as the following comments by the Director of the U.S. Food and Drug Administration's Center for Drug Evaluation illustrate: "[Drug] safety is always a relative concept . . . [i]t is a very personal issue . . . [similarly] effectiveness . . . is a very personal issue. Individuals—consumers, patients, and clinicians—vary in their responses and preferences with respect to safety" (10).

Thresholds of effectiveness, cost, and even appropriateness of clinical activity are ultimately value determinations. The recently updated JNC (Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure) and ESC (European Society of Hypertension) guidelines on hypertension provide an example of this (4). JNC guidelines contain a new classification of hypertension—"prehypertension"—that covers the range of blood pressure between 120 and 139 mm Hg systolic and between 80 and 89 mm Hg diastolic. Both sets of guidelines have been prepared based on virtually the same clinical evidence from large, randomized, controlled clinical trials and meta-analyses. Examining the data, European experts have emphatically opposed and refused to adopt the

prehypertension classification in their guidelines. The Chairman of the Organizing Committee for the 13th European Meeting on Hypertension, Professor Mancia, disapproved of the term prehypertensive. Would we, he declared, call a healthy subject "pre-diseased?" He went on to state that such classifications suggest that patients told by physicians they are prehypertensive would want to do something about it, thinking something is wrong when this is not medically indicated.

REASONABLY PARTIAL SPECTATOR

The focus of this paper is distribution—the "who should get what" function of guidelines—and its corollary, distributive justice, which suggests a fair, equitable distribution of scarce resources. Tensions emerge between bioethical principles concerned with the individual patient-physician relationship—beneficence and autonomy—and principles of distributive justice that entail withholding beneficial health-care services at the margin (28). When principles targeting the individual and society conflict, some form of reconciliation is desired. Might clinical practice guidelines provide such reconciliation? Suppose a guideline suggests that treating a frail 85-year-old patient with high blood pressure with a relatively expensive medication is comparatively cost-inefficient. What to do? Give in to the patient's demand for the expensive medication? Or attempt to dissuade the patient from taking the expensive drug while suggesting more cost-effective alternatives? The answer is not as easy as it may seem at first glance. Physicians value their clinical freedom to prescribe whatever they see fit. Likewise, patients are prone to want the latest in medicine no matter what the cost, in part because they are usually not the ones paying for it. By elucidating the evidence and rationale for guideline recommendations to both patient and physician, and by articulating the desirability of allocating scarce resources cost-effectively, guidelines may serve to improve the connection between the physician's clinical judgment and the patient's best interests.

There is a practical need to communicate guideline information effectively among patients and health-care practitioners. For convenience sake, we will assume that this hurdle can be overcome. An important hurdle that precedes deployment of clinical practice guidelines is how to establish guidelines that are considered fair by all parties involved: clinical specialists, general practitioners, nurses, patients, private and public insurers, public health departments, and the industries that procure health-care products and services. For this purpose, guidelines embed a reasonably partial spectator to align individual and societal interests—reasonably partial spectator—a common-ground perspective held by a person or group of persons from which claims on and appropriation of health-care resources can be adjudicated.

A Rawlsian social contract drawn up by impartial citizens behind a veil of ignorance supposedly removes biases of self-interest and partiality (20;21;26). However, the exercise that Rawls suggests citizens perform seems too rational and even oblivious to the roles that perspectives and emotion play when legislators, policy-makers, and others formulate social rules that pertain to distributive justice. Missing in the detachment of Rawlsian impartiality is attachment—"that which we care about most and which is closest to us. Moral decisions often require sensitivity to the situation, an awareness of beliefs, attitudes, and concerns" (27). If we leave perspectives and emotions out of the equation, we ignore that which may inform our very notions of fairness and justice. Guidelines, for example, are designed and developed by a motley assortment of clinical specialists, general practitioners, nurses and other caregivers, insurers, public health officials, and patient group representatives, each bringing their own beliefs, attitudes, and concerns to the table. Furthermore, guideline developers, auditors, and other stakeholders participating in the guideline process are not symmetrically situated. That is, a pecking order exists that sets the agenda and ultimately determines the direction the guideline is going. This social hierarchy is based on seniority, clinical clout, and professional and personal respect. The degree of respect granted to a designated committee member's interpretation of the evidence depends partly on that member's standing among peers and relative to nonspecialists. Personal characteristics such as rhetorical ability and even affability may be involved as well.

Contrary to Rawls, Adam Smith did not believe that ethical decisions can be made behind a veil of ignorance (11;12). Smith's account suggests there is a "moral" conversation between drafters of social rules concerned with distributive justice based on concrete examples that the drafters themselves have experienced. Therefore, ethical decisions are grounded to an extent on perspectives and passions. Nevertheless, ethical decision-making does not degenerate into a tug-of-war of perspectives and emotions because of the mediating role Smith assigned "impartial spectators."

Guideline chairpersons mediate in the guise of impartial spectator, as moderator of plenary sessions, as umpire settling disputes, and as setter of rules of the game of guidelines development. I say guise because they would like to be seen as impartial. However, their judgment is not impartial, it is reasonably partial. Guideline chairpersons and expert panels are partial to society's social norms, its moral presuppositions, which they in turn help to (re)shape, and are also partial to the interests of their constituents, to the disease under consideration, and to prevailing scientific norms (8). For example, guidelines invariably incorporate risk-based criteria to select patients for treatment. This finding is a reflection of utilitarian thinking—a scarce technology ought to be allocated to patients for whom it will achieve the greatest health benefit. Certain guidelines incorporate need-based criteria to select patients. Both normative perspectives, utilitarian- and need-based, can be subsumed under one guideline (2). A guideline could recommend using a

risk-based criterion to prioritize patient selection, provided every patient has equal access to a certain minimum floor of health-care resources below which they would cease to lead normal functioning lives (8). For example, in the case of the frail 85-year-old for whom an expensive angiotensin receptor blocker is cost-inefficient, policy-makers would ensure that resources in the form of less-expensive medications—diuretics, alpha- and beta-blockers—are available to him to treat the hypertension. This suggests that prioritization and, hence, expenditure of public money on the expensive medication ceases at the point at which the opportunity loss of giving the expensive medication to those for whom it is most beneficial is insufficient resources left over for the frail 85-year-old.

Guideline chairpersons are unique policy-makers. They are involved in both policy-setting and ensuing implementation, which accentuates their partiality. The spectator-agent distinction is ambiguous, as guideline chairs are literally engaged in practicing what they preach. They act from an agent-relative position and cannot derive their decisions from a standpoint of agent-neutrality. The moral problem for the guideline chairperson is that, if she sympathizes or empathizes too closely with a particular agent, a physician, a patient, a nurse, an insurer, a government official, she ceases to be a fair spectator of ethical behavior and may reach unreasonably biased moral judgments. Guideline chairpersons could attempt to eradicate unreasonable biases owing to excessive sympathy or empathy, undue influence from special interests, conflicts of interest, lobbying influences, and suppression of minority dissent. For example, guideline chairpersons could enjoin conflict of interest disclosure upon panel members. Additionally, stricter standards of rigor could be imposed on allowable scientific evidence. As rigor increases, subjectivity is likely to decrease as the weight of evidence shifts from anecdotal experiences, to expert opinion, to case reports, and finally outcomes-based clinical studies. Also, guideline chairs could contemplate imposing limitations on lobbying by the pharmaceutical industry. Finally, program directors responsible for commissioning guideline projects could mandate the inclusion of a dissenting opinion addendum in final drafts of guidelines.

HOW TO PUBLICLY JUSTIFY REASONABLY PARTIAL GUIDELINES

Although not (yet) legally enforceable, guidelines may be perceived of as impositions by those to whom they apply. This is not to say that guidelines are necessarily an unwelcome imposition. Health-care practitioners may appreciate the standardization that guidelines afford them. Nevertheless, guidelines can add an administrative burden. As such, guidelines need to be seen as reasonable and, hence, justified by clinicians and nurses who implement them, patients whom they directly affect, and the public at large. Moreover, those that remain skeptical vis-à-vis clinical practice guidelines should have adequate recourse to deviate from the prescribed guideline directives, especially because guidelines generally apply to a statistically average patient and not to individual patients. In this respect, guidelines that retain flexibility will likely garner more public support from skeptics than inflexible protocols.

A guideline advisory committee represents a democratic platform for members to justify to one another their judgments and also their reasonable biases. It is the guideline chairperson's responsibility to recognize the independent validity of member claims, especially with respect to clarifying the "who should get what" function of a guideline; that is, which patients to select for diagnosis and treatment and which resources to use to diagnose and treat. In addition, accountability to and input from the public must be ensured.

In the context of the ensuing debate, biases cannot be eliminated but rather should be examined openly and pruned of unreasonableness. During the debate committee members may weed out unreasonable biases underlying lines of argument, scientific evidence, and members' intentions. In cases of dispute, the advisory committee entrusts the larger shears to the guideline chair.

The test of whether guidelines are publicly justified lies in their clinical application. Once guidelines are published and disseminated, do health-care practitioners and patients willingly abide by what the guidelines recommend, do they begrudgingly acquiesce, or do they defy? In the event of defiance, do they offer a constructive alternative, perhaps based on a different normative perspective, or new clinical trial data? For example, results from the recently published Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) study have led to substantial changes in hypertension guidelines. The ALLHAT data indicate that, for some patients suffering from hypertension, cheaper diuretics and beta-blockers are as effective as more expensive angiotensin-converting enzyme inhibitors and angiotensin receptor blockers. Subsequent to the ALLHAT revelations, guidelines on both sides of the Atlantic were altered. However, changes were by no means uniform. As alluded to earlier, the chairman of the ESC guideline committee saw no reason to revise classifications of hypertension. Moreover, although affirming that diuretics and beta-blockers appear to be relatively cost-effective, the ESC guideline chairman reiterated his position that cost has to be a "secondary consideration" when deciding on treatment options for patients. In stark contrast, the JNC guidelines appear to give equal weight to cost and effectiveness in their latest recommendations. They also grant less leeway to health-care practitioners in addition to offering rigid classifications of (pre)hypertension (4). Ultimately, guideline revisions are driven both by (new) evidence and (changing) normative perspectives. The latter reflect not only philosophical positions with respect to cost-effectiveness analysis, but also

scientific and cultural viewpoints. In the case of hypertension, differences in perspective on disease itself led to different protocols.

POLICY IMPLICATIONS

Clinical practice guidelines set limits on resource use, for instance, age cutoffs for kidney dialysis treatment in the United Kingdom, and statin reimbursement in the Netherlands. For guidelines to attain legitimacy and, hence, command the respect of clinicians and patients, they should convey appropriate reasons for recommendations being put forward. Clinicians will not modify their current practices unless compelled by good reasons based on good evidence. Likewise, patients may be reluctant to comply with guidelines without being given proper rationale for doing so. As described above, guideline development involves norms, both scientific and moral. Particularly in light of this partiality, achieving broad acceptability of guidelines is more likely if the development process is transparent and publicly accountable. That is, a process that all stakeholders can navigate and in which all stakeholders are appropriately represented. The British National Institute for Clinical Excellence has taken the lead in promoting a publicly accountable guideline development process, subjecting development of clinical guidelines under its auspices to a rigorous procedural protocol. This action is commendable and should be followed by other guideline authorities.

CONCLUSIONS

I have tried to demonstrate how clinical practice guidelines are established mediated by a reasonably partial expert panel whose partial action is publicly justifiable, yet whose claims to impartiality are not. Guidelines inevitably convey value judgments. The aim of this study is not to discredit socially and culturally contingent value determinations. Nor is it to condone relativism or an "anything goes" posture. My purpose has been to examine the underlying premises, beliefs, moral presuppositions, and reasonable biases on which guidelines are constructed. The test of whether reasonably partial guidelines are publicly justified lies in their broad acceptability in clinical practice in the absence of a defeating constructive alternative. Particularly in light of this partiality, achieving broad acceptability of guidelines is more likely if the development process is transparent and publicly accountable.

REFERENCES

1. Anderson G, Hall M, Steinberg E. Medical technology assessment and practice guidelines: Their day in court. *Am J Public Health*. 1993;83:1635-1640.
2. Berg M, ter Meulen R, Van den Burg M. Guidelines for appropriate care: The importance of empirical normative analysis. *Health Care Analysis*. 2001;1:1-23.
3. Berger J, Rosner F. The ethics of practice guidelines. *Arch Intern Med*. 1996;156:2051-2057.
4. Brookes L. Medscape conference coverage, based on selected sessions at the 13th European Meeting on Hypertension. ALLHAT—Results and Reactions—Plus New Guidelines, New Approvals, and the Ethics of Journal Publishing. Medscape Cardiology. Available at: http://www.medscape.com/viewarticle/447590.
5. Brookes L. More new hypertension guidelines—but is anybody listening? Medscape Cardiology). Available at: http://www.medscape.com/viewarticle/458407.
6. CBO. Richtlijnontwikkeling binnen het Kwaliteitsinstituut voor de Gezondheidszorg CBO: handleiding voor werkgroepleden, 2003. Available at: http://www.cbo.nl.
7. Cohen J. Switching omeprazole in Sweden and the United States. *Am J Ther*. 2003;10:370-376.
8. Daniels N. *Just health care*. Cambridge UK: Cambridge University Press; 1985.
9. Daniels N, Light D, Caplan D. *Benchmarks of healthcare reform*. Cambridge UK: Cambridge University Press; 1996.
10. Food and Drug Administration Dockets Management Branch. Over-the-counter (OTC) drug products: requests for comments. *Fed Regist*. 2000;65:24704.
11. Griswold A. *Adam Smith and the virtues of the enlightenment*. New York: Cambridge University Press; 1999.
12. Harpham E. Enlightenment, impartial spectators, and Griswold's Smith. *Perspect Polit Sci*. 2001;30:139-146.
13. Institute of Medicine. In: Field M, Lohr K, eds. *Guidelines for clinical practice: From development to use*. Washington DC: National Academy Press; 1992:21.
14. Institute of Medicine. In: Field M, ed. *Setting priorities for clinical practice guidelines*. Washington DC: National Academy Press; 1995:2.
15. Kleinke J. Just what the HMO ordered: The paradox of increasing drug costs. *Health Affairs*. 2000;19:78-91.
16. Lewis S. Paradox, process and perception: the role of organizations in clinical practice guidelines development. *Can Med Assoc*. 1995;153:1073-1077.
17. Loewy E. Guidelines, managed care, and ethics. *Arch Intern Med*. 1996;156:2038-2041.
18. National Institute for Clinical Excellence. *Guideline development process: Stakeholder participation*, 2003. Available at: http://www.nice.ac.uk.
19. Niessen G, Grijseels E, Rutten F. The evidence-based approach in health policy and health care delivery. *Soc Sci Med*. 2000;6:859-869.
20. Rawls J. *A theory of justice*. Cambridge, MA: Harvard University Press; 1971.
21. Rawls J. In: Kelly E, ed. *Restatement of a theory of justice*. Cambridge, MA: Harvard University Press; 2002.
22. Reinhardt UE. Wanted: A clearly articulated social ethic for American health care. *JAMA*. 1997;278:1446-1447.
23. Ter Meulen R. Ethical issues of evidence based medicine, 2001. Available at: http://www.ccels.cardiff.ac.uk/launch/meulenpaper.html.

24. Ubel P, Goold S. Rationing health care: Not all definitions are created equal. In: Beauchamp T, Walters L, eds. *Contemporary Issues in bioethics*. Belmont, CA: Wadsworth; 2003.
25. U.S. Preventive Service Task Force. Behavioral counseling in primary care to promote physical activity: recommendations and rationale. *Ann Intern Med.* 2002;137:205-207.
26. Veatch R. Justice, the basic contract, and health care. In: Beauchamp T, Walters L, eds. *Contemporary Issues in bioethics*. Belmont, CA: Wadsworth; 2003.
27. Wax A. Something for nothing. *Emory Law J.* 2003;52:1-70.
28. Weinstein M. Should physicians be gatekeepers of medical resources? *J Med Ethics*. 2001;27:268-273.