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USING PRACTICE GUIDELINES TO ALLOCATE MEDICAL TECHNOLOGIES

An Ethics Framework

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Abstract

Clinical practice guidelines are expanding their scope of authority from clinical decision making to collective policy making, and promise to gain ground as resource allocation tools in coming years. A close examination of how guidelines approach patient selection criteria offers insight into their ethical implications when used as resource allocation or rationing instruments. The purposes of this paper are: a) to examine the structure of allocative reasoning found in clinical guidelines; b) to identify the ethical principles implied and compare how guidelines enact these principles with how explicit systems-level rationing exercises and health policy analyses have approached them; and c) to offer some preliminary suggestions for how these ethical issues might be addressed in the process of guideline development. The resulting framework can be used by guideline developers and users to understand and address some of the ethical issues raised by guidelines for the use of scarce technologies.

Keywords: Practice guidelines, Healthcare rationing, Patient selection, Social justice

Over recent decades, clinical practice guidelines have expanded their scope of authority from clinical decision making to collective policy making, and promise to gain ground as

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resource allocation tools in coming years. Guidelines originally emerged as "clinical policy" documents, designed by expert clinicians for their peers to apply to individual cases. The U.S. Institute of Medicine defined clinical practice guidelines accordingly as ". . . systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (57, 27). However, guidelines now also serve broader health services decision making outside the practitioner-patient encounter. Increasingly, institutional and corporate bodies author guidelines with management objectives in mind, and administrators promote practice guidelines to reduce unnecessary practice variations and to improve patient outcomes (36;56;70). Most recently, public policy makers have turned to guidelines as tools for allocating expensive or scarce technologies efficiently and for controlling health spending. In the United States, the federal government and private insurers have begun to use practice guidelines to help define appropriate services for coverage and provision (89). The U.S. federal government now sponsors a central clearinghouse for guidelines dissemination, in partnership with the American Medical Association and the American Association of Health Plans, which represents private insurers (78). Several Canadian provinces have begun to promote selected guidelines under joint initiatives between provincial ministries of health and medical associations (2;73). In New Zealand, health system reformers recently decided to implement practice guidelines to control health spending, in lieu of deinsuring services (15;28). New Zealand dialysis guidelines' recommended 75-year age limit has caused considerable public confusion and controversy about the fairness of the guideline in individual cases (38).

When promoted in policy contexts outside of the clinic to control utilization or spending, "practice guidelines" transform into "practice policies" (10) or "allocation guidelines" (6), with new ethical valence. Because guidelines are statements about what *should* be done, they necessarily—and unavoidably—convey values. Because of guidelines' tacit values, ethicists exhort healthcare analysts to pay closer attention to the nontechnical aspects of practice guideline formulation, particularly "the underlying premises on which they are constructed" (17).

Guidelines typically address one of two questions: a) for a given patient or condition, which technological options are most appropriate?; or b) for a given technology, which patients are most appropriate? The latter formulation most overtly "rations" scarce services, and this genre of guidelines is the topic of our analysis. We examine here how guidelines approach patient selection criteria for specific technologies. Patient selection criteria offer particular insight into guidelines' ethical impacts when used as rationing instruments.

The purposes of this paper are: a) to examine the structure of allocative reasoning found in clinical guidelines; b) to identify the ethical principles implied, and to compare how guidelines enact these principles with how explicit systems-level rationing exercises and health policy analyses have approached them; and c) to offer some preliminary suggestions for how these ethical issues might be addressed in the process of guideline development. We focus on psychosocial exclusion criteria because of their controversial meaning and validity, and will use content from recently published organ transplantation guidelines to illustrate key points. The resulting ethics framework can be used by guideline developers as well as guideline users to understand and address some of the ethical issues raised by guidelines for the use of scarce technologies.

FRAMING PATIENT SELECTION CRITERIA

Patient selection criteria are commonly found in guidelines designed to promote the appropriate use of specific interventions. Patient selection criteria typically include biomedical criteria that indicate need (e.g., the degree of end-organ failure) or influence patient outcomes (e.g., comorbidities). Selection criteria also sometimes include psychosocial indicators,

which may include, for example, behavioral or psychological issues, relationships with others, financial resources, social roles, or the candidates' living circumstances (42). Patient selection criteria may also include "ambiguous" indicators with both biomedical and psychosocial content, including characteristics such as age or body size. The following excerpts from heart, heart-lung, and liver transplantation guidelines, respectively, illustrate some psychosocial patient selection criteria:

> Heart transplantation continues to be an expensive procedure. The transplant candidate's family must have the means to cover expenses related to the pretransplant evaluation and waiting period, transplant procedure and hospitalization, and long-term care, including medications. (77, 47)

> . . . among the more severe contraindications for HLT [heart-lung transplantation] were . . . a recent history of intravenous drug abuse . . . Down's syndrome, active smoking . . . history of noncompliance with medical regimens . . . and age over 60. (46, 75)

> *Relative contraindications* [for liver transplantation]. Age is not a contraindication. In the elderly patient, the indications should take into account overall clinical condition rather than chronological age, together with the likely benefits in terms of the duration and quality of survival. . . . The patient's mental health and environment are important factors in predicting compliance with treatment, which is essential for long-term success. (23, 63S)

Clinicians are thus directed to assess factors such as family means, intravenous drug abuse, Down syndrome, active smoking, history of noncompliance, mental health, and patient's environment when selecting transplant recipients. Psychosocial criteria often appear in transplant programs' protocols, where they have controversial ethical and clinical validity and tend to be applied inconsistently (4;64;75;81;83). Psychosocial criteria also appear in guidelines for cardiac interventions (41;42). Such selection criteria are both medically and socially controversial. When applied broadly across the health system, they have the potential to affect both the quality and the equitable distribution of health care.

A content analysis of psychosocial patient selection criteria for cardiac and transplant procedures (41;42) suggests that indications and contraindications tend to be based on one of several underlying justifications. These may be grouped as either "risk-based" arguments or "need-based" arguments (Table 1). The ethical distinction between risk-based rationales and need-based rationales emerges most clearly in their differing views of tractable contraindications. Contraindications can be presented either as intrinsic and immutable qualities of the candidate or as negotiable barriers to the candidate's access. In essence, when a contraindication is interpreted as a risk, the message is: "Not a good candidate because outcomes will not be good (or not good enough)—therefore, no procedure." When a contraindication is instead characterized as a need, the message is: "Not a good candidate—what needs to be done to make this person a better candidate?" Within these two broad categories sometimes arise further ethical issues, including whether the candidate is personally at fault for the disqualifying contraindication and whether this fault should influence access, as well as whether others might have an interest in the candidate's receiving the procedure.

These ethical rationales are sometimes stated explicitly in practice guidelines, but are more often implied. They generally apply to both biomedical and psychosocial patient selection criteria. The various rationales invoke a variety of principles that can guide health resource allocation. Many of these principles are now routinely discussed in other policy-making contexts, especially in determining service coverage policies at the national, provincial, or health plan level (15;31;33;45;49;50;92;96), but are generally not dealt with explicitly in the context of guideline development.

Table 1. Summary of Rationales for Patient Selection Criteria in Clinical Practice Guidelines, and Ethical Principles Implied

Selection criterion and rationale	Implied principles
A. Risk-based rationale:	Utilitarianism
A contraindication because of a probability of less-than-optimal benefit from the intervention	If candidates are characterized as typically actively responsible for the problem: Personal responsibility, Individualism If candidates are characterized as not personally responsible for the problem: Fatalism
B. Risk-based rationale: An absolute contraindication because of a probability of net harm from the intervention	Nonmaleficence, Utilitarianism
C. Need-based rationale: A contraindication, but characterized as a need for adjunct intervention together with or prior to the primary intervention	Necessity, Solidarity
D. Need-based rationale: An indication, suggesting a need for the intervention, for the community's benefit (or a contraindication, suggesting denial of the intervention, to prevent community harm)	Necessity, Externality

Risk Factor Rationales

Patient selection criteria may be based on risk factors that affect expected outcomes of the intervention. For example, consider the following transplant guideline's recommendation:

> A comprehensive psychosocial evaluation is necessary to assess family (and an older child's) compliance to previous medical regimens and overall commitment to health care demands. Although it might be unusual to exclude a patient for transplantation on the basis of psychosocial criteria, a stable and supportive family environment is crucial to a successful outcome. (77, 46)

The selection criteria are justified on the grounds that they are necessary for a successful outcome. To understand the ethical implications, it is important to understand what is meant by a "successful outcome."

A guideline may contraindicate the procedure in a candidate with a given risk factor because, on average, this sort of candidate improves with the procedure, but not as substantially as would a candidate without the contraindication (see row A, Table 1). For example, people with coping skills and social support may recover better from major morbid events and invasive interventions than do people without them (11;18;53). Based on this information, guideline developers may consider it valid to characterize lack of social support as a relative contraindication for a major intervention such as transplantation or cardiac surgery. Typically, for the purpose of clinical decision making such factors are presented as relative, rather than absolute, contraindications. At the broader administrative level of decision making, these factors may be used to determine candidates' priority for access.

Risk factor rationales suggest that contraindications are intrinsic to candidates. In other words, the risk factor is a problem that is fundamentally the responsibility of the candidate, rather than of the candidate's community or provider. Presenting contraindications as risk factors for poor outcomes encourages providers to discriminate accordingly among candidates when deciding who will receive an intervention. Where resources are scarce, relatively

"at-risk" candidates may be denied access. Where interventions are more readily available, physicians may exercise discretion in offering the interventions, or may allow the candidates to make the choice themselves.

When interventions are denied on the basis of a risk factor that can lead to less-than-optimal (but still positive) outcomes, it is the population of procedure recipients as a group, and not the individual candidate him or herself, that is expected to derive health benefits. Providers, too, may benefit in terms of income, contracts, or reputation when this patient selection strategy leads to good provider outcome statistics. This type of contraindication is particularly ethically problematic in stringent "quality assurance" or "managed care" environments. Providers who are under pressure to demonstrate good outcomes in their treated patient populations face a clear disincentive to treat candidates with the contraindication, even though the candidates themselves would be better off with the intervention than without it (75).

When clinicians use such risk factors systematically to determine patients' priority for treatment, they enact the distributive principle of utilitarianism. Utilitarianism dictates that a scarce technology be allocated to candidates in whom it will achieve the greatest health benefit, to maximize the health of a population as a whole. This ethos of efficiency underlies the economic evaluation of medical technologies (94) as well as the call to consider cost-effectiveness information when developing practice guideline recommendations (58). Drummond summarizes the ethic: "Economic efficiency embodies an ethic of its own, i.e., resources should not be used in a given activity when they would generate more benefits if used elsewhere. Inefficient use of technology means that the community as a whole is worse off. Therefore, it could be argued that it is unethical not to consider costs" (35, 89). In practice, strict utilitarianism tends to be accepted under circumstances of extreme triage (e.g., battlefields), but less well accepted where resources are more plentiful or their supply is negotiable (e.g., most developed healthcare systems).

While the utilitarian ethic is broadly promoted by many system rationalizers interested in efficiency, it has been just as widely criticized as an unfair basis for both bedside decisions and system-wide rationing schemes. Strict utilitarian reasoning in health care is hampered by two drawbacks. The first is the analytic imperative to choose a single indicator of outcome (e.g., quality-adjusted life-years), when in fact many qualitatively diverse outcomes could arguably be valued (e.g., 75;79). The moral priority of different outcome measures, as well as the logical basis for combining them into unidimensional indices of utility, both remain controversial (e.g., 54). The second problem is utilitarianism's focus on the net well-being of a given population as a whole, to the neglect of the fairness of the distribution of burdens and benefits within the community (87;95). What is productively efficient for a population as a whole may require unacceptable sacrifices by particular individuals or particular subgroups within the population. "Contractarian" perspectives on social justice temper the utilitarian calculus by requiring that population outcomes be maximized only on condition of minimizing harm inflicted on members of the population (29;84). Translating this principle into practice raises formidable challenges (e.g., 44).

Personal Responsibility Issues

Different versions of the risk factor rationale can also enact principles in addition to utilitarianism, depending upon two alternative depictions of the genesis of the risk factor. In the first case, the individual is seen as actively responsible for her or his risk factor. The most typical contraindication that carries this implication is "noncompliance," portrayed as a willful act. Noncompliance is a common contraindication to complex procedures with strict follow-up regimens, such as transplantation. A poll of transplant physicians found that 88% believe that "unrepentant noncompliance" is a valid contraindication to transplantation,

notwithstanding the fact that 45% of the same group believe that using noncompliance as a contraindication will lead to discrimination against the poor and uneducated (83). This contraindication is applied by the majority of transplant centers (64) and has been formalized in some practice guidelines (41;42). One heart transplant guideline describes the issue:

> Inability or unwillingness to comply with long-term medical care precludes further consideration for transplantation. This aspect of the selection process may be subjective and may be the focal point of disagreement among physicians. Although an adequate psychological instrument to test compliance has not been universally accepted, compliance with a rigorous treatment regimen for congestive heart failure may be objective evidence of the patient's suitability for transplantation. (80, 1064)

Another common transplant contraindication, substance abuse, is portrayed as an individual choice by some guidelines, while as a disease by others. For example, one guideline author writes in a discussion of "relative contraindications" to liver transplants, "Patients who have damaged their livers with alcohol but who have genuinely stopped drinking are acceptable as candidates for liver transplantation in my institution" (14, 3S). A liver transplant guideline presents the implied ethical judgment explicitly (in the context of dismissing alcoholism as a contraindication):

> Whereas [other contraindicated diagnoses] are questioned because of their inferior survival rates, liver transplantation for alcohol-related liver disease was questioned mostly on ethical grounds. . . . The image of a drunken individual sleeping comatosely in an alley is the common picture that comes to mind when the public thinks about alcoholism. (63, 28S)

These cases share the image of the candidate disqualifying him or herself from access to the procedure. The implied principle of personal responsibility suggests that individuals are primarily answerable for their own well-being and at fault for many of their own health risks (e.g., 45). Underlying this view is the value of individualism, which stresses the virtues of independence, autonomy, and self-reliance (74;93). This principle does not necessarily empower individuals, however. In policy applications, an emphasis on personal responsibility for health status can deflect attention from environmental and social causes of morbidity and have the effect of "blaming the victim" (25;26;93). Active responsibility for one's health can also be characterized as a redeeming factor in overcoming contraindications, for example:

> [Relative contraindications:] . . . A well-motivated patient approaching 70, physically active and mentally alert, may be a better candidate for a liver transplant than an emaciated patient of 50. Consideration of age is therefore very much a relative matter. (16, 3S)

Alternatively, the candidate can be considered more passively responsible for her or his risk factor. For instance, although transplant providers widely consider a history of medical noncompliance a valid contraindication for transplantation, a poll of transplant physicians found that 82% would not refuse the retransplantation of an 8-year-old who had lost an earlier graft by noncompliant behavior (83). Only 20% of the physicians would not refuse for a 48-year-old patient, and only 9% for an alcoholic 38-year-old. Presumably these policy stances vary because the physicians consider children passively responsible for their behavioral risk factors, while they hold the adults (and alcoholics) actively responsible.

In contrast to the active responsibility view described above, here the risk factor is not necessarily the candidate's fault, and disqualification from the intervention is not a kind of natural retribution for her or his poor behavior or choices in the past. The procedure may be offered in conjunction with an intervention to remedy the risk factor itself (Table 1, row C). Alternatively, the risk factor could still be considered a contraindication for the

procedure, but disqualification from the procedure could be regarded less as self-inflicted than as the individual's unfortunate lot in life. The latter view evokes the principle of fatalism, defined as "a belief that all events are predetermined and therefore inevitable," or "a submissive attitude to events as being inevitable" (22, 426). Fatalism comes into play implicitly wherever clinicians refrain from intervention on the basis of futility, as well as when terms such as "the natural lottery" are employed to distinguish pathologies that are not self-inflicted (67;69).

When the risk factor is an absolute contraindication, the candidate's presumed responsibility (or not) for her or his condition does not affect the clinical action. However, where the factor is a relative contraindication, it may invite moral judgments that influence the provider's discretion to intervene. Traditionally, there has been more sympathy for persons portrayed as passively victimized by their risk factors than for persons portrayed as actively responsible for them. At the public level, the issue of personal responsibility and access to care most typically arises in the media, for example, when babies are portrayed as "innocent" victims of pathologies requiring "high-tech" treatment. As liver transplants have became more routinely available, there has been ongoing debate over the rights of alcoholics to access (e.g., 43;68;76;94), notwithstanding evidence that alcoholics have outcomes comparable to nonalcoholics (e.g., 34;90).

Finally, there is the case in which the selection criterion indicates that the candidate is expected on average not to benefit, but instead to suffer net harm as a consequence of the procedure (Table 1, row B). Such risk factors absolutely contraindicate the procedure, and the individual and the population clearly both benefit from its denial. Such policy is utilitarian in effect, but is perhaps more fundamentally based on the bioethical principle of nonmaleficence. This imperative dictates that clinicians do no harm, either by subjecting patients to unreasonable risks or by inflicting actual damage (5). Hippocrates' oath emphasizes the primacy of this principle with the maxim "first, do no harm." The nonmaleficence rationale for withholding a procedure is generally well accepted, and as a distributive principle it provokes little debate at either public or clinical levels of health policy making.

Need Rationales

Rationales for patient selection criteria may be based on the idea of need. Need underlies procedure indications intended to identify candidates likely to benefit. This conventional patient selection criterion raises little ethical controversy, except where degree of benefit becomes an issue (as depicted in Table 1, row A, and discussed above). *Necessity* refers to the imperative of providing what is needed. This principle is fundamental to most health systems, typically formalized in the mandate to fund and provide "medically necessary services." However, the concept of medical necessity can be problematic (7;21;54), as can the more essential concept of need (e.g., 66;85).

Risk indicators are interpreted not as contraindications, but rather as need indicators for adjunct interventions or other types of support to help the candidate qualify for the procedure in question. Adjunct support then becomes part of the total treatment regimen. Such an attitude toward contraindications is often found in the case of biomedical criteria for conditions that are amenable to medical intervention (for example, the directive to treat hypertension before kidney transplantation, to prevent damaging the graft). Some guidelines also discuss psychosocial risk factors for transplants as indicators of need:

> The main purpose of this evaluation [of the potential kidney transplant recipient] is to uncover any pre-existing medical or psychosocial conditions that could lead to increased post-transplant morbidity or mortality. In general, any condition identified should be corrected prior to transplant surgery and the introduction of immunosuppressive therapy. (39, 269)

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Cognitive impairment should not be used as a justification for denying transplantation unless it is of sufficient magnitude to impede consent or compliance and until potentially reversible causes, e.g., toxic or metabolic abnormalities, have been eliminated. In some cases mild, irreversible cognitive impairment may be removed as a barrier to transplantation by appropriately altering the patient's environment, e.g., by involving family, caregivers, or significant others. (60, 19)

Individual candidates potentially benefit more from a need-based than from a solely risk-based understanding of their contraindications. They stand to gain from intervention into comorbidities or other problems, as well as from the intervention that they seek. A need-based view of an individual candidate's contraindications may have utilitarian value (that is, benefit a population as a whole), but this benefit is not intrinsic to the rationale. Rather, the aim of "helping" individuals rather than "sorting" most promising candidates shifts the underlying distributive principle from utilitarianism to solidarity. *Solidarity* refers to the belief that members of a community are inexorably dependent upon, and therefore responsible for, each other's well-being. This principle underlies universal health insurance systems that require the healthy to subsidize the care of the sick (91). Many moral debates in contemporary health care reform revolve around defining the extent of—and limits to—solidarity between those with resources and those with needs (45;86). Closely related to this principle is the traditional clinical-level value of compassion. At the extreme, the "rule of rescue" dictates tending to dramatically needy individuals, sometimes to the neglect of less identifiable individuals (i.e., those in need of prevention rather than cure) or of the population as a whole (50).

The value of solidarity raises the question of how populations or communities should be defined for the purpose of mutual support: who is obligated to meet who else's needs? At the public level, this debate is most graphic in the case of intergenerational equity in rationing schemes, which some consider fair but others consider unfairly discriminatory (13;30;61). At the clinical level, by contrast, guidelines often present age without controversy as a biomedical contraindication for a procedure. If principles of solidarity between old and young are applied here, age might simply be withdrawn as a selection criterion. An alternative approach may be to reject the age criterion in favor of criteria related to more specific biomedical problems associated with age, such as comorbidities or functional disabilities (of course, these in turn can be cast as either risk factors or indicators of need).

Dealing therapeutically with contraindications (rather than simply using them to exclude candidates) raises a number of challenges for guideline developers and users. First, to be treated as a clinical "need," a contraindication requires a clear label that ideally would also indicate a relevant remedy. For example, tobacco addiction might lend itself to smoking cessation interventions. In contrast, a vague label such as psychosocial instability, because it less clearly describes a problem, also less clearly indicates appropriate interventions. Second, relevant interventions may or may not be very effective (and indeed, may add their own layer of candidate eligibility criteria to the patient's quest for treatment). For example, while smoking cessation may be indicated, it may work only for some, may not work at all, or may impose unacceptable burdens on the candidate or others. Evaluation evidence is necessary to answer these questions well. Third, to inform the decision to pursue adjunct therapy in order to qualify for a given intervention such as a transplant, decision makers would require rigorous effectiveness evidence on the treatment package as a whole (i.e., the adjunct intervention plus the primary intervention). This information is unlikely to be available in many cases, preempting an "evidence basis" for clinical decision making. Finally, addressing psychosocial contraindications in particular involves coordinated care not only among different medical specialties but also among medical and social services. Capturing such interdisciplinary perspectives in practice guidelines requires diverse professional input during the guideline development process.

A final rationale for a patient selection criterion is the argument that not only the candidate but also the candidate's community will be affected if the procedure is provided (or is withheld). This rationale, by definition, is germane only to psychosocial patient selection criteria (i.e., the indication is defined in terms of the candidate's social context or relationships to others). In this case, other people may be portrayed as in "need" of the individual receiving the procedure. For instance, some cardiac guidelines suggest that occupations such as airline pilot are imperative indications for a cardiac procedure, out of consideration for public safety (42). Conversely, others may be harmed by the candidate receiving the procedure. For example, "[Selection of pediatric patients for heart transplantation:] . . . The purpose of the extensive evaluation process is to determine the child's suitability as a transplant candidate and the family's ability to withstand the lifelong demands involved with this therapy" (77, 44). In these cases, the procedure is seen as having a potential benefit or harm to others besides the candidate, and these effects determine the candidate's own access to the procedure. Externality is the operative principle behind such indications for intervention. This economic concept holds that individuals can want good for others out of their own self-interest, when another's well-being will clearly affect their own (27;40). Externality is similar to the solidarity rationale, in that it recognizes the interdependence of peoples' well-being (although, importantly, the concept of externality is rooted in the economic concept of concrete self-interest, while the concept of solidarity is rooted in a social justice ethic).

DEVELOPING GUIDELINES AS RATIONING POLICIES

Historically, guideline developers have approached their task as a clinical-level quality improvement exercise. Because of guidelines' increasingly systematic application, however, guideline development is gaining new meaning as a societal-level resource allocation exercise. In coming years, guidelines will offer both opportunity and responsibility for ethical leadership in health resource allocation. Guideline developers can take some lessons from policy makers elsewhere in the healthcare system who have been more explicitly applying principles of resource allocation over the past two decades.

The framework described above highlights a number of ethical tensions in patient selection for procedures. For example, utilitarian rationales (e.g., "maximize population health," "do not sacrifice the health of the community to the treatment of very needy and perhaps less treatable individuals") and individualistic rationales (e.g., "communities have less obligation to treat people who create their own health problems") can conflict with solidarity rationales (e.g., "help individuals in need, whatever the origin of their pathology or their chances for recovery"). These rationales in turn imply conflicting clinical actions: should high-risk candidates be denied the procedure, provided the procedure, or provided adjunct therapy (medical or social services) along with the procedure? These tensions reflect broader ethical tensions in resource allocation throughout the healthcare system. Clinical leaders, policy analysts, and ethicists grapple with defining the nature, extents, and limits of both utilitarian and solidarity goals in health care. No universal or easy solutions have yet emerged from this vigorous discourse. However, as with most ethical problems, deliberation and debate seem crucial for reaching solutions that communities, candidates, and clinicians can accept.

Traditionally, healthcare rationing analyses have emphasized the importance of choosing and systematically applying certain allocation principles such as equity and efficiency. However, it takes institutional, social, and political (as well as ethical) reckoning to reconcile conflicting principles into legitimate and practical policies. The same is true of guideline development: the ethical implications may be profound, the key values may be debatable, but workable policies must nevertheless be developed. Most recently, the public-level

resource allocation literature has begun to draw lessons from practical resource allocation exercises, and places new emphasis on improving processes used to apply principles and ultimately to generate allocation decisions. A similar shift of focus in the guidelines development literature will help address guidelines' new ethical implications in their new economic, organizational, and practice contexts.

We turn now to a final set of principles for guideline development: principles that can guide the choice and application of the rationales described in the framework above. These "process principles" include critical analysis, transparency, and participation.

Critical Analysis

The guideline literature has produced contradictory recommendations regarding the appropriateness of some patient selection criteria, as illustrated, for example, by the following two transplant guidelines' approach to candidates' financial qualifications:

> In assessing a patient's candidacy, financial resources must be evaluated. Most third-party carriers and government programs will pay for cardiac transplantation for eligible patients. Nevertheless, the cost of medical care and the patient's subsequent need for social support may still be formidable and review of finances should be part of the preoperative evaluation. (80, 1064)

> In the light of the principles of distributive justice and equity, donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other considerations. (99, 1471)

How should guideline developers resolve such conflicting values? Guidelines should not automatically institutionalize the values that guide conventional clinical practices, nor even the values of the guideline developers, without first examining them critically and articulating them explicitly (e.g., 75). Critical analysis involves questioning the genesis and justification of patient selection criteria, as well as considering their meaning and impact in the relevant policy domain. These will be important elements of any deliberation process used to develop rationales for patient selection criteria in clinical guidelines.

Leaders in guideline development emphasize the importance of following a methodology, that is, systematic and formal processes for formulating and validating the content of guidelines (3;10;37;75;97). In addition to critical appraisal of evidence, expert consensus development, and other analytic techniques to support guideline development methods, systematic methodology also provides an excellent vehicle for the systematic, critical analysis of ethical implications. Using the ethics framework described above, for example, guideline authors could consider explicitly whether to portray a given risk factor as a contraindication for the procedure versus an indication for extra care, or to discuss the issue in an informative manner that could help guideline users decide which is appropriate in their practice context. Authors could also provide a valuable service by flagging certain contraindications (e.g., the need for financial resources or social support) as having ambiguous meaning and ethical justification. Both the development process and the published guideline should clarify and explicate the "who should get what" function of the guideline, especially when the guideline is to be used under conditions of constrained resources (be it an organ shortage or a health maintenance organization's cost-control program). Some guidelines in the transplantation field do discuss patient selection criteria in an explicitly critical fashion (e.g., 19;60); other guidelines could be improved by following such examples.

Transparency

Transparency refers to the imperative to clarify the basis for guidelines' content—in this case, content concerning patient selection criteria. While critical ethical analysis is part

of the guideline development process, transparency is a quality of the guideline document itself. It includes describing the ethical reasoning (in addition to evidence or biomedical reasoning) used to formulate a given patient selection protocol, for example:

> Given the lack of donor organs, care must be taken not to discriminate on the basis of social behavior such as alcoholism, especially since promising results have been obtained with liver transplantation over the last 10 yr [sic] in alcoholic cirrhosis. Refusal to transplant based purely on social behavior would be considered unethical. (23, 67S)

Many now propose that guidelines be evidence-based, which involves supporting recommendations with rigorous research evidence (16;52;98). This is a laudable goal, especially where patient selection criteria may be based on empirically untested beliefs. A transplant guideline cautions that evidence should underlie any psychosocial contraindication, for ethical as well as legal reasons (in the United States):

> . . . the perceived subjectivity of psychosocial assessments creates an even greater need to ensure that recipient selection is not unduly influenced by outcome predictors of questionable value. In addition, the Americans with Disabilities Act has added the force of law to the ethical requirement that psychosocial factors considered in the assessment of transplant candidates have intrinsic predictive validity. (60, 19)

In particular, guidelines using a poor outcomes rationale for a contraindication seldom clarify whether they mean suboptimal-but-net-positive outcomes (i.e., Table 1, row A) or a net probability of harm (Table 1, row B) in certain subpopulations. A dearth of citations to evidence makes this question nearly impossible to answer in most cases. As discussed above, however, the distinction is quite important from an ethical point of view.

An evidence basis by itself will not fully address the transparency imperative. In an absence of rigorous evidence, other justifications for guideline content (such as practice convention, expert opinion, or less rigorous evidence) should still be described transparently enough to allow the reader critical judgment (24;58). Supporting evidence should relate to the specific patient selection criterion. To be relevant, an empirical study's participant sample must adequately represent subpopulations of candidates with the contraindicated risk factor (12;82), and the analysis ideally should address the multiple and interacting determinants of effectiveness in these subgroups (8).

Third, and most importantly, the use of evidence is necessarily values-based. It is not adequately transparent simply to cite evidence relating a risk factor to poorer procedure outcomes. From an ethical point of view, effectiveness evidence alone does not legitimize the factor as a contraindication (which in turn becomes a systematic barrier to access to the procedure when guidelines are broadly applied as administrative or public policies). As discussed above, it is imperative to distinguish evidence of probable harm from evidence of probable modest (but positive) outcome. In the latter case, the individual candidate's interests may be at odds with the provider's or the candidate population's interests. Then the deeper rationale for the contraindication is not the evidence *per se*, but rather utilitarian reasoning structured to serve specific populations and specific health goals. Ethical transparency involves articulating these goals and the sacrifices individuals might have to make to serve them. In the interest of fairness, guidelines should also clarify how to apply a contraindication consistently and accurately. As examples, researchers may have operationalized and measured psychosocial instability in a manner not conventional or intuitive to the average clinician; in the case of advanced age, what seems advanced to one provider may not be so to another. Without diagnostic guidelines, selection criteria may be applied inconsistently, making access arbitrary and unfair.

Participation

Given that values play a role in the formulation of patient selection criteria, whose values should prevail? For example, a transplant guideline suggests that medical professionals exercise characteristic values in patient selection:

> . . . Although the medical profession is prepared to accept alcoholism as a disease, it is obviously not prepared to accept every patient with end-stage alcoholic liver disease as a transplant candidate. (63, 29S)

These values may not be shared by the community in which the physician practices, by the collective paying for the care (whether a public funder or a private insurer), or by the state. It is thus important that stakeholders, in addition to clinicians, participate in the guideline development process, especially to clarify what is considered fair access to care and to evaluate patient selection criteria in this light. Participation will determine the prevailing ethic and contribute as well to the quality of criticism involved in guideline development. Multidisciplinary participation is already recommended by some guideline methodologies, but the aim of participation has been somewhat too narrowly conceived as a way of balancing or neutralizing the biases of developers (e.g., 52). To address values dilemmas, biases should not be removed but rather examined and explicitly reckoned with. The key issues for guideline methodology are who should be represented as participants in the guideline development process and at what points in the process various stakeholders should participate (65). Similar questions have arisen in resource allocation exercises elsewhere in the healthcare system (1;62;71), and standard methods have not been established.

However, two key elements seem to be emerging. First, stakeholders should represent diverse interests effectively. Participants should probably include technical experts of varying disciplines (medical specialists, researchers, allied health and social service professionals, ethicists), users (clinicians, policy makers, administrators), and those affected directly and indirectly by the guideline's use (patients or consumers as well as members of the broader community or the public). Attention must be given to what it means for an individual participant to represent a particular population or stakeholder view (20). As participants, individuals must have more than token or watchdog roles on guideline committees. As representatives, individuals must also be accountable in some way to their constituencies (this is problematic, of course, in efforts to involve the public in any resource allocation debate). Developers also need methods for dealing with dissent, such as documenting minority opinions (10). Second, a dynamic and iterative development process offers more opportunities for "nonexpert" participation and values to play a meaningful part. Some characterize the practice guideline development process as an ongoing cycle, with regular opportunities for new evidence as well as stakeholder feedback to revise a guideline's content (10).

CONCLUSIONS

Practice guidelines are not a panacea for resolving "inappropriateness" in health care—be it inappropriate care, inappropriate costs, or inappropriate distribution of resources. Advocates may underestimate guidelines' shortcomings as effective instruments for controlling costs, as well as for allocating resources in a fair manner (6;9). Guidelines vary in their quality, especially in terms of the extent to which they are evidence-based (88). Physicians adopt and use guidelines less enthusiastically than expected, and are sensitive to factors such as authorship, topic, and dissemination methods (32;47;48;51;59;70;72). Nevertheless, guidelines formalize current practices as well as aim to change them (65). The diversity of many guidelines' patient selection criteria reflects a prevailing lack of agreement on (or attention to)

fundamental principles for allocating services. When guidelines standardize practice based on implicit bedside rationing conventions, they magnify and multiply the ethical caprice of bedside rationing. In doing so, guidelines may unwittingly exacerbate the very problems that policy makers hope guidelines will mend, such as inequity or inefficiency.

When health system authorities promulgate guidelines for systematic use in the clinical encounter to determine who gets what, guidelines become rationing tools. We need to examine whether practice guidelines, as macro-level policy instruments, fairly adjudicate competing claims on healthcare resources. We also need to expand the meaning of *rigor* in guideline development to include not only the scientific rigor of the evidentiary basis, but also the rigor of the transparency, criticism, and participation involved in formulating and presenting practice guidelines.

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