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A Framework for Rationing by Clinical Judgment

ABSTRACT. Although rationing by clinical judgment is controversial, its acceptability partly depends on how it is practiced. In this paper, rationing by clinical judgment is defined in three different circumstances that represent increasingly wider circles of resource pools in which the rationing decision takes place: triage during acute shortage, comparison to other potential patients in a context of limited but not immediately strained resources, and determination of whether expected benefit of an intervention is deemed sufficient to warrant its cost by reference to published population based thresholds. Notions of procedural justice are applied along with an analytical framework of six minimal requisites in order to facilitate fair bedside rationing: (1) a closed system that offers reciprocity, (2) attention to general concerns of justice, (3) respect for individual variations, (4) application of a consistent process, (5) explicitness, and (6) review of decisions. The process could be monitored for its applicability and appropriateness.

Increasing pressure to control costs is leading to a greater awareness of resource scarcity in health care. At the same time, there is considerable controversy regarding the acceptability of bedside rationing by physicians (Hiatt 1975; Loewy 1980; Levinsky 1984; Morreim 1991; Sulmasy 1992; Pellegrino 1994; Ubel 2001). The obligation to advocate for patients (Hiatt 1975; Loewy 1980; Levinsky 1984; Sulmasy 1992; Pellegrino 1997; Weinstein 2001; Askin 2002) and a lack of trust that physicians will make the right kind of rationing decisions (Veatch 1997) have prompted reservations about physician involvement in health care

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rationing. However, physician involvement also has been defended on the grounds that physicians are entrusted with the stewardship of scarce resources (Morreim 1991), that they could make cost control compatible with patient advocacy (Pearson 2000; Hardee, Platt, and Kasper 2005), and indeed that they may be in the best position to ration care in an appropriate and justifiable manner (Daniels 1981; Pearson 2000; Ubel 2001).

Debates regarding whether rationing of health care is acceptable rarely truly dispute setting *some type of* limits on care. Usually some threshold, such as the current standard of care, or patients' wishes, is taken for granted, and discussion focuses on whether setting a more restrictive threshold would be justifiable. Rationing, defined as "any implicit or explicit mechanisms that allow people to go without beneficial services" (Ubel 2001), must take place because the use of every single intervention that holds the smallest possibility of minute benefit seems financially untenable. Any clinical decision to place or to accept a limit on benefits for a patient constitutes rationing. Examples include such mundane decisions as early discharge to follow-up when there is a very small remaining risk of complication, such as post-operative deep venous thrombosis under appropriate prophylaxis. As this example shows, some instances of clinical rationing are routinely accepted and would be difficult to describe as immoral. Although some may criticize forgoing benefits in the abstract, few dispute that forgoing very marginal benefits may be reasonable.

Involvement of physicians in these decisions is and will remain a part of clinical practice. Physicians routinely make decisions regarding whether interventions with small benefits are worthwhile. They face requests for expensive interventions with little prospect of benefit to their patients (Hurst et al. 2005). Thus, physicians contribute to setting the threshold above which an intervention is "unreasonable." Such limit-setting is a "mechanism that allows people to go without beneficial services" (Ubel 2001). Furthermore, clinical judgment ought to contribute to these decisions: there will always be a degree of indeterminacy involved that cannot, and perhaps should not, be addressed beforehand by rules.

The question, then, is not whether physician bedside rationing is ever acceptable, but which thresholds and which processes are acceptable. The way in which bedside rationing is applied is the key question when considering its acceptability. Despite some study of public and physicians' attitudes toward theoretical rationing situations (Ubel et al. 1996a; Ubel et al. 1996b; Ubel et al. 2000a), however, little has been said about how bedside rationing ought to be practiced. Clinicians make rationing deci-

sions (Hurst et al. 2006) but cannot currently refer to a generally applicable rule, or to a widely accepted social understanding of where limits ought to be. The difficulty of such a controversial topic may play a part in this, but the very danger that bedside rationing could be done in an unacceptable way makes its examination all the more important. Explicit public understanding is needed to lend legitimacy to rationing decisions.

Our purpose in this paper is twofold. First, we wish to describe the kinds of activities that constitute bedside rationing. We also propose a framework and reasoning strategy to begin refining the processes of bedside rationing. Both aim to further the debate regarding the most justifiable way to practice bedside rationing.

TYPES OF RATIONING BY CLINICAL JUDGMENT

Setting limits at the bedside can occur in a variety of ways. As Robert Truog and colleagues (2005) have outlined, clinicians ration by three mechanisms: (1) in accord with external constraints, (2) by rules of medical practice, or (3) by exercising clinical judgment where the first two mechanisms do not apply. In this paper we examine the third of these mechanisms.

Rationing by clinical judgment itself also comes in three forms. First, it can occur as an instance of triage, where locally available resources are in obvious and immediate short supply and must be allocated between identified patients who are in competition with each other. Examples of triage are decisions regarding which patient receives the last available ICU bed or the organ available for transplantation (Table 1).

Second, rationing by clinical judgment can occur in a situation where resources are strained or subject to fixed limits. Although there is no immediate competition between identified patients, candidates for an intervention are nevertheless compared to other patients who potentially may need the same resource—e.g., residents of a community served by a hospital or the population covered by a health plan (Table 2) (Lee 2004).

Third, rationing by clinical judgment can be based on an opinion that using a specific intervention in a specific case will bring an incremental gain in benefit that is not worth the additional human or financial effort that this intervention will cost. Here, the clinician judges that the contemplated intervention, as reported in the literature for a population of like patients, shows a benefit, but that this benefit is, in the light of the expected cost, too small to put the intervention over a certain threshold that is deemed reasonable (Table 3). This is different from rationing by rules of clinical

TABLE 1. EXAMPLES OF TRIAGE SITUATIONS IN THE ICU

<i>Limited time</i>	The ICU team goes on rounds for 90 minutes each morning and has ten beds in the ICU. Inevitably many of the patients require more than 9 minutes of the team's attention to fully evaluate their status, consider the options, decide on a plan of care, and communicate this to the ICU staff. The patients in the first beds often get more time on rounds and the last ones barely get adequate attention. The staff wonders about how to best ration their rounding time. Should they move from bed to bed every nine minutes? Should they give more time to the patients who are more unstable? Should they give most time to the patients who are likely to benefit the most from their care? Should they simply reverse the rounding order so they start at the back end of the ICU on alternate mornings?
<i>Limited beds</i>	The ICU team often receives patients admitted from the Emergency Department during the night. When these patients need ICU care, the unit is often full and the question therefore arises as to whether there are any patients who could be transferred out of the ICU earlier than would otherwise occur. The team must review the ICU census and consider who is least likely to suffer adverse consequences if transferred. Should the patient with the poorest prognosis be moved? Or the patient who is most stable? Or the patient who is receiving the least monitoring?
<i>Limited staff</i>	The ICU has 5 nurses staffing each shift. This provides an average of one nurse for every two patients in the 10-bed unit. During one shift a patient in respiratory failure is so difficult to ventilate that the team judges that it is necessary to paralyze the patient and put him on volume control ventilation with a high I:E ratio. This will require that the patient have 1:1 nursing. The charge nurse must decide how to reassign the nurses in the ICU. Three patients will need to be assigned to one nurse to accommodate the nursing care needs of the patient in severe respiratory failure. Should a patient who is terminally ill and getting palliative care be one of them? Should a patient who is an acute asthmatic be one of them?

practice, because it involves an individual case assessment, in contrast to a general cost-effectiveness analysis (CEA) on a population. For example, a clinician could judge that although a single drug was shown to be effective in his patient's condition, the incremental cost-effectiveness of adding this drug to the many others already prescribed is low (Tinetti, Bogardus, and Agostini 2004).

In these three circumstances, the clinician is situating the patient at hand in the context of increasingly wider circles of competing patients

TABLE 2. EXAMPLES OF COMPARISON TO OTHER POTENTIAL PATIENTS

<i>Limited blood supply</i>	A patient is utilizing a great deal of the supply of a particular blood product for treatment of a severe bleeding diathesis; use by this patient is expected to limit the blood supply in a certain region. There is no immediate call for competing use of this blood product, but use of it for this patient could cause a shortage that could pose a potential threat to the remaining population.
<i>Influenza vaccination</i>	A 40-year-old patient in good health consults for influenza vaccination. A vaccine shortage has been announced for this year, and vaccination campaigns for the elderly are still underway. Will the benefit of avoiding absenteeism from work and unpleasant symptoms in this patient warrant risking a lack of vaccine for someone in an age group at risk of mortality from the complications of influenza?

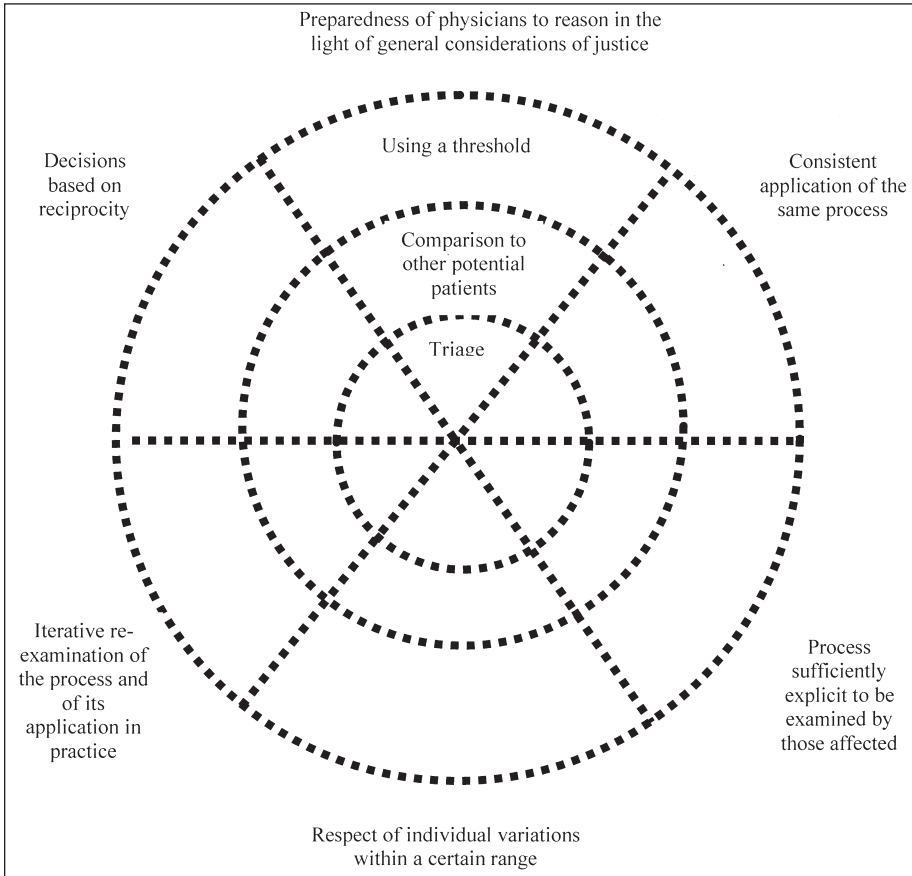
TABLE 3. EXAMPLES OF USING A THRESHOLD IN RATIONING BY CLINICAL JUDGMENT

<i>Assessment of individual benefit</i>	A patient suffers both from hormone sensitive metastatic breast cancer and from ischemic heart disease. Guidelines for the secondary prevention of coronary heart disease include treatment of hypercholesterolemia with statins. Will the benefit to this patient be sufficient to warrant prescribing a statin in her case?
<i>Assessment of individual cost</i>	A patient presents with uncomplicated myocardial infarction. It has been shown that a length of stay of over three days is not cost-effective (Newby et al. 2000),] but inpatient care is much cheaper in this area. How should this result be applied?

and deciding about the use of constrained resource pools with regard to these populations (see Figure 1).

Importantly, many difficult end-of-life choices regarding when to initiate or to continue “cure-oriented” treatments are not rationing decisions in this sense. Clinical judgment that an intervention will cause the patient more harm than good is a different consideration. However, when an

FIGURE 1. A FRAMEWORK FOR RATIONING BY CLINICAL JUDGMENT.



intervention contemplated in end-of-life care is indeed expected to bring more good than harm, but too little good to be indicated or reasonable, then forgoing it constitutes rationing by clinical judgment under this framework.

CONDITIONS FOR FAIRNESS AND LEGITIMACY
IN RATIONING BY CLINICAL JUDGMENT

One of the fears regarding rationing by clinical judgment is that it may be susceptible to subjectivity and bias. It has been noted that concerns about justice infrequently come into physicians' rationales for decision in the facing scarcity (Hurst et al. 2005). This is concerning, as it does suggest that links between general concerns for fairness and the clinical practice of bedside rationing may be weak.

Models have been proposed to increase consistency, openness, and participation by those affected in limit-setting decisions (Daniels and Sabin 1997; Pearson 2000). Outlining an approach that respects general conditions for fairness in rationing by clinical judgment faces several difficulties. First, it must be consistent and attentive to justice. In addition, it must be sensitive to relevant individual variations. These first two conditions can conflict with one another. In addition, any consistently applied framework must be revisable in the light of new theoretical and practical insights (Daniels and Sabin 1997), some of which will arise in the application of the process itself. All these features will be necessary for it to be a trustworthy process, one that is able to lend moral legitimacy to rationing decisions by individual clinicians. The final difficulty is that a framework for rationing by clinical judgment must in practice be applicable in the three different kinds of cases previously outlined, each of which poses certain specific difficulties.

ELEMENTS OF A FRAMEWORK FOR RATIONING BY CLINICAL JUDGMENT

A general framework for rationing by clinical judgment must recognize that a legitimate diversity of values will come into play. In this sense, Daniel and Sabin's (1997) *accountability for reasonableness* is convincing and influential. However, applying it to rationing by clinical judgment is not straightforward. First, the substantial content of a reasonable rationale is too vague for use in clinical practice. Additionally, the reasoning strategy that could be used to apply it in this setting is unspecified. Based on Daniels and Sabin's four conditions of publicity, relevance, revisions and appeals, and enforcement, a justifiable model seems to us to require the consistent presence of six minimal elements (Figure 1).

Physician Reasoning Based on General Considerations of Justice

Physicians should be prepared to reason about rationing in the light of general considerations of justice. It is essential that clinicians appreciate the concept and importance of fairness and apply considerations of justice to rationing decisions. This requires them to be aware of the various traditional theories of justice. They should understand the basic elements of utilitarian, egalitarian, and prioritarian theories and be aware that different theories of justice will lead to different outcomes. The requirement that physicians become knowledgeable regarding theories of justice may seem demanding. However, it is no more so than for other conceptual tools that medical practice now requires, such as the use of decision analysis in

diagnostic approaches or evidence-based medicine. Furthermore, physicians already are expected to have some understanding of medical ethics in general. They are quite familiar with issues of patient autonomy, beneficence, and nonmaleficence. They also are taught some nonprinciplist approaches to bioethics, such as virtue ethics and casuistry. However theories of justice are insufficiently taught. As it is necessary to address the competing duties to different patients in an even-handed way, an important clinical outcome, this educational requirement appears justified.

Respect for Individual Variations

Respect for individual variation within a certain range can be in tension with general considerations of justice, as it seems to contradict the demand for consistency. On the other hand, the degree of indeterminacy involved in these situations seems to require this flexibility. In addition, it seems that the assurance that individual circumstances have been taken into account would be important to most of us in accepting limit-setting decisions if we were affected. Indeed, much of the value of physician involvement in rationing lies in their ability to do just this: to balance respect for individual variation and consistency. No other locus seems better for achieving this balance.

Decisions Based on Reciprocity

Rationing by clinical judgment should only take place where reciprocity prevails. The process thereby becomes defensible to all affected by being applicable not merely to the patient who forgoes a potential benefit for the sake of others, but also, and similarly, to others for the benefit of this patient. Reciprocal sacrifice is a basic benchmark if one is to justify the sacrifices made by some for the benefit of others. It is a justified requirement because health care resources are shared resources, making them a common good to which rules of cooperative fairness will need to apply (Rawls 2001). This requires that the decision take place in a closed system in which it would be possible for the patient to benefit from a reciprocally offered sacrifice.

Consistent Application of the Same Process

The same process should be applied in every case to introduce a minimal procedural equity into rationing by clinical judgment (Daniels and Sabin 1997). This is also necessary if the process is to be justified by reciprocity.

Consistency is a limiting condition for the application of a process that could otherwise be applied in several different ways.

Explicit Process

The process should be sufficiently explicit to be examined by patients, physicians, and those who fund care (Daniels and Sabin 1997). In other words, the process must be outlined in a way that is understandable and accessible for examination by all those affected.

Iterative Re-Examination of the Process and Its Application

There should be an iterative re-examination of the process, so that new theoretical and practical insights can be included as they are brought to light (Daniels and Sabin 1997). There also should be an iterative re-examination of practices, so that they can (1) be evaluated for application of the process and (2) be a source of insight for new input into the process.

APPLYING THE FRAMEWORK

A framework for rationing by clinical judgment must be applicable in practice. For this purpose, knowledge is important (Rest and Narvaez 1994; Eastman, Eastman, and Tolson 2001)—in this case clinical knowledge as well as knowledge of ethical elements of fair allocation—but insufficient. Bringing considerations of justice, respect for variation, reciprocity, consistency, explicitness, and revisability to bear on actual decisions requires the use of specific reasoning strategies, akin to a reasoning strategy for ethical thoughtfulness. This is similar to other reasoning strategies learned by physicians, such as decision analysis or those involved in evidence-based medicine (EBM). Difficulties identified in getting physicians to use the reasoning strategies of EBM in clinical decision making include a persistent gap between theory and practice (Slawson and Shaughnessy 2005). A similar gap exists between theory and practice in resource allocation (Hurst et al. 2005). Thus, we outline proposals for the application of the elements outlined in the framework we have presented to rationing by clinical judgment.

Considerations of Justice

The application of general considerations of justice raises several questions. Must all clinicians, or at least any given physician, always apply the same theory? One might argue that consistency in applying theory will lead

to greater fairness. Physicians might consider which patients would benefit the most from resource use or who would face the least risk from having a resource withheld, using utilitarian logic. They might give priority to the patient who is the worst off. They might take an egalitarian approach and attempt to limit care on as even-handed strategy as possible.

However, there will not necessarily be a uniquely applicable or justifiable theory of justice for every case. Indeed, the existence of the various different views of distributive justice, all of which can be defended to some degree by reasonable people, makes this unlikely. The essential guide should be that application of theories of fairness by individual clinicians should function in such a way as to reduce arbitrariness. Always applying the same theory might be one way, but individual patients treated by different clinicians may still be treated very differently. Alternatively, clinicians might agree that they will vary the theory they each apply according to the situation, but do this in a predetermined and consistent manner. One approach could be to identify those theoretical views that are robust enough for legitimate controversy to exist as to which is the best one, and always to take all of these views into account. For example, the likely benefit from resource use, the degree of risk faced from having a resource withheld, and how badly off different patients are each will vary from case to case. This means that, in some cases at least, the degree of unfairness linked to setting aside one kind of consideration of justice will vary, and some theoretical approaches thus will weigh more heavily than others in a given case. For example, one could be considering the two following patients in a triage situation: one stands to gain slightly more from the intervention, but the second is much worse off. In this case, setting aside the prioritarian consideration to favor the worst off would result in a much higher degree of injustice on this view, than giving up a slightly higher overall benefit would constitute on the utilitarian view. Thus, priority should be given to the worst off patient in this case. For this to be a consistent process, it is necessary to be prepared to reach the opposite conclusion in opposite circumstances, namely, if one patient was only slightly worse off, but the other stood to benefit much more. This is different from proportional satisfaction of moral reasons (Broome 1991), because these are situations in which the resource cannot meaningfully be split. It is also different from choosing the best consequences, which would lead to the opposite conclusion in our example. What this approach amounts to is choosing the smallest available wrong.

Consistency and Individual Variation

This example also illustrates one of the ways in which the requirement for consistency will constrain the process. Consistency limits how reasoning in terms of justice can be applied to real cases. For example, it could dictate that the same theory of justice should be applied to all situations or that the strategy of weighing different theories of justice should be applied to all situations. In addition, there is a degree of tension between consistent application of the same process and respect for individual variations. Consistency also will dictate that the same kinds of individual characteristics of patients, such as preference, likelihood of benefit, and degree of need, be considered in all circumstances.

Reciprocity

In applying reciprocity, it should be understood that any organizational entity may support reciprocally offered sacrifices. In the United States, this could mean that any insured patient could be considered as part of one pool where reciprocal sacrifices will be accepted. On the face of it, a universal health care system appears to be a better environment for reciprocal rationing. However, it is not a necessary condition. A set of patients could be sharing health care resources reciprocally even in its absence. Thus, all beneficiaries of hospital services in a given area could form such a group. Applying rationing to them could take place in a closed system, and be fair. This sort of system, however, could not be viewed as closed with respect to any person not within the circle. Rationing from someone who was not covered by insurance in the first example, or who was not part of the area served by the hospital in the second, would thus not take place within a closed system; although it could sometimes be described as necessary, on our framework it would not be fair. Importantly, a universal health care system is not a sufficient condition for reciprocal rationing either. It only represents a more favorable set of initial circumstances. It does not, for example, preclude systematic discrimination against a specific group by a majority of health care providers.

Explicitness

Explicitness would require that physicians document these decisions, at least retrospectively. For example, intensive care units regularly must refuse patients who do not meet their criteria for inclusion, or who are in competition with other patients whose needs are, for example, greater.

Some ICUs keep logs of refused referrals with documentation of the reasons. This documentation can serve as a basis for review and critique later on. Such a system could be applied by surgical services to delays for elective procedures, or by hospital pharmacies for nonformulary requests. Decisions for rationing by clinical judgment also could be documented in patients' charts.

Clearly, not all such decisions could be documented in this way all the time. If one wishes to open these decisions to examination, however, one must start somewhere. Additionally, even if only some interventions are logged in such a way, or consigned to patients' charts, physicians will become better accustomed to thinking and justifying their rationing decisions in terms of the process, and they will be better able to compare their decisions with those of others. This is likely to improve rationing practice even in nonmonitored interventions. Documentation and examination would constitute a kind of quality control for the process. One also, as a quality improvement effort, could select certain routine decisions for review, such as hospital or ICU admission, or dialysis. In addition, the process should be publicly available in some form, and thus accessible to critique by those parties affected.

Revisability

Iterative re-examination could be done by a group of physicians as a self-evaluation of their rationing practices. Results would be disclosed to individual physicians only along with a comparison of their practices to the typical practices of colleagues in similar situations. It should be explicit that the "typical practice" is not a norm in the moral sense. It may very well be that physicians legitimately could depart from typical practices. Such periodic evaluation of clinician practices should not serve to enforce a return to the mean, but to foster regular thoughtful reevaluation of rationing practices.

Like other reasoning strategies, such as those incorporated in evidence-based medicine, this framework could serve as a check list for intuitive conclusions or be used to move forward in difficult situations. Use of the framework would require that physicians take pause and at least briefly question each point when making rationing decisions. It could also serve to guide physicians' general reflections on how to ration by clinical judgment. Time could be set aside every now and then to share experience, as it is for other difficult decision-making skills such as diagnosis. Indeed, if rationing by clinical judgment is part of physicians' role such time should

be set aside. This practice should be examined in the same kind of circumstances as other interventions are: continuing education time should be allocated to it.

SPECIFIC DIFFICULTIES FOR DIFFERENT TYPES OF RATIONING BY CLINICAL JUDGMENT

Unique issues will arise during each type of rationing situation encountered by clinicians: rationing by triage, comparison to other potential patients, and use of a threshold.

Triage of Identified Patients

During circumstances when triage is necessary the notion of reciprocity is not straight forward. When immediate demand exceeds fixed resources the circumstances do not permit immediate reciprocity and may not permit reciprocity in the future, particularly in life-threatening circumstances. Thus the demand for reciprocity cannot dictate that reciprocity should be literally feasible at the given moment a rationing decision must be made. It would not be possible to give adequately in return at the moment that a critically ill patient must forgo some share of a potentially beneficial intervention such as a doctor's or nurses' time. It should however be the case that if the patient who is about to forgo a resource were in the opposite situation, in the situation of the patient who will benefit from the sacrifice, the clinician would, upon reflection, be willing to parse out the necessary resource to her.

In such cases, reasoning based on general considerations of justice must take place in very limited time. This may imply using a simplified algorithm in certain cases. Although a simplified process is clearly a less than optimal way to use general considerations of justice, any improvement in the systematic application of such considerations to triage is certainly desirable (Repine, Lisagor, and Cohen 2005).

Comparison to Other Potential Patients

In situations where rationing by clinical judgment occurs by comparison to other potential patients who could benefit from the resources involved, the urgency of the rationing decision is not as obvious. The competition for resources is not as frenzied, which makes the notion of reciprocity more imaginable. Again, the clinicians should consider whether it is the case that if the patient who is about to forgo this resource were in the opposite situation, in the situation of the others who will benefit from the

sacrifice, the clinician would, upon reflection, be willing to parse out the necessary resource to her.

An added feature of this level is the risk that the “potential patients” used in this hypothetical comparison could be defined very differently. Consistent application of the same process would seem to require that the type of patient physicians use in these comparisons be explicitly examined. It is not realistic to expect these hypothetical patients to be identical for all physicians. However, they should not be allowed to vary on points that could lead to discrimination. For example, if physicians were systematically to compare their patients to people who were the same age as themselves, those physicians would be more likely to deny marginal benefits to patients who are not in that age range. Clinicians also should avoid comparison on the basis of characteristics considered morally nonrelevant, such as race or gender.

Use of a Threshold

In this circumstance, clinicians may judge that using a specific intervention in a specific case will bring an incremental gain in benefit that is not worth the additional human or financial effort that the intervention will cost. Although the reasoning that the clinician will use under these circumstances employs the logic of cost-effectiveness, the available literature does not suffice to answer the question of whether to intervene because the patient does not exactly match the patient population reported in the CEA literature.

The difficulty here is to maintain respect for individual variation when making a decision using analysis based on population data. An added difficulty is that there are in practice two thresholds. The first is the amount of expected benefit required to consider that an intervention is indicated, the second is the cost-effectiveness ratio required to judge that implementing an intervention is “reasonable.” Each threshold can be examined at the level of rule-setting or at the level of clinical judgment. The specificity of the threshold problem at the level of clinical judgment is that the tension between data gathered from groups and the care of individual patients is more palpable at this level (Saarni and Gylling 2004).

Clinical Judgment of Expected Benefit

Clearly, the benefit expected of a specific intervention will contribute to determining whether it is indicated. Thus, it is important to know what prospective benefit can be expected for this particular patient. Compari-

sons must be made between the individual patient and the study group. This is a standard necessity, and a standard difficulty, in the application of evidence-based medicine (Slawson and Shaughnessy 2005).

The result is an assessment of the amount of benefit expected from an intervention. Knowing if the expected benefit is sufficient for the intervention to be indicated will require further that there be an agreement on the level of expected benefit sufficient to warrant treatment. This is a value judgment that will vary individually. When costs are not considered, the main stakeholder is clearly the patient. The setting of clinical discussion thus can be legitimate and sufficient to set this first threshold on a case-by-case basis.

Clinical Judgment Regarding Expected Cost-Effectiveness for a Patient

In making a clinical judgment regarding cost-effectiveness and the reasonableness of paying for an intervention, a layer of complexity is added. The first question is the prospective cost-effectiveness level in this particular case. Here too, the best available evidence must be examined in the light of relevant patient characteristics. This is more complex than examining the question of benefit, because there are several parts to a cost-effectiveness ratio: the prospective benefit in terms of years of life gained, the prospective benefit in terms of quality of life, and the cost of the intervention. The standard unit of CEA is the cost per quality adjusted life year (QALY). The QALY is the number of years gained on average through the intervention, multiplied by the assessed value for the quality of life of the patient (V). This is a number between 0 and 1 where 0 is death, 1 is perfect health, and anything in between is life in less than perfect health.

The number of years gained from an intervention is based on data gathered from a study population. Thus, it is important to assess whether this patient differs from the study group. This is similar to the kind of clinical judgment required when applying any evidence-based practice guideline to individuals who do not quite fit the study populations. Here, the legitimacy of considering individual cases in the light of clinical judgment is relatively straightforward.

The assessed cost of the intervention or of the alternative against which it is being compared also can differ from the costs in the study group. As with the evaluation of differences between an individual patient and a study population on the question of a prospective health benefit, cost may not apply precisely to details in a particular clinical situation. Thus, there are circumstances in which the literature on cost-effectiveness suggests

that a treatment is not cost-effective and yet the cost of the intervention may be less than that indicated in the literature, placing this treatment above the threshold deemed reasonable. The opposite could happen in situations where the cost is greater than in the study population. For example, the indication of many preventive interventions, such as screening, is based on cost-effectiveness ratios. A physician who is deciding whether to schedule colonoscopies, or mammographies, will be basing her assessment on population-based data. If either the prevalence of the disease or the cost of the intervention in her area differs from that of the study population, the cost-effectiveness ratio may need to be tempered by this information. Currently, however, many cost-effectiveness analyses give clinicians insufficient elements to make this judgment. A clinician typically will be told the age range of the study group; whether they were male, female, or both; and some information regarding prevalence of the studied disease, co-morbidity, and similar information. The same type of general information about costs in the study also should be made available to clinicians if they are to apply CEA with the same kind of thoughtfulness as evidence-based medicine.

The assessed value for the quality of life of the patient, V , also could be different for an individual patient if she differs sufficiently from the kind of patient used in reaching this evaluation. Here, however, a problem arises. In clinical practice, it is considered important to leave the assessment of quality of life to the patient herself. In placing the value of V for CEA, however, this assessment is not left to the patient alone. Indeed, there is substantial controversy regarding what the best viewpoint for this assessment would be (Ubel 1997; Menzel et al. 1999; Nord et al. 1999; Ubel 1999; Ubel, Richardson, and Menzel 2000; Ubel et al. 2000b; Ubel, Loewenstein, and Hershey 2001; Ubel, Loewenstein and Jepson 2003). In adapting V to an individual patient who does not quite fit the study population, the difficulty regarding the best viewpoint from which to assess V is imported into clinical practice. If patient input is legitimate, then the clinical setting is the appropriate locale in which to allow this.

Importantly, then, there are elements of cost-effectiveness assessment that are compatible with respect for individual variations: the number of years gained, and the added cost of the intervention. Using input from clinical judgment in rationing through cost-effectiveness thresholds is thus already possible, and would be important. If a consensus could be reached regarding what constitutes a legitimate input by the individual patient on the assessment of V , this element may be adaptable as well.

Knowing how to adapt cost-effectiveness assessment to individual patients, however, goes only part of the way to deciding whether it is “reasonable” to implement an intervention in a specific case. Knowing if this level of cost-effectiveness is sufficient for the intervention to be “reasonable” further requires that there be an agreement on the level of cost-effectiveness sufficient for this to be so. This is a value judgment that will vary individually. At this point, however, the patient is no longer the only stakeholder. Whether she remains the *main* stakeholder is controversial. If any limit whatsoever is placed on potentially beneficial interventions, even where the chance of benefit is small and remote, then the clinician will be considering the cost born by third parties: all enrollees in whichever program pays in a third-party system—e.g., enrollees in a plan or tax payers in a state system. Considering that *some* threshold will be used, the question is how to decide legitimately what it should be. Whether the clinician’s judgment carries legitimate authority that is sufficient to answer this question is contingent on the presence of the six elements we outlined at the outset of our discussion.

CONCLUSION

The framework we have outlined contains minimal requirements for fair rationing by clinical judgment. It is intended to begin to refine the practice of rationing by clinical judgment. It needs to be judged realistic by other clinicians, as well as theoretically robust. By adopting minimal requisite conditions for rationing by clinical judgment, clinicians could practice bedside rationing more fairly. They would not cease to use their personal values, or intuitions, but would be able to complement them and subject them to more systematic examination. They also may be able to advocate more effectively for their patients in situations where pressure could be exerted on them to ration without meeting these requirements. In addition, the framework could serve as the basis for clinical tools for bedside rationing. To the extent that rationing is unavoidable, and that making it more explicit and equitable is desirable, such a tool would be valuable. Finally, in including iterative re-examination of the process and its application, the framework could serve as an assessment tool for clinical rationing. Such evaluation should help to foster regular moments of thoughtful reevaluation of rationing practices.

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