

6.2.1 Guidelines for Organ Transplantation from Deceased Donors

Transplantation offers hope to patients with organ failure. As in all patient-physician relationships, the physician's primary concern must be the well-being of the patient. However, organ transplantation is also unique in that it involves two patients, donor and recipient, both of whose interests must be protected. Concern for the patient should always take precedence over advancing scientific knowledge.

Physicians who participate in transplantation of organs from deceased donors should:

- (a) Avoid actual or perceived conflicts of interest by ensuring that:
 - (i) to the greatest extent possible that the health care professionals who provide care at the end of life are not directly involved in retrieving or transplanting organs from the deceased donor. Physicians should encourage health care institutions to distinguish the roles of health care professionals who solicit or coordinate organ transplantation from those who provide care at the time of death;
 - (ii) no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death.
- (b) Ensure that death is determined by a physician not associated with the transplant team and in accordance with accepted clinical and ethical standards.
- (c) Ensure that transplant procedures are undertaken only by physicians who have the requisite medical knowledge and expertise and are carried out in adequately equipped medical facilities.
- (d) Ensure that the prospective recipient (or the recipient's authorized surrogate if the individual lacks decision-making capacity) is fully informed about the procedure and has given voluntary consent in keeping with ethics guidance.
- (e) Except in situations of directed donation, ensure that organs for transplantation are allocated to recipients on the basis of ethically sound criteria, including but not limited to likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in certain cases, amount of resources required for successful treatment.
- (f) Ensure that organs for transplantation are treated as a national, rather than a local or regional, resource.
- (g) Refrain from placing transplant candidates on the waiting lists of multiple local transplant centers, but rather place candidates on a single waiting list for each type of organ.

AMA Principles of Medical Ethics: I,III,V

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report K-A-93 Ethical considerations in the allocation of organs and other scarce medical resources among patients

CEJA Report B-A-68 Ethical guidelines for organ transplantation

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Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients

INTRODUCTION

The Principles of Medical Ethics of the American Medical Association state that "a physician shall be dedicated to providing competent medical 'service with compassion and respect for human dignity."¹ Service to patients in accordance with their best interests and wishes is the fundamental mission of the medical profession. Physicians attempt to live up to this basic duty, and routinely exhaust all means available in their efforts to benefit their patients. Often, physicians' efforts on behalf of their patients require the use of resources which, because of a naturally limited supply, are not readily available to all who need them. For instance, the shortage of organs available for transplantation is due, at least in part, to the natural scarcity of appropriate donors. Even if every potential organ donor agreed to donate, there would still not be enough hearts, livers, kidneys, and other organs to provide for every patient who could benefit from transplantation.

Scarcity in any medical setting inevitably requires that, of all patients who could potentially benefit from the use of a scarce resource, some will receive it and some will not. The Council has previously stated that "a physician has a duty to do all that he or she can for the benefit of the individual patient."² The dilemma, then, is how physicians can live up to this principle when the care that they can provide is constrained by the scarcity of needed resources. In this report, the Council considers the ethical issues relating to the equitable allocation of scarce resources among patients, including the criteria by which scarce medical resources should be distributed and a suggested procedure for applying these criteria. In addition, the Council briefly considers the appropriate role of physicians in allocating scarce resources. This report focuses primarily on ethical allocation criteria; the Council will work with the Council on Medical Service to develop further guidelines for establishing appropriate decision making mechanisms for allocating scarce resources.

BACKGROUND

Though the shortage of organs is the most obvious example of scarcity in medical resources, the need to make allocation decisions arises in other contexts as well. For instance, during periods of high occupancy and limited bed availability, triage physicians must decide which patients gain immediate entry to the intensive care unit. Though intensive care differs from organs in that ICUs can more readily be expanded to respond to increased demand, changes in physical plant and staffing requirements take time and money to implement, making allocation decisions difficult to avoid in the interim.

In the past, organs and ICU beds have been allocated according to a wide range of criteria, some appropriate and some not. These criteria have included, among others, urgency of need, likelihood of benefit, quality of life, life expectancy, age, social worth, ability to pay, mental acuity, criminal record, family involvement, the patient's past behaviors, and the educational value of a case for physicians.⁵⁻⁸ Though many of the more objectionable of these criteria are no longer commonly in use, wide variation among institutions still exists. Criteria used for allocating space in the ICU vary, and individual transplant centers may deviate from the policies of the United Network for Organ Sharing, the organization under contract with the government to establish criteria for allocating organs.^{9,11}

In addition to the variation in allocation criteria, the party or parties designated to make allocation decisions also differs among institutions. Because of their responsibility to each individual patient, the physicians of patients actually competing for resources must be patient advocates. In fact, many

institutions have implemented mechanisms such as triage physicians and restrictive admissions policies to control access to the ICU, and mathematical allocation formulas are used to determine which patients will receive organs for transplantation.

The variation in allocation criteria and procedures may be problematic in two ways. First, reliance on criteria of questionable ethical value may lead to inherently unfair or unjust allocation decisions. Second, the different interpretations and valuations assigned to each criterion by different decision makers can result in inconsistent decisions across institutional lines. Differences in the actual patients receiving organs or other scarce resources are inevitable given the diagnostic and prognostic uncertainties involved, and are permissible as long as every patient - regardless of where treatment is sought - is treated fairly in a just allocation procedure. At present, however, the plethora of allocation criteria and their different interpretations inhibit the ethical distribution of organs and other medical resources according to “fair, socially acceptable, and humane criteria.”²

Some argue that, in addition to inherently scarce resources such as organs and ICU beds, a broader range of medical resources may become scarce in the future,^{8,11,12} as society rethinks its health care goals in the face of rising costs and competing demands in the realms of education, public safety, transportation, and a host of other concerns.¹² In order to pay for these other social priorities, it has been argued by some that money and resources should be conserved by denying marginally beneficial care to some patients on the basis of cost concerns alone, even when the resource needed by the patient is not inherently scarce. Lester Thurow summarizes such a view: “it will be far better if American doctors begin to build up a social ethic and behavioral practices that help them decide when medicine is bad medicine...because the costs are not justified by the marginal benefits.”¹³

The appropriateness of decisions to limit marginally beneficial care on the basis of cost is a subject of ongoing debate. American Medical Association policy strongly opposes rationing plans that would limit the provision of beneficial care to patients. As indicated in the Board of Trustees Report EE (1-92), the Association “believes that much can be done to reduce health care spending without the necessity of denying medically effective care to patients.”¹⁴ The debate over rationing and the setting of societal priorities in health care is beyond the scope of this report, which deals only with the allocation of inherently scarce resources, such as organs or ICU beds, by the individual institutions controlling them. However, should there ever be societal agreement to limit or deny medically effective care to some patients on the basis of cost, then the care being denied would in effect become a scarce resource, and the allocation criteria discussed in this report might then be applicable to those limited resources as well.

ACCEPTABLE CRITERIA FOR RESOURCE ALLOCATION AMONG PATIENTS

The Council believes there are five factors relating to medical need that may appropriately be taken into account when allocating organs or other scarce medical resources, such as spaces in the ICU. These include (1) the likelihood of benefit to the patient, (2) the impact of treatment in improving the quality of the patient's life, (3) the duration of benefit, (4) the urgency of the patient's condition (i.e., how close the patient is to death), and in some cases (5) the amount of resources required for successful treatment. Each of these criteria is considered below.

Likelihood of Benefit

Giving priority to patients with a greater likelihood of benefiting from treatment is necessary for any efficient use of medical resources,^{8,15} for channeling resources to those most likely to benefit is often an essential component in maximizing overall benefit to patients.

The major concern with a likelihood of benefit criterion is the uncertainty involved in making outcome predictions. Because of this uncertainty, only very substantial differences in likelihood of benefit among patients are relevant to allocation decisions. The larger those differences are, the more relevant a likelihood of benefit criterion becomes. For example, in allocating kidneys for transplant, it would be more justified to prefer a patient with an 80% chance of graft survival over a patient with a 10% chance than it would be to prefer a 60% chance to a 40% chance. Small differences in probabilities should not be used to fine-tune allocation decisions when dealing with patients with fairly comparable chances of benefiting from treatment. Likelihood calculations will probably become more accurate in the future as outcomes research improves physicians' prognostic ability, thus enabling more effective allocation decisions.

Two additional concerns arise in considering likelihood of benefit. First, there may sometimes be a failure to distinguish care that has a low likelihood of benefiting the patient from care that is truly futile. The Council has defined a treatment as futile when there is no reasonable chance that the treatment will benefit the patient, or else the expected benefit of the treatment cannot be expected to meet the patient's expressed goals.¹⁶ Clearly, patients who have no reasonable chance of benefiting from a scarce resource should not receive it. However, patients who do have some chance of benefiting, in whatever degree, cannot be ruled out in advance as inappropriate candidates for treatment.

The second concern with a likelihood of benefit criterion is the questionable or inappropriate factors that can be introduced as contributors to a patient's likelihood of benefit. Some criteria believed to detract from a patient's likelihood of benefit, like communication or transportation problems, may merely be inconveniences, rather than insurmountable obstacles. Other criteria, such as strength of character, fortitude, or the presence of a supportive home environment may contribute to likelihood of benefit,¹⁵⁻²³ but are very difficult to define or apply to individuals. Allocation decisions that put too much weight on non-medical contributions to a patient's likelihood of benefit run the risk of arbitrariness and overgeneralization.

In general, if patient traits or behaviors that may adversely affect the patient's likelihood of benefit are taken into account, at least two conditions should be met. First, reasonable extra efforts on the part of physicians or others must fail to overcome the obstacles posed by the patient's traits or behaviors; and second, the traits or behaviors must directly and substantially detract from the patient's likelihood of responding to treatment.

Change in Quality of Life

It is generally accepted that organs and other scarce resources should be distributed to maximize benefit to patients. Presumably, benefit will be maximized if treatment is provided to the patients who will have the greatest improvement in quality of life.

Though directing resources to patients who would benefit the most is an intuitively valid goal, in practice this is easier said than done. The biggest difficulty is deciding on a standard definition of quality of life to be used in comparing the degree to which potential recipients of treatment would benefit.²⁴

One possibility is to define quality of life in terms of functional status.²⁵ By this definition, improvements in quality of life would be measured for each patient by comparing functional status with treatment to functional status without treatment. Patients who would receive the greatest improvement in functional level would also be considered to receive the greatest improvement in quality of life. Making quality of life judgments in terms of changes in functional status is defended on the grounds that it facilitates comparisons between patients by allowing decision makers "to assess quality of life independent of the patient's feelings."²⁵

The problem facing any approach that equates quality of life with functional status is that defining the benefit gained from treatment, and determining its importance in a patient's life, cannot realistically be separated from patients' individual, subjective values.^{24,26-29} Attitudes towards a certain functional level may differ greatly; a disability that some believe would make life not worth living, others could view as acceptable. Though change in functional status is an important factor in defining improvements in a patient's quality of life, it is less important than the patient's *attitude* towards his or her change in functional status.

There are some strategies for determining quality of life that do rely on patients' expressed feelings and values. Several scales, such as the Index of Psychological Affect, the Index of Overall Life Satisfaction, and the Index of Well-Being, attempt to quantify patients' subjective views about the quality of their own lives.³⁰ However, while these indices may be useful in other contexts, they do not allow us to make useful comparisons between patients.¹ For example, though two patients may both rank their quality of life as a 10 on a scale of 15, what one patient means by "10" could significantly differ from what another means by "10". Moreover, patients who know that their expressed attitudes towards a change in functional status would affect their chances of receiving treatment may inflate their quality of life ratings to maximize their chances of being selected. Patient's scores on subjective indices thus might not accurately reflect their true valuations of treatment.

Given the inherent subjectivity involved and the huge range of variables that contribute to an individual's overall quality of life, it may well be impossible to define a standard that would provide accurate, complete quality of life evaluations. Nevertheless, while change in functional status is at best only a rough approximation of change in quality of life, in some cases the impact of treatment on functional status is so great (or so small) that to ignore this impact would constitute poor stewardship of scarce resources.

In considering quality of life in allocation decisions, the first priority should be to prevent death or an extremely poor outcome, such as a life of permanent unconsciousness or extreme pain and suffering. Thus, when admitting patients to a crowded ICU, a patient who would die or enter a permanent vegetative state if untreated should be favored over another patient who with ICU treatment would suffer a mild disability but would not die. A patient who would die or suffer an extremely poor outcome should generally be given higher priority than others, even if the patient has a pre-existing disability that limits the degree to which their functional status can be improved.

If none of the patients competing for spaces in the ICU face imminent death or an extremely poor functional status outcome, then patients should be prioritized to favor those who will receive the greatest improvement in functional status, measured by the difference between functional status with treatment and functional status without treatment. However, differences in the magnitude of change in functional status among patients are ethically relevant only when they are very substantial.

One implication of this two part approach to quality of life decisions is that, in some circumstances, patients who are closest to death will not receive priority over others who can, if treated, experience a significant improvement in quality of life. This would occur, for instance, when a patient who will die if denied immediate admission to the ICU will have an extremely poor outcome (such as PVS or a life of extreme pain and suffering) even if he or she is treated. Patients who face such extremely poor outcomes even if treated should not be given priority over other patients who will have substantially better outcomes.

This approach to quality of life decisions allows resources to be directed according to where they will do the most good, without discriminating against those with pre-existing disabilities. There may be

occasions where disabled patients receive lower priority because their potential improvement in functional status is limited by their disabilities. However, since only very substantial differences in the change in quality of life may be considered ethically relevant, a disabled patient will be given lower priority only when doing so allows others to receive a much greater improvement in quality of life than the disabled patient would have received. In addition, the provision giving highest priority to those who need treatment to avoid death or an extremely poor outcome protects all patients, including the disabled, from receiving low priority when their need is greatest.

Though change in functional status is an appropriate allocation criterion in certain circumstances, the difficulty in defining quality of life indicates that in most cases it should not be decisive. In fact, a patient expecting an extremely small change in quality of life will often have a very low likelihood of benefit or short duration of benefit as well, and would be given lower priority on the basis of those criteria without having to rely on more questionable qualitative evaluations.

Duration of Benefit

The length of time a patient benefits from treatment can, in certain situations, be an appropriate consideration in allocating scarce medical resources. By giving higher priority to patients who will benefit longer than other patients, organs and other scarce resources can be directed to patients who will benefit the most. For instance, when all else is equal, presumably patients whose renal allografts survive longer derive more benefit from transplantation than other patients, and patients who will survive for many years if treated in the ICU will benefit more than patients who will live only a few days or weeks.

The duration of benefit a patient receives from treatment will in many cases be limited by the patient's life expectancy. For example, a liver transplant patient who receives a highly successful graft may die of other causes long before the liver would have given out. This does not mean, however, that it is always appropriate to give organs or other scarce resources to the patient with the longest expected life span. There is often a lack of certainty in predicting life spans, especially at the individual level, as well as a risk of engaging in inappropriate age based discrimination.³¹

In addition, there may be situations in which giving priority to those who will benefit longer may not actually maximize overall benefit to patients. This concern is similar to the problem facing quality of life judgments: the degree to which a longer duration of benefit actually benefits the patient depends on the patient's subjective experience and values. The value of one more day, month, or year of life (or high quality of life) may vary among patients, making comparisons difficult. For instance, a patient who would live for only a short period of time in an ICU may arguably benefit as much as some longer-lived candidates, especially if that extra time allowed for the accomplishment of a major life goal, or offered the opportunity to say goodbye to loved ones.

However, as with the quality of life criterion, some claims to treatment that will bring only a small benefit to the patient are simply too tenuous to sustain in the face of scarcity. Hence, duration of benefit can be a legitimate consideration, but only when the differences among patients are very substantial. For example, when giving one patient an organ transplant that would fail within a few weeks would deny another patient the chance at a graft lasting many years, the first patient's claim is at least questionable enough to justify preferring the candidate who would receive the longer-lived graft. Though the difference between a few weeks and many years is clearly very substantial, more marginal differences should not be considered ethically relevant. Furthermore, in applying a duration of benefit criterion, patients should be evaluated according to their own medical histories and prognoses, not on aggregate statistics based on membership in a group.

Urgency of Need

Prioritizing patients according to how long they can survive without treatment can often maximize the number of lives saved. For instance, since spaces in an intensive care unit are ordinarily scarce only intermittently, giving priority to urgent cases is generally justifiable because it is likely that patients with less urgent need can still gain timely access to the ICU once the scarcity subsides.¹⁵ Similarly, kidney transplants should be allocated first to urgent cases because patients with less urgent need can be sustained through dialysis until more organs become available.

Depending on the kind of resource involved, however, an urgency of need criterion will not always maximize the number of lives saved.³² With heart or liver transplants, the persistent scarcity of organs entails that some patients on the waiting list will die before an organ becomes available for them. With cases of persistent rather than temporary scarcity, then, application of an urgency of need criterion determines merely *who* will survive, rather than maximizing the *number* of survivors.³²

In addition, patients who are more critically ill are often among the least likely to benefit from treatment. If a patient is set aside in favor of others until his or her condition worsens to the point of dire emergency, treatment may not be as beneficial as it would have been had it been started much earlier.

Thus, though it is often appropriate to give priority to those whose need is the most dire, urgency must be tempered with other considerations, including likelihood of benefit, the persistent or temporary scarcity of the resource involved, and the length of time other patients can survive without causing them irreparable harm. Also, an urgency of need criterion should only be applied to existing patients, not to hypothetical ones. Resources should not be denied to current patients because others with more urgent need may soon present themselves.

Amount of Resources Required

Occasionally, it may be appropriate to treat patients who will need less of a scarce resource rather than patients expected to need more. This would maximize the number of patients who could benefit from a scarce resource because each patient treated would require relatively little of it, thus making it more readily available for others.^{33,34}

Conscious attempts to conserve resources in the allocation process will in general prove unnecessary. For instance, patients who would be favored because they would require very little of a resource will often have a very high (or perhaps very low) likelihood of benefit as well. In such cases likelihood of benefit, not the amount of resources the patient requires, would be the relevant allocation criterion. When all else is equal, however, decisions that reflect the need to conserve scarce resources can be useful in ensuring efficient distribution among patients. For instance, given two patients needing a heart transplant who are equal in all other respects, it is justified to give lower priority to the patient who would also require a liver transplant. When all else is equal, giving the heart to one patient and the liver to a second patient can save two lives, whereas giving one patient both the heart and the liver can save only one life.

When very substantial differences in the amount of resources required do exist, this criterion can maximize the number of lives saved and is an appropriate factor in resource allocation. However, resources should not be conserved by denying existing patients access in the uncertain expectation that additional patients, who may require fewer resources for successful treatment, may soon present themselves. Rather, only when it is reasonably certain that conserving resources will have a good chance of saving more lives should the amount of resources required by a patient be considered relevant.

INAPPROPRIATE CRITERIA FOR RESOURCE ALLOCATION AMONG PATIENTS

The Council believes that the following criteria, though often used in allocating scarce resources, are ethically unacceptable: (1) ability to pay, (2) contribution of the patient to society, (3) perceived obstacles to treatment, (4) contribution of the patient to his or her own medical condition, and (5) past use of resources. Each of these is considered briefly below.

Omission from this list does not necessarily mean that a criterion is justified; the Council considers only these five because of their prevalence in the literature and in allocation decisions today.

Ability To Pay

This is perhaps the most ubiquitous allocation criterion employed today, yet from an ethical standpoint there is little to recommend it.³⁵ In the medical realm, consideration of a patient's ability to pay for treatment is more often considered a regrettable necessity than a positive ethical principle of distribution. If a patient cannot pay the full fee for care, many physicians will waive the fee or accept lesser payment according to the patient's financial resources.³⁶ When ability to pay does play a role in allocating scarce resources, it is usually at the point of access to health care. Physicians generally provide all necessary care to their patients, including fair access to scarce medical resources; however, not all who could benefit from these resources are able to present themselves as patients.

Consideration of a patient's ability to pay is problematic in many areas of health care, but especially when it comes to scarce, lifesaving resources. In other areas, a market-based distribution according to ability (or willingness) to pay may accurately reflect individuals' different valuations of various goods and services. At present, though, the disparity among incomes across society distorts the accuracy of the market model as a fair tool for distributing scarce medical resources, for the amount an individual can spend to gain access to a needed treatment will often fall short of his or her actual valuation of it.

Physicians and institutions should continue to accept patients with limited abilities to pay, and should not systematically deny needed resources to patients simply because of their lower economic status.

Social Worth

A patient's contribution to society-his or her social worth-should not be a factor in allocation decisions. When used, social worth judgments are usually, justified as an attempt to maximize the return on society's investment in medical resources^{32,37} and can take many forms. One of its most prevalent uses is to justify the denial of care to the elderly, who some argue no longer make a positive contribution to the social good.^{7,8,38} The myriad problems of age-based rationing have been discussed at length elsewhere, one of the most serious being that it “fails to take into account the heterogeneity within older age groups” and the “increasing proportion of the elderly population...still in the work force and leading active, productive lives.”³¹

A social worth criterion can also be used to justify discrimination against the young, on the grounds that those who have put the most into society are entitled to get the most back out of it.³⁹⁻⁴¹ This argument prejudices allocation decisions against the young as well as the unemployed, the mentally handicapped, wards of the state, prisoners, and virtually any other group not actively involved in the economic productivity of society. Distinctions can be made among economic contributors as well; for instance, white collar workers with higher salaries may be favored over blue collar workers or the working poor.

Social worth can also be measured by non-economic criteria. Artists, writers, musicians, and other cultural elite may be given priority over average citizens. People with dependents may be given priority over those without families.^{40,42}

Because of the pluralistic values of society, any single definition of social contribution or social worth is inherently suspect. Social worth judgments often reflect the preferences and values of individual decision makers rather than any objective criteria.⁴³ In addition, social worth judgments make unwarranted assumptions about the homogeneity of groups. In assuming that members of a certain group make greater social contributions than other groups, a social worth criterion ignores diversity and the value of each individual.

Above all, a social worth criterion is a marked departure from the traditional patient-centered orientation of the medical profession. By concentrating on maximizing benefits to society, a social worth criterion undermines medicine's focus on the welfare of the individual patient. Social worth considerations would destroy public confidence that physicians ultimately hold their patients' interests, rather than broad social utility, at heart. Medicine should continue to concentrate on the best interests of patients and avoid evaluations of social worth.

Perceived Obstacles to Treatment

This criterion attempts to exclude a wide variety of patients whose circumstances pose special challenges to successful treatment.⁴ These include patients with multiple diseases, alcohol and drug abusers, the indigent, the uneducated, patients with surmountable transportation problems or language barriers, patients with antisocial or aggressive personalities, and others. It is difficult to know for certain the extent to which perceived obstacles to treatment are a factor in allocation decisions. They may cause an unconscious prejudice in the minds of decision makers, who may think their considerations relate only to more objective medical criteria, such as likelihood of benefit. For instance, drug and alcohol abusers may be considered less likely to benefit from treatment because of their dependency, and indigent: patients, uneducated patients, or patients with language barriers may be perceived as bad risks for understanding and complying with a long or arduous course of treatment.

The danger is that some patients will be eliminated from consideration who, with a little extra effort and support, could benefit greatly from treatment. Thus, rather than eliminating drug and alcohol abusers from candidacy for treatment, decision makers should consider whether rehabilitation could be successful in improving the patient's chances of benefit. Similarly, arrangements can be made to help patients with transportation problems, or to provide interpreters for patients with language barriers.

Potential recipients of scarce medical resources should not be *prima facie* excluded because of surmountable difficulties attendant to their cases. Rather, physicians should encourage their patients to use additional resources, such as social workers, private charities, rehabilitation clinics, and other support networks to facilitate their care.

Patient Contribution to Disease

This criterion assigns a lower priority to patients whose past behaviors are believed to have contributed significantly to their present need for scarce resources. Examples include heart transplant candidates whose high fat diets may have contributed to their condition, or liver transplant candidates whose alcoholism led to cirrhosis of the liver.⁴⁴ The reasoning is that patients who failed to take action to prevent their illness are to some extent to blame for their conditions,⁴⁴ and thus have forfeited the right to be given the same priority for treatment as others.

This argument is flawed in several ways. First of all, it is not always clear which factors contribute to a disease, or which are more or less to blame than other contributing factors.⁴⁴ Secondly, of all the possible contributors to disease, only certain behaviors are singled out as justifications for denying treatment. Few would suggest giving lower priority to wealthy heart transplant candidates whose high stress occupations contributed to their heart disease, or denying intensive care to sky-divers or football players injured in the course of their sports. It seems that only certain socially unacceptable or morally suspect behaviors, like immoderate eating or drinking, are considered appropriate criteria for denying treatment. Yet using judgments about patients' morals to allocate health care seems grossly inappropriate and inconsistent; for instance, physicians do not refuse to treat patients who engage in other immoral behaviors, such as adultery or tax evasion.⁴⁵

Another problem with this criterion is its assumption that patients' past contributions to their own illnesses were the result of voluntary actions.⁴⁵ For instance, giving alcoholics lower priority for liver transplants seems to ignore some reasons for drinking, such as family history of alcohol abuse and possible genetic predilections for alcoholism, that are beyond an individual's control.⁴⁶ Some commentators argue that it is the failure to seek treatment, rather than having the problem itself, that is the morally blameworthy action.⁴⁴ However, it seems unjust to punish further those who already have suffered greatly from chemical dependency, especially when many may have simply lacked the education and awareness to know about treatment options or the support networks and financial resources necessary to seek out treatment. It would be fruitless and potentially devastating to try to allocate medical resources based on the perceived moral culpability of patients.

Past Use of Resources

It may be argued that patients who have had considerable access to a scarce medical resource in the past should be given lower priority than equally, needy patients who have received little or none of that resource. This view holds that each patient has an *a priori* equal right to a scarce resource, and therefore equally needy patients should each receive a share of the needed resource. A consequence of this view is that some patients currently using the resource may be displaced by others who have not yet had access. For instance, a patient could be displaced from an ICU by another patient with the same condition and prognosis but less past access, or a re-transplant patient could be denied any chance at all of receiving additional organs. The essential problem with a past use of resources criterion is that it rests on a fundamentally flawed conception of equality among potential recipients of treatment. Equality does not impose an ethical requirement that all patients receive the same amount of care; the only requirement is that patients be judged equally according to their current needs, based on their diagnoses and prognoses. Because past use is irrelevant to present need, it should not factor into allocation decisions.

APPLYING ALLOCATION CRITERIA

The preceding arguments discuss appropriate and inappropriate allocation criteria. The next step in defining an ethical allocation procedure is to examine how these various criteria fit together. The most important requirement is that all candidates for treatment be considered fully when allocating organs and other scarce resources. All patients desiring treatment must be evaluated according to all five of the ethically appropriate criteria defined earlier: likelihood of benefit, urgency, change in quality of life, duration of benefit, and (when applicable) the amount of resources each candidate requires. All of these criteria are appropriate in certain circumstances, but only when disparities between patients are very substantial. Once all the potential recipients have been evaluated, decision makers should allocate resources to maximize the benefit to patients and the number of lives saved.

The Council recognizes that in some cases, the application of these five criteria will not clearly identify which patients are the most appropriate for treatment. For instance, even if the application of these

criteria did identify some patients who clearly should be preferred over others, there might still be a number of patients who could not easily be prioritized according to these criteria. The differences among some patients might not be large enough to be ethically relevant; or, there might be some patients who could be given high priority on the basis of some criteria but low priority on the basis of others. When the application of these five ethical criteria does not clearly identify the most appropriate patients for treatment, some other method must be employed which provides each appropriate candidate with an equal opportunity to receive the needed resources.

Equal opportunity would not be provided if one criterion, such as likelihood of benefit or change in quality of life, were arbitrarily given precedence over the others and allowed to serve as a priority principle. It is impossible and counterproductive to give a precise order of priority to these five ethically acceptable principles; none is intrinsically more important than the others, and different criteria will be decisive in different cases. Nor would equal opportunity be provided if small differences between patients according to these five criteria were given more weight than is appropriate. Allocation decisions should not be fine-tuned by employing allocation criteria beyond the point at which the uncertainties or slight degrees of difference among potential recipients of treatment would make the use of such criteria arbitrary.

Rather than make allocation decisions through the use of priority principles or ever-finer applications of allocation criteria, equal opportunity' should be provided through the use of a first-come-first-served approach. It should be emphasized that first-come-first-served should not be used to abdicate responsibility for making decisions when appropriate criteria can give a sound basis for preferring some patients over others. Rather, if employed only when uncertainty is too great or the differences among candidates too close to call, first-come-first-served respects the equality of individuals who have equally strong claims to a scarce resource, and provides each with an equal opportunity to receive scarce resources.⁴⁷

To ensure that a first-come-first-served approach is truly equitable, all potential recipients of organs or other scarce resources must be able to present themselves as candidates for treatment in a timely fashion. For instance, if patients with insurance are likely to be diagnosed as having end stage organ failure earlier than similar patients without insurance, then a first-come-first-served approach would inappropriately favor insured patients over uninsured. First-come-first-served can be an appropriate equal opportunity mechanism for allocating organs or other scarce resources, but only if there are appropriate safeguards to ensure that differences in patient access diagnostic services are taken into account.

There are a number of ways this general approach, in which only substantial differences are considered relevant, could be implemented. For instance, the five ethical criteria could be used to identify three groups of patients: those who are clearly good candidates for treatment, those who are clearly poor candidates, and those who do not fall in either group.³² Within each group, patients could then be prioritized according to first-come-first-served or some other equal opportunity mechanism. Alternatively, the five criteria could be used to define a minimum threshold for receiving treatment, and all potential recipients exceeding this threshold would be prioritized according to first-come-first-served.¹⁹ One possible drawback to these strategies, however, arises in the attempt to draw lines and define the boundaries of these different groups. When there is a large pool of patients competing for organs, for instance, patients who fall just below the minimum threshold level or just miss entry into the group of clearly good candidates will probably not be substantially different from some other patients : who do make it into those groups. Wherever lines are drawn, the patient falling just above the line will be treated differently from the patient falling just below the line, even though the actual differences between these patients are not substantial enough to be considered ethically relevant.

To avoid drawing lines that may be arbitrary, an alternative approach would be to rank all potential organ recipients according to a weighted formula.³² Each patient would receive a chance at treatment commensurate with his or her prognosis and need, according to the five ethical criteria discussed earlier, but no candidates would be excluded entirely. The person who had the strongest claim to receive a transplant would have the best chance, and the person who had the weakest claim would have the worst chance. This approach is not without its drawbacks as well; for instance, there would inevitably be cases in which a patient would beat the odds and receive an organ before other patients who were clearly much better candidates for treatment.

All of these strategies for implementing the five ethical criteria would be ethically acceptable; however, because each approach has certain disadvantages, the Council does not feel that any single approach is ethically mandated. Whatever implementation approach is employed, it should reflect the values of consistency, flexibility, and fairness. Consistency should be ensured through agreement on which principles are appropriate to consider, and how far they can be applied before turning to an equal opportunity mechanism. Flexibility should be ensured by considering all the relevant circumstances of each case, and the comparative prognoses of the individual patients involved, until no more ethically appropriate distinctions can be made. Ethically valid distinctions are possible only when there are very substantial differences between individuals. Finally, fairness should be ensured through the use of an equal opportunity mechanism to make final allocation decisions among those with equally strong claims to a scarce resource.

APPROPRIATE DECISION MAKERS

The question of who makes allocation decisions is as important as the particular method decision-makers use. The choices involved in allocation decisions have life and death implications, and great care must be taken to prevent abuse of the power to make those choices. Full consideration of which decision-making mechanisms are best able to implement the ethical criteria described in this report is crucial. For the purposes of the present discussion, the Council will discuss only the ethical considerations that any decision-making mechanism should take into account.

The first component of any ethical decision-making process for allocating scarce resources is physician involvement. Physicians have an irreplaceable role in making diagnoses, prognoses, calculating probabilities, exploring patients' goals and values, and advocating on behalf of their patients. However, in cases in which patients compete for a scarce resource, the physicians of the patients involved are generally not in the best position to make an impartial decision. Physicians, out of loyalty to their own patients, might feel pressured to choose their own patients over others, and any choice involving two or more of a physician's own patients would constitute a serious conflict of interest. The physician's role as patient advocate would be jeopardized, and trust between physicians and patients would be undercut. Asking physicians to be primarily responsible for the distribution of society's scarce medical resources is in effect asking them to serve two conflicting masters, both their own patients and larger society.⁴⁸ Though individual physicians may have to decide which patients receive needed immediate care in some emergency triage situations, in general physicians should not be forced to make the decision to deny potentially beneficial care to their own patients.

In establishing mechanisms for making allocation decisions, at least three criteria should be taken into account: objectivity, flexibility, and consistency. Objectivity refers to the need for decision-makers not to be personally involved with patients competing for a scarce resource. Flexibility requires decision-makers to weigh carefully all the relevant facts of a case, and not reflexively to apply a blanket rule, such as an age cap, to all cases. Consistency requires decision-makers to consider the same (appropriate) criteria, interpreted in the same way, in order to ensure that all decisions are fair to the patients involved. Decision-making mechanisms for allocating scarce resources fall along a

continuum, ranging from highly centralized systems to more decentralized ones. These approaches vary in their ability to fulfill the criteria of objectivity, flexibility, and consistency. Centralized mechanisms such as the organ allocation formulas employed by the United Network for Organ Sharing⁴⁹ would probably generate the most consistent decisions. A problem With using centralized formulas, however, is their lack of flexibility. The particulars of individual cases may sometimes slip through the cracks in the formula.

A second problem with allocation formulas is that they may gloss over uncertainty in the assignment of discrete numbers. Quantitative values may be more comfortable to work with, but they still can only reflect our best guess as to which factors are more significant, and to what degree. In addition, assigning different numbers of points to various factors necessarily makes some factors more important than others. Thus, ethical decisions about the relative importance of various factors in allocation decisions can be disguised behind seemingly objective point values. Too often "numericalization and mathematicalization add a patina of 'objectivity' to any policy debate" that actually only "obscures the underlying assumptions of the users."²⁴ Because of the inevitable uncertainty involved and the need to make ethical decisions transparent, all allocation formulas should be periodically reassessed to ensure that they reflect the most current scientific and ethical consensus on allocation issues.

A more decentralized decision making process would not overcome the inevitable uncertainties involved in allocation decisions, and would probably be more difficult to apply consistently across institutional lines. However, a decentralized approach would probably have a greater ability to respond to the particular circumstances of the multitude of different cases faced by physicians. In addition, decentralized decision making on the hospital or institutional level would not necessarily result in unjust or arbitrary decisions. A more expansive understanding of the ethical issues involved in resource allocation decisions can go far in encouraging reasoned, fair, and consistent choices based on careful evaluation of appropriate criteria.

Again, the Council at this time does not advocate either centralized or decentralized approaches; further discussion of these issues will be necessary in the future.

PATIENT INFORMATION IN ALLOCATION DECISIONS

Physicians should explain the allocation criteria and procedure to their patients or designated proxies so that they understand their chances of receiving treatment and the method by which the decision is made. This information is in addition to all the customary information regarding the risks, benefits, and alternatives to any medical procedure. In addition, patients denied access to resources should be informed by their physicians of the rationale behind such decisions.

FUTURE DIRECTIONS

Resource allocation decisions involving scarce medical resources, because of their frequent life and death implications, are among the most difficult to make. The current lack of consensus on how such decisions should be approached reflects in part deep disagreement over appropriate allocation criteria, and in part a general unwillingness to face the problem of scarcity directly. More informed, public discussion of scarcity and allocation decisions will help ensure that access to scarce resources is provided equitably, and that no group or groups are unjustly excluded. The reality of scarce resources must be confronted not only by those who must make allocation decisions, but by all of society, which must live with the consequences of those decisions. Justice in the allocation of scarce resources will never be achieved until the limitations on care imposed by scarcity are accepted by all, without attempts to go outside of the allocative decision making process or manipulate it to one's own advantage.

Principles II and V and of the AMA's Principles of Medical Ethics discuss the obligations of physicians to "deal honestly with patients and colleagues"⁵¹ and "make relevant information available to patients, colleagues, and the public."⁵² Accordingly, physicians, hospitals, and other institutions controlling scarce medical resources should encourage public discussion of allocation issues. These procedures should also be subject to peer review and public auditing on a regular basis. Not only will such discussions direct public attention to the problem of scarce medical resources, but it may also encourage a broader consensus on how scarce resources should be distributed.

RECOMMENDATIONS

For the reasons described in this report, the Council on Ethical and Judicial Affairs recommends that the following guidelines be adopted and that the remainder of the report be filed:

1. Decisions regarding the allocation of scarce medical resources among patients should consider only ethically appropriate criteria relating to medical need.
 - a) These criteria include likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in some cases, the amount of resources required for successful treatment. In general, only very substantial differences among patients are ethically relevant; the greater the disparities, the more justified the use of these criteria becomes. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients.
 - b) Research should be pursued to increase knowledge of outcomes and thereby improve the accuracy of these criteria.
 - c) Non-medical criteria, such as ability to pay, social worth, perceived obstacles to treatment, patient contribution to illness, or past use of resources should not be considered.
2. Allocation decisions should respect the individuality of patients and the particulars of individual cases as much as possible.
 - a) All candidates for treatment must be fully considered according to ethically appropriate criteria relating to medical need, as defined in Recommendation 1.
 - b) When very substantial differences do not exist among potential recipients of treatment on the basis of these criteria, a first-come-first-served approach or some other equal opportunity mechanism should be employed to make final allocation decisions.
 - c) Though there are several ethically acceptable strategies for implementing these criteria, no single strategy is ethically mandated. Acceptable approaches include a three-tiered system, a minimal threshold approach, and a weighted formula.
3. Decision Making mechanisms should be objective, flexible, and consistent to ensure that all patients are treated equally. The nature of the physician - patient relationship entails that physicians of patients competing for a scarce resource must remain advocates for their patients, and therefore should not make the actual allocation decisions.
4. Patients must be informed by their physicians of allocation criteria and procedures, as well as their chances of receiving access to scarce resources. This information should be in addition to all the customary information regarding the risks, benefits, and alternatives to any medical procedure. Patients denied access to resources have the right to be informed of the reasoning behind the decision.

5. The allocation procedures of institutions controlling scarce resources should be disclosed to the public as well as subject to regular peer review from the medical profession.
6. Physicians should continue to look for innovative ways to increase the availability of and access to scarce medical resources so that, as much as possible, beneficial treatments can be provided to all who need them.

Appendix A: Ethical Issues in the Allocation of Intensive Care

In this appendix, the Council explores ethical dilemmas involved in the allocation of intensive care when spaces in the ICU are limited. Many hospitals experience periods during which their intensive care units are full to capacity and new patients requiring intensive care are admitted to the hospital.³ Even when the ICU is not full, occasionally the number of available beds or medical personnel is insufficient to handle an influx of new patients.

When the ICU becomes full to capacity, new emergency admissions who require intensive care can usually be transported to nearby hospitals whose ICU wards are less crowded. In some circumstances, however, transferring patients to other hospitals is impractical. For instance, especially in areas with high rates of violent crime, all the local hospitals can experience a bed shortage at the same time, making transfers impossible. Moreover, many areas are served by only one hospital, often with smaller intensive care units and fewer physicians and nurses to staff them than can be found in urban centers.

Most often, scarcity in the ICU setting is short-lived; spaces open up when patients stabilize and can be safely moved to other areas of the hospital, or when patients die despite physicians' efforts. However, the intermittent scarcity of space in the ICU is a serious ethical problem faced by many triage physicians.

Admission and Dismissal from the ICU in Periods of Scarcity

While triage physicians do not all allocate spaces the same way, studies have identified two common strategies employed to deal with a scarcity of ICU beds. One approach is to restrict admission to patients with more severe illnesses.⁵³⁻⁵⁵ Some patients who might have been admitted to the ICU under normal circumstances often are not admitted when beds are scarce, in order to make room for patients whose conditions are more serious. The second strategy to cope with a bed shortage is the earlier dismissal of patient whose conditions are stable enough to warrant a move out of the ICU. Studies have documented shorter stays for some patients,⁵³⁻⁵⁵ such as those requiring monitoring only, than they would have received under normal conditions.

These strategies are often successful - neither stricter admission criteria nor more liberal dismissal practices have resulted in any measurable increase in mortality rates among patients admitted to the ICU among those denied admission.^{53,55} One reason for the success of these strategies is the progress in outcomes research in intensive care, which increases physicians' accuracy in making diagnoses and outcome predictions. The Acute Physiology and Chronic Health Evaluation (APACHE) System, which measures patients' severity of illness through physiologic measurements and laboratory tests obtained early in a patient's ICU stay, has proven to be an accurate predictor of patient death rates, especially for low-risk patients.⁵⁶⁻⁵⁸ The APACHE system has also been shown to be an accurate predictor of patient mortality rates and length of ICU stay when applied to individual patients at the point of admission to the ICU.⁵⁸ As a tool for outcomes research and as an aid for making individual patient decisions, APACHE has proven its usefulness in helping physicians allocate spaces in the ICU.

Severity of Illness and Likelihood of Benefit

The strategies outlined above-giving higher priority to patients with more severe illnesses and lower priority to patients who can likely survive outside the ICU - reflect considerations of both medical urgency and patients' likelihood of benefiting from treatment. However, in many cases the use of these two criteria alone may not result in the most effective use of resources; triage physicians should give each potential recipient of intensive care full consideration according to all ethically relevant criteria based on medical need, including not only urgency (or severity of illness) and likelihood of benefit, but also improvement in quality of life, duration of benefit, and in some cases the amount of resources required for successful treatment.

In the ICU, the relation between a patient's severity of illness and likelihood of benefit can be complicated. For example, patients who can likely recover outside of the ICU are not only less severely ill (because they are not as close to death as others), but they are also less likely to benefit from admission to the ICU (because they would probably do just as well on another floor or in a step down unit). Hence, such patients may be given lower priority than others. In contrast, patients with more severe illnesses vary in how likely they are to respond to treatment. Often, the most severely ill patients will die regardless of whether they receive intensive care. Such patients may be given higher priority on the basis of their severity of illness, but lower priority on the basis of their low likelihood of benefiting from treatment. In general, in considering severity of illness and likelihood of benefit, triage physicians should strive to ensure that the number of lives saved by the limited resource is maximized. Thus, while patients who are closer to death should be given higher priority when other patients are "too well " to benefit from the ICU; ⁵⁹ distinctions based on medical urgency or severity of illness cannot be made among patients when all are likely to be seriously harmed if denied immediate intensive care. Distinctions may be made among equally urgent cases on the basis of likelihood of benefit, improvement in quality of life, duration of benefit, or the amount of resources each patient requires for successful treatment, but only when very substantial differences among patients exist.

Responsiveness to Treatment

In many cases, a patient's prognosis will become more evident once treatment is initiated and the physician can evaluate the patient's response to therapy. Giving patients time to respond to therapy and reevaluating progress, when practical, can help ensure that scarce resources are allocated effectively. In times of scarcity, however, it may be impossible to test the responsiveness of each patient to treatment. This in turn creates a dilemma: given the inability to predict how well patients will respond to treatment without first initiating it, and the inability in times of scarcity to initiate treatment with each patient who could possibly benefit, how does the triage physician decide which patients are given the opportunity to respond to treatment and which are not?

When faced with such a dilemma, the triage physician must make a choice as to which patients should be admitted, while realizing that the crucial information necessary to make the very best choices - the responsiveness of the patients to treatment - is not yet available. In such circumstances, if the prognostic uncertainties are so great that ethically relevant distinctions cannot be made among patients, then patients should be admitted in the order in which they presented themselves.

When there are more patients who need intensive care than there are spaces available, it would be a poor use of scarce resources to keep patients in the ICU who do not respond to treatment, or who respond only poorly. Thus, the allocation of intensive care must be an ongoing process; patients' responsiveness to treatment should be regularly reevaluated so that the most appropriate candidates can be ensured access according to the five criteria discussed in this report: likelihood of benefit, severity of illness (i.e., urgency of need), improvement in quality of life, duration of benefit, and the amount of resources required.

Conclusions - Allocation of Intensive Care

In the intensive care setting, allocation decisions usually arise when beds or medical staff are in short supply, and patients cannot be referred to other intensive care facilities for treatment. In such situations, patients are often prioritized according to their severity of illness and their comparative chances of benefiting from treatment. Triage physicians should consider more than just these two factors, however, for reliance on one or two criteria alone may not succeed in maximizing benefit to patients. Thus, the Council encourages triage physicians to consider the following in allocating intensive care:

- 1) During times of scarcity, triage physicians should give each potential recipient of intensive care full consideration according to all ethically relevant criteria, including urgency of need (i.e., severity of illness), likelihood of benefit, change in quality of life, duration of benefit, and in some cases the amount of resources required for successful treatment. All of these criteria can be relevant in different cases, but only when the differences among patients are very substantial. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients.
- 2) When no relevant ethical distinctions can be made among patients (and none faces death or an extremely poor outcome), priority should be given according to the order in which patients presented themselves to the ICU.
- 3) In many cases, testing a patient's responsiveness to treatment can be useful in allocating intensive care, for it enables the physician to confirm or refine a patient's prognosis.
- 4) Allocation of intensive care during times of scarcity must be an ongoing process; patients' responsiveness to treatment should be regularly reevaluated, so that the most appropriate patients can be ensured access.

Appendix B: Ethical Issues in Organ Allocation

In this appendix, the Council explores ethical dilemmas in allocating organs for transplantation.

The Current Organ Allocation System

Since 1987, the United Network for Organ Sharing (UNOS) has served as the Organ Procurement and Transplantation Network (OPTN) for the U.S. Department of Health and Human Services, as provided by the National Organ Transplantation Act of 1984.⁶⁰ UNOS performs many invaluable functions, such as the establishment of membership criteria for transplant centers and regional organ procurement organizations (OPOs), the maintenance of a national waiting list of potential transplant recipients, and the coordination of hospitals and OPOs in transporting donated organs to appropriate recipients.

UNOS also establishes the criteria by which donated organs are allocated among potential recipients. Though the allocation criteria differ according to the particular organ involved, UNOS relies on medical criteria such as likelihood of a successful graft, size of the organ, and medical urgency. The medical criteria employed by UNOS necessarily involve ethical judgments. While successful transplantation is the goal, defining success and identifying the pool of potential recipients are ethical decisions. Moreover, as noted in the main body of this report, assigning different numbers of points to various factors necessarily involves ethical judgements about how important a role these various factors should play in allocation decisions.

In order to focus the discussion, this appendix concentrates mainly on the allocation of kidneys. Kidney transplantation is the oldest and one of the most successful transplant procedures, with a generous body of data on graft survival, contraindications, and the demographics of transplant recipients.

The UNOS Kidney Allocation Formula

To minimize the risk of graft rejection, UNOS considers only candidates whose ABO blood type is compatible with the blood type of the particular kidney available.

Within the appropriate blood type, the UNOS formula assigns points to potential recipients according to five criteria: quality of human leukocyte antigen (HLA) matching (maximum 10 points, depending on the particular antigens matched); the level of panel reactive antibodies (either 0 or 4 points); age (1-2 points for children under the age of 11); time on the waiting list; and in certain circumstances medical urgency.⁶¹ In calculating waiting time, UNOS gives one point to the patient waiting the longest and assigns fractions of points to all other patients proportionate to their relative time waiting. In addition, each patient receives 0.5 points for each full year of waiting time.

The Importance of Blood Typing and HLA Matching

Two of the criteria in the UNOS kidney allocation process relate directly to a potential recipient's likelihood of benefiting from a given organ: blood type compatibility and HLA matching. Both of these factors influence the probability that the patient will receive a successful graft. Among patients with a blood type compatible with the blood type of the donor, those with more complete antigen matches generally have a smaller chance of rejecting the new organ.

As likelihood of benefit criteria, both HLA matching and blood type compatibility are important, ethically appropriate considerations. Moreover, the precision with which tissue can be matched, and the apparently higher likelihood of benefit among HLA-matched recipients compared to mismatched ones, have led some to argue that within a given blood group antigen matching could "serve as the sole basis for kidney allocation."⁶²

Since blood type incompatibility almost ensures graft failure, blood type compatibility is an appropriate factor in determining a patient's likelihood of benefiting from a particular organ. However, the usefulness of HLA matching may actually be over exaggerated in the organ allocation process. In one recent study of 100 kidney transplant recipients, patients having only one or two HLA antigen matches did nearly as well as patients having three to six matches.⁶³ In this study, the five-year graft survival rate in patients with three to six HLA matches was around 72%, as compared to 60% for patients with one or two matches. The chances of graft survival fell significantly (to about 24%) only when there were no HLA matches at all. Another analysis of 464 transplant recipients found no significant influence of HLA mismatching on three - year graft survival rates, which ranged from 69% to 94%.⁶⁴ Other studies have shown that while HLA matching does make some difference in graft survival rates, this difference does not exceed 10-20%, depending on the number of mismatches. For instance, an examination of data from the worldwide Collaborative Transplant Study concluded that at five years, the survival rate difference between grafts with zero or six mismatches is 20%;⁶⁵ another study used Scandiatransplant data and concluded that perfectly matched kidneys had a survival advantage of only 10-20% over the graft survival rates of mismatched grafts.⁶⁶

Drawing distinctions among candidates for treatment based on likelihood of benefit is appropriate only when the differences between patients are very substantial. Therefore, based on the findings of these studies, one or two HLA matches should be given approximately equal weight as three to six matches because the differences in likelihood of benefit range only from 10-20%. In the UNOS formula, however,

one to two matches gets a maximum of one point, whereas three to six matches gets anywhere from one to ten points depending on which antigens are matched.⁶⁷ By preferring patients whose HLA matches only slightly increase their chances of benefit, the UNOS formula may inappropriately fine tune allocation decisions and leave out many eligible candidates.

HLA matching is also linked to recipients' duration of benefit. Though a "successful" graft has no single interpretation, it is commonly defined in terms of the length of graft survival. Generally, the better the HLA match, the longer the graft is likely to survive and the longer the patient benefits from the transplant. Whether a graft that survives for some length of time counts as a "success" depends in part on what it is compared to. For example, a graft that survives twenty years seems significantly more successful than one that is rejected in only a few weeks or months, but perhaps not much more successful than a graft that survives fifteen years.

Given the different possible definitions of "success" in organ transplantation, it is questionable whether, again, the importance of HLA matching is overrated. One study in 1990 determined the one year survival rate among all kidney recipients to be 78%;⁶⁸ another reported that, except for recipients with no HLA matches at all, graft survival rates were above 60% after five years.⁶³ Thus, most recipients could expect their grafts to survive at least one to five years, even when their HLA matching was not optimal. Judging from this evidence, the UNOS formula arguably may make too fine a distinction among patients by preferring more long - lived grafts even when the differences in duration of benefit may not be that great.

There is as yet no consensus on the importance of HLA matching in ensuring a successful graft, and more studies in this area are needed. Since the actual medical significance of HLA matching is uncertain, the Council feels that one patient's *marginally* higher chance of a successful graft may not be a sufficient reason to give him or her the kidney over another. Until it is conclusively shown that heavy reliance on HLA matching can be justified, it may be preferable to give an equal number of points to patients who have one or more HLA matches with a particular kidney.

Change in Quality of Life

As stated in the main body of this report, improvement in quality of life may be an appropriate allocation factor when the differences among patients in the magnitude of change are very substantial. UNOS policy, however, does not mention improvement in quality of life as a criterion in selecting organ recipients.

In most cases, transplant candidates who would enjoy very little improvement in quality of life even with a new organ also have a very low likelihood of benefit, and so the issue of quality of life does not often come to the fore. UNOS's silence on quality of life issues may also reflect the fact that patients facing an extremely low improvement in quality of life often never make it onto waiting lists at all, even if their lives could be extended by transplantation. However, if distinctions are being made among candidates on the basis of quality of life, such distinctions should be subject to public scrutiny. It would be preferable to adopt an open policy that considers quality of life, for this would help ensure that scarce resources would be directed to patients who would derive the most benefit from treatment. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients.

Urgency of Need

The UNOS kidney formula takes the urgency of a patient's condition into account only in certain limited situations:

No points will be assigned to patients based upon medical urgency for regional or national allocation of kidneys. Locally, the patient's physician has the authority to use medical judgment in the assignment of medical urgency points if there is only one renal transplant center. When there is more than one local renal transplant center, a cooperative medical decision is required prior to assignment of medical urgency points.⁶⁹

UNOS downplays urgency as an allocation criteria for kidneys apparently because of the widespread availability of dialysis as an alternative treatment. Because in most cases potential kidney recipients can be sustained on dialysis, the possibility of imminent death unless a kidney is transplanted immediately is relatively uncommon. Exceptions could occur, of course, such as when a patient cannot undergo dialysis because all the possible shunt sites have been exhausted. Such patients should be given priority on the basis of their own urgent need and the lack of urgency among other candidates.

There is another aspect of the UNOS kidney formula which suggests an urgency of need criterion. Patients with high level panel reactive antibodies (over 80%) are given an additional four points¹⁰ because of the relatively low likelihood (compared to other transplant candidates) that organs suitable for these highly sensitized patients will become available. Highly sensitized patients are more likely than other patients to die before a suitable organ is found, in effect making their conditions more urgent. Hence, UNOS gives these patients special consideration when a suitable organ does become available, even if another, less sensitized patient has a better HLA match with the organ.⁷¹

Such special consideration is justified in light of the ability of most other kidney transplant candidates to be sustained on dialysis until another organ becomes available. A similar policy for other organs, for which an alternative treatment similar to dialysis does not exist, would be much more problematic, for then the preferential treatment would result in the deaths of other equally suited patients without giving them equal consideration.

With organs such as hearts and livers, for which transplantation is the only solution for organ failure, UNOS explicitly bases allocation on medical urgency. In liver allocation, for instance, UNOS identifies four categories of active waiting list patients, each representing a different level of urgency.⁷² Status 1 patients are "at home and functioning normally;" Status 2 patients require "continuous medical care;" Status 3 patients are "continually hospitalized;" and Status 4 patients are in an intensive care unit with a life expectancy without a liver transplant of "less than 7 days." Livers are offered first to Status 4 patients, according to patients' point totals, and then to patients having Status 1,2, or 3, also in descending point sequence.⁷ In preferring Status 4 patients first, the liver allocation scheme places significant emphasis on medical urgency.

However, when alternative methods for sustaining patients are not available, it may not always be appropriate to give priority to patients, such as Status 4 patients, who face imminent death. There is often a strong connection between urgency of need and poor likelihood of benefit, and it may not be wise to allocate organs to patients facing imminent death if they also have a poor chance of surviving even with an organ transplant. UNOS does consider likelihood of benefit in allocating livers by assigning points within each Status group on the basis of blood type⁷⁴ and donor size;⁷⁵ however, since these are not considered until after a person becomes eligible because of their Status group, the UNOS process may rely too heavily on urgency of need in prioritizing recipients of these organs. Preferring Status 4 patients may not always maximize the number of survivors.

Unlike kidney transplant candidates, with liver transplant candidates it is more likely that less urgent patients will be harmed if they are passed over, for they may be in much worse condition (or even dead) before another suitable organ finally becomes available. Thus, for livers and other organs for which

transplantation is the only solution to organ failure, it may be preferable to give fewer points on the basis of urgency and more on the basis of likelihood of benefit, duration of benefit, and change in quality of life.

Past Use of Resources - Retransplant Patients

One widely debated issue in organ transplantation is the status of transplant recipients who, because of a failed graft, require another transplant. Though some would argue that allowing re-transplant patients access to additional organs is unfair to patients needing transplants who have yet to receive even one, the Council rejects this view. As stated previously, scarce medical resources should be distributed according to medical need; because past use of resources is irrelevant to present need, it should not factor into allocation decisions. Though transplant recipients who are put back on the waiting list may not retain the waiting time they had accrued before their first transplant, justice does not demand that they be denied a future chance at receiving another organ.

UNOS policy in this area shares the Council's view and states that "all patients who are potential recipients of cadaveric organ transplants must be listed on the UNOS computer Waiting List,"⁷⁶ including patients who in the past have already received an organ transplant.

Amount of Resources Required-Patients Needing More than One Organ

The mandatory listing of all potential organ recipients on the UNOS waiting list also applies to patients suffering multiple organ failure. It is crucial that all patients who can benefit from transplantation be given full consideration in allocating organs; for instance, a multiple transplant patient who has a very high likelihood of benefit and expected improvement in quality of life compared to others may be the most appropriate patient to receive both a new heart and a new kidney. However, among patients who have an equally strong need for *lifesaving* organs (thus, excluding kidneys), the scarcity of organs may make it necessary to give lower priority to patients needing multiple organ transplants.

Scarce, lifesaving resources should be used to maximize the number of survivors. To accomplish this, it may occasionally be appropriate to give higher priority to patients who will need less of a scarce resource over those expected to need more. When potential transplant recipients cannot be distinguished on the basis of medical need or suitability, transplanting multiple organs into one patient may save one life, while transplanting those same organs into multiple patients could save many lives. In such situations, saving many lives must be preferred to saving one.

In most cases this is a moot issue because patients needing multiple transplants usually face a lower likelihood of benefit than other equally suitable organ recipients. Even if this were not the case, however, organs should be used to benefit the greatest number of patients possible.

Waiting Time

The UNOS Ethics Council has stated that, other things being equal, preferring patients who have been waiting the longest is a requirement of justice: "the fair or just thing to do in allocating among medically similar patients is to give the organ to the one waiting the longest."⁷¹ When differences among candidates based on medical need are not very substantial, these differences are not ethically relevant. In such cases, waiting time is an appropriate equal opportunity mechanism for making final allocation decisions.

The problem with waiting time as a factor in allocation decisions is how to measure it. Measuring waiting time from the moment one is placed on the waiting list may not always be an accurate reflection of how long a patient has actually needed a transplant. Physicians vary in how quickly they put patients

on transplant waiting lists, especially kidney patients who can be treated with dialysis. In addition, patients without insurance or ready access to medical care may often be diagnosed as needing a transplant much later than comparable patients who have had a strong and ongoing patient - physician relationship. There may be no perfect method for determining waiting time, but a more objective method may be to calculate waiting time from the time a patient becomes an appropriate candidate for organ transplantation, rather than from the time the patient is actually placed on the waiting list. In addition, physicians should strive to place patients on the waiting list as quickly as possible.

UNOS varies the number of points awarded for time on the waiting list according to the type of organ in question. For instance, whereas kidney transplant candidates can receive a maximum of one point for waiting time, plus 0.5 points for each year of waiting time accrued,⁷⁷ liver transplant candidates can receive up to ten points.⁷⁸ The reason for the difference between these two policies is not made clear. Presumably the reason is that, for kidneys, "great differences in expected medical benefit ... offset consideration of differences in waiting time,"⁷¹ while for livers this is not the case. That is, the ability to match patients with kidneys - due to HLA matching, PRA levels, blood type, and other factors - is relatively well developed, and UNOS feels that the detected differences in medical suitability among patients are great enough that ethically appropriate distinctions among patients can usually be made. Though it is true that medically relevant factors should be fully explored before turning to random selection, the Council feels that occasionally these differences in medical suitability are in fact not great enough to be ethically relevant. When the differences in medical suitability among candidates are not very substantial, the Council favors the use of a first-come-first-served or other equal opportunity mechanism to make final allocation decisions.

Geographical Priorities in Allocating Organs

One area of UNOS policy that has drawn criticism is its establishment of geographical priorities in the allocation of organs. In allocating organs, organ procurement organizations are generally required by UNOS to consider first patients on the local waiting list. If no suitable recipient is available at the local level, the OPO turns to the regional and then national waiting lists until one is found.⁷⁹ There are two plausible reasons for this policy. First, it is more practical to allocate an organ locally if the time involved in transporting it elsewhere would threaten its viability for transplantation. Second, it is believed that giving priority in allocation to local residents will boost the overall organ donation rate.⁸⁰ People would be more likely to donate knowing that their organs would probably go to patients from their own community.

Neither of these arguments is totally convincing. In some cases long - distance transportation of an organ is impractical. However, organs are being preserved for increasingly longer periods of time, especially kidneys, with few or no adverse effects. One study of 495 transplant recipients found that kidneys could be preserved up to 48 hours with no adverse effects on patients' one-year and five-year graft survival rates.⁸¹ UNOS in fact requires that certain organs be allocated on the national level first, such as a kidney which has a six-antigen, perfect match with a patient.⁸² If these organs can be transported literally from coast to coast, it seems likely that others could 'also be allocated over a broader geographical range without harm. In examining the possibility of allocating kidneys and other organs on the basis of a single national list, UNOS has concluded that such a system would be practically infeasible due to the time and expense that would be involved in cross - matching donor organs with a national pool of potential recipients.⁸³ If these barriers to the creation of a single, national waiting list cannot be overcome, it may still be feasible to allocate over a broader geographical range than the local area.

In addition, the current policy preferring local allocation goes against the predominant ethic that donated organs should be considered a national resource. The federal Task Force on Organ Transplantation recommended that "donated organs be considered a national resource to be used for the public good."⁸⁰

In addition, American Medical Association policy states that "organs and tissues retrieved for transplantation should be treated as a national, rather than a regional, resource and...(the AMA) opposes any legislation, regulations, protocols, or policies directing or allowing governmental agencies to favor residents of a particular geo - political jurisdiction as recipients of transplantable organs or tissues."⁸⁴ A local bias in allocating donated organs bases allocation decisions on the accident of residence rather than ethically appropriate criteria, and discriminates against patients not living in densely populated areas. Thus, unless it can be shown that a policy preferring local allocation substantially increases the willingness of the population to donate organs, geographical priorities in organ allocation should be allowed only when transportation of the organs would threaten their suitability for transplantation.

Multiple Listings

The Council opposes multiple listings and instead favors the establishment of a single waiting list for each type of organ. UNOS policy states that patients may be listed on the waiting lists of multiple local transplant centers.⁸⁵ Since organs are allocated first locally and then regionally, patients on multiple waiting lists have a greater chance of receiving organs. The problem with multiple listings is the unequal ability of potential organ recipients to take advantage of them. Patients with better information, more initiative, and more resources (for example, better access to transportation), are more likely to know about and be able to take advantage of multiple listings than the poor or uneducated. Though permitting multiple listings may enhance the autonomy of patients who are in a position to benefit from them, it does so only at the expense of equally suitable candidates who cannot take advantage.

Conclusions-Organ Allocation

The current method of organ allocation, governed by the United Network for Organ Sharing, is based on sound ethical principles such as likelihood of benefit, duration of benefit, urgency of need, and the use of waiting time to make final allocation decisions when there are no very substantial differences among patients. In its heavy reliance on human leukocyte antigen (HLA) matching to allocate kidneys, however, UNOS attempts to base allocation differences on medical criteria even when there may exist no ethically relevant distinctions to be made among candidates on that basis. The Council prefers an approach in which, when differences among candidates are not very substantial, no ethically relevant1 distinctions are considered to exist. Then, final allocation decisions can be made according to patients' seniority on the waiting list or other equal opportunity mechanism. Since there is presently no consensus on the importance of HLA matching in ensuring a successful graft, more studies in this area are needed to show if UNOS's heavy reliance on this criterion is justified.

In addition, the Council encourages the following changes to UNOS policies and allocation formulas:

- 1) Quality of life issues should be addressed. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients;
- 2) Less emphasis should be placed on medical urgency in allocating organs for which transplantation is the only effective therapy for organ failure;
- 3) The amount of resources required for successful treatment should be considered when evaluating patients needing multiple lifesaving organ transplants;

- 4) Waiting time should be calculated from the time the patient becomes an appropriate candidate for organ transplantation, rather than from the time the patient is actually placed on the waiting list, and physicians should place patients on the waiting list as quickly as possible.
- 5) Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation;
- 6) Patients should not be placed on the waiting lists of multiple local transplant centers, but rather on a single waiting list for each type of organ.

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REPORTS OF STANDING COMMITTEES OF THE HOUSE OF DELEGATES

JUDICIAL COUNCIL

Report A, "Nominations for Affiliate Membership in the American Medical Association," appears on page 200. The following Report B of the Judicial Council was presented by Elmer G. Shelley, M. D., Chairman:

B. ETHICAL GUIDELINES FOR ORGAN TRANSPLANTATION (Reference Committee E, page 242)

HOUSE ACTION: APPROVED

"It should be apparent that no stigma is attached to the performance of human experiments per se; disgrace and infamy can arise only through its misuse. The moral obligation of performing all human experiments, with due regard to the sensibility, welfare, and safety of the subject, must not be violated. As phrased by Claude Bernard in 1856, 'Christian morals forbid only one thing, doing ill to one's neighbor.' So, among experiments that may be tried on man, those that can only do harm are forbidden, those that are harmless are permissible, and those that may do good are obligatory."

S. S. Kety

The medical profession, in its never-ending search for ways to save human life, relieve suffering and improve health, has always been motivated and guided by the principles expressed in the above quotation. To achieve these goals, it has recognized that proper standards must be established and followed in clinical investigation and experimentation involving human beings.

In 1946, the American Medical Association succinctly listed three ethical guidelines to be followed in human experimentation in order to conform to medical ethics: (1) voluntary consent must be obtained from the person on whom the experiment is to be performed; (2) the dangers of each experiment must have been previously investigated by animal experimentation; and (3) the experiment must be performed under proper medical protection and management.

In 1964, the World Medical Association adopted the Declaration of Helsinki, which was later endorsed by the American Medical Association. The Declaration emphasizes "freely given consent" and differentiates between clinical research combined with professional care and nontherapeutic clinical research.

In 1966, the American Medical Association adopted a longer statement -- "Ethical Guidelines for Clinical Investigation." In part, these guidelines state:

(Judicial Council)

"In clinical investigation primarily for treatment --

- "A. The physician must recognize that the physician-patient relationship exists and that he is expected to exercise his professional judgment and skill in the best interest of the patient.
- "B. Voluntary consent must be obtained from the patient, or from his legally authorized representative if the patient lacks the capacity to consent, following: Disclosure that the physician intends to use an investigational drug or experimental procedure; a reasonable explanation of the nature of the drug or procedure to be used, risks to be expected, and possible therapeutic benefits; an offer to answer any inquiries concerning the drug or procedure; and, a disclosure of alternative drugs or procedures that may be available."

The Principles of Medical Ethics and these several statements have provided broad guidelines during the period when transplants of major body organs were first performed. In the opinion of the Judicial Council, these principles continue to be valid.

Now, theologians, lawyers and other public spirited persons, as well as physicians, are discussing with deep concern the many new questions raised by the transplantation of vital organs. Man participates in these procedures: he is the patient in them; or he performs them. All mankind is the ultimate beneficiary of them.

A man, in the final analysis, must make a decision whether to permit or to perform a transplantation procedure. The decision must be a reasoned, intellectual decision, not an emotional decision. As medical science advances, and as technological skill increases, the ethical questions involved may become increasingly complex and difficult.

The Judicial Council, therefore, commends discussions of the moral, ethical, legal, social, and other aspects of clinical investigation, experimentation, and organ transplantation in human beings. It commends all efforts which encourage respect for the dignity of man, and which seek to sensitize man's ethical conscience.

The Judicial Council of the AMA offers the following statement for guidance of physicians as they seek to maintain the highest level of ethical conduct in their practice.

1. In all professional relationships between a physician and his patient, the physician's primary concern must be the health of his patient. He owes the patient his primary allegiance. This concern and allegiance must be preserved in all medical procedures, including those which involve the transplantation of an organ from one person to another where both donor and recipient are patients. Care must, therefore, be taken to protect the rights of both the donor and the recipient, and no physician may assume a responsibility in organ transplantation unless the rights of both donor and recipient are equally protected.

(Judicial Council)

2. A prospective organ transplant offers no justification for relaxation of the usual standards of medical care. The physician should provide his patient, who may be a prospective organ donor, with that care usually given others being treated for a similar injury or disease.
3. When a vital, single organ is to be transplanted, the death of the donor shall have been determined by at least one physician other than the recipient's physician. Death shall be determined by the clinical judgment of the physician. In making this determination, the ethical physician will use all available currently accepted scientific tests.
4. Full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory. The physician should be objective in discussing the procedure, in disclosing known risks and possible hazards, and in advising him of the alternative procedures available. The physician should not encourage expectations beyond those which the circumstances justify. The physician's interest in advancing scientific knowledge must always be secondary to his primary concern for the patient.
5. Transplant procedures of body organs should be undertaken (a) only by physicians who possess special medical knowledge and technical competence developed through special training, study, and laboratory experience and practice, and (b) in medical institutions with facilities adequate to protect the health and well-being of the parties to the procedure.
6. Transplantation of body organs should be undertaken only after careful evaluation of the availability and effectiveness of other possible therapy.
7. Medicine recognizes that organ transplants are newsworthy and that the public is entitled to be correctly informed about them. Normally, a scientific report of the procedures should first be made to the medical profession for review and evaluation. When dramatic aspects of medical advances prevent adherence to accepted procedures, objective, factual, and discreet public reports to the communications media may be made by a properly authorized physician, but should be followed as soon as possible by full scientific reports to the profession.

In organ transplantation procedures, the right of privacy of the parties to the procedures must be respected. Without their authorization to disclose their identity, the physician is limited to an impersonal discussion of the procedure.

Reporting of medical and surgical procedures should always be objective and factual. Such reporting will also preserve and enhance the stature of the medical profession and its service to mankind.