Supply and distribution of hearts for transplantation: legal, ethical, and policy issues

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ONCE CONSIDERED experimental, transplantation for end-stage cardiac disease has now achieved accepted status. Survival rates of 70% to 80% for one year and 50% for five years are routine. Medicare has announced that it will cover heart transplants at selected centers. Many public and private insurers already extend this coverage.

As heart transplantation matures medically, a second generation of ethical and policy issues demands attention. The concerns about safety and efficacy, which led to a moratorium of the procedure in the 1970's, have given way to questions about increasing organ supply and developing fair systems for allocating and distributing the hearts that become available. While these questions are typical of later stages of biotechnological development, they present a new challenge to further progress in cardiac transplantation.

Scarcity as the key issue. A central fact about organ transplantation, and heart transplantation in particular, is the scarcity of organs for transplant. Only a minority of patients who would benefit receive transplants. Although twice as many people (719) received heart transplants in 1984 as in 1983 (365), more than 1000 patients died awaiting a donor heart.1 Many more who would benefit had not even been referred for evaluation. The National Heart Transplant Study found that 14,000 to 15,000 people a year could benefit from the procedure under current criteria for heart transplantation.2 Relaxing the criteria would make the gap between supply and demand even greater.

Yet donor supply is also limited by medical, social, moral, and legal factors. An estimated 17,000 to 26,000 persons annually become brain dead while maintained on respirators, a situation that makes them potential organ donors.3 (Changes in speeding, seatbelt, helmet, gun, and other laws could affect this number in either direction). It has been estimated that 12,000 to 14,000 persons in this group would qualify medically as heart donors. However, only a small percentage of this pool will end up donating hearts. Evans et al.1 found that only between 15% to 40% of kidney donors—the group most likely to donate hearts—would also qualify as heart donors. At present rates of donation (3500 cadaveric kidney donors in 1984), the supply of donor hearts falls between 400 and 1100, considerably less than the estimated 14,000 to 15,000 patients a year who might benefit from transplantation. Indeed, even if donor supply increased magically to meet this need, new indications for heart transplant would undoubtedly arise. Organ scarcity is a thus permanent part of cardiac transplantation.

The chronic shortage of hearts for transplant creates two central issues for policymakers. One issue concerns how to increase supply so that more heart transplants can be performed. Increasing the supply of donor hearts would require more efficient operation of the organ procurement system and acceptance of new procedures to identify potential donors. At some point it might also require reevaluation of the ethical and legal limits now placed on organ procurement.

The second issue presented by chronic scarcity is the need to ration the hearts that become available. Rationing entails ethical choices about who shall live and who shall die. Increased public awareness of rationing will lead to closer public scrutiny of the patient selection criteria and systems that now allocate donated hearts. A public perception that patient selection is fair and equitable is essential to the operation of the entire organ transplant system, yet determining “equitable” in a context that also emphasizes efficiency is difficult. A related question is whether organs should be regarded as a community resource and subject to public rules about how they are used.

Supply and procurement issues. While the supply of hearts for transplant is determined to a large extent by medical and storage factors, professional and public attitudes and legal and ethical judgments also play an important role. The legal framework for organ transplantation was established in the late 1960s and early

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Vol. 75, No. 1, January 1987

77
1970s, when kidney transplantation emerged as an effective medical procedure. The Uniform Anatomical Gift Act (UAGA), a uniform set of rules authorizing gifts of cadaver organs, was enacted in every state.\(^3\) State recognition of brain death as legal death also occurred during this period.

The present system of family consent for donation from brain-dead, heart-beating cadavers does not result in donation of all organs that are medically acceptable for transplant. The 3500 donors recruited in 1985 is a significant improvement over previous years, but it is only 20% of the estimated 17,000 to 26,000 potential donors.\(^3\) With only 15% to 40% of the pool of current donors also qualified to be heart donors, even significant jumps in the recruitment of donors will fall short of the need for donor hearts.

Still, a substantial increase in organ donation seems possible. Polls show wide knowledge and approval of organ transplantation, with 70% of persons polled being willing to donate a relative’s organ.\(^4\) Seventy percent of families requested to donate at time of death are reported to consent, although there are some socioeconomic differences in consent rates.

Increasing organ donation is a complex problem that requires public and professional education, efficient organ procurement agencies, and the willingness to use the tragic death of one person as the occasion to prevent the death of another. A brief discussion of several options for increasing organ supply both within and without the existing system of voluntary family donation from brain dead, heart-beating cadavers follows.

**Altering the brain death requirement.** Cadaveric organs for transplant are retrieved from heart-beating cadavers that lack all brain function. The concept of total brain death, first recommended by the Ad Hoc Committee at the Harvard Medical School on the Definition of Death in 1968, is now accepted by legislation or court decision in 43 states and will undoubtedly be recognized by courts in the remaining states.\(^3\) Indeed, active transplant programs exist in states (Kentucky, Missouri, and Utah) that have not yet explicitly recognized brain death.

Some persons have proposed loosening the requirement for total brain death to permit organ retrieval from persons who lack cortical function. In their view cortical function is an essential requirement for personhood; thus its irreversible loss marks the death of the person.\(^5\) Such a redefinition of death would allow organ retrieval from irreversibly comatose and anencephalic patients. While such a change is not likely to increase significantly the supply of adult hearts, it may be an important factor in the growing area of pediatric transplantation.

Yet the prospect of increasing organ supply through a relaxation of the requirements for total brain death is probably remote. Withholding treatment from patients with brain stem but no cortical activity is now legally accepted. Yet causing total brain death by organ retrieval clashes with symbolic concerns about active killing and with the letter of current homicide laws. These problems would vanish if death were redefined to include neocortical death, but the process of redefinition will itself raise these questions. Indeed, the very proposal reinforces the fear that organ transplantation will lead physicians to declare death prematurely or even kill patients to get organs for transplant, as portrayed in the popular film and novel *Coma.*

Yet proponents of such a change can point to some currently accepted practices for actively hastening death in hopeless cases. Analgesics for the pain of terminal cancer often depress respiration and hasten demise. Aggressive hydration to preserve organs for transplant in patients not yet fully brain dead is standard donor maintenance procedure once a case is hopeless, even though this management increases brain swelling and hastens total brain death.\(^6\) In California, parents of anencephalic newborns have urged that the state brain death law be changed to permit organ donation from anencephalic offspring while there is still some brain stem activity.\(^7\) While controversy on this issue is inevitable, it is possible that the total brain death requirement may be relaxed in the future to permit organ donation from anencephalics or near-dead patients, particularly if a great need for pediatric organs can be demonstrated. Yet even this change will not increase the supply of organs sufficiently to obviate the need for equitable selection mechanisms.

**Altering family consent requirements.** The current system of organ donation requires family consent for organ donation from brain dead patients. No doubt more hearts could be retrieved if the need for family consent were modified or eliminated. While such changes are not now being sought, a societal commitment to maximize organ supply might lead to policies that lessen the role of family consent in making cadaveric organs available.

The arguments in favor of some modification of the present system of family consent rest ultimately on the judgment that cadaveric organs are better placed in a needy recipient than buried or burned. This position views the harm to nonconsenting families to be of lesser concern than the harm suffered by patients and their families when transplant candidates die for want
of an organ. Several alternatives for modifying the family’s current dominant role in determining use of cadaveric organs have been discussed.

One alternative would allow the patient to decide for or against donation before his death. Indeed, the main impetus for passage of the UAGA in the 1960s was to clarify the deceased’s priority over the family’s in deciding on anatomical gifts at death. Although the law clearly gives the deceased this right, and many persons sign organ donor cards for this purpose, physicians are unwilling to retrieve organs on this basis alone. Legal fears cannot totally explain this reluctance, since the UAGA provides immunity for good faith retrieval practices and is explicit on the validity of organ donor cards. Misunderstanding of the law, discomfort with organ donation itself, and concern for the family once death has occurred no doubt play a role.

Another alternative to family consent is presumed consent, in which the consent of the family (or deceased) to donation is assumed unless they have objected. In fact, twelve states currently have presumed consent laws for corneas. These laws permit the taking of corneas without actual consent of the family, when there is “no known objection” to removal. Since these laws do not require that the family be informed of their right to refuse, they presume consent, putting the burden on the family to come forward and object. These laws have been very effective in increasing the supply of corneal tissue, have withstood constitutional challenge, and have produced thousands of corneas with very few complaints. Yet presumed consent for solid organs is not now seriously discussed as an option for increasing organ supply.

A third option, even more radical than presumed consent, would be a system of routine salvage of organs—the elimination of consent altogether. Routine salvage would treat the deceased’s organ or body as a community resource, and permit organs and tissue to be taken as needed. The notion that a cadaver would be considered the property of the community is not as outlandish as it seems. Every state has laws that give the coroner or medical examiner the right to conduct autopsies to determine the cause of death in cases of possible homicide, despite the personal or even religious objections of the family to autopsy. The military draft also shows the community’s willingness to take jurisdiction of the live body when an important public purpose—the safety of the community—is at stake. Saving the lives of persons with end-stage organ failure is arguably as important as saving lives by enforcing the homicide laws and raising armies, and may justify overriding the family’s traditional control of the deceased’s remains. Such a system might even permit exceptions for persons with religious objections to transplantation.

The absence of presumed consent/routine salvage from policy discussions is indicative of the greater importance now placed on the family’s wishes over the needs of candidates for transplant. Opposition to these alternatives is no doubt grounded in traditional notions of respect for the grieving family, the relative newness of transplantation, and the absence of an identifiable recipient. In the early years of transplantation, Duke-miner and Sanders argued that routine salvage was an ethically acceptable and practicable system of procuring organs for transplantation. This issue has not been seriously debated or considered since the expansion of transplant activity in the 1980s. Although a change is not likely in the near future, a greater public commitment to increasing organ supply could eventually lead to a shift in attitudes toward control of cadavers, viewing the deceased’s organ as a community rather than family resource, and lessening the role of family consent.

Routine inquiry or required request policies. Given these normative constraints, the best hope for increasing organ supply lies with implementing routine inquiry or required request policies. Since a required request system maintains respect for family wishes, it appears to be a reasonable compromise among the interests of grieving families, the medical profession, and persons with end-stage organ disease.

The required request or routine inquiry approach responds to the main flaw in the present organ procurement system—the reluctance of physicians, often neurosurgeons or neurologists, to discuss brain death and organ donation with grieving families. The reluctance to broach the subject of organ donation is attributable to many factors, including lack of knowledge about transplantation, misunderstanding of brain death, fears about legal liability, fears that discussions will be upsetting to families, and distaste for the subject. As a result, families are not asked to donate and potential donors are lost.

Yet none of these reasons is sufficient to deny families the opportunity to donate organs by routinely informing them of organ donation opportunities. The harm to families from discussing organ donation is minimal, and the benefits of discussion are great, since it gives them the chance for a meaningful act of generosity at a time of grief and tragedy. Fears of a legal suit

*Texas, Virginia, Maryland, California, Florida, Tennessee, Utah, West Virginia and Michigan have such laws. Only Texas, however, permits the cornea to be taken when an autopsy is not performed.

Vol. 75, No. 1, January 1987
resulting from discussion are not realistic. Indeed, as routine inquiry expands, failure to inform may become a firmer (although still unlikely) basis for a lawsuit. The burden of asking the family need not be borne by physicians. Once a potential donor family is identified, an expert in organ procurement can raise the subject.

Ideally, donor families should be identified and notified in every case in which a donation might be medically possible. Such routine inquiry or required request policies have been recommended by many groups, including the federal Task Force on Organ Transplantation, and in the past year have been enacted into law in over 20 states. These laws place a duty on hospitals (not on physicians) to adopt procedures for routinely identifying potential donors and notifying them of their legal right to donate organs. In some states the request must be noted on the death certificate.*

Selling organs. A market in organs has also been proposed as a way to increase supply. However, it is now a federal crime punishable by five years in prison to “acquire, receive or otherwise transfer any human organ for valuable consideration.” Opponents of an organ market point to the effect of sale on voluntary donation, the coercive effects on donors and families, and the dehumanizing symbolic connotations of selling organs.

Proponents of a market believe that these concerns can be minimized or are outweighed by the benefits to donors and recipients of a market-driven increase in the supply of organs. They assume that financial incentives would overcome the reluctance of donors and families to donate, and that the coercive and dehumanizing effects of selling organs are nonexistent or tolerable. If organ transplant operations are “sold” by surgeons, they see no harm in selling the organs that make the sale of the transplant operation possible.

The need for financial incentives to increase supply, however, is debatable. As we have seen, the inability to harvest all available organs stems largely from physician unwillingness to raise the issue, not from family reluctance to donate. Unless physicians are to be rewarded financially with identifying and discussing organ donation, making financial incentives available to donors will not have a great effect. Yet if more families are informed of donation options through routine inquiry policies, there would be no need to offer financial incentives to physicians to identify potential donors.

If public unwillingness to donate altruistically is shown despite widespread implementation of routine inquiry policies, then the federal ban on organ sales should be reconsidered. A strong showing that a market in organs would save lives is a powerful argument for use of financial incentives to procure organs. Measures to minimize the coercive and symbolic effects of a market—with different rules for cadaveric and living donations, for example—can then be addressed.

Xenografts. The use of animals as an organ source has also been suggested. The Baby Fae case, in which a baboon heart was transplanted into a two-week-old baby with a hypoplastic left heart, showed that a human could survive with a baboon heart for 20 days. Whether a more significant period of survival is possible is speculative. Moreover, the ethical and supply problems raised by xenografts make them an unlikely source of hearts for transplant.

The ethical problems concern respect both for human and nonhuman animals. Respect for humans requires that we not subject critically ill patients to burdensome experiments unless there is a reasonable chance of corresponding benefit. Experimental xenografts in terminally ill patients are ethically dubious given the harm to the patient and the very small chance of benefit. The procedure is intrusive and highly burdensome to the patient, and the chance of prolonging meaningful life, given our rudimentary knowledge of cross-species transplantation, is remote. Since few reasonable persons would incur such harm for such a slight chance of benefit, criticism of the xenograft in the Baby Fae case on this ground appears to have been proper.

Other ethical objections to xenografts come from persons concerned about the welfare of nonhuman animals, whose lives would be taken to obtain organs. Animal protectionists would have a stronger case if the benefits from animal sacrifice for organs were shown to be trivial or highly speculative. Concern for the animal sources of organs is much less compelling if xenografts prove as effective as homologous transplants. Indeed, such leading philosophers of the animal rights movement as Peter Singer and Tom Regan might accept sacrifice of the animal. For example, Regan, in his book The Case for Animal Rights, acknowledged that a dog could be thrown from a crowded lifeboat to make room for a human. While the cases are not exactly parallel, the concession admits that some sacrifices of animal lives to save humans are morally correct. Killing a primate to retrieve its heart for transplantation would undoubtedly be accepted by most people if efficacy were established. Without a clearer showing of benefit, however, sacrificing primates for experimental use of their organs will generate controversy.

*See, for example, New York, Chapter 801, Laws 1985.
Even if ethical problems were overcome, the supply of primates for xenografts is so limited that they are unlikely to play a major role in increasing organ supply. The number of primates available for medical research is very limited. For example, only about 50 to 60 experimentally naive chimpanzees are available for all medical research in this country annually. The use of even a few animals as organ sources would result in a direct trade-off with other research needs, many of which might reasonably be viewed to be of equal or greater importance than research into xenografts. Expanding the supply would require an expensive investment in breeding colonies and a long wait for organs to become available. For these reasons, xenografts from primates do not now appear to be a feasible source of hearts or other organs for transplant.

Distributive and rationing issues. The scarcity of hearts for transplant requires that available hearts be allocated or rationed among persons with end-stage cardiac disease. These choices will increasingly draw public scrutiny to ensure that the patient selection and organ distribution system is efficient and fair.

The system for distributing organs to recipients is complex, with several layers of decision making. It requires a system for identifying persons with end-stage disease, referring them for evaluation, selecting candidates for the waiting list, and then selecting recipients from the waiting list when donor hearts become available. Final selection must be coordinated with an organ procurement system designed to retrieve kidneys. The procurement system may also play a role in final selection of recipients from the candidate waiting list.

A noteworthy feature of the selection and distribution system for hearts and other organs is its decentralized, unstructured, and unrationalyzed character. It has developed incrementally, a product of "muddling through" rather than of rational planning from the inception. As heart transplantation moves into mainstream medicine, a more planned or regulated structure is likely to emerge.

Four key issues in the distribution of organs are: (1) the role of efficiency vs equity in choosing transplant recipients, (2) ownership of organs, (3) public funding of transplants, and (4) limitation of transplants to designated centers. A discussion of each follows.

Efficiency vs equity in selection decisions. The scarcity of hearts for transplant inevitably requires a rationing of the hearts that do become available. As with any rationing decision, the chief questions are "on what basis?" and "who decides?" This section discusses substantive criteria for rationing. The next section discusses who should determine the criteria and select individual recipients.

The basis for selecting recipients involves a choice between efficiency and equity in use of the organ. Should hearts be distributed on an equal basis to anyone who might receive some benefit, or should they be used to maximize the number and quality of life-years saved? Given the zero-sum nature of selection decisions (selection of one person means denial to another), a strong argument can be made that the "best use" of donated hearts is to allocate them to those patients who will live the longest and function best with the transplant. When not all can be saved, it is reasonable to save those who will live the longest with the best quality of life.

A bias in favor of efficient or most effective use of donated hearts is now the main criterion used in selecting patients for transplant, although there are some exceptions. Efficiency is clearly favored at the candidacy evaluation stage, while equity plays a larger role in deciding which candidates on the list receive the hearts.

The candidate evaluation process determines whether a patient meets medical criteria for a successful transplant. While "neutral" medical criteria are used, the decisions—like many medical decisions—are inherently normative judgments that balance efficiency and equity in the use of a scarce resource. The medical criteria assess the probability that patients will survive for a substantial period with a reasonable quality of life if they receive a transplant. Patients who do not fit these criteria are not accepted as candidates and may not even be referred for evaluation. While these criteria protect a patient from the risk that a burdensome operation will not be successful, they also ensure efficiency in organ use by maximizing the life-years saved by the transplant. Thus, some persons are rejected as candidates, even if the heart would extend their life for some period, because other persons are more likely to live longer with it.

Age, social support, and lifestyle criteria may also be used at this stage because of their perceived role in affecting medical outcomes. However, lifestyle, family stability, and marital status factors require special scrutiny to ensure that they do not reflect social and cultural biases, and that they actually affect medical outcome. A small difference in outcome might not be sufficient to justify use of criteria that may be manipulated to reflect nonmedical prejudice.

The cardiologist's role in referring patients for evaluation for candidacy plays an important role in the selection of patients for transplant and will draw great-
er scrutiny in the future. The frequency of referral for evaluation may vary with the knowledge and attitudes of cardiologists treating end-stage heart disease. If informed by current medical criteria for heart transplantation, these judgments will reflect the efficiency bias contained in the medical criteria for evaluating candidates. Physicians who are unaware of transplant options or who neglect to refer patients for evaluation may be denying their patients a viable therapy. Although malpractice suits challenging referral decisions have not yet been brought, negligence could occur in nonreferral of patients to transplant centers for evaluation.

But efficiency is not the only value at stake in allocating scarce organs. A variety of equitable concerns tied to widely held notions of fairness, nonabandonment, equality, and respect for life also play a role at both the candidate evaluation and selection stage. Ability to pay and citizenship, for example, are now requirements of selection as a candidate for a heart transplant, even though uninsured or noncitizen patients are medically identical to those who become candidates. Resolving the conflicts between medical efficacy and equity concerns will become increasingly controversial as the use of cardiac transplantation expands.

A major conflict with the efficient or “best” use criteria for use of a heart arises once patients have been selected as candidates for transplant. The person with control of the organ must decide which of the candidates within a four hour travel radius from the donor is to receive the heart. The current selection system gives priority to those candidates on the list whose cases are most urgent, including those who have rejected a transplant and those who have received a temporary artificial heart as a bridge to transplant. A strict concern with efficacious use of donated hearts might argue against such an allocation, for the most urgent cases are less likely to do as well as healthier candidates.

Yet it is not clear that decisions in favor of these candidates are ethically unacceptable. While efficiency is important, a strong equity consideration is to avoid abandonment of critically ill patients. Once on the candidate list one could argue that there is a special need not to abandon those in greatest need. Such a preference assumes, of course, that there are clear indicators of urgency that physicians will follow in placing candidates on the list of patients awaiting transplant.

Retransplant after rejection of a heart also appears to conflict with efficiency by allocating a second heart to a patient who does not have as good a chance of surviving as a healthier candidate. Yet aggressive efforts on behalf of a recipient in acute rejection are viewed by some physicians as essential to demonstrate commitment and to avoid abandonment. Such a choice is not unreasonable, and could justify a second transplant, even if some patients receive two hearts and still die and others receive none. Still, the value of demonstrating this commitment has its limits. Transplant programs usually will not transplant a third heart after a second rejection, because of the greater risk that this transplant will fail.

A variation on the efficiency-abandonment theme now arises with use of the artificial heart as a temporary bridge to a transplant. Since 40% of candidates die awaiting transplants, mechanical hearts have been used experimentally in several programs as a temporary bridge until a heart becomes available. For the consenting patient who is about to die for want of a transplant, even an experimental artificial heart may be desirable, despite the burdens of the procedure. But such recipients are not likely to do as well as recipients who are relatively more healthy and who have not received the mechanical implant.

The temporary artificial heart also exacerbates rather than relieves the supply problem for the entire group of potential recipients, although it benefits the individual involved. It increases the number of patients awaiting a transplant, thus increasing the pool of patients from which selection for the next available heart must be made. Moreover, these patients will by definition be urgent cases, since the risk of stroke increases and the likelihood of a successful transplant decreases with the duration of the artificial implant. While some experimentation with mechanical assist devices for bridging purposes is justified, it is important that the effect of such programs on the allocation of scarce hearts also be considered.

Another factor competing with efficiency in the distribution of organs are preferences for member of the local, state, regional, or even national communities from which the organs have been retrieved. For example, the federal Task Force on Organ Transplantation found that permanent residency—membership in a national community—was a relevant criterion in allocating hearts and livers, and recommended that American citizens receive donated hearts ahead of nonimmigrant aliens (however, 10% of kidneys could go to this group on humanitarian grounds).
waited as long or may be in less urgent need than a recipient elsewhere. Moreover, the local transplant center may not have as good a record as another center within geographic reach. Local preference and ease of access for local patients thus may clash with concerns for efficiency. It would seem that a larger community than the local one should decide whether this deviation from efficiency is acceptable. The other trade-offs now being made between equity and efficiency in distribution of donated organs also need more public scrutiny than they have received.

Rethinking ownership of donated organs. Given the conflicts between equity and efficiency that arise in allocating donated hearts, questions of who decides on the criteria and values used in rationing organs, and who selects the recipient when a heart becomes available, take on great significance.

Although federal law prohibits receiving “valuable consideration” for selecting recipients, the holder of a donated heart is legally free to select any of the candidates awaiting transplant within geographical reach of the donor.10 There is no legal requirement that the computer listing of patients awaiting transplant be consulted or followed, nor must the holder necessarily give an organ to the most urgent cases or send it to the best centers or those with the most patients waiting. The holder is legally free to maximize efficiency, equity, or particular notions of community as he chooses.

How the organ is allocated—how the lucky recipient is chosen—is of great importance and public interest since transplant candidates who do not receive a heart are likely to be dead with six months, with an average survival of 41 days.2 Such decisions have clear normative components that should meet prevailing standards of ethical acceptability.

This situation suggests the need to rethink the “ownership” of donated organs and consider whether explicit limitations on selection and rationing decisions are needed. Limitations could take the form of explicit rules or directions about who receives organs in what order. They could also take the form of designating different decision makers, in effect transferring ownership to persons or to agencies other than the current holders of that power. In either case current property rights to donated organs are likely to change as the community seeks a particular balance between efficiency and equity in the rationing process.

Evolution in the concepts of property and ownership of donated organs could thus shift from viewing them as the quasiproperty of individual donees, to the property of the community at large. Donated organs would become a public resource to be used according to a set of community norms about how this life-saving resource should be rationed or allocated among the various people who might benefit. For example, the federal Task Force on Organ Transplantation noted that the persons with dispositional authority should be regarded as trustees or stewards of this community resource for the good of the community as a whole.3 Indeed, the Task Force’s recommendations for a national organ-sharing network suggest that the network will have authority to determine the use of organs, exercising power through its governing board and the rules it sets. While these rules may delegate to physicians or otherwise leave room for local discretion, they come very close to making the network the legal owner of donated organs. Public policy thus appears to be moving toward a community-oriented notion of property with respect to donated organs.

Such a view of ownership reflects the view of many people now working in organ transplantation, including donors, organ-procurement personnel, and physicians. While cases of misuse for personal benefit occasionally occur, a wide consensus exists that the primary use of donated organs should be to advance the good of needy patients rather than the individual good of the donee. A more difficult question is whether the donee’s view of good stewardship should automatically prevail or whether the larger community should specify its view of stewardship. The current legal right of the donee to decide is thus being questioned, and may eventually be modified. Resolving conflicts over organ ownership may be controversial, but it is an inevitable part of the evolution occurring in how property in organs—the right to dispose of them—is viewed.

Public funding of heart transplants. Ability to pay is now a major factor in determining access to cardiac transplantation. Potential candidates for transplant must present proof “up front” of their ability to pay the $95,000 average cost of heart transplantation before being evaluated and placed on waiting lists.16 While 80% of private health insurers and the majority of state Medicaid programs now cover heart transplants, some 30 million Americans lack health insurance and Medicaid coverage.1 Medicare will now cover some of those persons, but many persons remain without coverage. The result is that medically qualified patients are excluded from heart transplants solely because of their inability to pay for them.

Equitable access to health care for uninsured persons is a major problem for society and the health care system. While many disparities between insured and uninsured persons with respect to access to health care
are tolerated, allocating a donated heart on the basis of wealth seems inconsistent with the altruistic nature of organ donation and a view of donated organs as a community resource. To ensure equal access to donated hearts for persons similarly situated medically, many persons and groups, including the Task Force on Organ Transplantation, recommend public funding of heart transplants for those who cannot pay. Others oppose spending large sums on catastrophic care for a few, when the acute needs of many other uninsured persons go unmet.

To assess the case for public funding, we must first distinguish the question of coverage of heart transplants under existing categorical health programs, such as Medicare and Medicaid, from funding for persons who do not qualify for those programs. Since these health programs cover "all reasonable and necessary medical procedures" for their beneficiaries, the main question is whether heart transplantation is reasonable and necessary. Is it accepted by reasonable physicians as a safe and effective medical procedure for the treated condition? The National Heart Transplant Study, commissioned by the Health Care Financing Administration to answer this question, found that cardiac transplantation survival rates give it accepted status. The ensuing decision by Medicare to cover heart transplants brings Medicare coverage policy into line with most private insurers and state Medicaid programs, which already cover heart transplants.

Coverage under existing categorical programs is consistent with their mission, even though it increases program costs. Designed to do away with wealth barriers for the covered group, programs committed to funding all reasonable and necessary procedures should follow their mandate and do so, regardless of the expense or recent origin of the procedure. Under the terms of those programs as they now stand, there is no basis for excluding recently developed or expensive safe and effective procedures.

Such coverage policies, however, raise the costs of these programs, and create pressure to reduce the program's commitment to provide access to health care for the covered groups. If coverage is to be reduced, the procedures to be excluded should be chosen after evaluation of the relative merits of all safe and effective procedures and the program's commitment to catastrophic care generally, rather than at the margin as new technologies are developed. Transplants, for example, should be compared with other covered catastrophic care. Rational assessment might show that $100,000 of public funding for catastrophic care is better spent on a heart transplant than on the high costs of care for cancer, AIDS, or premature infants under 700 grams. The hard questions about public funding of catastrophic care should be faced directly, rather than avoided by arbitrarily denying persons with end-stage cardiac disease access to an essential therapy.

The 30 million uninsured Americans without coverage under these public programs present a different problem. If one accepts, as the President's Commission for the Study of Ethical Problems in Medicine did in its 1983 report Securing Access to Health Care, that everyone is entitled an adequate minimum of health care, the question is whether heart transplants are part of an adequate minimum. Since an adequate minimum must provide some measure of catastrophic care, cardiac transplantation is a strong contender for coverage. It is an effective therapy; indeed, much more effective than many other forms of expensive catastrophic care. If some but not all catastrophic care is to be funded, heart transplants should be evaluated on their merits against other therapies and not automatically excluded.

Yet even if public funding of heart transplants were rejected as part of an adequate minimum, one could still argue that there is an obligation to eliminate discrimination on the basis of wealth in access to heart transplants because of the unique status of donated organs as a community resource. Since the entire community is asked to donate organs, the entire community of medically needy persons should be eligible to receive transplants regardless of ability to pay. In this view, distributing hearts on the basis of wealth is as unacceptable as auctioning them off to the highest bidder. The very existence of organ donation and transplantation requires the community to fund transplants for medically qualified uninsured persons.

While it is paradoxical that a higher cost procedure for a few would be funded before the health needs of many, there is a limit to the public cost that would be involved. Given the scarcity of donor hearts, the cost to Medicare in 1989 for heart transplantation is estimated to be $3.4 million, with the cost for all currently uninsured patients approximately $10 million annually. While not a trivial sum, the shortage of hearts limits the growth of public funding obligations. Increases in supply of donor hearts may indirectly increase the costs of public funding, but rapidly spiraling costs as occurred in the federal end-stage renal disease program are unlikely.

Would public funding of heart transplants set a precedent that would require public funding of artificial hearts? Since organ supply is not a constraint, the costs of artificial heart implants could be staggering. The
National Heart, Lung, and Blood Institute estimates that “the gross annual cost to society for 17,000-35,000 implants a year (at $150,000 per implant) could be in the range of $2.5 to $5.0 billion (1980) dollars.”

Coverage of the artificial heart under categorical programs raises the same issues as does categorical coverage of heart transplants. The question of funding for persons not covered by those programs, however, is different. Since donated organs are not involved, a case for funding implants based on community altruism in providing hearts for transplants cannot be made. The question would have to be decided independently in terms of a community’s obligation to provide an adequate minimum of health care. Public funding of heart transplants for noncategorical groups thus does not necessarily entail coverage of artificial hearts for those groups. The prospect of funding artificial hearts should not affect the decision on public coverage for heart transplantation.

**Center designation.** A major issue now that heart transplantation has achieved accepted status is whether there should be limits on the number of centers doing heart transplants. In 1983 only 12 centers did heart transplants. By 1985 the number had climbed to 71, with 198 projected in five years assuming Medicare coverage. Not surprisingly, the volume of transplants varies greatly among these centers. Only a third of the 71 centers in 1985 did more than 10 transplants.

Many persons argue that the proliferation of heart transplant programs is undesirable and favor regulation to limit the centers performing the procedure. The federal Task Force on Organ Transplantation recommended that heart transplants be done only at those centers meeting certain criteria, including a minimum volume of 12 transplants a year, the Medicare coverage decision announced in July 1986 also limits reimbursement to certain centers. Some states now restrict transplant centers under certificate-of-need laws and state reimbursement policies.

The question of center designation raises major issues of health and regulatory policy. The purpose of permitting only those centers that meet volume and survival criteria to perform heart transplants is, among other things, to protect recipients and ensure efficient use of scarce organs. Since neither physicians, patients, nor institutions have an inherent right to the use of scarce organs, the community is free to limit heart transplants to designated centers if it deems this limitation essential to efficient use of this scarce resource.

Physicians and institutions wishing to set up transplant programs and who are unable to meet minimum volume and other requirements no doubt would take a different view, disagreeing with the very concept of center designation or the specific criteria used. They might argue that volume requirements have not been shown to correlate with survival outcomes, and that access to a transplant in one’s own community is a distinct advantage for patients who could or would not move to another city for that purpose. They might also claim that the local community should receive first priority for use of organs donations that it generates, even if its center is not as experienced as centers in other locales.

Some limitation on the number of centers performing heart transplants may occur, either through the reimbursement policies of private, state, and federal payors, or through explicit state regulation. Pending such policies, physicians and hospitals conducting heart transplant programs that do not meet widely accepted criteria for center designation, such as those suggested by the Task Force on Organ Transplantation, should carefully consider whether the patients whom they want to treat might not do better at other centers.

They should also be aware that poor outcomes in centers that do not meet volume or other designation standards may be vulnerable to malpractice claims. It is arguably negligent to conduct a transplant program when components that are reasonably deemed essential to good outcome are missing.

In any event, it is essential that transplant candidates be informed of a local center’s deviation from volume and other standards. If transplantation in a “more qualified” center is not feasible, then a transplant in a “less qualified” center could still be a reasonable choice for the patient, even if it is not efficient for the class of recipients overall. A key question is whether a reasonable person informed of the relevant data about different centers would accept transplantation in a program not meeting center designation criteria. The patient’s choice is legally valid only if he is fully informed of the risks and benefits of alternative programs.

The qualifications of transplant centers and their different success rates should also affect the referral decisions of cardiologists and the organ distribution policies of organ-procurement agencies. Negligent referral is a well-recognized wrong in medical malpractice actions. Referring a patient for evaluation and transplant in a center that does not meet public criteria for center designation could lead to malpractice claims against the referring cardiologist, as well as against the center and physicians performing the transplant.

Organ-procurement agencies must also consider
whether it is wise to provide organs to programs that do not meet minimum criteria for safe and efficacious use of donated organs. While placing legal constraints on their organ placement decisions may be difficult, they could reasonably be viewed as having a moral duty to use donated organs efficiently, which would argue against providing them to less qualified centers when they would be used elsewhere. Presumably a national network that controlled organs would not permit distribution to unqualified centers.

Conclusion. As heart transplantation matures medically, questions of supply and distribution take center stage in the ethical and policy debates generated by this unique technology. Although receiving little attention when safety and efficacy were in doubt, the endemic scarcity of hearts for transplant requires that supply and distribution problems now be directly faced.

Organ supply is severely constrained by medical factors and by legal requirements of total brain death and family consent. Within these constraints, the most feasible route to increasing organ supply is the adoption of laws and policies that require that families be routinely informed of organ donation options. Increasing supply by changing brain death and consent requirements is highly unlikely, although a greater commitment to increasing organ supply may eventually loosen some constraints. Xenografts also face major medical and ethical barriers.

The medical and legal constraints on donor supply result in a chronic shortage of hearts for transplant. The demand for hearts will always outstrip the supply. How donated hearts are distributed—how recipients are selected—is now emerging as an issue of public concern, with demands voiced for public accountability in rationing organs. Medical efficacy plays a major role in selecting recipients, but a variety of equitable and other concerns also enter into the picture. More public scrutiny and debate about conflicts between efficiency and equity are likely, as is a reduction in the freedom now held by medical professionals to resolve these questions.

A trend toward viewing donated organs as a community resource to be used for the good of the community as the community decides is now evident. The concept of ownership of donated organs—the right to select recipients now held by physicians and organ-procurement personnel—is being rethought and may lead to legal changes as well.

The question of public funding of heart transplants for uninsured persons is also a major issue in the distribution of hearts for transplant. Although a costly technology, existing commitments in public categorical programs and the special nature of donated organs make wealth discrimination in the selection of patients dubious. The budgetary pressures that would result from public funding, however, may require a closer look at society’s commitment to provide catastrophic care generally. The question of limiting heart transplants to qualified centers also raises questions of efficiency and equity in the selection of recipients and use of donated organs. Some limitation on the number of centers performing heart transplants is likely.

Since little attention has been paid to existing practices for rationing hearts, the process of resolving the boundaries of professional and public control and articulating distributive norms is likely to be controversial. No doubt efforts to change “ownership” by altering current prerogatives in controlling donated organs will be resisted. In addition, there may be a strong tug to cloak efficiency-equity trade-offs as neutral medical questions to avoid explicit consideration of the tragic choices that rationing hearts entails. However, an open normative debate is essential if heart transplantation is to meet the needs of persons with end-stage cardiac disease.

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