Cardiac transplants and the artificial heart: ethical considerations

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THE ETHICAL CONSIDERATIONS relevant to cardiac transplantation and the artificial heart have evolved with intensity since the first human tissue transplant nearly 40 years ago. Ethical issues raised have led to an ongoing debate that permeates our entire society. Recent implantation of an artificial heart in a human being has made these issues even more cogent.

A brief historical perspective and some definitions may be useful. The ethical framework in which medical decisions relevant to cardiac transplantation and the artificial heart are made is evolving constantly. Typically, ethics help us make such decisions—i.e., decisions occasioned by changing technology. Should we choose A (the old way), B (the new way), C (seek yet another way), or D (elect not to decide)? Ethics provide protection against special threats to moral life, such as partiality and tendentious consideration of oneself or one’s group as being exempt from moral rules.

Ethical issues develop generally in four stages: threshold, conflict, debate, and adaptation. In the first stage, conditions for moral conflict are present. Isolated individuals may anticipate problems that later become more widely recognized. In the conflict stage, a number of significant or notorious cases arise, confirming predicted inconsistencies and leading to emotional polarization. In the third stage, social debate becomes widespread. Ethical principles are applied, solutions are tested, and evidence is gathered to support various alternatives. In the fourth stage, moral adaptations and the development and implementation of public policies with administrative and legislative formulations occur in this climate of socioethical debate.

With respect to human organ transplantation, the threshold stage (1944 to 1964) began with Cunningham and Medawar, who recognized the future implications of tissue transplants. Cunningham’s dissertation on the morality of transplantation, prepared for the Catholic University in 1944, was a pioneering and seminal work. Writing at a time when skin was the human tissue being transplanted, Cunningham maintained that even visceral organ donation was an acceptable practice under Roman Catholic ethics. He challenged inconsistencies in the old tradition of “physicalism” that stressed the biological aspect of surgery as opposed to any social, psychological, or spiritual benefits that it might confer. At the same time, Medawar’s research on graft rejection foreshadowed many of the problems of transplantation that would later come to the fore.

Shortly after World War II, the transplantation of human organs began in earnest. In accordance with the form and content of medical ethics at that time, peer review was the sole basis for decisions concerning transplantation. After colleagues in relevant medical disciplines had been consulted, decisions were made.

The earliest heterotopic transplant of a cadaver kidney occurred in 1947. The patient was pregnant and in severe shock, had been anuric for 10 days, and was in a deep coma. Because of administrative opposition, the surgery had to be performed under adverse conditions in a secluded area of the hospital. The transplanted kidney produced urine and was removed 2 days later. The patient recovered.

In the early years of renal transplants and dialysis (1954 to 1964) physicians identified ethical issues still relevant to cardiac transplantation and the artificial heart. Transplant surgeons developed guidelines for four basic problems: patient selection, donor selection, informed consent, and definition of death. Early guidance was provided by a code for transplant ethics published by the American Medical Association. However, discussion of the issues involved was limited primarily to members of the medical community.

Several less tractable issues also arose during the earliest experience with dialysis—namely, high

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costs, prolongation of life by artificial means affecting the quality of life, requests of patients to be allowed to die, and macroallocation issues. Because of the emphasis in American medical ethics on the individual patient rather than society as a whole, contributions from other disciplines were needed to help structure the social and ethical considerations involved.

Pressing legal questions required resolution. Hence lawyers were among the first of other disciplines to respond. The forms and decision-making procedures of medical ethics were about to undergo significant change.

The conflict stage (1964 to 1972) began when experimental transplants from primates to humans led to significant ethical challenges to then-current procedures. In 1964, a surgeon (supported partly by NIH funds) transplanted a chimpanzee kidney to a man who lived for 2 months. Soon another surgeon, who was also supported by NIH funds, performed a cardiac heterotransplant. The second patient died shortly after surgery.

Dr. James Shannon, Director of the NIH from 1955 to 1968, learned of the cardiac heterotransplant through the media. He was deeply concerned that the surgeon had gone ahead with the procedure "on his own without prior consultation with anybody in his own institution and with little prospect of therapeutic benefit or scientific information." Several doctors subsequently published ethical criticisms of the experiment. This controversial case, coupled with rising public concern over practices in clinical research, prompted an intensive review of ethics in research. In 1966 the Surgeon General of the Public Health Service mandated prior group consideration of research.

Amid growing public awareness of transplantation and hemodialysis, an international conference was organized in 1965 to examine the implications of the new procedures. Although a separate legal analysis addressed some of the ethical questions, no independent socioethical discussions appeared in the conference report.

In that same year, I had an encounter that illustrated how little progress had been made toward appreciation of the deeper ethical issues involved in transplantation. As a graduate student, I served as chaplain for the staff and students of the New York Hospital–Cornell Medical Center. While visiting a patient with end-stage renal disease, I learned that heterotransplantation was being considered. Dialysis had become impossible for technical reasons, and no cadaver kidney or living donor could be found for the man. The surgeon asked the patient to consider transplantation of a chimpanzee kidney, which might allow him to survive until a cadaver kidney were available. I asked that I be allowed to observe the consent process and to follow the patient before surgery. The surgeon agreed, and we reviewed all available options with the patient. A realistic explanation was given by the surgeon.

Since no human kidney was available, the patient preferred the heterograft to a lingering death. Some data existed documenting short-term survival in similar cases, and I found no reason to object when the patient asked me for guidance. I told him that I could support any decision he made. He died shortly after the operation.

On the following weekend, I met the surgeon by chance in the medical library. When he avoided me, I approached him and asked what was wrong. He replied that although he believed he had handled the treatment of his patient properly, he still "felt bad" about the patient's death. I stated that he had been honest with the patient and had done nothing of which to be ashamed. In retrospect, however, it is sobering to think of the great risk the patient chose to undertake, especially when no prior review of the plan had been completed.

In the public arena, the early discussions of cardiac transplantation were also marked by emotional polarization. Political leaders, such as Senators Mondale and Ribicoff, responded to the growing public interest in the issue. Senator Mondale introduced a resolution to establish the National Commission on Health Science and Society, a legislative precursor of the National Commission for the Protection of Human Subjects authorized by Congress in 1973. Mondale held hearings on the proposed commission in 1968. One exchange between Senator Ribicoff and Dr. Barnard is particularly worth recalling.

Senator Ribicoff: Do you think this matter is so open and shut, doctor, that the doctors only should decide between the multiplicity of patients, or do you think there is a matter of great social and ethical policy — that society has to do a lot of soul searching to determine how their decision ultimately will be made?

Dr. Barnard: Sir, I do not think the matter is open and shut. I think it is difficult — we have difficult problems, but I would like to point out to you . . . these problems the doctors have had to handle for many years. These are not new problems. You cannot tell me one single new problem in our heart transplantation that we have not had for many years.

Senator Ribicoff: Except the usual situation of a limited number of hearts available for transplanting . . .

What was new, however, was not only the prospect of limited donor organs, but the entire occasion: political leaders and physicians squaring off across an issue-board. The public, through their elected officials, ex-
expected reasonable answers. This led to new responsibilities for physicians: they had to learn to communicate their ideas to people outside the medical profession. Some physicians were ready for this challenge. Shumway, for one, supported the idea of a Commission

...not because of the regulatory aspects. I do not believe that such a Commission would strictly or regulate physicians. But what such a Commission would do is educate—not just Congress, not just lay people in general, but also physicians. And this is a very important thing.\textsuperscript{11a}

The beginning of the adaptation stage (1972 to 1980) was marked by widespread social debate, changes on the clinical level, and early public-policy decisions. The National Heart and Lung Institute convened the first panel charged with assessing the artificial heart (1972 to 1973). Although the panel’s work indicated that an attempt at assessment would be premature, their report served as a point of departure for more widespread debate. The National Commission for the Protection of Human Subjects (1973 to 1978) provided an important forum for the discussion of a wide range of issues in research ethics. The remainder of the 1970s was punctuated by authoritative views—from those in the fields of philosophy, religion, and public-policy sciences—on ethical issues in health care.

Clinically, physicians developed decision-making procedures that were more in line with evolving ethical standards. The secrecy that had surrounded the first decisions to perform cardiac transplantation (1967 to 1969) and to implant an artificial heart (1969) came to be viewed as not conforming to the ethical ideals of scientific investigation. New decision-making procedures involved higher standards for prior research review and opened the process to a wider range of community members. The rigorous prior review of the Utah artificial heart implant\textsuperscript{12} and the current cardiac transplant patient selection criteria\textsuperscript{13} exemplify these changes.

Three key public-policy initiatives influenced the development of cardiac transplantation and the artificial heart in this period. The Uniform Anatomical Gift Act (UAGA)—first proposed in 1968 and subsequently adopted in all the states—made a potential organ donor’s wishes binding after death and allowed family members to consent to the removal of organs. Twenty-five states passed laws that recognized brain death as a legitimate reason to declare that death had occurred. In 1972 Congress approved a measure to extend Medicare coverage to persons with renal disease requiring dialysis or transplantation.

Current social and ethical priorities

Recent advances in transplantation have led to impressive results: longer graft survival, lower cost, and longer patient life expectancy. The benefits of transplantation, coupled with the results of the recent artificial heart experiment in Utah, have elicited fresh concern and debate over the issues of organ procurement, resource allocation, and therapeutic research with human subjects. A search for new ethical guidance is now underway.

In cardiac transplantation, the lack of donor organs poses a critical problem. Even as its efficacy is being proven, dying patients are denied the procedure for reasons that do not conform to basic ethical principles.

Practices used in securing donor organs in the United States and 28 other countries have been discussed by Stuart et al.,\textsuperscript{14} who delineated two underlying problems that lead to a shortage of donor organs in the United States: the tendency to deny the possibility of one’s own death, and the reluctance of physicians to broach the subject with the families of potential donors.

The first of these problems was clearly illustrated when the state of Maryland first made the reverse side of drivers’ licenses available as donor cards; only 1.5% of eligible persons signed the cards. Another revealing statistic is the fact that only 20% of all persons who die leave wills.\textsuperscript{15} Clearly, the psychological constraints against imagining one’s own death and choosing to fill out a donor card are considerable.

The second problem, reticence on the part of attending physicians, involves the irrational but real guilt experienced by physicians whose patients have died. The surgeon I encountered in 1965 who “felt bad” when his patient died is a vivid example. Despite studies that show how families who give consent for donation benefit emotionally from the decision,\textsuperscript{16} physicians generally do not initiate the subject with a grieving family. Furthermore, since transplant surgeons do not attend patients who are the most likely organ donors, additional problems of communication and coordination arise.

The moral argument for organ donation is straightforward. The moral rule to be kind to kin, companions, and other members of society clearly supports acts that prevent death and disease. The decision to donate organs before death is a choice that costs its maker only the safety of a complex illusion that death befalls others but not self. Centuries of wisdom advise us to surrender this illusion. No violation of moral principles occurs if one chooses to open oneself to the reality.
of death and pass on the gift of life to others. On the contrary, any rational person would praise this choice.

In the interest of saving lives, several steps could be taken to mitigate problems of organ procurement. First, all states could, at registration and reregistration, assertively offer drivers the opportunity to indicate their donor choice (yes or no) on the reverse side of their drivers’ licenses. This policy is already in effect in Colorado, where 900,000 out of 1.3 million licensed drivers have registered as organ donors. Another approach would be for states to require that the donor choice section of drivers’ licenses be completed. A more assertive step would be a policy of presumed consent, whereby all persons would be presumed to have consented to donate organs unless they had registered an objection.

I know of no moral justification for interia in the opportunity to save lives. Therefore, if less assertive policies fail, I can see no weighty ethical objections to the presumed-consent approach. Under such a policy, individuals would be free to stipulate that they not be donors, thereby qualifying as legitimate exceptions to a general social policy.

Additional steps could be taken to improve procurement procedures in hospitals. Recent efforts in Atlanta area hospitals indicate that the education of physicians and the presence of transplant coordinators who can help to relieve attending physicians of some of the psychological burdens can increase organ donations in a short interval.

The clergy can contribute by intensifying their teaching about the moral issues involved in donation. Since the decision to donate can help those who otherwise feel helpless, clergy should consider suggesting donation to families in danger of losing a member to death. Family members can be encouraged to show forgiveness toward physicians who are not able to save the life of one of their relatives. Such acts of forgiveness have a real effect on physicians and, in the long run, may encourage even attending physicians to suggest organ donation.

Another burning issue is the question of resource allocation: how much should be spent on these expensive technologies? In the absence of more fairness in the distribution of the mundane aspects of health care, large expenditures on procedures like cardiac transplantation and the artificial heart widen the prospects for moral cynicism and despair. Moreover, present inequities in the distribution of health care affect the life chances of many persons, while relatively few individuals can be helped by cardiac transplantation or the artificial heart. In addition to the 20 million Americans who lack medical insurance because of poverty and chronic unemployment, an additional 11 million workers and dependents have recently lost coverage under employers’ insurance plans due to unemployment.

In 1980 Secretary of the Department of Health and Human Services (DHHS) Patricia Harris announced the general exclusion of cardiac transplantation from Medicare coverage. She also stated that it and other new health technologies should undergo careful review before any decisions are made to support their wide distribution. Along these lines, the then-extant National Center for Health Care Technology was to undertake a National Heart Transplantation Study. Although now being run under private auspices, this study is about to begin at six centers at which the technology is used. The findings of the study will likely determine the course of Medicare reimbursement policy for years to come.

In the wake of the recent trial with the artificial heart in Utah, another important study is being set up by the National Heart, Lung and Blood Institute. It will be conducted on a smaller scale, appropriate to the more limited (at present) availability of the artificial heart.

A third important study, recently completed by a President’s ethics commission, deals with the ethical implications of differences in availability of health services. The commission argues that society has a moral obligation to ensure access to an adequate level of health care for all without imposing excessive burdens on any group. Given the diverse membership of the commission and their virtual unanimity on the report’s central argument, this study may well be a fresh chapter in society’s quest for equity in health care.

I do not believe that the larger issue of fair access must be resolved before decisions on reimbursement for cardiac transplantation or the artificial heart. I would argue, however, that decisions about reimbursement must be made as rationing decisions in the light of a larger commitment to fairness. To pretend that we do not or will not ration health resources is merely to engage in one more form of denial.

On the whole, I take an evolutionary perspective on the ethical considerations involved with cardiac transplantation and the artificial heart. Our current ethical guidelines have evolved from the less complex medical ethics of the past. A richer, broader, and less partial array of ethical guidance now exists — an array that has evolved in the context of our larger socioethical system.

The direction we should take in the future is, as I see it, an open question. We must, however, preserve the
freedom to innovate in order to save lives, even while we strive to resolve the larger issue of fairness.

Society and its leaders cannot evade the "tragic choices" involved in allocation decisions. If ours is to remain an open society, we must expect that no single moral view or approach will prevail for long. In fact, we must depend on moral conflict to help determine morality. In a totalitarian society there is conflict, but no conflict of values. In our society, conflict and gradual harmony between a variety of moral traditions and approaches will be required for focus and formulation of new directions in cardiac transplantation and the use of the artificial heart.

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