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Organ Transplantation

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**CENTER FOR BIOETHICS
UNIVERSITY OF MINNESOTA**

**READING PACKET ON
ORGAN TRANSPLANTATION**

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OVERVIEW OF ORGAN TRANSPLANTATION¹

The first successful transplant of a major human organ was in 1954. Important advances in transplant technology, including improved surgical techniques and immunosuppressive therapy, now permit routine transplantation of the kidney, liver, heart, lung, pancreas, and various combinations of solid organs, with rapidly rising success rates. In 1996, more than 20,200 human organ transplants were performed in the U.S.,² a significant increase from 7,600 in 1984. Despite, or perhaps because of, such remarkable progress, organ transplantation continues to raise difficult moral and policy problems: How should organs be procured and distributed? Who should perform transplants? Who should pay?

Procurement

The number of people who die in the U.S. each year under circumstances that leave their organs viable for transplant is debatable. Published reports since 1975 have estimated the range of potential cadaver donors to be between 4,992 and 28,954 annually. Such wide variation in estimates indicates the lack of a uniform methodology. In a recent study, it was estimated that between 5,700 and 13,000 potential donors are available annually.³ For a variety of clinical and social reasons, however, not all potential donors become actual donors. For example, some organs, though procured, are not transplanted because after removal they are found to be damaged. In addition, roughly one-third of the time health care professionals fail to offer family members the opportunity to donate; and in another third, although families are asked to donate the organs of their next of kin, they decline to donate for a number of reasons.⁴ The result is that organs are obtained from only a fraction of the pool of potential donors. Since 1986, the number of actual donors has shown only a small increase.

Estimates of the number of people who would benefit from receiving organ transplants also vary considerably. These wide-ranging estimates are due in part to differences in the criteria used to identify potential transplant candidates. Irrespective of the estimates, however, consistently fewer organs

are available for transplant than are needed to meet demand. For example, despite the dramatic increase in the number of heart transplants performed, only a small fraction of persons who could potentially benefit from a heart transplant actually receives one. The shortage of donor hearts is especially acute for children in their first year who might benefit from transplants. While the number of infants listed for transplantation rose from 72 in 1988 to 200 in 1993, during that same period, the average waiting time for an organ to become available for infants increased from 35 to 48 days.⁵ Overall, more than 60,000 people die each year, or are maintained on suboptimal therapy such as dialysis, who could potentially benefit from an organ transplant.

As transplant procedures become more successful, candidate selection criteria become less restrictive, creating a corresponding increase in the number of candidates. Though not all persons who could potentially benefit from a transplant are placed on waiting lists, increases in the pool of persons wanting transplants reflect the impact of rising success rates. Between December 1988 and December 1996, for example, the number of people awaiting transplants increased steadily from 16,026 to 50,047. In contrast, during the same period, the supply of organs available from both cadaveric and living donors only increased from 5,910 to 8,367.⁶ In sum, chronic shortages characterize the field of organ transplantation today and will continue to do so for the foreseeable future.

Legal Framework

The Uniform Anatomical Gift Act (UAGA), which was passed in the late 1960s and early 1970s in all 50 states and the District of Columbia, reflects the right of individuals to determine the use of their organs through voluntary donation. This Act allows individuals to indicate their willingness to donate their organs after death using an organ donor card. All 50 states and the District of Columbia have created programs allowing people to register as donors when they apply for or renew a drivers license. Even if no card is signed, families may donate organs unless the individual has clearly objected to donation. In practice, however, the next of kin almost always makes the final decision, regardless of the wishes of the deceased person.

Public opinion polls consistently indicate that a majority is supportive of organ donation. Surveys show that approximately two-thirds of Americans express a willingness to donate the organs of their deceased relatives, while slightly less than half are willing to donate their own organs. However, actual donation rates are much lower. In one recent study, only 46% of families of eligible donors agreed to donate organs.⁷ Other investigations have suggested that nondonors may lack trust in the fairness of organ procurement and distribution systems, and this might well be a major factor influencing the low rate of organ donation among African-Americans.⁸ Because of the relatively low rate of donations, the system of "encouraged voluntarism" of the UAGA is now generally viewed as inadequate to meet the growing need for organs. The failure of this approach may also be due, at least in part, to a general reluctance of health care professionals to discuss death and organ donation, and to approach relatives after the death of suitable donors.⁹

A second initiative to increase the supply of organs was the establishment of "required request" laws. By the early 1990s, nearly all of the states and the District of Columbia had passed such legislation, which requires hospital personnel to approach family members of suitable donors with requests for donation. The current Minnesota statute, for example, requires hospitals to develop procedures in order to: 1) ensure that patients or their relatives are made aware of the option of organ and tissue donation and the option to decline; 2) identify patients who have previously agreed to donate their organs at death; and 3) ensure that potential organ recipients or appropriate organ procurement organizations are notified when donated organs become available.

In 1986, the U.S. Congress passed required request legislation making hospitals' eligibility for Medicare reimbursement contingent on the existence of protocols for informing families of the option of organ donation. The Department of Health and Human Services regulations which implement the statute went into effect on March 31, 1988. Also, since 1988, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requires hospitals to follow required request policies.

The effectiveness of required request laws remains unclear. Studies indicate that: 1) hospital compliance with the laws is, in general, fair but improving; 2) these laws significantly increase the supply of tissue available for transplantation, but only marginally increase the supply of organs; 3) donation rates are below what public opinion surveys indicate they should be; and 4) the people who do make donation requests are not always adequately trained or monitored. The lack of hard data collected in a systematic manner still impedes a comprehensive assessment of the impact of required request laws.¹⁰

Living Organ Donation

Many believe that a promising alternative for increasing the supply of organs is to make greater use of living donors. Organs from living donors have been employed for transplantation since the earliest days of this field. An increasing number of studies have shown that transplants using organs from living related donors offer the best long-term patient survival. Accordingly, many transplant centers and surgeons favor using organs from living donors genetically related to recipients rather than from cadaver donors. Yet the use of living donors remains controversial. The major concern is the danger to which the donor is exposed. Although the risks are small (for example, mortality rate of less than 0.1%, and a major postoperative complication rate of less than 3% for living kidney donors) organ donation is clearly not entirely risk free. Questions remain regarding the risk to which a healthy individual should be subjected from a procedure providing him or her with no direct medical benefit. The doctrine of informed consent, however, would require potential donors to be allowed to decide for themselves, rather than having transplant physicians deciding for them, whether the benefits of living donation are worth the risks involved.¹¹

Concern has also been expressed about whether or not a potential living donor could truly provide informed consent without being subjected to external (e.g. family) or internal (e.g., guilt) coercion.¹² A related informed consent issue is raised by the steadily increasing number of transplant procedures employing only a portion (or lobe) of a liver, lung, or pancreas from a live donor. In many cases where organs have been procured from living donors, the donor has been genetically and emotionally related to the

recipient (e.g., mother and child). This circumstance has led some to question whether the parent/donor can give voluntary, informed consent as proxy decisionmaker for the child/recipient.¹³

Another source to increase organ supply is unrelated living donors. A growing number of studies demonstrate that transplants of organs from unrelated living donors can be successful when combined with donor-specific transfusions and/or immunosuppressive drugs. And, not surprisingly, the risk of donation for unrelated donors is no greater than for living related donors. Some transplant physicians have expressed fears that unrelated living donors may be motivated by psychopathology, but such concerns have not been borne out by empirical studies. As some researchers have noted, the bonds may be as strong or stronger when emotionally-related (e.g., spouses) rather than genetically-related donors are involved. Others have also claimed that unrelated living donors present fewer problems of informed consent since they are less likely to be subject to external pressures to give their consent. Nonetheless, only a small minority of transplant centers actively seek organs from unrelated living donors.¹⁴

Finally, there is an ongoing debate about whether organs should be removed from anencephalic infants who are born without a forebrain and without a cerebrum. These infants usually die within a day, although there are reports of much longer survival if aggressive treatment is provided. They are believed incapable of experiencing any thoughts, feelings, sensations, desires or emotions; to be totally unaware of their existence and the environment in which they live. In 1988, the Council on Ethical and Judicial Affairs of the American Medical Association concluded after reviewing the issues that it was morally permissible to remove organs from anencephalic infants only after they have died.¹⁵ In June 1994, however, the Council revised its position, and now holds that removal of organs from anencephalic infants is permissible if parental consent is obtained and certain other safeguards are followed.¹⁶ Under current laws, however, it remains illegal to take organs from live anencephalic infants.

Non-Heart Beating Donors

Another strategy that has been proposed to increase the supply of organs for transplantation is to relax the criteria for donor eligibility so that organs can be obtained from non-heart-beating cadaver donors (NHBCDs). These patients meet traditional cardiopulmonary rather than brain-oriented criteria for death. Before brain-death criteria for donor status became widely accepted in the 1970s, NHBCDs were a major source of organs for transplantation. Indeed, one reason for adopting irreversible loss of brain function as a criterion for death was to permit organs to be removed and preserved before irreparable cell and tissue damage resulted from loss of blood flow (warm ischemia).

Two approaches to circumventing the problem of warm ischemia have been proposed by those who favor procuring organs for transplant from NHBCDs.¹⁷ Both raise difficult moral questions. The first approach involves *in situ* preservation of organs, providing adequate blood supplies while they remain in the donor's body, immediately after uncontrolled cardiac death. However, it is often impossible to obtain family consent in the short time within which action must be taken to preserve the organs. Although some argue that it is permissible to preserve organs *in situ* without consent, buying time so that families can be approached in a less urgent manner,¹⁸ others object that the requirements of informed consent must apply to procedures intended to preserve organs as well as the actual removal of organs.¹⁹

In the second approach to dealing with the problem of warm ischemia, consent is obtained from patients or families who have decided to forgo life-sustaining treatment, thus permitting the time and place of death to be controlled.²⁰ Questions remain, however, about blurring the boundary between life and death, the perhaps unspoken motivations of members of the transplant community, and whether the care of terminally ill patients might be compromised once they are identified as donors.²¹ This last issue is particularly troublesome since prospective donors are sometimes subjected to procedures intended to maintain the viability of organs for transplant rather than to provide any therapeutic benefit to the patients themselves.²² Charges have even been leveled that drugs intended to ensure that organs will be well supplied with blood actually hasten the death of donors.²³ The perplexing ethical and policy issues surrounding the use of NHBCDs to increase the

supply of transplantable organs must be subjected to public scrutiny and debate if the transplant community is to retain the confidence and support of the American people.

The Use of Animal Organs

In order to address the chronic shortage of organs available for transplantation, some researchers have looked to animals as a potential source of organs. Such cross-species transplants, known as xenografts or xenotransplants, raise an array of moral issues. In the present, highly experimental, state of xenografting, we must ask who should be the first subjects of research, and how they should be recruited. Also, given the high risk of failure in the early stages of clinical research, clearly articulated procedures for ending an experiment must be in place.²⁴ Finally, some have questioned the assumption that human interests should be accorded greater moral consideration than the interests of animals.²⁵ Though this debate is unlikely to be resolved soon, even proponents of xenograft research acknowledge that animals raised to supply "spare parts" for research or therapy must be treated humanely and not made to suffer needlessly.

Distribution

The shortage of transplantable organs naturally gives rise to questions about the most ethical methods for distributing this scarce resource. Determining who gets organs involves selection decisions at two distinct levels – placing potential recipients for organ transplantation on a waiting list, and then selecting a recipient from the waiting list when an organ becomes available. Procedures for choosing transplant recipients – at both levels – appear to vary among transplant centers.

In response to concern about wealthy foreigners gaining priority over Americans in access to transplants, the 1984 National Organ Transplant Act (PL 98-507) expanded and centralized the nationwide network for procuring and distributing organs. The United Network for Organ Sharing (UNOS), based in Richmond, Virginia, holds the federal contract for maintaining a nationwide network to obtain organs and match them with recipients. The network works with the many local organ procurement organizations (OPOs) that coordinate the regional recovery and distribution of organs.

Relatively little is known about the criteria that determine referral patterns for consideration for a transplant or for placement on a particular center's waiting list. Typically, a transplant center's interdisciplinary team does an initial evaluation of the newly referred patient based on objective medical criteria such as the diagnosis, extent of disease, and probability of success. In some circumstances, financial and social factors may also be considered relevant factors. One commentator notes that "age, geography, ability to pay, patient and referring doctor perseverance, if someone is an interesting or unusual case, if someone has the disease qualifications to enter into an ongoing research study, the presence of disability or mental illness, the availability of a supportive family, and having a good psychological profile, including the right (positive, and, once in a while, grateful!) attitude, all play important roles."²⁶ The relevance of factors like a patient's family situation to the prospects for success are widely recognized, but there is disagreement about whether, or to what extent, this should influence decisions about whether to list a patient for transplant. Questions have been raised about whether the use of psychosocial criteria to assess candidates for organ transplantation might violate the Americans with Disabilities Act (ADA), which prohibits discrimination on the basis of disability.²⁷

Once transplant candidates have been placed on a center's waiting list, selection of organ recipients is governed by two sets of allocation rules, those specific to the transplant center and those set by UNOS. For some organs, UNOS criteria may be subordinated to the distribution rules of an individual center. Nevertheless, there is general agreement that candidate selection from a waiting list should be primarily based on medical criteria, and that race, gender, economic status and other demographic criteria which are not directly related to the individual patient's medical condition are inappropriate.

Different kinds of medical criteria, however, may lead to different decisions. One set of criteria represents the urgency of medical need, and reflects the ethical value of compassion for those who suffer. Employing this standard, we would give priority to the patients with the most pressing need for a transplant, that is, to the patients whose diseased organs are nearest to

complete failure. An alternative set of criteria, reflecting the ethical value of utility, would lead to selection of patients with the most favorable post-transplant prognosis. The tension between these criteria may be inescapable, and is especially apparent in cases where a patient is being considered for cardiac retransplantation, since survival rates for a second transplant are significantly lower than for initial transplants.²⁸ This has led some to argue that it would be unfair for one individual to be given two or even more chances while others are still awaiting their first chance for the same organ.²⁹ UNOS policies for the distribution of organs, however, give somewhat greater emphasis to criteria such as urgency of need and time spent on the waiting list than to criteria reflecting the medical benefits likely to accrue to transplant recipients.³⁰ Depending on which medical criteria the transplant center uses, when an organ becomes available through the organ distribution network, it is usually the patient highest on the waiting list with suitable tissue and blood type who receives the transplant.

Other factors which have been thought relevant to determining whether a patient should be eligible for organ transplant, such as whether alcoholics should receive liver transplants,³¹ whether incarcerated criminals³² or patients with a history of attempted suicide³³ should be eligible, are more controversial.

It has also been suggested that eligibility for transplants should be linked directly to donor status, so only registered donors would be able to receive transplanted organs.³⁴ Many have argued, however, that even the category of medical criteria is poorly defined. Do medical criteria, for example, include the existence of a family or social network of support for the patient, which may increase the probability of a successful outcome? To minimize subjective selection factors, it has been suggested that once a waiting list is established (based on medical and, perhaps, other criteria), the final selection from equally eligible patients be made on the basis of chance.

Suggested decision makers at both selection levels include third party payers, referring physicians, transplant teams, and appropriately constituted committees. Each of these alternatives raises concerns; for example, can physicians be asked to make these rationing choices without undermining the patient-physician relationship?³⁵ Can committees overcome the biases of

their membership? No agreement has been reached on who the decision makers should be, but there is consensus that they must be held accountable and that whatever selection process is used must be equitable. The importance of public perceptions of the field of transplant medicine has been underscored by reports of prominent public figures receiving transplants within a very short time after being listed as candidates.³⁶ Since patients frequently wait several months for a transplant, these episodes prompted questions about fairness and favoritism in the selection process. If the public does not believe the process is fair, support for altruistic donation of organs and continued commitment of funds to pay for transplants may be seriously eroded.³⁷

Performance

One result of the remarkable progress in organ transplantation is a growing number of hospitals performing transplants. For example, between 1980 and 1996, the number of transplant centers in the U.S. increased from 170 to 281.³⁸ Perhaps surprisingly, there is relatively little regulation of which hospitals may perform organ transplants. So long as a hospital meets broad Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and receives U.S. Department of Health and Human Services (DHHS) certification, it can perform transplants and receive reimbursement from third-party payers. Another requirement, since October 1, 1987, is that all hospitals performing transplants must belong to the United Network for Organ Sharing (UNOS) in order to receive Medicare and Medicaid reimbursement.

Now, however, greater restrictions are contemplated. For example, although Medicare has determined liver transplants to be therapeutic and provides coverage for them, only liver transplants performed at designated "centers of excellence" are reimbursed. A similar policy was instituted by Medicare requiring heart transplant programs to be in existence for at least three years, to perform at least 12 transplants each year, and to have one and two-year survival rates of 73% and 65% respectively. The requirement that at least 12 transplants be performed each year has been questioned, however, since empirical studies have shown that a somewhat lower volume of procedures does not adversely affect outcomes.³⁹ Following the lead of Medicare, a few

major employers, HMOs, other third-party payers, and state Medicaid programs limit reimbursement to transplants performed at designated hospitals – selected on the basis of transplant volume and success rates. Unfortunately, reliance on these selection criteria, when coupled with the rapid growth in the number of transplant centers, has fueled a sort of competition among centers for organs which, as we have seen, are in short supply.

Payment

Organ transplants are expensive, and charges continue to increase. Medical costs for a transplant can vary considerably depending both on the patient's condition and on the center where the transplant is performed. In one study, the total charges accumulated from date of transplant through the first year for a liver transplant were \$302,900; for a heart-lung transplant, \$246,000; for a lung transplant, \$243,600; for a heart transplant, \$209,100; for a kidney transplant, \$87,700; and for a pancreas transplant, \$65,000.⁴⁰ These estimates include charges for immunosuppressive therapy necessary to prevent organ rejection which average \$8,000 to \$15,000 per year. Despite the extraordinarily high per unit cost of transplants, however, total annual costs for all transplants performed in the U.S. account for less than 1% of all health care expenditures.

Third-party payers, such as Medicare and Blue Cross/Blue Shield, pay for organ transplantation after they have independently determined that transplants qualify as therapeutic and are no longer experimental. A number of other insurers simply adopt the determinations of industry leaders. The factors used to differentiate between therapeutic and experimental medical procedures vary among payers, but generally include relative risks and benefits and the probability of success. Medicare also pays for immunosuppressive medications for one year after the transplant procedure. A majority of third-party payers now consider most organ transplants therapeutic and, accordingly, provide coverage. All kidney transplants are covered by Medicare's End-Stage Renal Disease Program, which became effective in October 1972. Though the trend is toward including organ transplants in health care plans, coverage is far from universal. Thus, for people without specific coverage for organ transplants or without any health

insurance, as well as for recipients of experimental transplants, payment for organ transplants remains problematic. Donors are not liable, however, for any costs incurred in organ retrieval.

As the evolving American health care system comes more and more to adopt the vertically structured form of practice called managed care we will inevitably have to address the difficult question of what role organ transplantation efforts should play in our health care delivery system. The most significant factor influencing the shift toward managed health care delivery is the need to control the rapidly escalating costs of health care and, as indicated above, organ transplants are very costly. Managed care organizations contract with their insured populations to provide a set of “basic” health care benefits, and questions arise about which transplant procedures should be included in this set.⁴¹ At a more global level, we must question whether it is justifiable for our society to devote substantial health care resources to the replacement of organs while large numbers of our population lack access to primary health care.⁴² As a society, we may be forced to decide whether our limited health care resources should be directed toward the needs of the many or the few.

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- 1 This reading packet is on solid organs only. It does not discuss tissue transplants (e.g., cornea, skin, bone) which raise a distinct, albeit related, set of moral and policy problems.
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UNFOLDING ISSUES FOR ORGAN TRANSPLANTATION

Should the supply of organs be increased by expanding the number and type of potential donors?

Should aborted fetuses, anencephalic infants (born with most of their brain missing), or patients in a permanent vegetative state (who are not brain dead) be used as donors?

Should xenografts (organs obtained from animals) be used for transplants into humans?

Should organs be procured from non-heart-beating cadaver donors (NHBCD)?

Should artificial organs be further developed to replace living organs?

Should the supply of organs be increased by changing the current procurement system?

Should government expand its role?

Should monetary incentives be provided to potential donors?

Should the basis of procurement shift from "required request" to "presumed consent" where organs would routinely be harvested from cadavers unless the individual or family members objected?

What standard criteria should be used to allocate organs?

Should criteria be applied at a national level, a local or regional level, or by individual transplant centers?

Should patients in greatest need of a transplant receive priority, i.e., should the sickest go first?

Should the use of artificial organs as a bridge affect selection of transplant recipients?

Should retransplantation (performing another transplant if the patient's previous one fails) be limited?

Should foreign nationals have equal access to organ transplants at U.S. hospitals or should Americans have priority?

What should be the role of the media in distributing organs?

Should the number of hospitals performing organ transplants be restricted, e.g., by designating certain hospitals "centers of excellence"?

Should transplant success rates, number performed, or other measures of minimal levels of skill be used to designate hospitals as "centers of excellence"?

Who should decide the experimental/therapeutic status of organ transplants?

Should organ transplant coverage be mandated of all health insurance plans?

Should transplants be available to all people regardless of ability to pay?

Should government programs or insurance pay for immunosuppression and related non-hospital costs for organ transplants?

Minnesota Statutes 1996
Chapter 525.9214

525.9214 Routine inquiry and required request; search and notification.

(a) If, at or near the time of death of a patient, there is no documentation in the medical record that the patient has made or refused to make an anatomical gift, the hospital administrator or a representative designated by the administrator shall discuss with the patient or a relative of the patient the option to make or refuse to make an anatomical gift and may request the making of an anatomical gift pursuant to section 525.9211 or 525.9212. The request must be made with reasonable discretion and sensitivity to the circumstances of the family. A request is not required if the gift is not suitable, based upon accepted medical standards, for a purpose specified in section 525.9215. An entry must be made in the medical record of the patient, stating the name of the individual making the request, and the name, response, and relationship to the patient of the person to whom the request was made.

(b) The following persons shall make a reasonable search for a document of gift or other information identifying the bearer as a donor or as an individual who has refused to make an anatomical gift:

(1) a law enforcement officer, firefighter, paramedic, or other emergency rescuer finding an individual who the searcher believes is dead or near death;

(2) a hospital or emergency care facility, upon the admission or presentation of an individual at or near the time of death, if there is not immediately available any other source of that information; and

(3) a medical examiner or coroner upon receipt of a body.

(c) If a document of gift or evidence of refusal to make an anatomical gift is located by the search required by paragraph (b), clause (1), and the individual or body to whom it relates is taken to a hospital, the hospital must be notified of the contents and the document or other evidence must be sent to the hospital.

(d) If, at or near the time of death of a patient, a hospital knows that an anatomical gift has been made pursuant to section 525.9212, paragraph (a), or a release and removal of a part has been permitted pursuant to section 525.9213, or that a patient or an individual identified as in transit to the hospital is a donor, the hospital shall notify the donee if one is named and known to the hospital; if not, it shall notify an appropriate procurement organization. The hospital shall cooperate in the implementation of the anatomical gift or release and removal of a part.

(e) A person who fails to discharge the duties imposed by this section is not subject to criminal or civil liability.

History: 1991 c 202 s 31

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