INCREASING ORGAN AND TISSUE DONATION:

WHAT ARE THE OBSTACLES, WHAT ARE OUR OPTIONS?*

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The Procurement of Organs and Tissues in the United States: Grappling with Scarcity

Inadequacy in the supply of organs and tissues has been a constant and frustrating reality in the field of transplantation for more than a decade. While no reliable statistics existed as to the number of Americans waiting for solid organs until 1987, and no precise numbers exist now as to how many Americans are waiting for tissues, scarcity has long been a fact of life for those in need of transplants.

At the end of 1987, the United Network for Organ Sharing (UNOS) waiting list for solid organs showed 13,396 names. In 1989 there were 19,173 names. At the end of 1990, there were 22,008 names on the list, an increase of more than 40 percent from the previous year. The list has been growing despite the fact that a record number of solid organ transplants, 15,162, were performed in 1990, a significant increase over the 13,176 organ transplants done in 1989.

Two thousand new patients are added to the list of those waiting for organs each month. Between a third to a half of all Americans on transplant waiting lists for hearts, livers, lungs, and heart and lungs die before a transplantable organ is found. Some experts estimate that a new name is added to the list of those waiting for organ transplants every 30 minutes.

As of March 11, 1991 the number of persons on the UNOS waiting list were:

Kidney	18,205	Heart/lung	181
Lung	410	Pancreas	524
Liver	1,311	Heart	1,899

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Between 2,500 and 4,000 Americans are on waiting lists for cornea transplants during any given month. Tens of thousands more await transplants of skin, bone, ligament, joints, dural matter, heart valves, and bone marrow.

The shortage of organs for newborns and very young children is especially acute. Twenty five percent of those waiting for liver transplants are children less than 10 years of age. In 1990, nearly 400 infants born with congenital defects of the heart died because there were no donor hearts available for them.

There are many reasons to believe that the demand for organs and tissues will continue to increase at a rapid rate. There have been major improvements in the efficacy rates associated with all forms of transplantation. The shift in the demographics of our nation's citizenry toward an older population means that more individuals are likely to need transplants. Improvements in immunosuppressive drugs combined with a better understanding of the genetics of the immune system, provided by knowledge acquired through the human genome project, hold out the promise of continuing improvements in efficacy rates and for increasing the number of potential recipients of transplants. And, there are more and more centers capable of performing transplants.

In the past two decades there has been an explosion in the number of medical centers performing both tissue and organ transplants (Russell, 1986). Whereas only a decade ago a mere handful of medical centers were capable of even attempting bone marrow transplants, today dozens of centers have done so. In 1985 one center had done pediatric heart transplants. In 1990, 35 medical centers reported experience with at least one pediatric heart transplant. In 1991, 20 more medical centers had indicated to the International Heart Transplant Registry that they intended to perform pediatric heart transplants (personal communication, 1991). Rapid increases in the number of centers capable of performing liver, lung, pancreas, intestinal, and heart transplants means that there will be increased demand for these solid organs. Similarly, the number of medical centers willing to undertake non-related bone marrow transplants has been growing at a very rapid pace.

As transplant surgeons begin to fully master the techniques of transplantation and as newer forms of immunosuppressive drugs become available, the eligibility standards for potential recipients are expanding. Broader standards of candidacy promise to fuel a continued demand for organs and tissues (Caplan, 1989). Age limits of 55 for heart and liver transplants that prevailed in the 1970s have long since been broken. Diabetes is no longer an absolute contraindication for kidney transplantation. Persons suffering liver failure resulting from alcohol abuse have been successfully transplanted. Fetus to fetus bone marrow transplantation has been attempted for various metabolic disorders.

All of these factors contribute to what will be an inevitable increase in the demand for organs and tissues. Improvements in techniques for 'bridging' those in need of transplants, new forms of cellular transplantation such as myoblast transplants for those with muscular disorders, and the modification of the immune system of donor and recipient through genetic engineering will only add to the demand. Scarcity is the single greatest challenge facing those in need of transplants and those who wish to help them and will be so for the foreseeable future. The challenge facing our nation is to understand the organizational, legal, moral, regulatory, educational, and financial factors that currently underpin organ and tissue procurement in order to see whether there are any changes that can be made which will help bridge the gap between supply and demand in transplantation.

The History of Public Policy and Ethics Regarding Procurement

Organs and tissues have historically been obtained almost exclusively from human sources. The primary source of organs and tissues in the United States has been cadavers. While living donors have been used to obtain kidneys, bone marrow, and, in recent years, segments of pancreas, lobes of lung and liver, cadaver donation is the single most important source of transplantable organs and tissues. Yet, because of the particular way in which transplantation techniques have evolved over the past four decades, public policy, law, and morality regarding cadaver donation has been strongly influenced by policies that were formulated primarily in response to the practice of using living donors.

Voluntary Choice

The first organ transplants were attempted in the early 1950s. These early efforts involved kidneys from living donors. Since there were no reliable methods for overcoming immunological differences between donors and recipients, no techniques for preserving organs outside the body, or for artificially maintaining bodily functions in cadavers, the only possible donors and recipients of kidneys were twins or biological siblings.

Law, religion, and public policy viewed the early days of transplantation with apprehension. Kidney transplants were seen as highly experimental. Some religious leaders worried that organ donation involved the mutilation of the body solely for the benefit of another and, as such, constituted an immoral act (Vatican, 1960, Meyers, 1990). Still other religious groups were concerned that God's gift of stewardship over one's body might not permit organ donation (May, 1985).

Those asked to provide donor kidneys were seen as requiring the protection of the state and the legal system so that neither coercion or ignorance were allowed to play roles in efforts to secure organs. Since the outcome of kidney transplantation was not known, American courts would only permit the use of living sources if organs were voluntarily donated. Donors had to give informed consent knowing that their sacrifice might not eventuate in success. Courts held surgeons responsible for making sure that no one served as a donor as a result of coercive pressure from the potential recipient or other family members.

American courts and State legislatures generally held that incompetent persons such as children or persons who were either severely mentally ill or retarded could only donate organs if surrogate consent was provided by family members or guardians. The imposition of risk on incompetent persons was only allowed under the presupposition that the decision to donate is one that the incompetent person would have made were they to suddenly become competent (substituted judgement) or that the prospective donor could be harmed by the knowledge that a sibling had died because an organ was not available (best interest) (Meyers, 1990). The norm of voluntary choice is amply reflected in a long series of state court decisions to allow incompetents to donate based upon the doctrine of substituted judgement (Scott, 1982).

The emphasis on voluntary choice as the moral basis for permitting donors to assume risks in the face of uncertain benefits was carried over to cadaver donation. The concern about informed consent grew when it was discovered that during the 1960s some physicians had surreptitiously removed pituitary glands from cadavers in order to obtain growth hormone to help children born with congenital dwarfism (Caplan, 1984). Public and Congressional outrage over the removal of tissues from bodies without consent was so overwhelming that it resulted in an effort by health care professionals, government officials, and lawyers to create a means wherein voluntary choice could be guaranteed as a condition of cadaver organ or tissue procurement (Sadler and Sadler, 1984).

In the 1960s a flood of new technologies including respirators, heart-lung bypass machines, and artificial feeding tubes swept into medicine. These technologies allow physicians and nurses to keep organs functioning in individuals in whom no brain functions can be detected. This led physicians to call for a modification in the definition of death to include not only the traditional definition of the cessation of cardiac and respiratory function but also the complete and irreversible cessation of all brain function. Various model statutes were advanced proposing a brain death standard in the late 1960s (Capron and Kass, 1972) and had been adopted by more than 30 State legislatures by 1975.

As the concept of brain death gained acceptance in medical and nursing circles, it became clear that a mechanism was needed to allow individuals who wanted to donate organs or tissues upon their deaths to do so. The concern about the need for voluntary consent and the deeply held conviction that removing organs or tissues from a cadaver without consent was manifestly immoral and repugnant led to the idea of an advance written directive for donation--the donor card (Sadler, Sadler and Stason, 1968).

Altruism

By the late 1960s transplantation had made great progress. Kidney transplantation could be successfully accomplished using cadaver sources. Techniques had emerged for preserving and shipping kidneys and other solid organs. Surgeons were experimenting with transplantation of the liver and heart. Cornea transplantation had become a well-established therapy.

This progress led to a good deal of public debate about whether public policy should be changed with respect to organ and tissue procurement. Some analysts argued that the success of transplantation justified abandoning the prerequisite of informed consent in favor of laws and public policies which would permit the routine salvaging of cadaver organs (Dukeminier and Sanders, 1968, Columbia Law Review, 1969). Others argued that, rather than abandon informed consent, the time had come to consider permitting financial rewards to those willing to make organs and tissues available after their deaths (Michigan Law Review, 1974).

Neither of these proposals to change the moral and legal foundation of organ and tissue procurement was successful. Critics of presumed consent and routine salvaging argued that it was unfair to imperil the rights of those opposed to organ and tissue donation on religious grounds (Ramsey, 1970). Others were concerned that public policies which allowed either the routine removal of organs and tissues from cadavers or financial incentives to encourage making organs available would corrode social attitudes toward the dignity of the body and the sanctity and worth of the individual (May, 1973). The argument that prevailed was that public policy and law should favor both voluntary choice and altruism because these moral values were consistent with the desire of Americans to respect individual autonomy and liberty and that public policies based on these values might permit an adequate supply of organs and tissues to be obtained from cadaver sources if adequate efforts were made to encourage public altruism (Caplan and Bayer, 1985)

These moral values, informed choice and altruism, still constitute the ethical foundations of organ and tissue procurement in the United States today. One option that exists to increase the supply of organs and tissues from either cadaver or living sources is to institute laws and public policies that are not grounded by these values. Any assessment of the desirability of pursuing such strategies requires some understanding of the nature of existing State and Federal laws.

State and Federal Laws Pertaining to Donation

The concern that the donation of organs and tissues be voluntary and altruistic was reflected in the earliest national legislation dealing with donation. In 1968, the National Conference of Commissioners on Uniform State Laws adopted the Uniform Anatomical Gift Act (UAGA). By 1972, versions of this law had been passed in all 50 States. The Act specifies who may execute an anatomical gift and how individuals may do so--by signing a donor card. State laws recognized a signed card as, in and of itself, completely sufficient for donation. There was and remains no need for next-of-kin to be approached or to consent when a donor card exists. Health care professionals who make a good faith effort to locate next-of-kin prior to relying on a donor card to remove organs and tissues are immune from legal action. To ensure that decisions to donate were autonomously and altruistically made, subsequent State and Federal legislation, the National Organ Transplant Act of 1984, explicitly prohibited the sale of organs.

If a deceased person has not completed a donor card then the UAGA permits donation based on the consent of relatives or guardians. In such circumstances family members are given the right to veto a donation. The law clearly recognizes that family members have a legitimate interest in the fate of the cadaver, but does not recognize a property interest.

Initial efforts to increase organ and tissue procurement were tied to this legislation. Public education campaigns encouraged persons to sign organ donor cards. These early campaigns appealed to altruistic motivations to encourage donation. People were encouraged to "Make the Gift of Life". Many States enacted laws allowing a modification of their driver's license applications to permit the indication of a willingness to serve as an organ or tissue donor.

In the 1980s two major legislative changes were introduced in an effort to increase procurement. One set of changes aimed at increasing the efficiency and proficiency of organ procurement organizations. The other aimed at encouraging greater awareness of the option of donation and more opportunities for donation to occur.

The National Organ Transplant Act of 1984 established a grant program whereby the Secretary of the Department of Health and Human Services could make grants for the establishment, initial operation, and expansion of qualified organ procurement organizations. These organizations were to establish procurement agreements with hospitals and health care professionals regarding donations. Later legislation, including the Omnibus Budget Reconciliation Act of 1986 and the Health Omnibus Act of 1988, attempted to further increase OPO efficiency and power by setting minimal standards for procurement performance. Tissue procurement organizations were not affected by these laws.

Legislation was also enacted requiring that request for donations be made of family members at the time of death. Initially, required request laws were enacted by States. Both Oregon and New York passed such legislation in 1985. By 1988, 44 States and the District of Columbia had enacted some form of "required request" legislation governing both organs and tissues from cadaver sources.

Two types of required request laws were passed. Twenty-six states and the District of Columbia have "strong" required request laws. These laws require health care professionals to document in writing on the death certificate that a request was made and the outcome of the request. The remaining States have "weak" laws which simply require that hospitals develop protocols to ensure that family members are made aware of the options of organ and tissue donations.

In 1986, the United States Congress enacted legislation requiring hospitals to institute weak required request policies. The Health Care Financing Administration issued regulations on July 31, 1987 and made the existence of protocols for informing families of the option of donations a prerequisite for Medicare reimbursement eligibility. These regulations went into effect on March 31, 1988. Shortly thereafter, the Joint Commission on Accreditation of Health Care Organizations established a policy of weak required request for hospital accreditation. It is important to note that the National Organ Transplant Act explicitly affirmed the prohibition on the sale of organs and some tissues. The Act was modified in 1988 to include a ban on the sale of fetal organs. Numerous States have also acted to ban the sale of organs and some tissues. Exceptions to these policies have been made for certain types of replenishable tissues such as plasma and sperm.

It is interesting (and an exception to the general voluntarism and altruism of procurement policy) that 10 States and a small number of cities have enacted legislation granting authority to medical examiners and coroners' offices to procure organs and tissues from unclaimed bodies undergoing autopsy. For example, Louisiana, Florida, Ohio, San Francisco, and Denver permit procurement from bodies under the control of medical examiners when no family members can be found and there is no reason to assume any prior objection to procurement.

Public Support for Organ and Tissue Donation: Surveys, Polls and Studies

There are a variety of ways of measuring public opinion on organ and tissue donation. One strategy is to see how well informed members of the general public are about various aspects of donation and transplantation. Another indicator is determining how willing individuals say they are to donate their own organs, or assessing the reported willingness of the public to donate the organs of their family members. In addition to prospective attitudinal studies, actual donation rates can be determined as can the percentage of people carrying organ donor cards. These indicators offer somewhat inconsistent findings about public support for organ and tissue donation.

According to numerous public opinion surveys and polls conducted over more than 10 years, public education campaigns undertaken by various organ and tissue procurement organizations, community groups, government agencies, and private foundations have been quite effective in increasing public awareness regarding transplantation (American Council on Transplantation, 1985; Caplan and Bayer, 1985; Task Force on Organ Transplantation, 1986). Recent polls show that 98.7 percent of Americans are aware of transplantation (Evans and Manninen, 1988). Over 78 percent of adults say their overall feeling about being an organ donor is favorable. A majority accept the idea that being an organ donor helps other people and is the "right thing to do."

Various public opinion polls have indicated that between one-half and three-quarters of those polled would want to donate their own organs after death (Caplan and Bayer, 1985). People are more likely to report being willing to donate their loved ones organs than their own (62.5 percent vs. 49.3 percent in Evans and Manninen, 1988)

Some studies in the early 1980s showed consent to donation rates as high as 80 percent being obtained by some OPOs (Prottas, 1984). But more recent studies indicate that there may be a serious gap between hypothetical responses and real world behavior. Health care professionals report that roughly three-quarters of all families they approach are very likely or likely to refuse (Caplan and Virnig, 1990). Some States report consent rates at 15 percent or less (Edwards, Ohio Department of Health, 1991).

The disparities reflect inaccuracies inherent in asking questions about hypothetical behavior. For example, a frequently cited reason for the disparity between willingness to donate their loved ones' organs and their own is based on the fear that their families will allow their organs to be removed before they are 'really dead' (Caplan, 1992).

Some of the disparity between the small proportion of people who report carrying donor cards and the larger proportion who report being willing to donate their organs can be attributed to uncertainty about the donation process (Manninen and Evans, 1988). Some people, while sympathetic to transplantation, appear not to have actually thought about the donation process (Nolan, 1989).

Among families who have actually donated a relative's organs surveys reveal that they overwhelmingly did so from the belief that something positive would come out of a tragedy. They also felt that donating helped them in their grieving process and they were motivated by the hope that someone else might live. Of the families who have donated, 89 percent report they would do so again (Prottas and Batten, 1986).

Questions of allocation are important to the public--black and white alike. Evans and Manninen (1988) report that over 88 percent of those surveyed were concerned that 'organs be distributed fairly and equally,' and over 81 percent reported that 'medical need, not social or economic factors should be the only criterion used to select transplant recipients.' Likewise, Watts (1991) reports that participation in organ donation programs is inhibited by doubts about fairness in the allocation of organs and tissues.

Public opinion polls support the hypothesis that blacks are less supportive of donation than whites (Callender, 1989; Watts, 1991). There are several possible explanations for this cultural difference. One study suggests that there may be a tendency for white health care professionals to be less willing to ask black families to donate (Maximus, Inc., 1985). Callender (1989) suggests that blacks are less likely to donate because of a lack of awareness about transplantation, religious fears, distrust of the medical community, fear that donors will be declared dead prematurely, racism (blacks do not want to give their organs to non-blacks). Interestingly, similar reasons are cited in explaining low donation rates generally (Basu, 1989, Watts, 1991). Among the reasons cited for a lack of willingness to donate are: religious objections (Watts, 1991), a fear that they will be allowed to die prematurely, (Nolan, 1989; Watts, 1991), a desire to bury the body intact (Nolan, 1989) and uncertainty about whether anyone will really benefit from donation or that everyone has a fair chance of benefitting (Watts, 1991).

In recent years, social scientists have studied the factors influencing people's views regarding organ donation and their decisions to sign (or not sign) an organ donor card. These studies show that:

1. Persons of color are somewhat less enthusiastic about transplantation and are less likely to sign donor cards than are whites. In a recent survey (Gallup, 1991 for Partnership for Organ Donation) 76 percent of whites and 45 percent of blacks say they would be likely to donate.

2. Favorable attitudes toward donation are also more common among women, persons with a higher socio-economic status, greater education, and serious health problems. A variety of psychometric studies show that people who are more materialistic view their organs as more central to their sense of self. Interestingly, some studies suggest that patients are more likely to donate when told about the benefits to themselves rather than emphasizing the benefits to others.

3. Despite the generally positive public opinion toward transplantation and donation, at most only a quarter of the public has signed an organ donor card. This rate is especially low among teenagers and young adults. A variety of explanations for this relatively low percentage have been offered including:

   a) People do not fill out organ donor cards because to do so would make them aware of their own mortality (Watts, 1991).

   b) People's positive views regarding donation are outweighed by their fears concerning organ donation. The most common concerns are being declared dead prematurely so that organs may be procured for others and the fear of mutilation. One study found that two facts about death - the attitude toward death and the fear of being declared dead too soon - are predictive of organ donation behavior with respect to carrying a donor card.

   c) There is growing evidence that people's concern regarding the fairness of organ distribution adversely affects the decision to sign donor cards (Watts, 1991).

   d) Donor cards are not where the public wants them. A recent public opinion poll found that a substantial minority did not know where to obtain donor cards; they are not available in health care facilities where the public expects to find them (Watts, 1991).

Empirical inquiry via polls, surveys, and studies reveals high levels of public understanding about transplantation and relatively high levels of general support for transplantation. On the other hand, respondents to surveys are more likely to say they would be willing to consent to the donation of an organ by a relative than they would be to donating their own organs or tissues. There are many fears and doubts about the process of donation which seem to trouble large numbers of Americans. Most importantly, the hypothetical levels of support are not born out in practice either with respect to the number of Americans who have donor cards or with respect to the number of families who actually give their consent to donation when a death occurs.

Organ Donor Cards

Forty-five States allow people to indicate organ donor status on their drivers licenses (Overcast, 1984). The proportion of persons reported in the literature as carrying a donor card varies, ranging from less than 8 percent (Bermel, 1984) to over 37 percent (Basu, 1989). Data consistently indicate that more highly educated people are likely to report carrying a donor card (Simmons, Bruce, Bienvenue and Fulton, 1974; Mannienen and Evans, 1985; Basu, 1989). Some studies have also found that younger people and women are more likely to carry donor cards (Simmons, 1974; Lewis, 1986).

The actual value of organ donor cards in obtaining organs is unclear. Some suggest that their primary value is encouraging discussion with families, rather than as an indicator of patient's wishes at the time of death (Prottas, 1983; Caplan, 1984). Others have noted that physicians and nurses very rarely look for donor cards prior to making requests of families, and that the presence or absence of a donor card is not overly influential to health care professionals (Caplan, 1984; Overcast, 1987).

There are other important limitations to donor cards' ability to increase donation. The most important limitation is that most organ procurement agencies will not procure organs without family consent, regardless of the presence of a donor card. Overcast et al., (1984) surveyed OPO and district attorney offices in all 50 States and the District of Columbia to determine the extent to which donor cards were effective in obtaining organs. Few donors were known by hospital personnel to be carrying cards at the time of death. Caplan informally polled groups of OPO and tissue bank personnel in 1984 and 1985 and found no reported instance in which an organ or tissue had been procured solely on the basis of a donor card. Despite the legal sufficiency of donor cards, misunderstanding of existing State laws plus the fear of adverse publicity has led hospitals to de facto require family consent prior to donation.

Cards do not seem to be effective as a means to facilitate donation. However, they may play a pivotal role in influencing the attitudes of family members if they are approached about donation.

The Performance of the Current System for Obtaining Organs and Tissues

There are many steps in the process of procuring organs. These include:

1. a traumatic injury or accident occurs
2. resuscitation efforts are made
3. transfer to hospital
4. treatment attempts
5. recognition of the inevitability of death
6. recognition of potential donor status
7. decision to cease treatment efforts
8. discussion with family of imminence of death

9. diagnosis and declaration of death
10. discussion with family concerning donation
11. request to family for donation
12. consent
13. establishment of donor suitability
14. notification of OPO for procurement

(adapted from Waltzer, 1983)

All of these steps must occur in the order described for procurement to happen under the laws, regulations, and practices that currently control cadaver organ procurement. Tissues differ in that the sequence begins with the pronouncement of death. Modifications can be attempted at any one of a number of points in this sequence in the attempt to elicit increases in organ and tissue procurement. We will only focus on four especially crucial stages in the sequence: identification of donors, discussion of donation with donor families, obtaining consent, and the procurement of organs concurrent with OPO identification.

Identification of donors

The donation of internal organs such as liver, heart, kidney, and lung is restricted largely to brain dead, heart beating cadavers. Thus, most organ donors are found in hospital Intensive Care Units (ICUs), having suffered an acute catastrophe such as a car or gunshot accident, a drug overdose, or a cardiac arrest. Tissues, such as cornea, bone, and skin, can be obtained within 6-24 hours of a cardiac arrest. In many cases those who could not donate organs may be eligible to donate tissues since organs are currently taken only from those pronounced brain dead.

There is some disagreement about the frequency with which organ donors are distributed in acute care hospitals. Some studies indicate that the majority of prospective organ donors cluster in hospitals which handle high volumes of trauma (Partnership for Organ Donation, 1990; Garrison, et. al. in press). Other studies indicate a much broader distribution of prospective organ donors (Nathan, et. al., 1991) throughout various sizes and types of hospitals. Potential tissue donors are generally thought to be widely distributed throughout the acute care hospital system.

A recent study of the size of the potential donor pool in a large eastern State showed that the number of donors was between 38 and 55 per million population (Nathan, et. al., 1991). This was estimated to be about three times the rate currently procured nationwide. Other research suggests that patients admitted because of traumatic intracranial injury were identified as possible donors most frequently while patients suffering vascular or anoxic catastrophes were identified less frequently. Unidentified donors had been admitted to three major services (neurosurgery, neurology, and internal medicine). The percentage of 'missed' potential donors was highest among internists.

Unrecognized donors tended to be older and had longer hospital stays. Interestingly, there was no clear influence of hospital size, trauma center designation, or the number of ICU beds on the number of missed potential donors.

Health care professionals fail to identify medically suitable donors for a variety of reasons (Toole, 1983). Failure may result from the lack of a comprehensible hospital policy clearly designating the health care professionals responsible for assessing patient's medical suitability. Some hospitals require that attending physicians or their designees carry out this task, but make little effort to educate physicians.

Health care professionals' lack of knowledge may decrease their ability to identify eligible donors. Some doctors and nurses have trouble understanding or accepting the concept of brain death. In one study only 35 percent of 195 physicians likely to be involved in procurement correctly identified the legal and medical criteria for brain death (Youngner, 1989). Some ICU nurses and physicians are uncertain about the validity of brain death (Martyn, Wright and Clark, 1988). OPO directors claim that in roughly 12 percent of cases, brain death is either unrecognized or recognized but not declared.

Other studies have documented a more general lack of knowledge regarding procurement criteria (Diamond, Campion and Mussoline, 1987). In one study roughly one-half of ICU nurses said that doctors were unaware of donor eligibility criteria and one-third said that nurses were unsure (Prottas and Batten, 1988).

Problems of donor identification may relate less to a lack of knowledge or responsibility than to lack of time or interest. Other responsibilities may be more salient to health care professionals than determining donor eligibility (Robinette, 1985). Nurses are especially likely to feel too overburdened with other responsibilities to spend a great deal of time identifying potential organ donors (Caplan and Virnig, 1990).

Discussion of donation with families

Numerous studies over the past decade show that a relatively small percentage of hospitals were responsible for supplying a large percentage of organs and tissues. For example, one small study found out that one-third of 105 hospital patient deaths were eligible to donate corneas, but that families were approached in only 16 percent of cases. In a recent survey of neurosurgeons, over two-thirds were hesitant to cooperate with organ procurement because they feared speaking with families.

A study of organ procurement in a trauma population in Vanderbilt Hospital from 1984 through 1987 revealed that 23 percent of eligible donors were not asked to donate. Why is there such resistance to approaching family members to discuss donation?

First, in many hospitals no person or group of persons is clearly responsible for talking with families about organ and tissue donation (Caplan and Virnig, 1990). Consequently, families may never be approached about donation.

Second, health care professionals who do discuss procurement with families may be uneasy about performing this task or lack training as to how to do so. One study found that 50 percent of health professionals reported that their fear of upsetting a grieving family inhibited their initiating discussions. Other health professionals were concerned about the amount of time such discussions require (Robinette, 1985). Another study found that 20 percent of ICU nurses had strongly ambivalent feelings about the organ procurement process which may interfere with their ability to discuss donation (Sophie, 1983). In some instances physicians and nurses are reluctant to approach families when they feel a sense of guilt or responsibility for the death of their patient. This is especially so in the case of children and newborns. Finally, concern regarding legal liability is common among physicians and may also affect discussions regarding donation (Prottas and Batten, 1988).

Consent

Although, as noted earlier, numerous public opinion polls report that families are willing to donate their relatives' organs, these polls and surveys do not provide accurate predictions of actual behavior. As Manninen and Evans (1985) note, people are likely to want to respond positively to a hypothetical question about donation because of the high value our society places on voluntarism and altruism.

In fact, family refusal to donate is a key reason procurement efforts failure. Nathan, et al. (1991) found that between 29 and 39 percent of the unrealized potential donors were attributable to family refusal. Studies which have directly examined potential donor families' willingness to donate find that between 23 percent and 63 percent of families consented to donation. According to a 1989 survey of OPO Directors, 38 percent of donors are lost due to family's refusal to consent--the most frequent barrier to procurement.

Fewer studies have examined the situational factors affecting the procurement of tissue and organs. These include the surroundings in which the request takes place and the attitudes of hospital personnel approaching the family. Anecdotal accounts claim that a brusque approach or one that consists of nothing more than the mere invocation of a State or Federal requirement are unsuccessful in obtaining consent (Perkins, 1987). Others feel that confusion and equivocation regarding the declaration of death is likely to result in confusion regarding the patient's condition, decreasing the likelihood that the family will donate (Caplan, 1988; Wikler and Weisbard, 1990). Asking in the presence of family and friends or in an informal, quiet, private setting also appear to be associated with higher rates of family consent (Simmons, 1987).

Recent data suggest that an especially critical determinant of consent is the timing of a request relative to the pronouncement of death. There is reason to think that there is a real need to delay requests for donation until after the family has acknowledged the death of their loved one. In a retrospective study, University of Kentucky researchers found that 53 of 93 families agreed to donate if they had clearly understood that their loved one was dead before they were asked. When the request for donation accompanied the notification of death only 11 of 62 families consented to donation (Garrison, et. al., forthcoming).

The identity of the person who interacts with the family may also be important. Researchers at Vanderbilt Medical Center found that families were more receptive to donation requests when they were asked by health care professionals with whom they had a good rapport. Pre-existing factors such as the requestor's professional background and training, race, and personal characteristics may also influence the effectiveness of requests for donation.

Some have argued that organ procurement agency personnel, because of their greater expertise and interest, are more likely to obtain family consent (Prottas, 1990). Others feel that the most important determinants of consent are social demographic factors or the circumstances surrounding the patient's death. Unfortunately, there is no systematic data concerning the factors associated with family consent.

Little is known about why families refuse to donate. Their refusal may reflect a conscious rejection of altruism and voluntarism. On the other hand, families' refusal may be the result of inadequate communication and misunderstanding. There is some evidence that many families who refused, when approached long after the patient's death, had changed their minds and wish they had donated.

Procurement of organs and OPO contacts

After the family consents to donation, care must be taken to support the heart beating cadaver until solid organs can be retrieved. A recent British study revealed that a significant percentage of organs were lost because the patient's heart stopped before organs could be procured. It is not clear what factors, financial or otherwise, influence a hospital's decision to institute a brain death protocol.

There are currently 69 HCFA-certified organ procurement organizations in the United States. Individual OPO rates of cadaver organ procurement range from a low of 5.6 donors per million to a high of 32.5 per million. There is little explanation for these differences in OPO performance (Nathan and Jarrell, 1991).

There is some evidence available that hospital personnel historically have been uncertain about exactly which OPO to contact regarding procurement. As the number of OPOs has consolidated, this problem is decreasing at least in some parts of the country. However, hospital personnel still report confusion in deciding who to contact among organ, cornea, skin, and other kinds of tissue banks. Moreover, their confusion is increased by variations in the eligibility standards used by these agencies. In some parts of the United States agencies do not do a good job of referring potential donors among themselves.

Another source of complaint by hospital personnel and some donor families is that OPOs and tissue banks do not always do a good job of follow-up to report on what happened to donated organs and tissues. While many OPOs and tissue banks insist that letters and other contacts are made to let those involved in donor identification and maintenance know the results of their efforts there is at least a groundswell of anecdotal reporting that says these attempts are not effective.

Clearly, each of the steps in the donation sequence can be impeded or derailed by many different factors. While the opportunities for change are numerous, the risk of unintentionally harming or compromising the requisite sequence of events is high.

The Impact of Required Request/Routine Inquiry Legislation

One of the most significant attempts to modify public policy on organ and tissue donation during the past 10 years has been the creation of State and Federal laws mandating hospital personnel to make requests. This policy, while respectful of the value base of donation, decreases the autonomy and freedom afforded health care professionals in the hope that by asking for organs and tissue more voluntarism and altruism will be forthcoming.

Unfortunately, little data exist documenting the effect of this public policy on the procurement process. In part this is a function of the fact that organ and tissue procurement do not exist in a vacuum. A variety of other changes including shifts in the organization and number of organ procurement agencies, changes in laws governing drinking and seatbelt use, gun control measures, the proliferation of emergency services, and the rise of the AIDS epidemic makes it difficult to analyze the specific impact of a required request policy. In part, the lack of study is a function of the fact that the laws are so new that it will take time to see their impact.

Caplan and Welvang (1989) polled health departments, eye banks, organ procurement agencies, and hospitals in the first 10 States to pass required request laws. While most reported increases of 20 percent or more in the number of cornea, skin, and bone donors since the enactment of required request laws, the increase was still substantially less than might have been expected based on the estimates of eligible donors. Organ donation increased 10 to 20 percent in four States surveyed, while in the remainder, the number of donors was constant or decreased. The reasons for this disappointing response varied from poor compliance, to the absence of formal training programs, to problems in developing a workable method to monitor requests and donations.

Data from individual States on the impact of required request policies is quite varied. New York has some information available because its law required the State health department to report to the legislature on the effects of required request by July 1987. In 1986, heart donations increased by 94 percent, livers by 96 percent, and kidneys by 23 percent (Miller, 1991). There was a 58 percent increase in eye donors and skin availability increased by 180 percent (Miller, 1991). Oregon also reported dramatic increases in cornea, bone, and skin donors and a slight increase in organ donors during this same period.

The State of Ohio has attempted to monitor the impact of its required request law. Organ donation in Ohio increased nearly 50 percent during the first 6 months the law was in effect. However in subsequent years donation levels remained stagnant. In 1989, the third year of required request, a serious effort by the health department to enforce compliance by hospitals resulted in a 24 percent increase in the number of livers, a 30 percent increase in kidneys, and a 74 percent increase in cornea donors (Edwards, 1991).

In other areas the data is more discouraging. Both Los Angeles and San Francisco reported temporary increases in referral following the passage of required request laws but the number of donors stayed the same. In Tennessee, the total donor referrals increased in the year following implementation of required request laws but fell to pre-required request levels over the next year. New Jersey's enactment of a strong required request law did not result in a statistically significant change in organ procurement. Although there was a large increase in the number of referrals, the number of families consenting to donation decreased. Minnesota saw a rapid increase in cornea and skin donors in the month in which the State's required request laws went into effect, but a negligible impact on organs.

The reasons required request laws have not fulfilled expectations are not well understood. With rare exceptions, the majority of studies have not empirically examined the problems of donor procurement as a process constituting several steps, each of which is affected by structural and organizational variables as well as by health care professionals' attitudes. Assessments of the policy have tended to focus almost exclusively on organ donations to the exclusion of tissue donations.

Probably the critical factor behind the failure to obtain an immediate response to the creation of State and Federal laws was the poor record of hospital compliance with those laws (Caplan and Welvang, 1989; Caplan and Virnig, 1990). In the past year there is some evidence that more hospitals are beginning to comply with the new public policy and that more health care professionals are asking about donation. This is born out by the latest figures from the AOPO and UNOS which show significant increases in the number of organs available during the past year (Caplan, 1991).

Localism

Some transplant surgeons and OPO officials argue against creating a single national list for allocating tissues and organs, claiming that people donate with the intent that the donation will benefit someone from their region or State (Edwards, 1991). A preference for localism and regionalism is often cited by transplant surgeons and procurement personnel from States which are net exporters of organs and tissues on the grounds that a 'neighbors first' policy is of concern to donors. Yet there is little empirical evidence to support the claim that localism, while important to transplant centers, is important to donors or donor families.

OPOs and tissue banks

Since organ procurement agencies began to operate on a large scale about 15 years ago, there have been two distinct organizational forms: hospital-based and independent. For most of the history of organ procurement, hospital-based OPOs have predominated. As late as 1982, two-thirds of OPOs were hospital-based. These hospital-based OPOs are usually located in a Department of Surgery, or Division of Transplantation, are generally under the direct supervision of the transplant surgeon, and are often staffed by nurses previously employed at the hospital's transplant service. Hospital-based OPOs generally tend to serve only the transplant hospitals in which they are located whereas, free-standing OPOs are separately incorporated entities providing only procurement services. They also serve several hospitals. Independent OPOs are larger than hospital-based ones and have more full-time as opposed to part-time employees. They have been a more effective segment of the organ procurement system (Prottas, 1989).

Nonetheless, larger does not necessarily mean more efficient. The 16 largest OPOs, servicing 85 million people, had retrieval rates of less than 5 donors per million and 13 other OPOs covering 4 million inhabitants had retrieval rates of 10 donors per million. The national average donor retrieval rate was 16 donors per million. The most successful procurement organizations in the nation had retrieval rates of 30 to 35 donors per million (Nathan and Jarrell, 1991). These were generally small OPOs covering populations of a few million people, and operating almost exclusively at the local community level in close contact with their transplant centers (Rapaport and Anaise, 1991).

The National Organ Transplant Act of 1984 was the first Federal legislation designed to organize, control, and establish accountability in organ donation and transplantation. This legislation mandated the formation of the Organ Procurement and Transplantation Network (OPTN). A Task Force was commissioned to examine and report on pressing issues in the field of transplantation, such as networking for organ sharing, education, procurement, research, and patient access to transplant services (Rogers, 1989). The Act established a grant program for the establishment, initial operation, and expansion of qualified organ procurement organizations. The Act requires OPOs to establish procurement agreements with hospitals located within their service areas. Professional responsibilities of OPOs include public and professional education, procurement, and preservation of donated organs, allocation of donated organs according to established protocol, and coordination of activity with other transplant programs (Rodgers, 1989).

The United States operates the largest organ procurement system in the world. Medicare has been the main source of financing for OPOs since the passage of the End-stage Renal Disease Act in 1972. There are currently 69 federally funded, HCFA-certified organ procurement organizations, a significantly smaller number than the 90 which existed in 1985. Fifty OPOs are independent free-standing organizations; the rest are hospital-based. All OPOs are non-profit organizations or part of not-for-profit organizations or hospitals. With minor exceptions, every region in the United States is served by an OPO (Abt Associates, 1990) since there are OPO arrangements with over 4500 community hospitals. In 1988, the number of procurement organizations decreased for the first time as a result of Federal pressure to consolidate a number of these agencies. Many of these OPOs have been restructured as free-standing entities (Prottas, 1989).

Federal law does not mandate the relationships which should exist among hospitals and health care professionals and procurement organizations, namely, OPOs, tissue banks, and eye banks. Although no formal survey has ever been conducted that systematically examines this question, anecdotal evidence supports the claim that the structure and nature of these relationships varies geographically.

The Omnibus Budget Reconciliation Act of 1986 (OBRA) was another step in the process of institutionalizing, refining, and regulating organ donation and transplantation, including the relationship between the potential source of body parts (i.e., the hospitals) and the agents of procurement and distribution (i.e., the OPOs). OBRA, institutionalizing required request, mandated that hospital's receiving Medicare and Medicaid must establish written protocols that reasonably assured that families of potential donors will be offered the option of donation, and that the appropriate regional OPO will be notified of all potential donors.

Moreover, institutions that perform transplant procedures must participate in and abide by the rules of UNOS, a private, nonprofit, national organ sharing organization authorized by the OPTN to facilitate the equitable distribution of organs. For OPOs to receive reimbursement for costs associated with organ recovery, the organization must be certified as qualified by the Secretary of Health and Human Services. Thus, OPOs are required to participate in UNOS and to abide by its policies. Only one OPO per service area is designated by the secretary. Failure to comply with the statute means revocation of Medicare funding (Rodgers, 1989). This has encouraged hospitals and OPOs to work together to procure solid organs.

During the late 1970s and early 1980s, concern increased over the allocation policies used to distribute donated organs. UNOS was awarded the contract to fulfill the goals of OPTN, and today, develops the national policies of organ distribution. All potential organ recipients must be listed on the UNOS computer. Organs are shared based upon a point system. The potential recipient with the highest point rating will receive an available organ. The current point system tends to emphasize the importance of need and medical urgency over prognosis post-transplant.

There is no evidence that the general public is aware of the standardization of allocation policies. This is a serious problem given the frequent concerns of prospective donors and the general public about the degree to which the allocation of organs and tissues is fair.

One significant difference between organ and tissue procurement organizations is that the latter may be for-profit. The National Organ Transplant Act requires that OPOs receiving Medicare funding be non-profits. The Act prohibits the sale of any human organs but does not address tissue.

Most for-profit tissue banks are involved in the preparation, storage, and shipping of bone implants or heart valve implants. The preparation of bone for medical use requires expensive equipment and highly trained personnel and such tissue banks require considerable capital outlay. Non-profit agencies are less able to provide these services. As a result they are more likely to have to compete for these particular tissues with for-profit organizations. With the exception of bone marrow, Congress is not extending Medicare funding to tissue banking activities. As a result, for-profit tissue banks face little competition (Rodgers, 1989).

Much of the controversy surrounding for-profit tissue banking is ethical in nature. Donors and donor families voluntarily give their anatomical gifts. Most are stimulated by altruistic feelings, the belief that a part of them lives on or the death of a loved one is not in vain. It is questionable how these individuals would accept the knowledge that their gift was resold at a profit to somebody else. Public anger over stories (Gaul, 1990) detailing the ways in which voluntarily donated whole blood is resold and reprocessed into saleable products suggest that the reaction would not generally be positive.

However, until non-profit organizations provide equal services, for-profit tissue banks seem secure, provided they do not violate the Federal prohibition on the purchase of organs or any applicable State laws dealing with the sale of organs. The reality is that hospitals and surgeons demand these tissues in treating their patients and, to date, the for-profit sector of tissue banking has been the only sector capable of meeting the demand.

It is also true that organ distribution remains heavily controlled by the individual transplant centers. Only a few years ago, transplant centers that could not use an organ they retrieved would, on the basis of private conversations, send that organ to another center. That center might be in the same State, another State, or for that matter, in another country. Local discretion over distribution of organs is no longer allowed. The OPTN requires that centers and OPOs have formally stated criteria governing the distribution of organs and that OPOs use the national organ center for distributing any organs they cannot use within their own service areas.

Through the OPTN's local use policy, the 250 transplant centers are allowed to retain almost all the organs they have retrieved. They enter into cooperative agreements with an OPO or other centers only at their own volition. If they wish, they can make arrangements concerning the distribution of organs with the donor hospital and/or an OPO in other service areas. The distribution system is also localized in the sense that most organs procured in a service area never leave that area. These arrangements represent institutional agreements between hospitals and OPOs. However, we know little about the key relationship; that is, the interface between OPOs and the health care professionals upon whom the OPOs depend to identify potential donors.

Many OPOs make themselves visible to hospital personnel through providing educational "in-services" with hospital staff, especially nurses. Many hospitals now have standing committees or designated staff who are specially trained to deal with donation issues. To make all hospital personnel aware of the OPOs' activities, hospitals often post stickers, posters and incorporate information about the donation process into their procedural manuals. Hospitals also often enter into voluntary agreements with OPO staff. For example, some hospitals have volunteered to inform their local OPOs about every hospital death. The OBRA Act of 1986 and the passage of State laws which required that hospitals formulate and carry out a required request protocol have no doubt acted as catalysts for these agreements.

Communication among OPOs, tissue banks, and eye banks varies according to locale. There is very little communication between those involved in the newly created National Marrow Donor Program and other organ and tissue organizations.

In certain regions, there are close relationships between OPOs and tissue banks, with the organizations working as a team. For instance, a central office might take all calls concerning donation and advise on eligibility for solid organs, tissues, and corneas. In other regions, these organizations are more atomized. Hospitals may find themselves dealing with three, and sometimes more, organizations. The advantages or disadvantages of a unitary vs. individual procurement system are unknown.

Experience of Other Nations with Organ and Tissue Donation.

Most nations in the western world have made a strong commitment to the same moral foundation of cadaver organ transplantation, voluntarism and altruism, as has the United States. The system of donation in Canada, Holland, the United Kingdom, Australia and nearly all of Central and South America is very similar to that which exists in the United States.

Some nations which operate with a voluntaristic, altruistic values foundation and an opt-in, donor card approach to cadaver donation have resisted the formal recognition of brain death, i.e., Japan, Denmark. However some others with similar dominant value frameworks have recently enacted brain death laws or witnessed their courts affirm this definition i.e., Israel, Sweden.

Some nations have decided to pursue an opt-out policy of routine salvage or presumed consent. France enacted a presumed consent law in 1976. Austria has had what amounts to a routine salvage policy for nearly 100 years with a reaffirmation of this policy taking place in 1988. Belgium moved to institute a presumed consent policy in 1988. Also in 1988, Singapore instituted a donation policy wherein those willing to serve as donors would receive priority of access to transplants as against those who were not, for whatever reason, willing to list themselves as potential cadaver donors.

Following enactment of its presumed consent law, France saw a small increase in kidney donation but most of the increase has been used to decrease the number of kidney transplants involving living donors so there has been no overall increase in transplant rates. Austria saw a significant increase in kidney availability in the year following enactment of its law but organ availability fell significantly in 1990 (Eurotransplant, 1991).

A few nations permit financial incentives for living donors including India, the Pnilippines, and Brazil. No nation appears to allow financial rewards with respect to cadaver donation though there have been recent reports of payment for both live and cadaver kidneys emanating from China, Haiti, and Hong Kong (Crosette, New York Times, 1991).

Distribution of organs and some tissues is handled on a regional basis in Europe. The Benelux countries and Germany cooperate with one another through the Eurotransplant Foundation. A similar regional group exists for Scandinavia.

Most European countries do not have specialized personnel serving as organ or tissue procurement specialists (Prottas, 1984). But this may be changing as at least some countries, i.e., Sweden, are moving toward the creation of organ and tissue procurement specialists.

Conclusions and Options

Increasing Public Knowledge and Encouraging Altruism

Polls indicate many Americans still have reservations about the effect of organ and tissue donation on a cadaver. Public education efforts could be mounted which specifically address concerns about mutilation and destruction of the cadaver. Similarly, educational campaigns could be undertaken to assuage public concerns that prospective donors will not receive aggressive treatment and that organs and tissues are fairly and equitably distributed among those in need. These efforts need to involve the mass media which, in recent years, has conveyed erroneous and frightening images to the public about organ donation in a number of prime time, popular television programs and movies. And continuing efforts need to be undertaken to inform the public about the brain death standard and the tests used to establish that brain death has occurred.

Donor Cards

A variety of strategies are available for trying to increase the percentage of Americans who carry donor cards. All persons applying for licenses could be required to select a donor status as a condition of licensure. Or all persons admitted to hospitals or nursing homes could routinely be asked about their donor status as part of the Patient Self Determination Act of 1990. State provisions requiring two witnesses to validate a donor card could be modified. Videotapes and educational materials could be created which target high school and college age persons about the importance of donor cards.

OPO and Tissue Banks

Efforts could be made to help consolidate the relationships that exist between procurement organizations and hospitals. If a multiplicity of procurement organizations proves confusing to hospital personnel in terms of understanding donor eligibility or whom to call for help, then OPOs could be encouraged to create 'one stop' hot lines for contacting all procurement organizations through a single telephone number. The need for clear, unambiguous, current and uniform national eligibility standards must be addressed to see whether uncertainty and confusion about OPO and tissue bank standards can be reduced.

There is some evidence available (Caplan and Virnig, 1990) that hospital administrators are poorly informed about organ and tissue donation laws, regulations, and policies. Moreover, administrative responsibility for monitoring institutional performance with respect to donation is not always clearly assigned and is not routinely a part of licensure and accreditation requirements in many areas.

It is important that competition among organ and tissue banks and between tissue banks be kept to a minimum. Continuing attention needs to be paid to the domain of tissue procurement especially in light of the tension that exists in some parts of the country between profit and not-for profit tissue banks.

OPOs and tissue banks need to be encouraged to focus their educational efforts on donor identification and the proper techniques for making requests. In their educational efforts, some OPOs and tissue banks do not attend to the early stages of identification, eligibility, and requests to families in ways that reflect current empirical studies about how best to handle these issues.

OPOs and tissue banks need to understand the importance of adequate feedback to both hospital personnel, administrators, and donor families. These organizations must also realize that the general public does not distinguish between tissue and organ transplantation (they are seen as the same) so that inappropriate or negligent behavior on the part of one procurement organization adversely reflects upon all others.

Expanding the Pool of Cadaver Donors

One possible strategy for increasing the number of organs and tissues available is to increase the size of the cadaver donor pool. This could by done by instituting efforts to improve the identification of brain dead patients. A variety of studies show that between a third and two-thirds of eligible patients either are not identified as eligible, or their families are not approached for donation. Strenuous educational efforts as well as monitoring could be instituted in certain key hospitals in order to make sure that all potential brain dead donors are identified.

Efforts could be made to identify institutions where brain dead patients are likely to be. There is still much controversy over which hospitals and trauma centers are likely to see the largest number of potential donors. Similarly it is not known which sorts of institutions are most likely to have potential tissue donors. Identifying such institutions would help focus educational and training efforts concerning donor identification, interactions with families, and contacts with OPOs and tissue banks.

Unrealized potential donors are disproportionately admitted to internal medical services, have long lengths of stay, and tend to be older. These facts emphasize the importance of educating internists regarding eligibility as well as neurologists and neurosurgeons.

A recent study by a team of Welsh physicians suggests that it may be advisable to think about the elective use of mechanical ventilation solely to permit organ donation in persons who otherwise would have died. In persons dying from cerebrovascular accidents where life-support has not been used it would be possible to institute a policy to ask families for their consent to the use of mechanical ventilation in order to make organ donation possible.

Another strategy for expanding the cadaver donor pool would be to support research on allowing the use of organs from persons who arrive at hospitals DOA. It may be possible to develop preservation techniques that allow organs to be salvaged in vivo. It will also be necessary to develop appropriate public policy and consent procedures to accompany this sort of strategy.

It may be possible to make more efficient use of the cadaver donor pool than is currently the case. For example, if waiting list allocation rules were to place less emphasis on severity of illness and waiting time and more on likely prognosis, the same number of cadaver organs might be able to save more lives. Similarly, if more selective criteria were used in determining eligibility for transplants including discouraging or prohibiting retransplantation or, in some cases, the use of assist devices and bridging technologies, overall survival rates post-transplant might be increased.

Improving Consent Rates

During the last 2 years there has been increasing evidence that families frequently refuse health care professionals' requests to donate. Despite public opinion polls showing widespread support for organ donation, family refusal is a barrier to procurement. It is not clear whether this is a failure of voluntarism or a result of health care professionals insensitively or inadequate explanations of the reasons for organ donation. Without adequate empirical information, it is impossible to determine whether the appropriate public policy response is more training for health care professionals, more public education, changes in the timing, setting or identity of those making requests, or abandoning voluntarism in favor of a policy that is more responsive to self-interest.

Recent revisions in the UAGA suggest that hospitals ask all patients upon admission about their organ donor status. Some States have enacted this requirement into law. The Patient Self Determination Act of 1990 mandates that all prospective patients be appraised of the importance of having a living will and many of the standard forms of this document contain a provision regarding organ donation. These steps may increase consent rates but there is some fear among organ and tissue procurement professionals that asking at the time of hospital admission is as likely to produce refusals as it is prior consent (personal communication, 1991).

Health care professionals' attitudes about organ and tissue transplantation as well as brain death need to be assessed and, if necessary, enhanced. This may facilitate more enthusiastic compliance with existing State and Federal laws regarding requests. Stronger efforts are needed to ensure compliance with existing routine inquiry and required request laws prior to concluding that existing policies are inadequate. Unfortunately, most State laws contain neither provisions nor monies to assure adequate compliance. Developing adequate methods of quality assurance is an essential aspect of any public policy. We are quite encouraged by efforts such as Nathan et al. to develop a computerized program which allows OPOs to track hospital performance, identify outliers, and then investigate the reasons for procurement problems.

Without clear data about the impediments to procurement, one cannot be absolutely confidant which changes will improve the system. To date, studies of donation have been piecemeal, focusing on only one part of the entire process. Most studies have relied strictly on chart review or public opinion polls. The few reports about actual consents or refusals rely on nonsystematic observations or anecdotal reports. Only systematic data regarding the organizations, health care professionals, and situational factors affecting organ/tissue donation will provide the information necessary to improve the procurement process. It is essential that further research be conducted on families who did and did not agree to donation to better understand their motives, knowledge, fears, and feelings.

Policy Changes--required referral

Prottas and others have suggested requiring that OPOs be called about all deaths. This might increase identification of eligible donors and ensure that the health care professionals who discuss the issues are adequately trained to do so. Information regarding how such a proposal would work or evidence regarding its feasibility should be required prior to this proposal's adoption. Would the organ procurement agencies be called about all patients admitted to the hospital? To an intensive care unit? Who would do the calling? What role should OPOs have in managing the care of the "near brain-dead?" Would such a screening process be cost or time effective?

The Use of Financial Incentives to Encourage Donations

There are a host of ideas about the ways in which families might be encouraged to donate by appeals to self-interest. These include the payment of funeral expenses, direct cash payments, discounts on estate taxes, or tax deductions to surviving family members (Cohen, 1990, Peters, 1991). All such proposals need to be closely evaluated on both empirical and philosophical grounds. Putting aside the ethical concerns that financial incentives may raise (Pellegrino, 1991), there is no empirical evidence that families will be more willing to donate if offered incentives such as burial cost. Post hoc surveys of families who have agreed to donate or nation-wide Gallup polls of what people say they will do in the abstract are not predictive of what families will actually do when faced with these decisions. Nor is there any empirical evidence to support the claim that a significant segment of the American public either wants or expects financial incentives as a condition of donation.

Prior to accepting any new proposals the Federal government could evaluate their likely impact on donation through demonstration projects. Before changing our deeply entrenched, national public policy regarding cadaver procurement, strong empirical evidence is needed to show that these proposals will increase the number of transplantable organs.

Presumed Consent and Routine Salvage

It may be possible to persuade Americans that it is more reasonable to presume a willingness to donate and subsequently to construct public policy so that the burden of proof falls upon those who wish to 'opt out' of this presumption. However, it is important to keep in mind that the nations which have moved toward this type of public policy have encountered strong resistance from health care professionals who are reluctant to take organs without routinely asking the family about their willingness to donate. It is also important to keep in mind that the increases in organ donation as reflected in kidney donations, have not been especially impressive in France or Austria--two nations with long-standing public policies of presumed consent.

Alternative Sources of Organs and Tissues to Cadavers

The demand for transplants will outstrip our ability to procure cadaver organs. The number of heart beating cadavers is limited. Given the increasing success of organ transplantation, it is likely that the number of organs needed will always be greater than the number of potentially or even possibly available cadavers. It is therefore imperative that the transplant community and public officials begin discussing alternatives to cadaver donation.

There has been some discussion of broadening the definition of, or the criteria used to determine, death. For example, some have suggested permitting the use of different criteria for determining brain death in anencephalic infants in order to facilitate their use as organ donors (Kaufman, 1988). Others suggest that the concept of donor be expanded to include persons in permanent vegetative states (Cranford, 1989).

Increased reliance on living donors may be one way to respond to the shortage of cadaver organs. Nearly one-third of all kidneys transplanted in the United States are obtained from living donors. Some programs have turned to unrelated persons as possible sources of kidneys. Transplant surgeons have also obtained bone marrow, lobes of liver and lung, and segments of pancreas from living donors. The use of living donors, especially those not capable of giving informed consent, raises many complex ethical questions that will have to be addressed if live donation is to expand as an alternative to cadaver sources.

Another strategy to increase the pool of organs and tissues available is to turn to animal sources. There are obvious ethical, psychosocial, and public policy issues involved in pursuing this alternative. Many Americans believe that it would be immoral to kill animals, particularly primates, for the sole purpose of harvesting their organs. Others note that the use of animals is currently so experimental that informed consent procedures must be especially rigorous and peer review exceedingly conscientious before any potential recipients can be recruited.

CONCLUSION

The scarce supply of transplantable organs and tissues is the greatest challenge facing transplantation professionals as well as those in need of transplants. Unfortunately, changes in public policy or public education are not going to solve the problem of donor scarcity. For the foreseeable future, modest increases in the supply of human cadaver organs and tissues will not meet increases in the demand.

However, we must continue efforts directed toward increasing the number of cadaver organs and tissues that are available for transplant. Much public and professional attention has, in recent years, focused on the prospects for dramatically changing existing public policy on obtaining organs and tissues. Some believe that the United States either ought to permit a market of some sort in body parts or should move toward a system of presumed consent where those who do not wish to make their organs and tissues available would have to make their objections known. However, public support and trust in the system of procurement and distribution of organs and tissues plus deeply held values within American society make radical change unlikely. Refusal rates to requests to donate are in the 60 to 70 percent range or worse, and many major religious groups insist that cadaver donation be based on altruistic choice. These realities show that the prospect is poor for a shift to a public policy which has as its sole moral concern an increase in the supply of cadaver organs and tissues.

Moreover, many aspects of the existing policy (permitting cadaver donation only by a voluntary written directive from the deceased or consent of their next of kin or guardian) can and should be examined before there is any attempt to drastically alter that policy. The public needs more education concerning the concept of brain death and the realities of organ distribution in order to persuade more persons to donate. Health care professionals need to exert greater efforts to routinely identify prospective donors and to make requests of their families. Medical examiners, coroners, and funeral directors need to become more actively involved in matters pertaining to donation. Organ and tissue procurement agencies must try to more closely coordinate their efforts in both education and procurement. Government and professional societies need to make sure that health care professionals understand their obligations and responsibilities with respect to offering the option of donation and in making sure that those gifts which are obtained are acknowledged and handled with respect and fairness.

Scarcity is likely to be a reality in transplantation for the rest of this century. The steps that are taken to minimize the problem must be consistent with the values of autonomy, altruism, and voluntarism which have dominated American attitudes toward the procurement of cadaver organs and tissues since the beginning of this century.

References

Abt Associates, Inc. Evaluation of the Organ Procurement and Transplantation Network. Cambridge, Mass, August 21, 1990.

American Council on Transplantation. The U.S. Public's Attitudes Toward Organ Transplant/Organ Donation, 1985.

American Red Cross, St. Paul, MN. Number of Potential Donors Rises. Tissues, Summer, 1991: 3.

Anaise D, Smith R, Ishimaru M, Waltzer WC, Shabtai M, Hurley S, Rapaport FT. An approach to organ salvage from non-heartbeating cadaver donors under existing legal and ethical requirements for transplantation. Transplantation, 49, 2, 1990:290-94.

Basu PK, Hazariwaza KM, Chipman ML. Public attitudes toward donation of body parts, particularly the eye. Canadian Journal of Ophthalmology 1989; 24(5):216-9.

Bermel J. Barriers to organ procurement: why donor cards fail. Hastings Center Report, 14, 4, 1984:6.

Brahams D. Kidney for sale by live donor. The Lancet 1989: 285-6

Callender CO. Organ donation in blacks: a community approach. Transplant Proceedings 1987a; 19:1551-7.

Callender CO. Organ donation in the black population: where do we go from here? Transplant Proceedings 1987b; 19:36-40

Caplan AL. Organ transplants: the costs of success. Hastings Center Report, 13, 6, 1983: 23-32

Caplan AL. Organ procurement: it's not in the cards. Hastings Center Report, 14, 5, 1984: 6-9.

Caplan AL. Professional arrogance and public misunderstanding. Hastings Center Report, 18, 2, 1988: 34-7.

Caplan AL. Problems in the policies and criteria used to allocate organs for transplantation in the United States. Transplantation Proceedings, 21, 3, 1989: 3381-7.

Caplan AL. "Assume nothing", Journal of Transplant Coordination, 1, 2, 1991: 78-83.

Caplan AL, Bayer. Ethical, legal and policy issues pertaining to solid organ procurement. Hastings Center/Empire Blue Cross-Blue Shield, October 1985.

Caplan AL, Welvang P. Are required request laws working? Clinical Transplantation, 3,3, 1989: 170-6

Caplan AL, Virnig B. Is altruism enough? Critical Care Clinics, 6,4, 1990: 1007-18.

Capron A, Kass L. A statutory definition of the standards for determining human death: an appraisal and a proposal. University of Pennsylvania Law Review, 87, 1972: 98-108.

Cleveland SE. Changes in human tissue donor attitudes: 1969-1974. Psychosomatic Medicine, 37(4), 1975:306-312.

Cohen LR. Increasing the supply of transplant organs: the virtues of a futures market. 58, 1, George Washington Law Review, 1989.

Cohen LR. A market for increasing the supply of cadaveric organs. Clinical Transplantation, forthcoming, 1992.

Corlett S, Robinette MA, Stiler CR. Public attitudes toward human organ donation. Transplant Proceedings, 17, 6, 1985:103-10.

Cranford RE, Roberts JC. Use of anencephalic infants as organ donors: crossing a threshold. In: H. Kaufman, ed. Pediatric Brain Death and Organ Donation, New York: Plenum, 1987: 59-74.

Dukeminier J, Sanders D. Organ transplantation: a proposal for routine salvaging of cadaver organs. New England Journal of Medicine, 279, 1968: 413-19.

Edwards BC. Evaluating required request: lessons to date. Division on Organ Transplantation Consensus Conference, Washington, D.C., 1991.

Eurotransplant Newsletter. Statistics, 85, 4, 1991a: 1-2.

Eurotransplant Newsletter. Statistics. 86, 5, 1991b: 1-2.

Evans RW, Manninen DL. Public attitudes and behavior regarding organ donation. Journal of the American Medical Association 1985: 253(21): 3111-5.

Evans RW, Mannien DL. U.S. Public opinion concerning the procurement and distribution of donor organs. Transplant Proceedings. 1988: 20(5): 781-5

Evers S, Farewell VT, Halloran PF. Public awareness of organ donation. Canadian Medical Association Journal, 1988: 138:237-39.

Gallup. For partnership for organ donation, Americans and organ donation: current attitudes and perceptions, 1991.

Garrison RN, Bentley FR, Raque GH, Polk HC, et.al. There is an answer to the organ donor shortage. Surgery, Gynecology and Obstetrics, forthcoming.

Gaul G. The blood brokers. The Philadelphia Inquirer, Sept. 24-28, 1989.

Gore SM, Ross Taylor RM, Wallwork J. Availability of transplantable organs from brain stem dead donors in intensive care units. British Medical Journal, 302, 1991: 149-152.

Holtkamp S, Nuckolls ES. The incomplete gift exchange. Journal of Transplant Coordination, 1, 1991: 31-5.

International Heart Transplant Registry (personal communication). 1991.

John Paul II, Statement on organ donation. First International Congress for the Society for Organ Sharing, Rome, Italy, June 21, 1991.

Kandela P. India: kidney bazaar, The Lancet, 337, 1991:1534

Kaufman H, ed. Pediatric brain death and organ procurement. New York: Plenum, 1989.

Lee PP, Stark WJ, Yang JC. Cornea donation laws in the United States. Archives of Ophthalmology 1989; 107:1585-9.

Martyn S, Wright R, Clark L. Required request for organ donation: moral, clinical and legal problems. Hastings Center Report, 18, 2, 1988: 27-34.

Maximus, Inc. Phase I report, Assessment of the Potential Organ Donor Pool: Literature Review and Data Source Assessment. McLean, VA, 1985.

May WF. Attitudes toward the newly dead. Hastings Center Studies, 1, 2, 1973: 10-12.

May WF. Religious justifications for donating body parts. Hastings Center Report, 14, I, 1984: 38-42.

May WF. Religious obstacles and warrants for the donation of body parts. Transplant Proceedings 1988; 20(1):1079-83.

McReavy D. Organic transplantation--a reported condemnation. The Clergy Review, 41, 1956:164-168.

Meyers DW. The human body and the law. Stanford, California: Stanford University Press, 1990.

Michigan Law Review, The Sale of Body Parts. 72, 1974: 1215-28.

Miller T. The New York State experience with required request. Division of Organ Transplantation, Consensus Conference, Washington, DC, 1991.

Nathan HM, Jarrell BE, Broznik B, Kochik R., et. al. Estimation and characterization of the potential renal organ donor pool in Pennsylvania. Transplantation, 51, 1, 1991a: 142-49.

Nathan HM, Jarrell BE. National multi-center potential donor study. Presented to AHCPR, March 18, 1991b.

Nolan BE, Spanos NP. Psychosocial variables associated with willingness to donate organs. Canadian Medical Association Journal 1989; 141:27-32.

Overcast TD, Evans RW, Bowen LE, et. al. Problems in the identification of potential organ donors. JAMA, 251, 12, 1984: 1559-1562.

Overcast TD. Legal aspects of death and informed consent in organ Transplantation. In Human Organ Transplantation, eds., DH Cowan, J Kantorowitz, J Moskowitz, PH Rheinstein, Ann Arbor, MI; Health Administration Press, 1987: 55-80.

Partnership for Organ Donation, Inc., Solving the Organ Donor Shortage, 1990.

Perkins KA. The shortage of cadaver donor organs for transplantation: can psychology help? American Psychologist, 42, 1987: 921-30.

Peters TG. Life or death: the issue of payment in cadaveric organ donation. JAMA, 265, 1991:1302-5

Pius XI. Casti Connubi, A.A.S., XXII, 1930: 33-4.

Prottas JL. Encouraging altruism: public attitudes and the marketing of organ donation. Milbank Memorial Fund Quarterly 1983; 61(2):278-305

Prottas JL. An effective approach to organ procurement. Lecture Presented at the Hastings Center, November 19, 1984.

Prottas JL. Shifting responsibilities in organ procurement: a plan for routine referral. JAMA, 260, 6, 1988: 832-3.

Prottas JL. Organization of American organ procurement. Journal of Health Policy, Politics and Law, 14, 1, 1989: 41-55.

Prottas JM, Batten HL. Attitudes and incentives in organ procurement. Report to Health Care Financing Administration, 1986.

Ramsey P. The patient as person. New Haven; Yale, 1970.

Robinette MA, Stiller CR. Summary of task force findings. Transplantation Proceedings, 17, 3, 1985: 9-12.

Robbins RA. Signing an organ donor card: psychological factors. Death Studies, 14, 1990: 219-229.

Rodgers SB. Legal framework for organ donation and transplantation. Nursing Clinics of North America, 24, 4, 1989: 837-850.

Russell PS. Centers for transplantation--how many should we have? Surgery 100, 5, 1986: 867-76.

Sadler AM, Sadler BL, Statson EB. The uniform anatomical gift act. JAMA, 206, 11, 1968: 2501-06.

Sadler AM, Sadler BL. A Community of givers not takers. Hastings Center Report, 14, 5, 1984: 6-9.

Scott R. The Body As Property. New York; Viking, 1981.

Simmons RG, Klein SD, Simmons RL. Gift of life: the social and psychological impact of organ transplantation. New York; Wiley, 1987.

Simmons RG, Bruce J, Bienvenue R, et. al. Who signs an organ donor card: traditionalism versus transplantation. Journal of Chronic Diseases, 1974; 27: 491-502.

Sophie LR, Salloway JC, Sorock G, Voleck P, Merkel FK. Intensive care nurses' perceptions of cadaver organ procurement. Heart and Lung, 12, 1983: 263-7.

Swerdlow JS. Matching needs, saving lives. Washington, DC, The Annenberg Program, 1989.

Task Force on Organ Transplantation. Organ Transplantation. Washington, DC: HHS, April, 1986.

Tufts A. Germany: kidneys from Moscow. The Lancet, 337, 1991: 605.

Waltzer WC. Procurement of cadaveric kidneys for transplantation. Annals of Internal Medicine, 98, 1983: 534-8.

Watts M. How people feel about organ donation. Lieberman Research, Inc., 1991.

Wolstenhome GEW, O'Connor M, eds., Ethics in Medical Progress with Special Reference to Transplantation. London; Churchill, 1966.

World Health Organization, Guiding principles on human organ transplantation. The Lancet, 337, 1991: 1470-l.

Youngner SJ, Landefeld S, Coulton CJ, et. al. Brain death and organ retrieval. JAMA, 261, 1989: 2205-2210.