



December 1983

Organ Transplants: The Cost of Success

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Recommended Citation

Caplan, A. L. (1983). Organ Transplants: The Cost of Success. Retrieved from http://repository.upenn.edu/bioethics_papers/1

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Abstract

Just thirty years after the first kidney transplant between identical twins was undertaken in 1954, organ transplantation has come of age. Today many transplant surgeons have attained success rates of over 80 percent survival for at least five years among those who have received kidneys from live related donors. The survival rate for those who receive cadaver kidneys five years after surgery is 60 percent. More than 95 percent of corneal transplant recipients have their sight restored.

Comments

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The Hastings Center Report, Vol. 13, No. 6. (Dec., 1983), pp. 23-32.

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Organ Transplants: The Costs of Success

by ARTHUR L. CAPLAN

Just thirty years after the first kidney transplant between identical twins was undertaken in 1954, organ transplantation has come of age. Today many transplant surgeons have attained success rates of over 80 percent survival for at least five years among those who have received kidneys from live related donors. The survival rate for recipients of cadaver kidneys five years after surgery is 60 percent. More than 95 percent of cornea transplant recipients have their sight restored. Aided by new immunosuppressive drugs such as Cyclosporin, better tissue-matching capabilities, and improved surgical techniques, medicine has also made great strides in the past ten years in transplanting bone marrow, hearts, livers, lungs, pancreases, and spleens. In the course of one recent week at the University of Minnesota transplant center, says Chief Surgeon John Najarian, "We transplanted eight kidneys, two hearts, two pancreases, and one liver."

But technological progress has also created a wide range of moral problems. Whereas thirty years ago the primary moral question raised by organ transplantation was whether to subject patients to experimental, last-resort procedures, today the ethical questions concern the inadequate supply of organs and their inequitable distribution, the high cost of transplantation, and the lack of adequate governmental regulation and control over the technique. The policies developed in the early stages of organ transplantation—a system of what might be best termed "encouraged voluntarism" for donations, and government subsidization of the costs of kidney transplantation—were geared toward a small-scale effort involving only the kidney and a few, carefully screened patients. A system designed for a technology in its infancy, it was, in retrospect, limited in its vision. Today new policies are needed to confront the challenge posed by a technology on the verge of widespread success in an era of increasingly scarce resources.

The Emergence of "Encouraged Voluntarism"

Since the 1950s American courts have emphasized voluntarism and informed consent as the key moral guidelines that ought to govern the procurement of organs. State and federal courts ruled that rational adults could volunteer to donate their organs to their relatives. The courts also per-

mitted minors to donate organs with the consent of their parents and with judicial approval.

In the 1960s advances in medical technology allowed doctors to artificially maintain vital biological functions in dead patients. Respirators and heart-lung machines permitted many organs to be salvaged for transplantation. These technological advances were partially responsible for the shift in the legal definition of death toward the so-called "brain death" standard, which was advanced largely in response to the urgings of the transplantation community. Brain-death statutes permitted organs to be harvested from those who had suffered an irreversible loss of brain function if there was no objection by the next of kin.

By the end of the 1960s it had become clear that simply making voluntary organ donation legal was not sufficient to assure the supply of organs needed by recipients. A variety of policy options were advanced. One option, favored by writers such as Paul Ramsey, Alfred and Blair Sadler, Jay Katz, and Renée Fox and Judith Swazey, was to move from a system of pure voluntarism to one of "encouraged" voluntarism by legally enabling individuals to donate organs through the use of "living wills" or donor cards.¹

Critics of encouraged voluntarism pointed out that the high costs of promoting such a policy through public and professional education were unnecessary, given the willingness of Americans, as revealed in various public opinion polls, to have their organs utilized upon their deaths. They also worried that a dependence upon encouraged voluntarism would eventually produce a commercial market in organs. Both the living and the next-of-kin of dead people would have an interest in selling organs for transplantation.

As an alternative, scholars such as Jesse Dukeminier and David Sanders argued for a different policy—that of presumed consent—whereby physicians, acting with state or federal authority, would simply take needed tissues and organs from cadavers unless an individual carried a card prohibiting such tissue transfers or unless the deceased person's next-of-kin objected.² This system treated bodily organs as property and based its legal justification upon the constitutional authority of the state to mandate that bodies be treated in certain specified ways upon death.

Critics of presumed consent, such as Paul Ramsey and Leon Kass, argued that such a policy was too coercive and could result in the abuse of the rights of religious minorities, who were opposed to any form of autopsy or "mutilation" of dead bodies.³

In the end, public policy tipped toward encouraged voluntarism. The Uniform Anatomical Gift Act of 1968 recog-

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nized the legal status of donor cards and living wills, as well as the right of next-of-kin to make donations for relatives who had never indicated an unwillingness to serve as an organ donor. The moral argument that carried the day was that voluntarism encouraged socially desirable virtues, such as altruism and benevolence, without running the risk of abusing individual rights. Moreover, proponents noted, such a policy did not require as strong a governmental role as did a policy of presumed consent. Therefore it merited a trial, since it seemed to preserve free choice while posing less of a risk to the rights of religious minorities.

This policy debate took place in the context of a heated dispute about the adequacy of pure voluntarism with respect to blood donation. The book *The Gift Relationship* (1971) by the British professor of social administration, Richard Titmuss, played a key role in pushing public policy toward encouraged voluntarism. Titmuss argued that a voluntary system, supplemented with appropriate efforts to educate the public about the need for blood, had produced and would continue to produce a safe and sufficient supply of blood. He claimed that empirical evidence showed that the British system of voluntary blood donation produced a safer and more adequate supply of this vital substance than did the American, which relied on a mixture of voluntarism and commercial blood banks. Persuaded by such arguments, many states moved to ban the sale of blood on the grounds that the dangers from hepatitis and other communicable diseases were far greater in systems that permitted individuals to be paid for blood.

Throughout the 1970s a number of court cases reaffirmed the centrality of voluntarism in adjudicating the ethical quandaries raised by organ transplantation. In the *Shimp* case, for example, a Pennsylvania court refused to order a life-saving bone marrow donation between cousins even though the transplant was relatively safe and entailed no major risks to the donor.⁴

The Failure of “Encouraged Voluntarism”

In the 1970s and 80s, a variety of commercial arrangements emerged for procuring biological goods and services. While the system of whole blood donation for transfusion remained almost totally voluntary, a network of pay-for-blood centers that bought plasma and other blood parts used, for example, in treating hemophiliacs, was established in major urban areas. Many of the growing number of sperm banks that supplied sperm for artificial insemination routinely reimbursed donors. With the decline in adoptable babies as a result of legalized abortion, surrogate mothering became an alternative; nearly all the women expected payment for “wombs-for-hire” services. To some extent the fears of the critics of encouraged voluntarism came true—what could be given away freely could also be sold.

The decision to rely on a policy of encouraged voluntarism for cadaver organ transplantation also resulted in the creation of a complex network of organizations, civic

groups, profit and not-for-profit procurement agencies, which took on the job of matching potential donors with those in need. Many private organ procurement agencies established an admirable track record in locating and harvesting organs for donation. Other agencies, for a variety of reasons, did not fare as well.

The agencies quickly learned that in a voluntary system success in finding suitable donors depended almost entirely upon their ability to maintain frequent and amicable relationships with nurses, residents, and other emergency room personnel. Many agencies lacked the trained staff necessary for undertaking this complex educational task. Some agencies found themselves in competition for donors in their region, while potential donors in other parts of the country remained relatively underutilized.

Organizations such as the National Kidney Foundation undertook massive publicity efforts to educate the public about the need for organs and the desirability of carrying a donor card. However, many people found the subject of donation so gruesome that they ignored appeals, even though opinion polls consistently showed that most people were willing to serve as donors upon their deaths. Given the relatively low rates of public participation in the donor card program, it is quite unlikely that anyone who might actually serve as a donor would be carrying a card at the time of death. Nor were hospitals particularly eager to become involved with cadaver organ transplantation even when potential donors did in fact carry a donor card. Despite the law sanctioning the legitimacy of the cards, many hospitals were afraid of facing costly litigation by family members who did not agree with the wishes of the deceased. Other hospitals saw no financial incentive for taking on the complex and timeconsuming procedures of organ salvaging. Many hospital personnel were unwilling to broach the subject of transplantation with family members under any circumstances and simply disregarded the cards to protect the family from further “unnecessary” anguish.

The Growing Gap Between Supply and Demand

The effort to capitalize on encouraged voluntarism as the driving moral force behind organ transplantation may have been a noble experiment in 1968, but fifteen years later it is clear that this effort has failed. Continued progress in organ transplantation has widened the gap between the demand for organs and the number actually available for use. The gap has grown so wide that medical hucksters now offer to “solve” the problem by importing organs from paid donors overseas.

In the New York City area approximately 450 people are waiting for corneal transplants to restore their failing sight. Some of them have been on waiting lists for six months or more. Nationwide, more than 4,000 blind people are waiting for corneas.

The New York City area waiting list for kidney transplants numbers well over 600 individuals, including some

who have been waiting over six years. Nationwide, somewhere between 6,000 to 10,000 people are on waiting lists. Dialysis is an alternative treatment, to be sure, but it is considerably more expensive. It costs approximately \$35,000 per year to treat an individual with dialysis, whereas the cost of maintaining someone on a kidney transplant is \$5,000 to \$8,000 per year postsurgery. Moreover, the quality of life enjoyed by transplant recipients is usually much better than that afforded those who receive dialysis treatments.

In the New York area, with a population base of over 12 million, only 100 kidneys per year are salvaged from cadaver donors. Of the 120 area hospitals that could supply cadaver donors, less than 40 percent have provided one kidney during the past five years.⁵ Statistics from other regions are similar. During the past year in the Pittsburgh area, which has an extensive and aggressive procurement network, only thirty hospitals out of 135 provided kidneys from cadavers for use in transplantation. Organs for less well-established transplant procedures are even scarcer. In the past year alone the parents of Jamie Fiske, Brandon Hall, and others have conducted campaigns through the national media in order to obtain livers for their children. John Najarian commented recently: "Had Mr. Fiske not made a special plea, the chance of finding a suitable liver [for his daughter Jamie] would have been very remote."

Lungs for transplant are just as rare. The waiting list at Montefiore Medical Center in the Bronx, where the vast majority of lung transplants have been undertaken, numbers over fifty individuals at any given time. Some persons have waited for a suitable lung for over ten months and many have died without any attempt at transplant. Last year Montefiore was able to do only seven lung transplants even though the hospital has the staff and equipment to perform many more.⁶

Bone marrow transplantation between nonrelated donors is another evolving area of transplant research where supply simply does not approximate demand. Edgar Frenkel, a Long Island physician, recently offered a \$25,000 reward from privately generated funds in order to locate a suitable matched marrow donor. He also mounted his own (successful) procurement campaign, in the press, complete with press releases and taped appeals.

While not all experts accept the figure, the Centers for Disease Control in Atlanta estimates that approximately 20,000 people die each year from causes such as brain injuries, tumors, or strokes, which would permit them to serve as organ donors. Yet, in 1982 no more than 2,500 cadavers were utilized as organ donors.

The time has come for seriously reexamining the alternative option of a policy based upon presumed consent. A centralized system for the mandatory salvaging of organs, with protections for those who wish to dissent, could help to increase the supply, reduce the cost, and alleviate the emotional problems that encouraged voluntarism has produced.

John Q. Public On Organ Donations

In January 1983 the Gallup Organization conducted a survey for the National Kidney Foundation on attitudes of Americans toward kidney donations. The survey consisted of personal interviews with a representative sample of about 1500 men and women age 18 and over.

Almost all of those interviewed (93 percent) had heard something about organ transplants and most of the sample (76 percent) were aware of the existence of donor cards. Nevertheless, only a small proportion of those who knew about donor cards (18 percent) had signed one.

Even among those who felt somewhat inclined to donate their kidneys after death, only a third had signed a donor card. Less than half of that group had told family members about their desires and even fewer (18 percent) had told close friends, informed a doctor (5 percent), or mentioned donation in a will (4 percent). Among those who were aware of organ transplants almost three-quarters felt very inclined to give permission to remove the kidneys of a "loved one," and half said they would probably donate their child's kidneys in the event of a tragic accident. However, when it came to their own kidneys this group was a lot more cautious. Only a quarter said they would want their own kidneys donated after death.

When asked why they felt that way 20 percent of the respondents chose as a "very important" reason "I never really thought about it" or "I don't like the idea of someone cutting me up after I die." Fifteen percent felt very concerned that "they might do something to me before I am really dead," and an equal number said "I don't like thinking about dying." Very few (only 7 percent in each case) were reluctant to donate an organ for religious reasons or because it was complicated to give permission.

The survey also indicated some misconceptions about organ donation procedures. Almost all those who had signed a donor card believed, correctly, that they could not be forced to give up a kidney for a transplant, and that they could change their minds once they had signed. But almost half believed, erroneously, that "there is a central file of people who have signed donor cards which is made available to doctors or others who are trying to locate a kidney donor." In addition, almost one third of those who were aware of organ transplants believed, incorrectly, that there are kidney banks, just as there are blood banks.—J.B.

The Charade of Consent

A public policy that insists upon informed consent by the families of those recently deceased has been considered the only means by which personal autonomy can be protected against the powerful demands of both the medical profession and those desperately in need of a transplant. But there are many reasons for doubting whether informed consent does or can protect personal autonomy.

Consider the psychologically wrenching circumstances

under which family members must be approached about the possibility of organ donation. Almost always the potential organ donor has died suddenly and unexpectedly. Relatives or friends are in a state of shock, grief, and confusion.

In such situations it is difficult to see how families can have a real opportunity to make an informed or voluntary choice. Basic factors ordinarily held to be absolutely necessary for any choice to be informed and free—time and a suitable decision-making environment—are often absent in a busy hospital corridor or emergency room. The capacity of bereaved family members to comprehend information under such circumstances is highly questionable.

Moreover, it is very difficult to know when encouragement to donate becomes pressure or coercion to do so. Those involved in organ procurement are well aware of the

strategies that are most likely to produce a donation—identifying a specific recipient for a particular donation whenever possible; painting an overly optimistic picture of the chances of benefiting others; downplaying the possibility that the organs that are obtained will not be suitable for transplant; and talking in a general way about the overall success rates for organ transplantation rather than about the particular rate of success in the program or hospital where the organ will be utilized. Given these kinds of biases, do individuals really choose to have a loved one serve as an organ donor, or are they pressured, cajoled, shamed, or even coerced into consenting?

It is also difficult to understand how recruiters, faced with the urgent demand to produce a suitable supply of organs for desperately ill people, can present full and complete in-

How Organs Are Distributed by Donald Denny

In July 1973, funding became available under Social Security for procuring kidneys as well as transplanting them. Up to then procurement and distribution of organs were not well organized. Hospitals, schools of medicine, and some nonprofit organ procurement programs were seeking to increase the number of kidneys available in their areas, but no systematic means existed for distributing kidneys between centers.

When I started in 1974, there were about 125-30 organ procurement programs, attached either to a single transplant hospital or to a group of hospitals in one area. When we had a kidney we couldn't use locally, I would sit at the phone and call each program to ask, "Do you have anyone who's a suitable match?" Increasingly we came to recognize that this was inefficient.

By 1975, a group of about thirty transplant centers called the South East Organ Procurement Foundation (SEOPF) had developed a computerized system for listing names, tissue types, and blood types of people who were waiting for kidney transplants. This information was available only to SEOPF members, but in 1977 the computer system was made available to nonmembers. Today that computer system—now known as UNOS (United Network Organ Sharing)—is the mainstay for distributing kidneys.

The UNOS computer is located in Richmond, Virginia, and is available to all transplant centers in the country. Simply by paying for storage and time charges all centers can list their recipients waiting for renal transplants and use the system to match kidneys with the nationwide pool of recipients. Of the approximately 150 kidney transplant centers now operating in the country, over 130 register their patients on the computer. (Among the large centers that don't belong is the University of

California at San Francisco. They don't share information. I don't know why.) It takes the computer five or ten minutes to come up with the required information in the form of a list of suitable recipients from about 6,000 patients now on the computer. But the computer doesn't tell us who should get the kidney. That is a value judgment. Most programs offer available kidneys to centers that have the best matched recipient(s) first and then to lesser matched patients. But some use other criteria.

In Pittsburgh we want to use our kidneys for local recipients. That's our basic value judgment. If the kidney is unsuitable, we will enter the donor's blood and tissue type into the computer. When we get the printout, we start calling. We always start with the best matches, but if, say, thirty hours have already gone by, and we have two good possibilities, we may choose to call Philly over Albuquerque to save time. The computer only gives us information. We select who to call. Let me be frank. Some institutions have a poor track record for using kidneys sent to them. They may be understaffed or have a poor commitment, or whatever. We tend not to call them.

Let me tell you the difference between distributing kidneys and hearts and livers. We travel 150 miles or so from Pittsburgh to other hospitals to retrieve a kidney. When we go to Altoona, say, 130 miles away, we don't know who the recipients will be. We just go there, take out the kidneys, come back to the lab, have the lab work (tissue and blood typing) done, which takes five or six hours, and see if we have a good match. With kidneys we can do that. We can preserve donor kidneys for two days.

But with livers and hearts the preservation time is much shorter. A liver can be preserved as long as twelve hours. Dr. Thomas E. Starzl, professor of surgery at the University of Pittsburgh School of Medicine, has done this, but doesn't like to go beyond eight hours from the time the blood flow in the donor ceases to the time the blood flow is restored in the recipient. We can keep hearts viable for four hours, but we like to preserve them

DONALD DENNY is director of organ procurement, Transplant Foundation, University of Pittsburgh Medical School.

formation to bereaved family members. Those working for organ procurement agencies are under severe pressures from both their own organizations and the transplant hospitals to locate and obtain organs.

Another difficulty with informed consent arises from the varying attitudes of hospital personnel. In many hospitals medical personnel never ask permission from bereaved family members to harvest organs. Some do not ask out of ignorance; others are understandably reluctant to broach the subject with people who are emotionally devastated. Comments like "I feel like a vulture" and "the requests make me feel too ghoulis" are typical of the burdens voluntarism places on those who must confront families under the most trying circumstances imaginable for obtaining informed consent. However, in other hospitals medical personnel are

no more than three. Therefore, we do not employ tissue typing to decide who the recipient will be. There simply is no time. We need to know who the recipient will be before the heart or liver is removed. Thus we have set up a system that is designed to complement the computer system. Actually, it's turned out to be the best system employed for hearts and livers. It's a service of the North American Transplant Coordinators Organization (NATCO).

With hearts and livers we think of blood type and size compatibility and the temporal factor. So in many ways matching is much simpler. Liver and heart transplant recipients are terminally ill. They will die within weeks without a transplant. Kidney patients have the alternative of dialysis. They can afford to wait.

The national UNOS system is available for hearts and livers, as well as kidneys. But I must access the terminal from my office (some terminals are in a lab, and you need to get clearance to get in). Let's say a call comes in at 2 A.M. Altoona says, "We have a possible liver donor." It is not efficient to drive seven miles to my office, first getting a printout of patients who are waiting for livers around the country and then going out to talk with the donor's family and to evaluate the donor—speed is important. Instead, I use the 24-ALERT phone system.

I pick up the phone from my home or in my car on the way to the hospital and dial a number known only by organ procurement people. The 24-ALERT number has been in effect since September 24, 1982, and the listing it provides is updated at least once a day and sometimes as many as four times daily. I get a recording of what every liver and heart center needs in the way of donor organs. I listen for eight or ten minutes. There will not be a listing of names of patients—only of blood type and weights of donors needed. We have ____ number of children (or adults), blood type ____, weights _____. The patients for whom organs are needed are categorized by priority codes—priority 1 indicates those who are hospitalized and critically ill. These patients are given first opportunity for a donor organ because they are near death. If a

well trained and quite willing to make a request. Some hospitals have a policy of asking every family member; some do so only on a selective basis.

Fairness alone demands a more equitable distribution of the burdens of decision making among the relatives of potential donors. The reliance on a public policy of encouraged voluntarism produces a situation where geography and chance play the key roles in determining which families are asked and which are not.

The Advantages of Presumed Consent

Not only has voluntarism failed to meet the existing demand for organs; it has also produced decisions that are highly suspect because they are made in an emotional cli-

patient in Minnesota is priority 1 and a patient in Tennessee is priority 3 (stable and waiting at home), I'll call Minnesota. There is a similar phone number on the west coast. Those hospitals in the center of the country will put their donor needs on both.

UNOS charges to register for hearts or livers (because the cost of the system is not government-reimbursed). But it's not so much the cost that deters transplant centers from using it. The phone is more accessible and provides immediate information. Let me give you a real example.

The Philadelphia organ procurement program got a call from a local community hospital, which had an apparently brain-dead accident victim. The hospital staff thought the family would be willing to donate. The transplant coordinator went to the hospital, looked at the chart, did tests, and found that the victim was a suitable candidate for donation of heart, liver, and kidneys. He consulted with the family. They gave permission. The coordinator then called 24-ALERT to find who had suitable recipients and were within flying range of Philly. A team came down from London, Ontario, for the heart; from Philly for the kidney; and our team came from Pittsburgh for the liver.

From September 24, 1982, through September 30, 1983, through the 24-ALERT system 122 livers were recovered and transplanted at nine centers in the U.S. and Canada; seventy-three hearts were recovered and transplanted at nine institutions in the U.S. and Canada; and two heart/lung blocs were recovered and transplanted in two centers in the U.S. and Canada. If the number of potential recipients for hearts and livers grows, as we anticipate, we will need to devise a different system. In fact we have already begun planning to upgrade the system to a voice computer accessed by push button telephone. This system will be capable of talking to the user and will provide recipient information selectively based on the donor data entered by the caller. The system will continue to be offered at no charge to transplant centers. But right now our present system is equitable and it works.

mate of sudden death, grief, and vulnerability. Given the obvious burdens that voluntarism places on both medical personnel and family members, a public policy of presumed consent with respect to cadaver donation would be far more just and humane to both.

Families should be asked not whether they will consent to the donation of organs but whether they have any objections. As James Muyskens has rightly observed,

When we find ourselves in . . . "boundary situations" —when our lives have become unraveled—we need ritual, routine, and automatic procedures. These procedures ought to be those that reflect our collective judgment expressed in more normal times.⁷

Every opinion poll taken over the years shows a majority of citizens willing to serve as organ donors upon their death. If it is possible to fully and adequately protect the interests of those who do not wish to so serve, then it makes no sense to force a small minority of families to confront the question of donation under conditions that make rational deliberation not only difficult but also painful.

If all hospitals were required by law to utilize all suitable cadaver organs for donation unless an individual had (a) placed his or her name on a central computer registry indicating an objection to transplantation; (b) carried a card indicating that he or she did not wish to be a donor; or unless (c) family members had raised an objection to donation, we would create a public policy far more likely to bridge the current gap between supply and demand, while assuring the autonomy and free choice of every citizen. Even if we adopt the most conservative position and do not take organs in the rare situations where there is no indication of the individual's wishes and no family members can be located, there would still be a sufficient supply.

Under such a system the burden of decision with respect to cadaver donation would be equitably allocated. Anyone suffering the tragic and unexpected loss of a loved one would know that organ donation was routine. Medical personnel would be asked to perform the far more psychologically manageable task of inquiring whether the potential donor or family had any objection to ordinary practice. Governmental and regulatory authorities would be responsible for assuring that all hospitals complied with the society's frequently expressed desire to utilize organs to save lives and restore vital biological functions whenever possible. Moreover, such a system might reduce major costs that are involved in maintaining a system based upon encouraged voluntarism. First, massive advertising and public education campaigns must be constantly maintained to remind individuals about the need for organ donation. Though it is difficult to obtain exact figures, the Red Cross, the National Kidney Foundation, and the numerous eye banks located throughout the United States estimate their advertising and promotional costs to be in the millions of dollars.

A voluntary system must also educate emergency room staff to be on the watch for potential organ donors. This "in-service" professional education is very expensive since

Another View On Presumed Consent

Most of the people I've spoken to, including the Health and Scientific Affairs Committee of the National Kidney Foundation, feel that presumed consent is not quite the American way. It is relatively coercive, compared to the more classical freedom of choice that characterizes our way of life. Consent should be positive, not implied. Those who are very anxious for more organs are tempted by such ideas.

True, there is a need for more organs, though because of dialysis the kidney recipient is not as great an emergency as the person waiting for a liver or a heart. The National Kidney Foundation recommends trying to work through physicians, state and county medical societies, and the American Hospital Association to establish procedures to assure that registered donors are identified at the time of admission to the hospital. That should be done whether the admission is routine or emergency.

The Joint Committee on Accreditation of Hospitals could require hospitals to ask about organ donation at the time of admission, but I don't know if JCAH is interested in doing that. If there were such a requirement, it would subtly raise the question of organ donation in the minds of the family and the patient at an early time. The admission form could have a space for indicating whether the patient had registered as a donor on a driver's license or card. That information should be on the record and follow that patient to the ICU. This is by no means done uniformly now.

We have made progress in educating the public. Now we also need to educate physicians and ICU unit personnel in order to establish a new way of thinking.

David A. Ogden, M.D. *President, National Kidney Foundation*

trained personnel must visit hospitals on a regular and continuous basis if the training is to be effective. The frequent turnover of emergency room staff in most hospitals further adds to the cost of continuing professional education. The New York Regional Transplant program estimates that the cost of education for procuring one kidney is \$3,500.

New Policies to Protect Living Donors

A policy of presumed consent would improve the system by which organs are procured from cadavers; but what about living donors? One of the central problems of organ donation by living donors is the need for access to medical records in order to locate suitable donors. This is especially so for transplantation involving renewable tissues such as bone marrow where it may be necessary to search through biological information on literally millions of candidates in order to establish a suitable match. Much of the information

about tissue types now contained in medical records and data banks was gathered for purposes other than organ donation—for routine blood donation, for example. When a patient requires a transplant, searches of existing data banks are often conducted surreptitiously—and unethically.

It is difficult to protect the identity of those whose names are stored in hospital computers. Staff leaks are not uncommon, and the media pressure can be intense to release the name of a person who may be able to make a life-saving tissue donation. For example, William Head, a victim of a fatal form of leukemia, recently attempted to pressure an anonymous California woman to make a donation of bone marrow to him, first through the courts and then later through the media.⁸ He learned of the woman's existence as a possible donor as a result of an inadvertent disclosure during a telephone conversation with a hospital technician at the University of Iowa. The mother had been tissue-typed as a potential donor for her child who later died of leukemia.

The Head case illustrates the need for creating a national registry of consenting organ donors. A serious effort must be made to obtain appropriate consent from those whose names are already listed on existing tissue registries. This could be done by phoning or writing to all of them and deleting the names of those who do not wish to be listed as potential organ donors.

But when new people are entered into the data banks, a policy of presumed consent should govern. That is, when information concerning a person's blood type, HLA type, or other biological markers is collected, that person should be told that this information will automatically be stored for purposes of possible organ donation at a future date. Those who do not wish to participate in organ donation should be given the opportunity to withhold their consent to information storage for such purposes and their names should not be included in any tissue registries.

While the costs of compiling and maintaining such tissue registries may be high, it makes sense to institute a policy of automatically storing biological information unless an objection is raised. Such a policy would significantly increase the number of candidates available as potential donors while helping to alleviate further conflicts between those in need of transplants from living donors and the privacy and confidentiality interests of possible donors.

Many of the transplant procedures now being attempted fall into the category of experimentation. Living donors, like any other human subjects involved in experimental procedures, should be able to make free, voluntary, informed choices about whether they wish to participate. Free choice requires adequate time and a suitable environment for making decisions. Voluntariness means that no coercion or duress should be brought to bear. And subjects can only be said to be informed when they comprehend all relevant and reasonable facts about the procedure that is being proposed. Thus it seems inappropriate to allow potential donors to be

approached by courts or harangued by the media concerning their willingness to serve as organ donors for someone who needs a transplant.

Some organ transplants, such as those involving kidneys, have been so successful that it seems odd to view them as experimental. Nevertheless, from the live donor's point of view, removing an organ for transplantation does not meet the ordinary definition of what constitutes therapy in medicine. There is no direct benefit for the donor other than, perhaps, some emotional or psychological rewards. The intent of transplantation is never to benefit the donor medically; it is always to benefit an identified or potential recipient.

In light of the nontherapeutic status of live organ donation it seems reasonable to adhere to the strictest standards available in deciding what values should govern informed consent even in proven forms of transplantation. The current procedures and protections inherent in existing informed consent doctrines seem to satisfy this requirement, but public policy must be modified to insure that they are always strictly followed.

In the heated and stressful environment that surrounds a request for transplantation from a living donor, there is a tendency to forget that time is needed for someone to make a voluntary choice. Cooling-off periods, access to privacy, and time to consult with friends, relatives, or experts all appear to be necessary conditions for informed choice.

Voluntariness is also difficult to achieve. Potential donors can be and have been—as in the Head case—subject to tremendous pressures, especially when the needs of a particular person have been widely publicized. Direct personal appeals can be tremendously coercive. Given the kinds of pressures a needy person can bring upon a donor it seems reasonable to institute policies that discourage or minimize direct contacts between organ recipients and potential donors, to the extent that this is possible.

It is equally important to respect the potential donor's right to say no. Once a person has been given all pertinent information and a reasonable opportunity to decide, those attempting to obtain informed consent—be they family, clergy, medical personnel, or the recipient—must be willing to accept the decision, whatever it may be. Once a donor has said no to a reasonable request, continued approaches constitute coercion. Courts, health professionals, and legislators must understand that a commitment to voluntarism as the policy governing donations from living donors requires that individuals be given the chance to say no as well as yes.

The Costs of Organ Transplantation

Organ transplantation, whether from living or cadaver donors, is enormously expensive for the patient, particularly for new and evolving techniques. The costs of heart transplants are estimated at \$100,000, of lung transplants \$80,-

000, and of kidney transplantation \$30,000. Very few people can pay these sums out of their own pockets. Yet both government and third-party payers have been reluctant to bear such huge costs, fearing that continued progress with respect to transplantation will saddle them with enormous medical expenses. The number of people who could potentially benefit from the transplantation of kidneys, hearts, lungs, pancreases, and livers numbers in the millions, and it is not clear whether or how such costs should be borne in our society.

Given the high cost of transplantation and the uncertainties over who will pay, it is not surprising that many people are currently being denied transplants solely because they cannot pay. Some hospitals refuse to operate on those who lack private means or third-party coverage. Other hospitals will take as patients only community or state residents. A few hospitals demand full cash payments in advance before they will even enter a candidate's name on a waiting list for a liver or pancreas.

A public policy of presumed consent regarding cadaver donation would help to reduce the current costs involved in transplantation. To some extent, the cost of professional education, advertising, and donor recruitment is factored into the rates patients are required to pay. Further cost savings for patients could be obtained if a national registry of living donors could be organized to expedite the matching of willing donors and suitable recipients.

Nevertheless, despite the cost savings that could be expected from these policies, there are still enormous costs associated with transplantation. Historically our society has been reluctant to withhold life-saving medical treatments on the basis of an inability to pay. Nowhere has this reluctance been more in evidence than in the End Stage Renal Disease Program (ESRD), created in 1972 under Medicare to cover the costs of dialysis and transplantation for those suffering from renal failure. At that time the federal government solved the problem of allocation by deciding to reimburse the cost of care for every patient.

In today's constrained economic times such a policy would be very difficult to expand to the newest forms of organ transplantation. With millions of persons potentially in need of transplantation now or in the future, a blanket reimbursement for the procedure would eventually bankrupt the Medicare and Medicaid programs. What then should governmental policy be regarding reimbursement of transplantation?

First, reimbursing the costs of transplantation may not always be the best policy to adopt toward diseases of the heart, liver, lung, and pancreas. Most of the 60,000 patients receiving dialysis or transplants under the ESRD program suffer from kidney failure as a result of genetic conditions, hypertension, or the side effects of diabetes. Very few could be held liable for directly causing their disease.

The same cannot be said about many of the diseases that afflict the heart, lungs, or liver. The vast majority of adult

How Other Countries Handle Consent

Thirteen countries already depend on presumed consent as the basis for removing organs for transplantation and some of them also use some form of donor card. These findings emerged from a survey conducted in 1979 by Frank P. Stuart, Frank J. Veith, and Ronald E. Cranford ("Brain Death Laws and Patterns of Consent to Remove Organs for Transplantation from Cadavers in the United States and 28 Other Countries," *Transplantation*, Vol. 31, No. 4, pp. 238-244). The survey was based on responses from organ transplant centers in twenty-eight countries.

In about half the countries with presumed consent (Finland, Greece, Italy, Norway, Spain, and Sweden) physicians still consult the families of the deceased to make sure they have no objection to organ donation. But in Austria, Czechoslovakia, Denmark, France, Israel, Poland, and Switzerland, physicians proceed without asking unless a prior objection has been raised by the family or the deceased.

All the English-speaking respondents (Australia, Canada, Great Britain, Ireland, New Zealand, and South Africa) rely on donor cards or family consent. In the absence of family, all but three of the twenty-eight countries (India, Japan, and South Korea) permit organs to be removed at the request of hospital officials or medical examiners.

Though countries with presumed consent laws come closer to meeting the demand for organs, the authors say, they still have sizable waiting lists for kidney transplants. The reason for the disappointing results is that "presumed consent laws increase the likelihood of kidney salvage after a potential donor has been identified, but they do little or nothing to stimulate hospital based nurses and physicians to aid in that identification." The problem of encouraging donations from hospitals distant from or unfamiliar with transplant centers, they conclude, "is a serious one for countries with and without presumed consent laws." —J.B.

patients who would be candidates for transplantation of these organs are suffering as a result of smoking or drinking. In the long run, it would be cheaper as a matter of public policy to attempt to modify personal lifestyles than to reimburse the costs of replacing ravaged organs after twenty, thirty, or forty years of damage. Society may well be willing to pay for transplants for children suffering from hereditary liver defects. It will be far less willing to pay for a transplant resulting from cirrhosis of the liver induced by years of alcohol abuse. At minimum, funds for organ transplantation should be matched on a dollar-for-dollar basis with funds for public health efforts to prevent the medical consequences of smoking, drinking, and other deleterious personal behavior.

Of course budgeting funds now to lessen the need for organ transplantation does not solve the problem of decid-

ing what to do about those already afflicted. The flaws of the ESRD program are particularly instructive here.

The political atmosphere surrounding reimbursement for transplantation closely resembles the one that governed paying for dialysis fifteen years ago. Powerful lobbying efforts were brought to bear on the Congress to fund the emerging therapies of dialysis and kidney transplantation. At the time proponents estimated that the ESRD program would require a maximum expenditure of \$400,000 for all eligible recipients. A patient was dialyzed on the floor of Congress to show the life-saving power of the technology. Local communities mounted campaigns directed at state and federal authorities to cover the medical costs of their residents.

This scenario is being replayed today with respect to transplantation. Dramatic Congressional hearings have already been held in which patients and their families have made special pleas for compensation. Physicians at the University of Pittsburgh, where most of the liver procedures are currently being done, have published cost estimates for the surgery ranging from \$40,000 to \$55,000 per patient.⁹ Experts in liver transplantation have estimated that no more than a few hundred individuals per year will require transplants.

The problem with these predictions, as was the case with respect to kidney dialysis, is that they are based upon underestimates of both cost and need. While the published figures at Pittsburgh are in the \$50,000 range, hospital administrators at the same institution have required prepayments of \$100,000 or more by out-of-state patients for a person to be placed on a waiting list for a liver transplant. The \$50,000 gap between the cost estimates and prepayment requirements is due to very conservative accounting of the "costs" of liver transplantation by those doing the procedure. It does not include the current costs of organ procurement, rehospitalization in case of organ rejection, and rehabilitation and psychiatric follow-up for this type of surgery. The Task Force on Liver Transplantation in Massachusetts, which reported to the state's Commissioner of Public Health in May 1983, estimated the total costs associated with a single liver transplant at \$230,000.

Similarly, estimates of the number of candidates for this form of transplantation are based upon existing criteria for medical suitability at the few centers around the world where the procedure is done. These criteria exclude almost all patients over fifty, anyone suffering from cancer of the liver, and anyone suffering from severe emotional or psychological difficulties. This patient profile closely resembles that of the first patients selected for either dialysis or kidney transplant fifteen years ago. Patients tended to be between fifteen and fifty, had no psychiatric problems, had stable family support, and were almost always free of other complicating illnesses. However, once physicians became familiar with the techniques of dialysis and kidney transplantation the criteria for medical suitability expanded very quickly. By 1983, dialysis was being performed on persons

regardless of age, on persons with grave psychiatric and behavioral disorders, and on people who had other complicating conditions and illnesses. The same broadening of the medical criteria can be anticipated for liver and other types of transplantation. Definitions of need are always made relative to the state of the art at a given time, and there is every reason to assume that liver transplant techniques will undergo the same kind of advances that characterized dialysis and kidney transplantation.

Unquestionably, even in their current state of development, the many recent forms of organ transplantation, particularly of the heart or liver, can extend life. But survival rates of two years or even five do not settle all the difficult policy questions that need to be addressed with respect to reimbursement. Those involved must at least provide accurate cost information concerning organ procurement, surgery, rehabilitation, and patient management if reliable cost projections are to be made. Also, the cost information now available is based upon a highly selected sample of recipients. When the pool of recipients expands, radically different cost information must be obtained if the government and third-party payers are to avoid the cost overruns that continue to haunt the ESRD program.

The Need for Evaluation and Regulation

Historically, there has been almost no federal regulation of evolving medical techniques and therapies. Organ transplantation is no exception to this pattern. Given the cost of organ transplants and the scarcity of the supply of organs, the time has come for the federal government to take a more active role in monitoring this procedure. Who should be allowed to do transplants? What level of success should constitute minimally acceptable performance? The history of the ESRD program suggests that a federal agency must both monitor and assess information on organ transplantation in order to facilitate the safe, efficacious, and efficient delivery of organ transplants to those in need.

When the ESRD program was launched no provision was made for carefully monitoring the effort. Despite the large costs associated with the program—over \$2 billion in 1982—no effort was made to collect basic epidemiological information concerning who received dialysis, where they received treatment, the mortality figures at various centers, the quality of life afforded by the treatments, and the costs of transplant versus home or institutionally-based dialysis. Without a single national center or agency to monitor the program, differences in cost and efficacy among different centers and providers went unchecked. A repetition of this history with respect to transplantation would be financially and morally intolerable.

Since it is very likely that Medicaid, Medicare, and third-party insurers will continue to be asked to cover the costs of heart, liver, lung, pancreas, and other newly evolving forms of transplantation, it is essential that an agency be created

within the Health Care Financing Administration to supervise the costs of these procedures and assure the collection of all necessary information concerning epidemiology, clinical course, quality of life, side effects, and demographics. A separate center, perhaps a revitalized National Center for Health Care Technology (NCHCT), or, as proposed by Congressman Albert Gore, Jr., of Tennessee, a National Center for Organ Transplantation (NCOT) within the Department of Health and Human Services, should be charged with the tasks of assessing organ procurement, monitoring the safety and efficacy of transplant techniques, and helping to determine which institutions should be eligible for federal funding.

Consider the role such agencies might play with respect to liver transplantation. The NCHCT or NCOT should require all hospitals conducting liver transplants to compile complete patient profiles (age, race, sex, complicating illnesses, socioeconomic status, etc.) in a standardized manner. Since very little is known about the relationship between the type and severity of liver disease and transplantation success rates, this data must be collected and reported as well. The side effects of liver transplantation and of the various immunosuppressive drugs utilized in such surgery, such as Cyclosporin, must also be monitored. The effects of blood transfusions, mismatches in tissue type, and concurrent physical and psychological problems should be analyzed.

The national center would also be responsible for detecting differences in success and survival rates of both transplanted organs and patients among various institutions. With such information reasonable guidelines could be set for the selection of patients for liver transplant attending to factors such as age, psychiatric history, mental status, and alcohol abuse. Such data would allow liver transplantation to be defined as safe, efficacious, and therapeutic for certain populations while still experimental and unproven when applied to other groups.

HCFA should commit itself to a policy of controlled dissemination of liver transplantation through its Medicaid and Medicare compensation powers. The agency should set financial caps on the overall costs that a particular institution may incur in a given year for liver transplantation. HCFA should certify institutions as eligible for compensation through federal programs only if: (a) they comply with all reporting and monitoring requirements of the national center, (b) they meet minimal standards of tertiary care for this complex procedure, and (c) they have established fair and equitable selection criteria for candidates. In bureaucratic life it is always easier to expand a program than to shrink existing programs. This norm should guide HCFA's deliberations as it considers whether to certify a particular institution as Medicaid/Medicare eligible for liver transplantation.

Important though it is, a policy of independent assessment and controlled dissemination at the federal level will not do away with the terrible moral dilemma of allocating resources among the medically needy in our society. If liver

transplantation is approved only for those few who have nonalcohol-related causes of hepatic failure, 40,000 individuals will still die each year without hope of a life-saving transplant.¹⁰ Hard choices will have to be made no matter what policy is adopted in liver transplantation. There are simply not enough organs to transplant to all in need. More important, not enough is known about the procedure to say that it is safe and efficacious for every candidate. Nevertheless, a stronger federal role in monitoring and assessing transplantation would help to assure a more equitable distribution than is provided by leaving allocation to hospital administrators and physicians.

The New Era of Transplantation

Progress in transplantation has highlighted the inadequacy of existing public policy. There is too great a gap between supply and demand, too little protection for families and prospective donors, and too much potential for economic abuse to continue to rely on a system built around encouraged voluntarism and laissez-faire in the procurement and allocation of scarce organs.

A policy of presumed consent both for cadaver donations and for determining the eligibility of living donors with respect to data banks and registries could help to alleviate the shortage of organs that permits so many to die without an opportunity for treatment. Presumed consent would also routinize the procurement of organs in a way that best protects the interests of all parties involved in organ transplantation—donors, families of donors, recipients, and medical personnel. A new public policy committed to independent assessment and controlled dissemination of transplantation services, and to presumed consent, would greatly help to reduce the unavoidable moral and economic costs of medical success.

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