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Ethical Issues in Organ Procurement and Transplantation

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Abstract

The Ciba Foundation held the first international, interdisciplinary conference on ethical and legal issues in transplantation in March 1966. Many of the ethical issues discussed at that conference remain with us today. Organ procurement and transplantation have forced the medical community and society at large to ask such fundamental questions as when are we dead, how can death be declared so that any life-support measures can be discontinued? Is it ethical to remove an organ or part of an organ from a living person? Since there is such a shortage of organ and people on transplant waiting lists die for lack of an organ, what types of incentives, if any, can be used to increase the organ supply? Transplant centers face additional ethical issues. How can a limited supply of organs be fairly allocated to a large number of patients on the waiting list? Are the methods of putting patients on the waiting list appropriate? Transplant centers are regulated by a variety of governmental organizations. These organizations may have performance criteria. Do these performance criteria lead transplant centers to modify which organs they will accept or which patients they will list? As long as a shortage of organs remains, these ethical issues are likely to persist.

Keywords: organ procurement, transplantation, organ allocation, brain death, organ donors, donor registries, international organ trade, transplant waiting list, transplant regulation

1. Introduction

The first successful organ transplant occurred in 1954 when Dr. Joseph Murray and his team in Boston transplanted a kidney between identical twin brothers. This was not the first kidney transplant reported. Dr. Yu Yu Voronoy reported, in 1936, a kidney transplant using a deceased donor [1]. That and several kidney transplants by Dr. David Hume in the early 1950s, also in Boston, were not successful. Once the success of transplantation was demonstrated and the

development of immunosuppressive drugs permitted survival of organs from non-identical twins, transplantation rapidly developed. It was not long before the number of people needing organ transplants outpaced the supply of organs. The disparity between need and supply—currently in the United States, there are more than 120,000 people awaiting an organ transplant yet in 2015 there were only just over 30,000 transplants performed—has given rise to the issues that generate the most ethical discussions in organ procurement and transplantation: (1) How can we increase the number of both living and deceased organ donors and (2) What is the best way to allocate (ration) the scarce organs that are available? Twenty people on the waiting list die every day. Many others are removed from the waiting list because they become too sick while awaiting an organ. And things may even be worse. Because of the organ shortage and regulatory oversight of outcomes, transplant centers feel forced to list only the best candidates. Probably, many others could benefit from an organ transplant. Regulatory oversight of transplantation and organ donation with its performance requirements may have also contributed to having fewer organs for transplantation and fewer transplants [2].

The situation is similar in Europe and many other countries with a great disparity between the number of organ donors and the transplant waiting list. In many other countries, there is no or only minimal access to organ transplantation. These disparities between the number of donors and the number of patients on the transplant waiting list gives rise to several potential ethical issues.

2. Ethical issues in organ donation

2.1. Declaration of death

The first kidney donor was an identical twin. Since that time both living and deceased donor organs have been used. Initially, living organ donation was limited to blood relatives, because it was believed that there would be less likelihood of rejection. Since that time, immunosuppression has become so effective that currently virtually any healthy adult can donate. Kidneys are the most common organ from living donors, but livers, lung, intestine, pancreas, and even one heart (from an individual with a healthy heart who had it removed as part of a combined heart–lung transplant) have been performed.

Most organs, however, come from deceased donors. From the beginning, transplant programs have followed the dead donor rule (DDR): organs should only be recovered from donors who have died and nothing should be done by transplant or organ recovery programs that would hasten the death of a donor. There are two ways someone can be pronounced dead: by neurologic criteria and by circulatory criteria. Donation after neurologic determination of death (DNDD), also called brain death, occurs when the entire brain including the brain stem has no detectable function. Some physicians also complement the clinical examination with a radiologic test that shows no blood flow to the brain. Donation after circulatory determination of death (DCDD), also referred to donation after cardiac death, occurs when there is no detectable blood flow in a patient. There is usually a waiting time of 2–5 min to ensure that

blood flow will not spontaneously reoccur, but some hospitals may use a shorter or longer waiting period. Both measures for determining death have raised concern.

The first kidney transplants used organs from donors who died from circulatory death [1]. The concept of neurologic or brain death did not come about until the late 1950s. It arose with the development of ventilators and intensive care units. There were patients who demonstrated no clinical brain function but who when maintained with the aid of a ventilator continued to make urine, have a normal blood pressure, and exhibit many normal physiologic findings. Yet, these individuals never recovered. That caused physicians, ethicists, philosophers, religious leaders, and government officials to ask what it really means to be alive or dead. Ultimately, the concept of neurologic death came about, albeit with much controversy. The concept of neurologic death changed the criteria for determining death that had been used for thousands of years. Many physicians and ethicists initially believed it was not ethical to consider neurologic death. And, the new concept seemed to violate traditional religious concepts of determining death.

Some individuals (and some cultures and religions) feel it is wrong to “desecrate” the body of a dead person by using the body parts for transplantation. But this is a minority view. The three Abrahamic religions—Christianity, Islam, and Judaism—while believing that a dead body should not be desecrated and should be treated with great respect, all feel that preserving life through organ transplantation is a higher good. Therefore, recovery of organs for transplantation is not only permitted, it is to be commended [3].

Virtually, all hospitals are required to have brain death policies. But brain death is not likely to be pronounced in hospitals without intensive care units or that do not have the ability to ventilate patients such as rehabilitation hospitals, psychiatric hospitals, and hospitals without intensive care units. The criteria used to diagnose brain death may vary from state to state. Some states require only one physician to pronounce brain death, while others require two physicians to make the diagnosis before death is declared. The definition of brain death is frequently according to generally accepted medical criteria. One set of criteria has been defined by the American Academy of Neurology [4].

Ultimately, death determination by neurologic criteria became accepted by most individuals, including religious experts. The use of organs from DCDD donors was greatly reduced and, in many places, was eliminated altogether. But growing shortage of organs sparked renewed interest in DCDD. In the United States, several organ procurement organizations (OPOs) began to recover organs from these donors, because transplant centers were willing to use them. The same changes occurred in many other countries as well. But now, the medical and lay communities had grown so used to organs recovered from DNDD donors that some individuals objected to using organs from DCDD. They asked whether these donors were really dead. The United Network for Organ Sharing has published a set of guidelines for recovery of organs from DCDD donors: Model Elements for Controlled DCD Recovery Protocols (<https://www.unos.org/about/governance/>).

The controversy about the ethics of DCDD and DNDD continues to this day. Some people question whether these donors are truly dead. Rady et al. [5] have reviewed the arguments

against the validity of neurologic and circulatory death. Objections to neurologic death include that neurologically dead patients maintain many functions that are coordinated by the brain. There is often preservation of hypothalamic–pituitary functions. A non-flat-line electroencephalogram (EEG) can frequently be obtained. Clinical tests to confirm irreversible cessation of whole brain and brain stem functions are not completely reliable. But brain-death determination requires that the function of the brain and brain stem should be permanently absent. It does not require that every cell in the brain be dead. The EEG is unreliable as a determinate of cerebral activity, since it is sensitive to surrounding electrical activity in the environment.

Objections to using circulatory death determination include the possibility of spontaneous autoresuscitation or the presence of electrical activity of the heart after 10–15 min of circulatory arrest, preservation of cerebral activity on EEG after three minutes of circulatory arrest and that hearts recovered after circulatory arrest can be successfully transplanted. There are other objections as well. Heparin, an anticoagulant, is usually given to the donor just before death occurs to prevent clotting in the organs. Heparin could theoretically hasten death if it induces bleeding into the brain. But since it is given only in the agonal stages of life immediately before death, it is unlikely to hasten death [6]. If the donor does not die within 60 min after withdrawal of ventilator support, recovery surgeons usually do not recover the organs, because the hypotension and lack of oxygen in the blood may have damaged the organs. But with new preservation techniques, surgeons are waiting up to 120 min and even longer in some cases. The waiting time after cessation of circulation may not permit sufficient time for the brain to die.

Because of difficulties some ethicists had with issues involved in assuring those declared dead by either neurologic or circulatory criteria are really dead, they feel that the dead donor rule and current methods of declaring death were accompanied by illusions and myths and that organ recovery may hasten the death of the donor [7–9]. They propose that the DDR should be abandoned and that a different recovery process should be initiated in patients with severe, unrecoverable brain injuries. Patients with devastating brain injuries, who would otherwise be declared brain dead or withdrawn from life support, should have their organs recovered under general anesthesia as part of the process of withdrawal of life support [5]. In their view, such recovery would avoid the fiction of declaring death by current methods and permit the recovery of more organs for transplantation.

2.2. Living donors

Living donors are those individuals who are alive at the beginning of organ donation and are expected to be alive at the end. They donate one organ or, in some cases, a portion of one organ. There were approximately 6000 living donors and 9000 deceased donors in the United States in 2015. Removal of an organ from a living donor is the only operation that is done specifically to help another person. In fact, living organ donors are chosen because they are healthy. So living organ donation would seem to violate one of the tenants of medicine: *primum non nocere*, first do no harm. Although they cannot be physically better off from the donation, they can receive psychological benefit from having helped a loved one or another person they may not even know.

But living organ donation has the potential to do great harm. First, there is the risk of death from the operation itself. The risk of dying during donor partial hepatectomy is 0.2%, and the risk of death during nephrectomy is 0.03% [10, 11]. The mortality risk of donor pancreatectomy or lung donation has not been determined. Even if the donor survives the operation, long-term health outcomes may still be at risk. Some liver donors have had to have liver transplants themselves because of injury to the bile duct. Most of the long-term outcome results have been recorded in kidney donors. Some reports from the United States have reported no adverse effects on longevity, hypertension renal function, or quality of life with follow-up as long as 40 years after donation [12]. Other studies, however, report a higher long-term mortality and risk of renal failure in kidney donors followed for as long as 44 years [13]. In the United States, data regarding living kidney and liver donor complications are available in reports of the Scientific Registry of Transplant Recipients [14].

Because of the real and potential risks to living organ donors, it is critical that these donors be carefully selected so as to minimize the short-term and long-term risks. In fact, Moore [15] questioned many years ago whether it was ever morally right and ethically acceptable to injure one person to help another. A statement by the Live Organ Donor Consensus Group did provide some guidelines for the evaluation and education of potential living donors [16]. Every transplant center would like to use only people who are in a state of perfect health and have normally functioning kidneys. But in an evaluation of the Organ Procurement and Transplant Network (OPTN) database, Davis and Cooper [17] found that 19.5% of donors were obese, 2% had a history of hypertension, 3.5% had proteinuria, and 12.2% had no health insurance. So one concern is whether it is ethically justifiable to use anyone as a living donor who is in less than perfect health, and, if so, how far can a donor deviate from less than perfect health?

Transplant centers differ greatly in their living donor acceptance criteria. And, the transplant centers that do accept (as most do) donors with less than perfect health can have different criteria. What degree of renal dysfunction or hypertension would disqualify a potential candidate? And on what basis does the center make its decision other than personal feeling of the selection team. Grams et al. [18] have recently created a model that can help to predict the risk of eventual renal failure in potential kidney donors. But there will always be some uncertainty in donor selection. Steiner [19] has pointed out that a "safe" kidney is a delusion. Centers should not ignore risk quantification, however, imperfect and only do what they are "comfortable" doing, because they must have defensible reasons for doing what they do. It is unethical to allow or to deny transplants without good reason.

It is important that potential living donors be fully evaluated and psychologically screened. It is possible that family members may have pressured someone to donate an organ. If the transplant team learns that the person does not really want to donate, many transplant centers will provide a medical excuse that eliminates him as a donor and does not alienate him from the rest of the family. Yet providing such an "excuse" involves intentional dishonesty by the transplant center. Is such behavior ever ethical? Even without pressure from family members, Testa [20] has raised the issue of whether donation can ever be completely voluntary because of the emotional relationship to a family member who needs an organ, something he has called "pressured consent."

Transplant centers are understandably wary with donors who are not relatives of the recipient or even have no relationship and who are willing to donate to whomever needs a kidney. The United States, Canada, and some European countries have recognized these non-related donors or altruistic, although their evaluations may receive special psychological scrutiny. Guidelines for non-directed donation have been developed in the United States by the United Network for Organ Sharing and the American Society of Transplant Surgeons [21].

Because of the unique nature of organ donation, it is important that the surgical team that cares for the donor be completely separate from the team that cares for the recipient. A consensus document advocated donor counselors who are independent of the transplant center to prevent the self-interest of the transplant center from influencing their judgment. Independent counselors or donor advocates could prevent the donation if they detected any unacceptable psychological or medical issues.

However, if it is accomplished, donor autonomy must be preserved, and the donor must be fully informed of potential short-term and long-term risks. And yet, transplant centers may vary in how they present risks. They can cite papers showing that kidney donors live longer or shorter than non-donors or that there is no difference. Many donors have made up their minds to donate before their first visit to the transplant center and are not easily dissuaded by any discussion about risks. Nevertheless, it is incumbent on every transplant center to present an honest and factual assessment of donor risks to the best of its ability.

2.3. Financial incentives

One of the most contentious issues is whether incentives—financial or otherwise—should be used to increase organ donation. In the United States, the National Organ Transplant Act (NOTA) has made offering organs for “valuable consideration” illegal. It is illegal to sell organs in every other country as well except for Iran. Saudi Arabia had an experimental trial of financial incentives in Riyadh that showed that it could substantially increase organ donation [22]. Yet, the public in the United States are in favor of some sort of reimbursement [23]. Until recently, living donors endured expenses such as travel, lodging, meals, and lost wages. Recently, in the United States, the National Living Donor Assistance Center (www.livingdonorassistance.org) began making help available for travel and lodging but not for lost wages.

Those who argue against incentives for organ donation point out that the altruistic system currently in place has served transplantation well. They maintain that having only altruistic donors—whether related to the donor or not—has eliminated any sense of coercion. Opponents of incentives also emphasize the potential risk to donors and the impact incentives might have on society’s moral perspective. They cite harms such as coercion, exploitation, undermining dignity, repugnance, and commodification [24]. They talk, however, about unregulated markets. Placing a price on body parts would lead to commodification of the human body, something that runs counter to religious teaching and good ethical practice. Other ethically appropriate methods should be used to increase donation. Furthermore, they argue, offering payment for organs would offend the sensibilities of many people and might result in fewer organs donated.

Those against financial incentives for living donors also claim that it is unethical for medicine to harm paid kidney donors for the benefit of others and that removing an organ, usually a kidney, leaves the person in poorer health. If that is so, of course, then removal of an organ for transplantation from any living donor would also be unethical. In some of these discussions, the international organ trade becomes conflated with financial incentives for living donors within a country.

Those in favor of incentives point out that the current system is not functioning adequately as attested by the long wait for an organ and an increasing number of deaths on the waiting list. Matas and Hays [25] favor regulated markets and maintain that a government regulated system would prevent the concerns voiced by opponents. Advocates of incentives claim those who are against having at least a trial of incentives are willing to see people on the waiting list die to preserve their own moral purity. Matas and Schnitzler [26] showed that living unrelated kidney donation would save more than \$90,000 (2002 US\$) and 3.5 quality-adjusted life years. They calculated that offering kidney “vendors” \$90,000 would be the break-even point for society (because of the high costs of maintenance hemodialysis) and would greatly help alleviate the waiting list. They are in favor of a regulated system of payment; there would be no payment outside the regulated system. Matas and Hays [25] argue that with organ donors remaining steady for the last 10 years and that during those 10 years more than 60,000 candidates have been removed from the waiting list because of death or because they became too ill. They maintain that those in favor and those opposed to incentives should stop talking past each other and carry out a well-designed clinical trial of incentives.

Those in favor of financial incentives add that payment for living kidney donors has eliminated the waiting list in Iran, the one country in the world that permits payment for kidney donation (which may not be considered an actual donation). Iran has had a regulated system of payment for living kidney donors for several years [27, 28]. The government provided payment of a fixed sum (\$3000–\$6000) to the donor. In addition, he was exempted from military service and received 1 year of health insurance [28]. Recently potential donors and recipients have been allowed to bargain directly and to agree on an amount for the kidney. This system has eliminated the kidney waiting list. Indeed, the only waiting list is for those who want to be kidney donors. But kidney donors in Iran tend to be the poorest individuals from the poorest part of the country. And many of them have had complications and poor health outcomes. Many, however, look on the Iranian model as exploiting the poor to benefit the rich.

Financial and other incentives have also been proposed as a way to increase the number of deceased donors. Considerations such as providing payment to the donor’s family, funeral expenses, donation to a charity, reduction in taxes, provision of health insurance, or preference on the waiting list should they ever need a transplant are some that have been suggested. All such incentives are currently illegal everywhere. But recently, the American Society of Transplantation and the American Society of Transplant Surgeons held a workshop on increasing organ donation [29]. They noted that NOTA was recently changed to allow certain expenses of living donors to be covered. While they believed NOTA did not permit direct payments for deceased organ donation, it could be interpreted to permit certain expenses of the donor or family to be covered. In a similar vein, a panel of ethicists, organ procurement

organization executives, physicians, and surgeons reported in 2002 on financial incentives for deceased organ donation [30]. The panel addressed whether an ethically acceptable pilot trial of financial incentives could be proposed for the family to consent to the donation of organs from a deceased relative. While the panel was unanimously opposed to the exchange of money, either directly or in the form of a tax incentive, for donation, they believed that it would be ethical to provide funeral expenses or a charitable contribution that conveyed the appreciation of society to the family for the donation. And since the panel believed that direct financial incentives are unethical, there could be no ethical trial of direct financial incentives. However, with several restrictions there could be a pilot trial of funeral expenses or a charitable contribution.

There are many arguments against financial incentives. There are also many arguments in favor of incentives. Many of the arguments against financial incentives have been summarized by Arnold et al. [30]. Generally, the arguments against financial incentives claim that they would violate altruism in organ donation and would commercialize organ donation in an unacceptable way by commodifying donor organs. Such commodification “uses the human body as a means rather than as an end in itself and brings an unacceptable commerce to the value of human life” [30]. They point out there is no evidence that financial compensation will increase organ donation (of course, except for Iran, it has not been tried).

Paying for organ donation would exploit the poor who would be most likely to accept financial incentives, and the organs would likely go to wealthier patients. But as some have pointed out, it is the poor who disproportionately are increased on the waiting list but who receive relatively fewer kidneys than wealthier waitlist candidates, and the poor die at a higher rate on the waiting list. Perhaps financial incentives, even if the poor are more likely to take advantage of them, will more likely help poor patients on the waiting list. An incentive system could increase the likelihood of transplanting organs from donors with diseases that might be transmitted to the recipient if the donor or family withheld important medical information in order to receive a financial incentive. Incentives could also influence the family to withdraw care prematurely. It could blur the line between withdrawing life support and donating organs [30]. It would also be difficult to standardize a system of payment and might introduce bargaining between donor families and recovery organizations, especially for organs of better quality and would place the transplant community on a pathway to paying for organs from live donors [30]. Those in favor of financial incentives or a “market” that would allow organ sales often offer an economic analysis of cost-effectiveness, but that still does not make the buying and selling of organs ethically acceptable. Furthermore, organ sales would likely not add additional organs for transplantation. Rather, sales or financial incentives would result in less altruistic donation. Organ sales would have an adverse effect on society and medical professionalism [30]. It would be difficult or impossible to set up a truly regulated market as many favoring incentives favor, because those in need of organs who have the means would likely make additional offers or go outside the system to make sure they got an organ.

There are also many cogent arguments in favor of financial incentives—if not totally changing the law, at least conducting a carefully regulated clinical trial [31–35]. The House of Delegates of the American Medical Association has come out in favor of a pilot study of financial

incentives for organ donation [36]. Those in favor of incentives or a market in organ sales point out that with current methods of altruistic organ donation, the number of donors is woefully inadequate to meet the need of those on organ waiting lists. The lack of organ donors becomes worse every year in relation to the wait list. And the waiting list may only represent a portion of those who could potentially benefit from an organ transplant. Transplant centers know there is a great shortage of organs and may only list their best patients. If many more organs became available, they might list additional patients who could also benefit from a transplant. The current altruistic system of obtaining organs has failed to supply enough to save the lives of thousands who could benefit. Even some of the most vocal opponents of financial incentives have favored a small reimbursement (\$300), which is meant to express appreciation for the donation and not to provide payment for it [37]. But this “appreciation” is still a payment of money to the family of an organ donor and would not occur without the donation.

If an important part of a government’s job is to preserve the lives of its citizens, and if financial incentives would increase the number of organs available, then government is not fulfilling its obligation. But by denying financial incentives because they would exploit the poor, harm the donor and commodify the human body, those who are against incentives claim to know what is best for potential donors and donor families. They can be accused of denying autonomy to the poor. We ask the poor to do many jobs that we ourselves would not want to do. And they may be anxious to do them, because they may not be qualified for more skilled, higher paying jobs. Furthermore, society does allow the sale of eggs, sperm, plasma, and the temporary sale (rental) of uteri for surrogate births. But those who are against incentives do not claim that all of these should be outlawed.

The issue of financial incentives either for living or deceased donors is not likely to be settled anytime soon. It could be that two ethical principles seem to clash. On the one hand, incentives might be bad for the reasons those opposed give. Yet the other ethical principle of valuing human life and attempting to preserve it by making more donors available with financial incentives is also a good argument.

2.4. Donor registries and authorization

Given that the current methods for determining someone is really dead are valid and that we are not breaching any ethical issues by recovering organs from them (despite that some continue to disagree—see above), what methods besides financial incentives can be used to increase the number of donors to help alleviate the great shortage? In 2015 there were 9080 deceased donors in the United States [38]. Yet, according to a study by Klassen et al. [39], there are more than 37,000 potential donors. No doubt, similar shortfalls in actual versus potential donors exists everywhere in the world.

In the United States as well as many other places in the world, organ donation has long relied on opting in; the donor while alive or the family has to grant permission for organs to be recovered after death. Some have argued that we all have a duty or moral obligation to our fellow man (or woman) to donate our own organs after death or those of a loved one who is a potential candidate for donation [40–43]. Menzel [43] maintains “contributing cadaver organs is not a matter of charitable goodness but instead normally an instance of the moral duty of

easy rescue.” The main argument has been that donation (some do not even like the word “donation” because it implies that the person has a choice and is not obligated) after death does great good, causes no discomfort to the organ donor, and does not cost the donor and the family anything [40].

With opting in, the transplant community has relied on donor and family altruism to grant permission for organ recovery. Public education and pleas to stress the need for organs have been used to increase organ donation. There are many routes to educating the public about the need including newspaper and magazine articles, television and radio announcements, billboards, posters and cards in public venues, distribution of donor cards, teaching materials for schools, talks by health personnel or donor families or living organ donors, and appearances at health fairs [44]. In recent years, the internet has also been used to promote organ donation through social media and a variety of web sites. In the United States, Donate Life Month occurs in April. Many public and private organizations promote organ donation and educate the public about the need for organs. Education of key hospital is also needed so the OPO is called every time there is a potential donor.

People can sign to be on a donor registry at a driver’s license facility or through the internet. Information is provided at the driver’s license facility and on registry sites on the internet that are inform the public about what agreeing to be an organ donor entails. Registration only covers brain dead donors. For donation after circulatory death, the family must still give its agreement.

In recent years, donor registries have registered individuals during life who have indicated their willingness to be organ donors when they die. And the transplant community has gone to great effort to increase the number of people who sign up for donor registries, either when renewing their driver licenses, signing organ donor cards, or registering on the internet. In many states, signing organ donor cards or being on state registries enables organs to be recovered after death even if the family objects. Israel gives individuals who have agreed to be an organ donor if they die preference on the waiting list if they should ever need a kidney transplant [45].

Because large organ shortages continue with opting in systems, some countries have adopted other organ recovery strategies and still others have been proposed. These include opting out, mandated choice, and financial incentives.

The United States and most other countries have long had an opting in form of consent whereby the donor while alive or the family of a deceased potential donor must give consent for organ donation before organs can be recovered. But many countries have adopted an opting out (also commonly called presumed consent) strategy to increase organ donation. Veatch and Pitt [46] have pointed out that none of the laws in the countries that permit organ recovery without explicit consent of the donor while alive or family actually mentions the words presumed consent. Among countries with versions of opting out laws are Austria, Belgium, Finland, Italy, Norway, Spain, and Switzerland. Cyprus, Hungary, Singapore, and Syria also have laws authorizing organ recovery without claiming to have presumed consent [46]. In these countries, organ recovery can occur following death unless the family specifically objects or the

donor while alive has indicated while alive that he does not want recovery to occur, but organ recovery agencies do not have to ask permission. While presumed consent still permits families to object to donation and to prevent it from occurring, the onus is on them to take the initial steps. Presumed consent has led to an increase in organ recovery in many countries that have adopted it. Spain is the most successful country in the world in organ recovery. In addition to presumed consent, Spanish hospitals have physicians who are responsible for identifying organ donors and promoting donation in the intensive care units [47].

There are ethical and practical issues in adopting opting out or presumed consent. It is counter to current practice in the United States and requires new legislation. Some claim it would be more humane than opting in, because organ procurement coordinators would not have to discuss organ donation at a difficult time for the family. But it may overlook the family's knowledge of the individual's preferences and may increase distrust of the medical community with concern that death may be declared prematurely [44]. Presumed consent would also cloud who has control over a deceased person's body (there is no ownership rights to a dead body). Veatch and Pitt [46] prefer the term "routine salvaging" to presumed consent as being more honest, because that term refers to a policy that is not grounded in presumption, but rather in a belief that society has a right to recover organs without individual consent. In other words, Can the state maintain that one of its important functions is to preserve the lives of its citizens and therefore can salvage (some would say confiscate) dead bodies for the purpose of organ recovery?

Mandated choice would require every adult to decide and record whether they wish to be an organ donor when they die. No country currently has a policy of mandated choice. It would eliminate the need to obtain consent. It would relieve the family of what might be an agonizing decision and prevent family disagreement. Because the person made a decision about their body before death, many of the objections of presumed consent would be obviated. Mandated choice has been criticized as being insensitive to families and forcing individuals to confront their own death. The American Medical Association Council on Ethical and Judicial Affairs feels mandated choice is not coercive because individuals are free to say no [48]. And by requiring individuals to decide on donation, it promotes autonomy.

2.5. The international organ trade

Many people, usually from First World countries and wealthy individuals from other countries among which are European nations, the United States, Japan, and the Gulf States, travel to Second and Third World countries where they can purchase kidneys and receive transplants. Also called transplant tourism, this travel is due to the insufficient number of organs in their home countries. In 2007, the World Health Organization estimated that of the 60,000 kidney transplants performed annually around the globe, 5–10% were due to the international trade in organs [49]. In 2011, the Institute, Global Financial Integrity, ranked the international organ trade in the top 10 of the world's most profitable crimes, with an estimated profit of \$614–\$1200 million per year [49]. The European Union has funded the formerly Human Organ Trafficking for Transplantation (HOTT) project, which addresses "trafficking in human beings for the purpose of organ removal" [49]. With the primary concern being exploitation of the

poor, virtually every country has made the international organ trade illegal and numerous international organizations have written position papers condemning it including the Transplantation Society, the Council of Europe, the World Medical Association, the Bellagio Task Force, and the Declaration of Istanbul (by the Transplantation Society and International Society of Nephrology, the World Health Organization, and the International Congress on Transplantation in developing countries) [50–52]. But transplant tourism continues to occur.

In addition to the ethical arguments against paying for organs given above, the international organ trade is also condemned because of the types of people willing to sell organs and the negative effects kidney removal has on the organ sellers. It is not ethical to take advantage of poor organ sellers for the advantage of the rich. People willing to sell their kidneys are poor and live in the poorest parts of the poorest countries. Their desperate situations mean that the choice to sell a kidney is not free or autonomous [42]. The international organ trade results in transferring kidneys from the poor to the wealthy who can afford to pay for transplants and the travel to countries where they can receive a transplant. These desperate kidney sellers may not provide a complete medical history either from ignorance or from fear of being rejected as a donor, which can further lead to adverse effects on their own health or to transfer of disease to the kidney recipient. After the kidney removal, the sellers have numerous problems including hypertension, kidney insufficiency, infection, and other medical problems [52]. They have limited, if any, access to medical care should they need it. They frequently become unemployable, because they are usually unskilled and not able to sustain heavy agricultural or construction work. Furthermore, they may become social outcasts and are alienated from their families, excommunicated from their churches, and excluded from marriage.

But there are opposing viewpoints that argue in favor of allowing individuals in any country to sell their kidney to willing buyers. Bakdash [52] who himself grew up in poverty says that “*poverty itself* is a kind of coercion. None of the decisions any poor person makes is made on the basis of free will—instead, these decisions are all dependent on the person’s dire financial situation.” He points out that the desperately poor may have to choose between selling a kidney and letting their children starve. People may be willing to sell their kidneys because they want a chance at a better life.

All the condemnations by the numerous health and transplant organizations have not stopped the buying and selling of organs in Second and Third world countries. While those who oppose buying and selling of organs point out that poor organ sellers frequently get poor medical care, Bakdash [52] points out that if medical care for these individuals were taken out of the shadows and brought into the open through a regulated market, they would be able to avail themselves of better medical care. Radcliffe-Richards and colleagues [53] have pointed out that there is much greater opportunity for “exploitation and abuse when the supply of desperately wanted goods is made illegal.”

Others maintain that prohibiting organ sales takes away the potential seller’s autonomy and is paternalistic. They believe that the wealthy who write the rules and regulations find it convenient to tell the poor what is good for them and to deny them the opportunity to possibly improve their situation.

2.6. Ethical issues in transplantation and organ allocation

As long as there is a shortage of organs for transplantation, there will be a requirement that those organs be offered to patients on the waiting list in an ethical manner. The allocation system should be “fair.” The Organ Procurement and Transplant Network/United Network for Organ Sharing (OPTN/UNOS) Ethics Committee adopted and updated in 2015 a white paper, “Ethical Principles in the Allocation of Human Organs” [54]. These principles provide a framework for regulations for the organ allocation policies.

The three ethical principles that govern organ allocations policies are as follows: “utility (doing good and avoiding harm), justice, and respect for persons” [54]. Utility “refers to the maximization of net benefit to the community (taking into account both the amount of benefit and harm and the probability of such benefit and harm)”. Justice refers to the fair distribution of benefits. And respect for persons refers to telling the truth, keeping commitments, and, especially, respect for autonomy. The OPTN/UNOS Ethics Committee realized that recommendations are for policy in a pluralistic society in which individuals may hold conflicting, yet reasonable, positions on organ allocation.

The three ethical principles individually may lead to policies that conflict with each other. Therefore, the principles have to be balanced in order to achieve an equitable outcome. Utility should lead to maximizing the net benefit for the community, thus incorporating the ethics principles of beneficence (doing good) and non-maleficence (not doing harm). In maximizing utility factors such as patient survival, graft survival, quality of life, alternative treatments, and age can be taken into account [55]. Social aspects such as social worth, social status, occupation, race, and so forth should not be considered in formulating policy.

The OPTN/UNOS Ethics Committee uses justice to refer to “fairness in the pattern of distribution of the benefits and burdens of an organ procurement and allocation program” [54]. It does not mean treating all patients the same but does “require giving equal respect and concern to each patient”. Factors to be considered in the application of justice include medical urgency, likelihood of finding a transplant in the future, wait list time, first versus repeat transplant, age, and geography. Autonomy requires treating people as ends in themselves, not only as means. But sometimes, respect for autonomy conflicts with other ethical principles, and sometimes, autonomy must be respected and other times, it must give way.

These ethical principles may lead to conflict when it comes to formulating actual policies. The OPTN/UNOS white paper also provides guidelines for resolution among principles. As a compromise when ethical principles conflict, an attempt should be made to formulate policies that give each of the conflicting principles equal weights rather than ranking them in some order.

Even though the white paper serves as an important set of guidelines, there have been strong disagreements about how to put them into practice. The OPTN has periodically changed the allocation scheme for every organ, always trying to achieve a new policy that would be more fair and better reflect the ethical principles. Yet as long as the organ shortage remains (which it will for the foreseeable future), any change in policy that increases organs to one group of patients must take away from another group. The dilemma of selecting ethical allocation

schemes was shown in recent years in the United States with the proposed revision kidney allocation using projected survival after transplantation and kidney quality and in 2011 to use kidney quality and allocating 20% of kidneys to patients with the highest estimated post-transplant survival. The current system, based primarily on waiting time, is patient centered. The proposed system which recognizes the value society places on the life-extending potential of a scarce resource is resource centered. Proponents and opponents of this proposed allocation scheme use practical and ethical arguments to support their positions. For instance, one reason proponents are in favor is because it would lead to more life years in recipients and would direct more kidneys to younger patients who have not had the opportunity to live as long as older individuals on the waiting list, while opponents object because the new allocation scheme would result in age discrimination.

Other alterations to the allocation of kidneys to favor the young by giving them primary access to kidneys from younger donors that are regarded to be better quality than kidneys from older donors is disadvantages to older patients on the waiting list. Allocation schemes that favor multiorgan transplants over single organ transplants disadvantage patients who would otherwise have received the second organ. Directing kidneys preferentially to highly sensitized patients with high panel reactive antibody may be good for this set of difficult-to-transplant patients but directs kidneys away from patients with lower antibody levels. Directing organs to maximize patient survival may lead to one set of allocation schemes whereas allocating organs to the sickest (and thus preventing imminent deaths of other patients) could favor a different allocation scheme. All these allocation schemes by favoring one subset of patients may be good for society overall, but they necessarily discriminate against other groups of patients on the waiting list. Should patients who have had one transplant that has failed be given a second transplant when so many patients have not even had a single transplant?

As Chumfong and colleagues [55] said, "all allocation systems ought to achieve a version of distributive justice for the good of society. The fundamental issue at odds in the current and new allocation systems is what exactly the good of society is."

While the current discussion is mainly from the perspective of the ethical issues involved in kidney allocation in the United States, these same issues apply to virtually every other country and to other organs as well. As long as the shortage of organs continues, good, well-meaning people will disagree on precisely what form the best and most ethical policy is. This disagreement may stem from their unique situations in life and work, their backgrounds, culture, perhaps even their genetics. What is interesting, although subject for a different discussion, is just why people who agree on ethical principles may disagree vehemently on their actual application. Nevertheless, the allocation system in the United States is always a work in progress as UNOS constantly strives for more fairness for patients, better outcomes, and minimizing wasteful discarding of transplantable organs.

2.7. The waiting list

Currently, individual transplant centers determine which patients are placed on the waiting list. There may be guidelines, but there are few established criteria. The actions of individual transplant centers are important, because who is on the list affects who gets transplanted and

therefore how organs are allocated. Thus, important ethical considerations can affect allocation before an organ even becomes available.

Both medical and non-medical criteria are used in deciding whether a potential candidate should be placed on the waiting list. Each organ may have its own set of criteria. For instance, to be placed on the waiting list for a kidney transplant, patients frequently have their renal function and bladder function evaluated. Some patients may also undergo cardiac evaluation, assessment of immune status against certain infectious agents, etc. Transplant centers frequently differ in how they use the results of medical testing in their decision to list patients. Patients may be turned down at one transplant center but accepted at another, leading some patients to “shop” for a transplant center willing to list them. Differences in medical criteria between transplant centers may not pose ethical issues; they may just represent honest disagreements between centers [56].

Transplant centers also evaluate patients using behavioral and other non-medical criteria. Virtually, everyone agrees that group characteristics such as religion, ethnicity, race, etc. should not enter into the decision of whether to place a patient on the waiting list. The UNOS Ethics Committee has recently addressed the non-medical considerations in assessment for transplant candidacy [54]. While age or co-morbidity should not arbitrarily be used as criteria for listing patients, life expectancy with a functioning graft using factors such as age, co-morbidities, and other factors can be used if it is significantly shorter than the expected life span of the transplanted organ. But these decisions based on age and comorbidities should be made on an individual patient basis.

Transplant programs frequently refuse to list patients who exhibit some behavioral characteristics such as smoking, addiction, drug abuse, history of noncompliance with a medical regimen, or mental disability. Caplan [57] has written that such exclusion of categories of patients such as these increases doubt about the equitable allocation of organs. But transplant centers that do use these categories to exclude patients from listing justify their actions on the basis of being good stewards of precious organs. It would be a tragedy to transplant an organ and have it rejected because the patient did not take her antirejection medications because of behavior characteristics that were known before listing. Every transplant center has had experience with patients losing organs for these reasons. If this type of loss occurs, it means the recipient had an operation for no benefit (and likely would need a second operation to remove the organ or a second transplant) and another patient on the waiting list was denied access to that organ. Furthermore, the donor family who often are in contact with the recipient of their loved one's organs may experience a second loss if the transplanted organ is lost. This exclusion is especially true if a behavior contributed to organ failure such as alcohol consumption and liver failure or smoking and lung failure. These transplant centers require patients to quit using alcohol and smoking, although they may disagree how long abstinence is required before listing. And some centers permanently remove such patients from the waiting list should they relapse. Caplan [57] might think that is too harsh and would lead to doubt about the allocation of organs (since allocation begins with who is put on the waiting list). But most transplant centers believe such exclusions are good medical practice and the correct ethical decision.

Behaviors that may exclude patients from listing may not be permanent. The ethical issue for transplant centers is whether patients can recover from what they consider to be unacceptable behaviors and what criteria the patients must demonstrate to show they are now an acceptable candidate. An issue for the UNOS Ethics Committee is whether non-compliance behavior is serious, consistent, and documented in current or previous treatment [54].

2.8. Transplant volume and regulation

Other ethical issues for transplant centers arise at the juncture maintaining quality, increasing numbers of transplants, minimizing costs for the hospital, and satisfying regulators [58]. Transplant physicians and surgeons generally want to perform as many transplants as they can in order to serve their patients on the waiting list and to increase the status of the program. This may cause them to place patients on the waiting list who are far from ideal candidates. And because many transplant candidates have other health issues in addition to the primary organ failure, the issue becomes how far can one deviate from an ideal candidate and not pose too great a risk both for the patient and the transplant program. With too great a set of qualifications to be on the waiting list, the program may deny access for many qualified candidates. But too few qualifications also are unfair to the patient because of the excessive risk, it may impose from transplantation. There are no firm guidelines and programs differ in their qualifications for listing.

Similarly, transplant programs must accept organs that have a high certainty of function when transplanted. In order to increase the number of transplants, it is tempting for transplant centers to accept organs that are less than ideal. But how far can an organ depart from ideal and still be ethically acceptable to transplant? Here, again there are no firm guidelines and transplant centers differ in organ acceptance criteria. Patients are supposed to be informed if the organ is less than ideal, but most patients have limited ability to appreciate the many subtleties that go into the decision to accept an organ. But it is more likely that transplant centers turn down organs that can be transplanted. Many organs are discarded that are suitable for transplantation [59].

Listing patients for transplantation and accepting organs are influenced not only by the patient's need for a transplant. Also important, although not frequently mentioned, are other important influences that affect these decisions. Hospital administrators want transplant programs that are successful and do not operate at a loss. They want a high-quality program that performs many transplants. They may pressure transplant physicians and surgeons to minimize hospital stay to shorter than they think is best for the patient, use less expensive medications, and to transplant only well-insured patients, and not place higher risk patients on the waiting list because they usually have much higher costs. They may not express these feelings overtly, but the transplant physicians and surgeons usually get the message very clearly.

Regulators also play a role in creating ethical dilemmas. The Centers for Medicare and Medicaid Services (CMS) in the United States, which regulates and funds much of transplantation, in 2006, published the Conditions of Participation for Transplant Centers [60]. The

Conditions of Participation for Organ Procurement Organizations were published a year later [61]. The conditions of participation (COP) for transplant centers had performance criteria with expected outcomes. Transplant centers could be closed if their outcomes were below expected levels. This threat may have caused transplant centers to become more conservative in their acceptance of organs, because no center wanted to be closed. Whereas the number of transplants increased every year before the COP, they stabilized for several years and there was no increase [62]. Similarly, publication of the COP for OPOs led to a stabilization of the number of deceased donors recovered, although it too had been increasing in previous years. Like transplant centers, no OPO wanted to be closed if it could not meet the performance measures. By limiting the number of transplants, acceptance of organs, and limiting the number of deceased donors they recovered, both transplant centers and OPOs sought to continue their existence. Thus, regulation may have an adverse effect on some aspects of transplantation. Another issue for regulators is to design performance measures that do not stifle innovation and experimentation. How can transplant centers that want to try new, unproven techniques or therapies not be punished if these innovations turn out to be unsuccessful and lead to worse outcomes? Because of the negative feedback about COPs from transplant centers and OPOs and the adverse effect, the COPs may be having on outcomes and the number of transplants performed; CMS is currently engaging transplant centers and OPOs to revise performance metrics. Hopefully, these revised metrics will remove disincentives and will result in more patients being transplanted and better outcomes.

3. Conclusion

The Ciba Foundation held the first international, interdisciplinary conference on ethical and legal issues in transplantation in March 1966. Some of the issues discussed included the following: definition of death, removal of kidneys from moribund but not yet dead patients, use of living kidney donors, ensuring consent for kidney removal in living donors is voluntary, organ markets, and economic barriers to transplantation [63]. After 50 years, many of these ethical issues remain. How best to organize organ transplantation, to increase the number of organ donors, allocate organs, and regulate transplantation and organ donation are constantly works in progress. Changes try to improve patient access, improve transplantation outcomes, and increase the number of transplants. As long as the shortage of organs continues, as it will for the foreseeable future, there will be ethical challenges to confront. Any changes may solve some ethical problems but are likely to introduce new ones.

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