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Virtual Mentor

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FROM THE EDITOR

The Frontiers of Organ Transplantation: “Oh, The Places We’ll Go”

A few months ago, during my renal pathophysiology course, I spent an afternoon in a dialysis unit, where I met Mark. Mark is just a few years older than I am, and we share a passion for professional football and a penchant for quoting *Modern Family* episodes. But we differ markedly in the health challenges we face. It is a matter of a few millimeters—his ureters did not connect to his bladder—that divides Mark and me. In utero, he suffered hydronephrosis and was born with neither kidney functioning properly. Today, both of his kidneys have failed, requiring 4 hours of hemodialysis three times a week to cleanse his blood artificially. Mark is upbeat and positive, but his only hope to return to the life he led before dialysis rests on a kidney transplant.

The simple idea of replacing an unhealthy organ with a healthy one was a dream early in the twentieth century. Due to the courage and passion of scientists, physicians, and patients, transplantation has become a viable therapy for a multitude of failed organs. The history of organ transplant is rich and diverse, but a good place to begin is 1954 at the Brigham and Women’s Hospital in Boston, Massachusetts. A team of health professionals led by Drs. John Harrison, John Merrill, and Joseph Murray conducted the first kidney transplant between identical twins. This seminal moment sparked an inquiry into transplantation that opened the window into what is now modern immunology, winning Nobel prizes and uncovering therapies that save countless lives. Today organ transplantation stands at a precipice, a new frontier. It has graduated from being simply a marvel of science and must now harness all of its capabilities to serve patients best.

With traditional clinical ethical values in mind, medical policies are constructed to facilitate best practices in which every patient is given an equal chance for an optimal clinical outcome. The arena of organ transplant, where the number of organs needed far exceeds the number available, challenges this ideal every day. As of February 14, 2012, 112,987 people were listed for an organ in America—with the numbers who need organs ever-growing—and in 2011, only 26,246 transplants were performed. Many patients go without, and 6,523 died waiting last year [1].

This issue of *Virtual Mentor* examines the many areas within organ transplantation worthy of rigorous intellectual inquiry. Seasoned clinicians and scholars have delved deeply into the major ethical and policy questions facing the field today including: how to find more organs for those in need without disregarding or undermining the best interests of potential donors, how to allocate direly scarce organs most fairly and efficiently, how to manage the costs of transplantation and posttransplantation care,

and how to temper excitement about technological advancement with caution and sobriety.

This issue of *Virtual Mentor* is dedicated to all who currently wait for an organ and all those who may one day wait themselves. Together as health professionals we are charged with addressing this significant shortage; it is frightening for Mark and for us. But if we remember how far we have come in the short span of organ transplant history, we can imagine “oh, the places we’ll go!”

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ETHICS CASE

Assessing the Motives of Living, Non-Related Donors

Commentary by Katrina A. Bramstedt, PhD, and Francis L. Delmonico, MD

Dr. Tan had been a transplant surgeon for 7 years but had never come across a case like this. His patient Victoria had grown tired of waiting for help. She had been diagnosed with end-stage renal disease 3 years prior and was in need of an organ transplant. Due to her illness and the burdens of dialysis she had been unable to keep up with her college classes, and her modeling career, once blossoming, now seemed over. None of her living relatives was a match, and she knew her chances of receiving a deceased-donor organ in Massachusetts, her home state, were low. So she took matters into her own hands and created a profile on matchingdonors.com. She included her compelling narrative and a picture of herself.

It was through this site that Carolyn contacted her. Carolyn had lost her sister to kidney failure and had looked through the profiles to find an individual she considered worthy of receiving one of her kidneys. She read Victoria's profile and wanted to donate to her. Carolyn flew to Massachusetts from Wyoming to meet with Victoria and the transplant team.

Dr. Tan brought up this case and his hesitation during the transplant center's organ selection committee meeting. He said, "What is our experience using online portals for living donation? I have to admit I have never come across a donation like this. Radical altruism that involves a life-threatening sacrifice calls for careful scrutiny. It is our job to assess our potential donor, considering all dimensions. Is this type of organ solicitation fair? Does it threaten the view that an organ is not a commodity that can be bought and sold? Is our donor candidate trying to compensate for depression, seeking media attention, or harboring hopes of becoming involved in the recipient's life? Is operating outside United Network for Organ Sharing (UNOS) legitimate?"

Commentary

Cases such as the one described by Dr. Tan are not uncommon at transplant centers in the United States. The Internet and social media tools are now being used to facilitate access to transplantation [1, 2]. Most adults are users of the Internet in some format (e.g., web browsing, e-mail, blogs, Facebook, Twitter), so it is not surprising that it could be a resource for those with end-stage disease seeking an organ donor. Formal websites that attempt to link potential donors and patients include matchingdonors.com, kidneymitzvah.com, and kidneyregistry.org. Informal mechanisms include Internet chat rooms and message boards.

Society (and transplant centers) cannot regulate how people establish relationships, but when a donor-recipient pair comes together through Internet solicitation, the transplant center has a responsibility to evaluate the intended donation carefully, not only clinically but ethically, by assessing the donor's motivations [3]. Specifically, the transplant center is looking for donor candidates with altruistic rather than self-serving motivations (e.g., seeking publicity, psychological repair, monetary reward). In the United States, donors may receive reimbursement for their donation-related expenses, but they must not be paid for their *organ*—it is a *gift*.

How Do Living-Donor Teams Accomplish Their Task?

The use of a multidisciplinary approach to explore the medical, surgical, psychosocial, and ethical issues in live organ donation is especially necessary in these instances of Internet solicitation. The transplant team must assess the potential donor to rule out “high-risk” candidates for a current or prior psychiatric history (including substance abuse or dependence), financial problems that might result in extortion of the recipient, impaired cognition that might compromise the donor's ability to understand the nature of the surgical procedure and the potential for complications, ambivalence about donating, unrealistic expectations about the donation, a self-centered motivation (as described above), and lack of a stable support system for the donor during the recovery process [4, 5]. Thus, Dr. Tan's concerns are pertinent regarding Carolyn's donation as a remedy for depression, a means for seeking media attention, or a hope of being involved in the life of the recipient.

Dr. Tan should also be concerned that Carolyn has “shopped” among many needy patients for a recipient who is “worthy” of her kidney. When a deceased person's organs are donated, although directed donation to family or friends is permissible, the family of the deceased is not allowed to discriminate among candidates on the basis of religion, gender, ethnicity, or socioeconomic status [6]. Carolyn's motivation in selecting Victoria needs to be explored carefully. If the living donor team concludes that Victoria's social “worth” is indeed a criterion for Carolyn's donation, then she may be disqualified as a donor candidate even if she is medically suitable.

If Carolyn is disqualified, she could appeal the decision by the transplant center, or she and Victoria could present them to another hospital for consideration. This latter opportunity may be difficult logistically, depending upon the proximity of other transplant centers. From a legal perspective, nothing prevents Carolyn from hiding her prior disqualification or creating a new, “acceptable” donor narrative. Her candidacy history could easily be questioned, however, if an insurance review reveals multiple charges associated with attempts to assess the same donor candidate at different transplant facilities.

The questions Dr. Tan poses at the close of the scenario are important. It is indeed Dr. Tan's responsibility to assess all of the aspects of Carolyn's proposed donation we have noted. He wonders, next, about the fairness of Internet solicitation. While it

may not be “fair” for Victoria to have obtained Carolyn’s kidney through the Internet when there are many waiting with just as much need, UNOS cannot regulate the development of relationships as if it were a democratic process. The development of programs of paired donation in the United States is helping to dispel unfairness because altruistic donors can now be aware their gift sets in motion a chain of multiple transplants affecting many potential recipients.

In chain donations, a good Samaritan donor starts a chain reaction of donations by giving to someone who has an incompatible but willing donor. That incompatible donor instead gives to another patient who also has an incompatible intended donor, and so on, creating a cascade effect [7]. Good Samaritan donations, whether in pairs or chains, might still involve the Internet, but the contextual features of these donations free them of the possible ethical problems with general Internet donor solicitation (e.g., selection bias or discrimination, organ vending) [1].

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ETHICS CASE

Should a Nonadherent Adolescent Receive a Second Kidney?

Commentary by John D. Lantos, MD, and Bradley A. Warady, MD

Carl is 17-1/2 years old and has familial nephrotic syndrome due to focal segmental glomerulosclerosis. His sister also developed renal failure; she underwent hemodialysis and then transplantation. Carl had observed that her quality of life was much better after transplantation.

Carl's mother died when he was an infant. His father has mental health problems and struggles to cope with those and his two chronically ill children.

The nephrology team was worried about Carl's ability to comply with a posttransplantation medication regimen, but nevertheless proceeded with a preemptive (i.e., without prior dialysis) transplant when Carl was 14 years old and showed signs of impending renal failure. He had excellent graft function for 9 months, but then experienced acute and, later, chronic rejection due to suspected, but not admitted, nonadherence to medications. He began dialysis the next year. His course on dialysis has been complicated by frequent episodes of fluid overload, hyperkalemia, and hyperphosphatemia. He also has exaggerated fistula pain. He remains short in stature.

Carl does not want to continue on dialysis and has repeatedly asked the nephrology team to list him for another deceased-donor transplant. The health care team has severe reservations about listing him for a second transplant because of the history of presumed medication nonadherence and his ongoing management issues during dialysis. No living-related donor is available.

Commentary

One of the most common causes of graft failure after a kidney transplant in adolescents is nonadherence to posttransplant immunosuppression medication. In a recent review, Rianthavorn and Ettenger noted the frustrations that this engenders among nephrologists: "adolescents enjoy the best 1-year graft survival of any age group. However, the long-term transplant outcome in adolescents is disappointing. Nonadherence with immunosuppressive medications is one of the most important contributing factors for graft rejection and loss in teenagers" [1]. In order to be successful, renal transplantation requires the teenager to follow a complex medication regimen which includes multiple immunosuppressive agents that must be taken on a prescribed schedule to prevent rejection. The use of some of the medications may be associated with cosmetic side effects. Many teens have

difficulty with this, fail to take their medications as recommended, and, as a result, their grafts fail.

The phenomenon of nonadherence among teens creates ethical dilemmas about the appropriate treatment of end-stage renal disease (ESRD) in the adolescent patient population. Though kidney transplantation is the preferred treatment in most cases, the chances of graft failure in this population are high, and kidneys for transplantation are a scarce resource. There is a long waiting list for deceased-donor kidneys [2].

In most cases, teens with ESRD can be treated with dialysis. Some argue that this is the better approach since it allows them to mature and to then get transplants when they are psychologically more capable of adhering to a complex medication regimen. Additional neurocognitive development may also result in a better understanding of the consequences of treatment nonadherence. (Even then, they, like other transplant patients, need support from family or social service agencies.)

However, delaying transplantation is not without costs. Transplantation is less successful for patients who have been on dialysis than for those who have not [3]. The best time to do a kidney transplant is early in the course of ESRD.

Ethical Analysis

Fundamental ethical principles conflict in a case like this. The principle of respect for autonomy would demand that we honor the patient's wishes, values, and preferences. Carl can be treated with either dialysis or transplantation. He would prefer transplantation. He clearly understands what it means to have ESRD and be on dialysis. He understands this as a result of his own experience and as a result of seeing his sister's responses to these different modalities of therapy.

The implications of the principle of beneficence are not straightforward in this case. On the one hand, transplantation would most likely lead to better outcomes for the patient than continued dialysis. But that would only be true if the transplantation were successful, and it would only be successful if the patient adhered to the complex posttransplant medication regimen. If he could not do so, and the graft failed, he could be worse off than if he had continued dialysis and not received a transplant. Transplant rejection and attempts at reversal can lead to hypertension, weight gain, fluid retention, infection, absence from school and work, impaired quality of life, and persistent poor kidney function. Also, further antibody formation might adversely affect Carl's ability to ever obtain another transplant.

Dialysis might be the better option for Carl at this point in his life because it would buy some time for him to mature and to better understand his condition and the implications of medication nonadherence. This might lead to a higher chance of posttransplant success in the future. However, his prognosis may be worse if he remains on dialysis for a long period of time.

Considerations of justice lead us in a different direction, requiring us to ask not just what the patient wants, or what the doctors think would be best, but, instead, what is most fair. There is an absolute shortage of deceased donor kidneys. The number of patients on the national waiting list in the U.S. for a deceased donor transplant has risen from 41,177 people in 1999 to 76,089 people in 2008 [4]. Given the number of people waiting for a transplant, justice demands that cadaveric organs be preferentially allocated to recipients for whom they would be most beneficial. Patients who are at high risk for nonadherence and graft failure thus should not get high priority. These sorts of considerations, however, require that doctors ignore their patients' preferences and their own medical judgment of what is best for the individual patient.

Evaluating the Likelihood of Nonadherence

Nonadherence to medical treatment is a well-recognized problem in adolescents that arises not just in renal transplantation but in many other clinical situations. It has been described in the treatment of cancer, cystic fibrosis, seizures, diabetes, asthma, and many other clinical conditions. The unique problem in ESRD is that there are two standard approaches to treatment that have different implications for quality of life, different requirements for adherence and consequences of nonadherence, and different implications for justice. In evaluating which of these is best for any particular patient, physicians must consider both short-term and long-term outcomes.

It would be inappropriate to give a teenager a kidney if the odds of graft survival were low. This would not only be a poor allocation of scarce resources, it would also be dangerous for the teen, as noted above. It would be equally inappropriate to deny a teenager access to a transplant simply because he was judged on the basis of age to be at high risk for nonadherence.

The best approach in this situation is to make an individualized assessment of the barriers to adherence, the likelihood of nonadherence, and the potential benefits of interventions that might improve adherence. In this case, since the patient is already on dialysis, his ability to adhere to the demands of that regimen might be considered a "trial of therapy" that will give information about the likelihood that he would adhere to posttransplant treatment. He should be given clear instructions about what is expected of him, feedback whether or not he adheres to the demands of dialysis, and an endpoint to this "trial of therapy." If he is able to take medication, manage his diet and fluids, and keep his appointments in clinic and in dialysis, then he should be eligible for a second transplant.

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ETHICS CASE

Family Physicians' Role in Discussing Organ Donation with Patients and the Public

Commentary by Keren Ladin, MSc, and Douglas W. Hanto, MD, PhD

In a small town in Maine, a school board gathered for its monthly meeting. Dr. Gomez, present at the meeting, had practiced family medicine in this town for more than 25 years and his three children had gone through the local school system.

Weeks before, a serious car crash involved several high school students and resulted in the death of an 18-year-old boy, Keith. Talk of the crash and death consumed the “new business” portion of the evening.

Towards the end of the discussion, a pair of parents slowly rose in the back of the gym.

“Our daughter Stephanie has been lying in a hospital bed for the past 13 weeks. She is there because she is dying of end-stage liver disease; the only thing that will save her now is a liver transplant. We recognize the tragedy of Keith’s death and we are hoping to take this moment to raise awareness about organ donation.” Keith had not listed himself as an organ donor on his license.

“It is never easy when a family or our community confronts such heartbreak as this terrible accident. It would have been possible, however, for good to have come from Keith’s organs. There is a tremendous shortage. Donating your organs is the ultimate gift—the gift of life for desperately ill people.”

This emotional plea sparked a fervent debate among parents. Many left wondering whether conversations like these had a place at school board meetings or in schools themselves. Many in the community turned to Dr. Gomez for his opinion. Did he believe in educating patients about organ donation? He could bring it up at yearly physicals, as he did with advance directives—why didn’t he? Did he think it was an appropriate topic for a public forum?

Commentary

In the aftermath of a seemingly heated public debate about organ donation at a school board meeting, Dr. Gomez faces difficult questions related to physicians’ moral obligations to promote the well-being of patients and society. This case raises three main questions. First, do family physicians have a moral responsibility to educate patients about organ donation? Second, should organ donation be discussed at yearly physicals, following the model of discussions about advance directives?

Finally, do physicians have a moral obligation to discuss organ donation in public forums as part of a professional commitment to social responsibility? These questions are undoubtedly important and familiar, reflecting dilemmas faced by many doctors. In this commentary, we will address these questions and argue that, as part of the oath taken to promote patient health, doctors have a moral obligation to promote community health because of the links between community and individual health.

In meeting their ethical responsibilities, physicians are obliged to promote the best interests of patients in their immediate care and to advocate for the health of society at large, which encompasses all potential patients. Established theories of medical ethics describe physicians as being professionally bound by four principles: beneficence (promotion of the health of patients and the public), nonmaleficence (not harming patients), respect for autonomy (promotion of patient self-determination), and justice (promotion of equitable distribution of life-enhancing treatments) [1]. In fulfilling their obligation to promote health and well-being, physicians should be inclined to discuss donation in an attempt to increase donation rates and mitigate the organ shortage. Promoting organ donation serves both individual patients, who very well may need an organ, and society, by decreasing the financial and human costs of many life-threatening conditions.

Organ Donation in the United States

The scarcity of and waiting times for routine health care treatments in the United States generally decrease as their usage spreads, but waiting time for organ transplants has grown in recent years and is projected to increase further due to rising demand and stagnant donation rates. This creates a growing public health concern—18 Americans die every day waiting for an organ.

Two factors underlie the organ shortage: a limited pool of eligible donors and difficulty converting eligible donors into actual donors. Despite expansion of the donor eligibility criteria, the availability of deceased-donor organs is finite and cannot meet current demand. The pool of potential brain-dead donors is thought to be approximately 15,000 per year [2]. The conversion rate (potential donors who actually donate organs) is estimated to be between one-third and one-half [3, 4]. Of families approached about organ donation in hospitals, less than half agree to donate [5, 6]. Increasing the number of willing prospective donors and those who actually donate, however, is possible. More importantly, donor registration and conversion of prospective to actual donors are strongly influenced by encounters with medical teams and discussions about preferences for end-of-life care.

Although the public is generally supportive of organ donation, less than 30 percent of Americans are registered organ donors [7]. Consent to organ donation can occur in ICUs or hospitals in acute situations of impending death, or in nonmedical settings, such as at the Registry of Motor Vehicles or online. While these venues present good opportunities for donor registration, people may feel that they do not have adequate time or information to consider the benefits and ramifications of organ

donation fully. This may be particularly true for those considering organ donation in nonmedical settings, as they are often forced to decide about donation without the ability to discuss their options with a trusted and knowledgeable advisor. Lack of discussion with patients about the implications of organ donation overlooks an opportunity to educate them about donation and dispel misconceptions related to organ donation and transplantation.

Should Family Physicians Educate Patients about Organ Donation?

Do physicians have a moral obligation to educate patients about donation and discuss this option? They do, insofar as informing patients about organ donation fulfills their duties of beneficence, respect for autonomy, and justice. If we adopt the World Health Organization's definition of health, "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" [8], it becomes clear that promoting organ donation and altruistic behavior while encouraging action that is consistent with the patient's worldview is an integral part of health promotion.

Shared decision making, in its simplest interpretation, places the physician in the role of imparting value-free scientific information based on his or her expertise and training, to educate the patient about the risks and benefits associated with each treatment option. In this dynamic, the patient has the responsibility to provide the moral compass and tailor the decision to his or her conception of the good. Although these conditions are necessary for shared decision making, they are not sufficient.

But, as Dan Brock and others suggest, shared decision making does *not* require value-neutrality of physicians [9]. Instead, physicians are ethically obligated to advocate on behalf of their patients and promote their health and well-being, while preserving their autonomy and self-determination. Even seemingly straightforward health promotion, as conventionally practiced, is often value-laden. It suggests, for example, that restoring function is good, even if it requires invasive interventions. This may be in stark contrast to conceptions of the good held by a patient, who may, for example, believe that preserving the sanctity of the body is more important than such interventions. In the context of organ donation, these principles imply that family physicians (and other doctors) have the obligation to educate patients about organ donation in an effort to provide information necessary to making a decision about donation. Furthermore, because a patient's future need for an organ is unknown, it is in all patients' best interest to mitigate the organ shortage by increasing donation rates.

Discussing organ donation with a physician, particularly a primary care physician (PCP), could significantly benefit patients for four reasons. First, PCPs have an established relationship of trust with patients, stemming from multiple discussions about delicate medical matters, often over the course of many years. As a result, they may be more aware of the patient's cultural and moral preferences and can better tailor information and engage in shared decision making. For example, despite needing kidneys at a disproportionately high rate, African-Americans are far less likely to be registered donors [10]. This may be due, in part, to misinformation about

the risks and benefits of donation, not being presented with the opportunity to donate (particularly in acute situations), and higher levels of distrust attributed to institutionalized racism. Tailored interventions, such as culturally sensitive discussions with a PCP about organ donation and end-of-life care preferences, could help to alleviate disparities by ensuring more equitable information about care options.

Second, as Thornton et al. suggest, the ambulatory setting may be particularly well suited for discussions about organ donation because people under the age of 50, who comprise over a third of deceased organ donors, utilize ambulatory services at disproportionately high rates [11]. Third, PCPs have successfully engaged in difficult conversations about end-of-life care that have increased the number of patients who completed advance directives [12, 13]. Finally, for patients, designating donor status allows them to preserve their autonomy by documenting and communicating their wishes in case situations arise in which they cannot do so. Such peace of mind is important and allows people to feel confident that their end-of-life treatment will be consistent with their wishes and their worldview.

Discussion about organ donation can greatly benefit patients' families too. Advance planning helps surrogates, relieving them of the burden of making such difficult decisions under stress. Discussions about donation occur in situations of extreme grief and uncertainty. Numerous studies have demonstrated that prior knowledge of the deceased's preferences help families heal by maintaining unity and confidence in the decision [14].

PCPs have ethical grounds to be concerned with and discuss the organ donation status of their patients—the principles of beneficence, respect for autonomy, and justice all require it.

Discussing Organ Donation in Public Forums

The physician's moral obligation to promote the health and well-being of his or her patient and to respect patient autonomy may flow readily from the principles of beneficence and nonmaleficence. This is a well-accepted tenet of the physician's ethical conduct. However, Dr. Gomez, and many other physicians, may wonder whether they are morally obligated as medical professionals to advocate publicly for health improvement. More specifically, are physicians morally obligated to advocate for *organ donation* publicly, and, if so, what is their role in this debate?

To better understand physicians' ethical obligations, we turn to the concept of the social contract between medicine and society. Sylvia and Richard Cruess write that the social contract “granted physicians status, respect, autonomy in practice, the privilege of self-regulation, and financial rewards on the expectation that physicians would be competent, altruistic, moral, and would address the health care needs of individual patients and society” [15].

The core of the relationship between the medical profession and society entails that physicians act as advocates of public health. Reaffirming this social contract, in their role in establishing guidelines of medical professionalism, the Accreditation Council for Graduate Medical Education (ACGME)'s "professionalism" competency requires, among other things, that physicians demonstrate "accountability to patients [and] society" [16]. The American Medical Association, in its declaration of professional responsibility, encourages physicians to "advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being" [17]. The social contract between medicine and society, as well as the well-documented effects of social determinants on individual health, compel physicians to act in a way that promotes equity and enhances the chances of all persons to live a healthy life.

Policy Recommendations

Many legislative and regulatory initiatives have aimed to improve rates of consent for donation. These include the Uniform Anatomical Gift Act (UAGA), Medicare coverage and federal oversight of transplantation, the National Organ Transplantation Act (NOTA), and required request laws (necessary for the Joint Commission on Accreditation of Health Care Organizations hospital accreditation and Medicare reimbursement). Despite these efforts, donation rates remain low.

What prevents people from donating? Many studies suggest that the reasons are multifactorial, and include lack of information about donation, misperceptions related to organ procurement (e.g., that doctors may try less hard to save the lives of organ donors, that donors will be unable to have an open casket), and negative perceptions of medical treatment or organ procurement workers. Doctors, too, may have negative attitudes about and discomfort with discussing donation with patients. Many of these factors can be overcome by training physicians to have effective and sensitive discussions about end-of-life care with patients.

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MEDICAL EDUCATION

Online Ethics-Education Modules and Ethics Forums of the American Society of Transplant Surgeons

John M. Ham, MD

The American Society of Transplant Surgeons (ASTS) is committed to excellence in health care, teaching, and research. In keeping with its mission, the leadership of ASTS developed an educational program for fellows and residents to ensure that the foundation of learning and discovery strengthen the individual and the society and that transplantation continues to improve the lives of patients.

Ever-changing attitudes and economies that revolve around a life-saving resource such as a gift organ have led the ASTS to promote ethical norms to afford the best possible outcomes for patients. Transplant programs and surgeons attempt to provide benefit, protect autonomy, ensure as much safety as possible, and strike a balance between equity and utility. Though there is no perfect way of distributing a scarce resource, we have to assure patients, regulators, hospital leadership, payors, and our transplant teams that we are managing this process as well as possible.

There is a networked monitoring of transplant practice ethics by many, including the Institute of Medicine, the United Network for Organ Sharing (UNOS), the Centers for Medicare and Medicaid Services, and the federal Health Resource and Services Administration to assure the best possible outcomes based on probabilities established through extensive analysis of a robust, yet imperfect, large national database maintained by UNOS. The programs are reviewed, audited, and required to comply with policies and guidelines that are specific to each organ system. The Centers for Medicare and Medicaid Services perform independent audits to see that we meet the standards in the federal register. All this indicates a widespread acknowledgment that the ethics of transplantation is complex, requiring much thought and oversight.

Online Educational Resources

With this in mind, the fellowship training committee of the ASTS has developed a series of web-based educational modules for members and fellows presented by transplant surgeon teachers that covers some of the ethical issues relevant to transplant care and discoveries in the field. (Tools for medical students are in progress.) Module topics include biomedical ethics in general, the allocation of deceased-donor organs and access to care, and living donors.

Each module has several sessions. The module on the allocation of deceased-donor organs, for example, has five parts: two sessions on the ethics of allocation and

access, one on the ethical implications of (opt-out) legislation that would presume consent for organ procurement, one on donation after brain death or circulatory arrest, and one outlining the challenges of balancing equity and utility in distributing a scarce resource.

The ethics module gives background in biomedical ethics, then progresses to requirements for ethical practice and describes various opposing opinions regarding controversial issues. For example, are we paternalistic in our approach to living-donor autonomy, and is it coercive to require donors to agree to prolonged follow-up after donation for the purposes of tracking outcomes over the long term? This might be an inconvenience to the donor, and one might conclude that research is being carried out that does not follow guidelines mandated by the Office of Human Research Protection. This is a public policy debate that has significant ethical implications.

Many other ethical concerns are touched upon. Should we pay donors as an incentive to donate? At what point does innovation in surgery cease to be “experimental” and become the standard of care? Are patients and donors truly informed? Are we following ethical norms when younger patients are not given priority over older patients in allocation of a scarce resource? Is there an ethical way to discriminate? Is a donor who has been determined to be irreversibly dead on the basis of circulatory arrest really dead if the heart can be resuscitated and then used for transplantation? The list of questions seems never-ending.

Each module contains a text summary, a recommended-reading list, a self-assessment tool, and a feedback mechanism. Because the primary purpose of these learning modules is to help fellows attain mastery in transplantation surgery, no CME credit is given.

Group Discussions

An additional feature that the society offers and strongly recommends is a yearly forum for second-year fellows. Here many challenging ethical cases are presented by surgery faculty from the society, and the fellows are given an opportunity to participate in group discussion of these cases in an interactive manner with leaders in the field of transplantation.

The ASTS also holds forums at major national and international meetings of transplantation societies to discuss issues of importance, such as the “Declaration of Istanbul” regarding trafficking of organs, the use of prisoners as donors in China, incentives for donors to come forward to donate, and the protection of donors’ autonomy.

Conclusion

ASTS aims to serve both those entering the field and those who would like to participate in a more robust discussion of the issues. The presentations, reading lists, and self-assessment opportunities are useful as a starting point, and face-to-face

meetings provide an opportunity to delve deeply into the issues with other transplant professionals. The society's efforts in ethics education are ongoing and evolving. The society is open to engaging in other venues with other organizations to increase the depth of discourse and to engender careful, thoughtful consideration of the ethical procurement and distribution of scarce and vital resources.

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THE CODE SAYS

AMA Code of Medical Ethics' Opinions on Organ Transplantation

Opinion 2.16 - Organ Transplantation Guidelines

The following statement is offered for guidance of physicians as they seek to maintain the highest level of ethical conduct in the transplanting of human organs.

- (1) In all professional relationships between a physician and a patient, the physician's primary concern must be the health of the patient. The physician owes the patient primary allegiance. This concern and allegiance must be preserved in all medical procedures, including those which involve the transplantation of an organ from one person to another where both donor and recipient are patients. Care must, therefore, be taken to protect the rights of both the donor and the recipient, and no physician may assume a responsibility in organ transplantation unless the rights of both donor and recipient are equally protected. A prospective organ transplant offers no justification for a relaxation of the usual standard of medical care for the potential donor.
- (2) When a vital, single organ is to be transplanted, the death of the donor shall have been determined by at least one physician other than the recipient's physician. Death shall be determined by the clinical judgment of the physician, who should rely on currently accepted and available scientific tests.
- (3) Full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory. The physician should ensure that consent to the procedure is fully informed and voluntary, in accordance with the Council's guidelines on informed consent. The physician's interest in advancing scientific knowledge must always be secondary to his or her concern for the patient.
- (4) Transplant procedures of body organs should be undertaken
 - (a) only by physicians who possess special medical knowledge and technical competence developed through special training, study, and laboratory experience and practice, and
 - (b) in medical institutions with facilities adequate to protect the health and well-being of the parties to the procedure.
- (5) Recipients of organs for transplantation should be determined in accordance with the Council's guidelines on the allocation of limited medical resources.

(6) Organs should be considered a national, rather than a local or regional, resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.

(7) Patients should not be placed on the waiting lists of multiple local transplant centers, but rather on a single waiting list for each type of organ.

Issued prior to April 1977; updated June 1994 based on the report adopted June 1993.

Opinion 2.15 - Transplantation of Organs from Living Donors

Living organ donors are exposed to surgical procedures that pose risks but offer no physical benefits. The medical profession has pursued living donation because the lives and quality of life of patients with end-stage organ failure depend on the availability of transplantable organs and some individuals are willing to donate the needed organs. This practice is consistent with the goals of the profession—treating illness and alleviating suffering—only insofar as the benefits to both donor and recipient outweigh the risks to both.

(1) Because donors are initially healthy and then are exposed to potential harms, they require special safeguards. Accordingly, every donor should be assigned an advocate team that includes a physician. This team is primarily concerned with the well-being of the donor. Though some individuals on the donor advocate team may participate in the care of the recipient, this team ideally should be as independent as possible from those caring for the recipient. This can help avoid actual or perceived conflicts of interest between donors and recipients.

(a) To determine whether a potential living donor is an appropriate candidate, the advocate team must provide a complete medical evaluation to identify any serious risk to the potential donor's life or health. This includes a psychosocial evaluation of the potential donor to identify disqualifying factors, address specific needs and explore potential motivations to donate.

(b) Before the potential donor agrees to donate, the advocate team should provide information regarding the donation procedure and its indications, as well as the risks and potential complications to both donor and recipient. Informed consent for donation is distinct from informed consent for the actual surgery to remove the organ.

(i) The potential donor must have decision-making capacity, and the decision to donate must be free from undue pressure. The potential donor must demonstrate adequate understanding of the disclosed information.

(ii) Unemancipated minors and legally incompetent adults ordinarily should not be accepted as living donors because of their inability to fully understand and decide voluntarily. However, in exceptional circumstances, minors with substantial decision making capability who agree to serve as donors, with the informed consent of their legal guardians, may be considered for donation to recipients with whom they are emotionally connected. Since minors' guardians may be emotionally connected to the organ recipient, when an

unemancipated minor agrees to donate, it may be appropriate to seek advice from another adult trusted by the minor or an independent body, such as consultation with an ethics committee, pastoral service, or other counseling resource.

(iii) Potential donors must be informed that they may withdraw from donation at any time before undergoing the operation and that, should this occur, the health care team is committed to protect the potential donor from pressures to reveal the reasons for withdrawal. If the potential donor withdraws, the health care team should report simply that the individual was unsuitable for donation. From the outset, all involved parties must agree that the reasons why any potential donor does not donate will remain confidential for the potential donor's protection. In situations of paired, domino, or chain donation withdrawal must still be permitted. Physicians should make special efforts to present a clear and comprehensive description of the commitment being made by the donor and the implications for other parties to the paired donation during the informed consent process.

(c) Living donation should never be considered if the best medical judgment indicates that transplantation cannot reasonably be expected to yield the intended clinical benefit or achieve agreed on goals for care for the intended recipient.

(2) Living donors should not receive payment for any of their solid organs. However, donors should be treated fairly; reimbursement for travel, lodging, meals, lost wages, and the medical care associated with donation is ethically appropriate.

(3) The distribution of organs from living donors may take several different forms:

(a) It is ethically acceptable for donors to designate a recipient, whether a close relative or a known, unrelated recipient.

(b) Designation of a stranger as the intended recipient is ethical if it produces a net gain of organs in the organ pool without unreasonably disadvantaging others on the waiting list. Variations involve potential donors who respond to public solicitation for organs or who wish to participate in a paired donation or "organ swap" (e.g., blood type incompatible donor-recipient pairs Y and Z are recombined to make compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y) domino paired donation, and nonsimultaneous extended altruistic donation (also known as chain donation).

(c) Organs donated by living donors who do not designate a recipient should be allocated according to the algorithm that governs the distribution of deceased donor organs.

(4) Novel variants of living donation call for special attention to protect both donors and recipients:

(a) Physicians must ensure utmost respect for the privacy and confidentiality of donors and recipients, which may be more difficult when many patients are involved and when donation-transplantation cycles may be extended over time (as in domino or chain donation).

(b) Physicians should monitor prospective donors and recipients in a proposed nontraditional donation for signs of psychological distress during screening and after the transplant is complete.

(c) Physicians must protect the donor's right to withdraw in living paired-donations and ensure that the individual is not pressured to donate.

(5) To enhance the safety of living organ donation through better understanding of the harms and benefits associated with living organ donation, physicians should support the development and maintenance of a national database of living donor outcomes, similar to that of deceased donation.

Issued November 2005 based on the report "[Transplantation of Organs from Living Donors](#)," adopted June 2005; updated June 2011 based on the report "[Nonsimultaneous, Altruistic Organ Donation](#)," adopted November 2010.

Opinion 2.157 - Organ Donation After Cardiac Death

Given the increasing need for donor organs, protocols for donation after cardiac death (DCD) have been developed. Controlled DCD allows patients who have agreed to be taken off of life support or their surrogate decision makers the opportunity to donate the patients' organs once death has been declared. In these cases, life support is discontinued in or near the operating room so that organs can be removed promptly after death is pronounced. DCD also may be considered from patients who suffer unexpected cardiac death (uncontrolled DCD). It requires that they be cannulated and perfused with cold preservation fluid (in situ preservation) within minutes after death to maintain the viability of organs. Both of these methods may be ethically permissible, with attention to certain safeguards.

(1) Hospital policies should specify important details of the DCD process, such as the required time delay before death can be pronounced after cardiac arrest.

(2) In all instances, it is critical to avoid perceived or actual conflicts of interest in the health care team with respect to caring for the patient versus facilitating organ donation. The health care professionals providing care at the end of life should be distinct from those participating on the transplant team. No member of the transplant team may have any role in the decision to withdraw life support or in the process leading to pronouncement of death.

(3) Clear clinical criteria should be in place to ensure that only appropriate candidates, whose organs are reasonably likely to be suitable for transplantation, are considered eligible to donate organs under these protocols.

(4) Palliative care for DCD candidates should continue after removal of life support until death is declared.

(5) In controlled DCD, the decision to withdraw life support should be made by the patient or the patient's surrogate decision maker before any mention of organ

donation (unless the patient or surrogate spontaneously broaches the subject). This is meant to ensure that withdrawal of life support is not influenced by the prospect of organ donation.

The informed consent for controlled DCD should include specific discussion of pre-mortem interventions aimed at organ preservation, to improve the opportunity for successful transplantation, rather than to benefit the patient. Interventions that are likely to hasten death must not be used.

(6) In cases of uncontrolled DCD, prior consent of the decedent or consent of the decedent's surrogate decision maker is ethically required. Perfusion without consent to organ donation violates requirements of informed consent for medical procedures and is not permissible.

Issued June 1996 based on the reports "[Ethical Issues in the Procurement of Organs Following Cardiac Death: The Pittsburgh Protocol](#)" and "[Ethical Issues in Organ Procurement Following Cardiac Death: In Situ Preservation of Cadaveric Organs](#)," adopted December 1994; updated November 2005 based on the report "[Organ Procurement Following Cardiac Death, Amendment](#)," adopted June 2005.

Opinion 2.151 - Cadaveric Organ Donation: Encouraging the Study of Motivation

Physicians have an obligation to hold their patients' interests paramount and to support access to medical care. To discharge these obligations, physicians should participate in efforts to increase organ donation including promotion of voluntary donation. Beyond educational programs, however, physicians should support innovative approaches to encourage organ donation. Such efforts may include encouragement of and, if appropriate, participation in the conduct of ethically designed research studies of financial incentives.

Because the potential benefits and harms of financial incentives for cadaveric organ donation are unknown, physicians have an obligation to study financial incentives. Whether or not they are ethical depends upon the balance of benefits and harms that result from them. Physicians should encourage and support pilot studies, limited to relatively small populations, that investigate the effects of financial incentives for cadaveric organ donation for the purpose of examining and possibly revising current policies in the light of scientific evidence.

Pilot studies of the effects of financial incentives for cadaveric organ donation should be implemented only after certain considerations have been met, including:

(1) Consultation and advice is sought from the population within which the pilot study is to take place.

(2) Objectives and strategies as well as sound scientific design, measurable outcomes and set time frames are clearly defined in written protocols that are publicly available and approved by appropriate oversight bodies, such as Institutional Review Boards.

(3) Incentives are of moderate value and at the lowest level that can be reasonably expected to increase organ donation.

(4) Payment for an organ from a living donor is not a part of any study.

(5) Financial incentives apply to cadaveric donation only, and must not lead to the purchase of donated organs; the distribution of organs for transplantation should continue to be governed by United Network for Organ Sharing (UNOS), based on ethically appropriate criteria related to medical need.

Issued December 2002 based on the report “[Cadaveric Organ Donation: Encouraging the Study of Motivation](#),” adopted June 2002.

Opinion 2.152 - Solicitation of the Public for Directed Donation of Organs for Transplantation

The obligation of physicians to hold their patients’ interests paramount and to support access to medical care requires that maximizing the number of medically suitable solid organs for transplantation by ethical means should remain a priority of the medical profession. Donation of organs to specified recipients has been permitted since the beginning of organ transplantation. Although directed donation is permitted under current national policy, solicitation of organs from potential donors who have no preexisting relationship with the recipient is controversial. The following guidelines regarding solicitation of organ donors are offered:

(1) Solicitation of the public for organ donation has unknown effects on the organ supply and on transplant waiting lists. Policies should be based, as far as possible, on facts rather than assumptions, so physicians should support study of the current system and development of policy based on the results of such studies.

(2) Directed donation policies that produce a net gain of organs in the organ pool and do not unreasonably disadvantage others on the waiting list are ethically acceptable, as long as donors receive no payment beyond reimbursement for travel, lodging, lost wages, and the medical care associated with donation.

(3) The health care team must fully evaluate the medical and psychosocial suitability of all potential donors, regardless of the nature of the relationship between the potential donor and transplant candidate. A physician should resist pressure to participate in a transplant that he or she believes to be ethically improper and should not pressure others to participate if they refuse on ethical or moral grounds.

Issued November 2006 based on the report “[Solicitation of the Public for Directed Donation of Organs for Transplantation](#),” adopted June 2006.

Opinion 2.155 - Presumed Consent and Mandated Choice for Organs from Deceased Donors

The supply of organs for transplantation to treat end-stage organ failure is inadequate to meet the clinical need. Therefore, physicians should support the development of policies that will increase the number of organ donors. Two prominent proposals aimed at increasing organ donation would change the approach to consent for deceased donation: mandated choice and presumed consent.

Under a presumed consent model, deceased individuals are presumed to be organ donors unless they indicate their refusal to donate. Such donations would be ethically appropriate only if it could be determined that individuals were aware of the presumption and if effective and easily accessible mechanisms for documenting and honoring refusals to donate were established. Moreover, physicians could proceed with organ procurement only after verifying that there was no documented prior refusal by the decedent and that the family was unaware of any objection to donation by the decedent.

Under a mandated choice model, individuals are required to express their preferences regarding organ donation at the time of performing a state-regulated task. This contrasts with the widespread model of voluntary organ donation under which individuals are afforded an opportunity to indicate their preferences. A mandated choice model would be ethically appropriate only if an individual's choice were made in accordance with the principles of informed consent, which would require a meaningful exchange of information. Physicians could proceed with organ procurement only after verifying that an individual's consent to donation was documented. It is not known whether implementation of ethically appropriate models of presumed consent or mandated choice for deceased donation would positively or negatively affect the number of organs transplanted. Therefore, physicians should encourage and support properly designed pilot studies, in relatively small populations, that investigate the effects of these policies. Unless there are data that suggest a positive effect on donation, neither presumed consent nor mandated choice for deceased donation should be widely implemented.

In all models, education of individuals to facilitate informed consent is requisite. Issued November 2005 based on the report "[Presumed Consent for Organ Donation](#)," adopted June 2005.

Opinion 2.161 - Medical Applications of Fetal Tissue Transplantation

The principal ethical concern in the use of human fetal tissue for transplantation is the degree to which the decision to have an abortion might be influenced by the decision to donate the fetal tissue. In the application of fetal tissue transplantation the following safeguards should apply:

- (1) The Council on Ethical and Judicial Affairs' guidelines on clinical investigation and organ transplantation are followed, as they pertain to the recipient of the fetal tissue transplant;
- (2) a final decision regarding abortion is made before initiating a discussion of the transplantation use of fetal tissue;
- (3) decisions regarding the technique used to induce abortion, as well as the timing of the abortion in relation to the gestational age of the fetus, are based on concern for the safety of the pregnant woman;
- (4) fetal tissue is not provided in exchange for financial remuneration above that which is necessary to cover reasonable expenses;
- (5) the recipient of the tissue is not designated by the donor;
- (6) health care personnel involved in the termination of a particular pregnancy do not participate in or receive any benefit from the transplantation of tissue from the abortus of the same pregnancy; and
- (7) informed consent on behalf of both the donor and the recipient is obtained in accordance with applicable law.

Issued March 1992 based on the report "[Medical Applications of Fetal Tissue Transplantation](#)," adopted June 1989; updated June 1996.

Opinion 2.162 - Anencephalic Neonates as Organ Donors

Anencephaly is a congenital absence of major portion of the brain, skull, and scalp. Anencephalic neonates are thought to be unique from other brain-damaged beings because of a lack of past consciousness with no potential for future consciousness.

Physicians may provide anencephalic neonates with ventilator assistance and other medical therapies that are necessary to sustain organ perfusion and viability until such time as a determination of death can be made in accordance with accepted medical standards, relevant law, and regional organ procurement organization policy. Retrieval and transplantation of the organs of anencephalic infants are ethically permissible only after such determination of death is made, and only in accordance with the Council's guidelines for transplantation.

Issued March 1992 based on the report "[Anencephalic Infants as Organ Donors](#)," adopted December 1988; updated June 1994; updated December 1994 based on the report "The Use of Anencephalic Neonates as Organ Donors," adopted December 1994; and updated June 1996 based on the report "Anencephalic Infants as Organ Donors - Reconsideration," adopted December 1995.

Opinion 2.145 - Pre-embryo Splitting

The technique of splitting in vitro fertilized pre-embryos may result in multiple genetically identical siblings.

The procedure of pre-embryo splitting should be available so long as both gamete providers agree. This procedure may greatly increase the chances of conception for an infertile couple or for a couple whose future reproductive capacity will likely be diminished. Pre-embryo splitting also can reduce the number of invasive procedures necessary for egg retrieval and the necessity for hormonal stimulants to generate multiple eggs. The use and disposition of any pre-embryos that are frozen for future use should be consistent with the Council's opinion on frozen pre-embryos.

The use of frozen pre-embryo identical siblings many years after one child has been born raises new ethical issues. Couples might wait until they can discover the mental and physical characteristics of a child before transferring a genetically identical sibling for implantation, they might sell their frozen pre-embryos based upon the outcome of a genetically identical child, or they might decide to transplant a genetically identical sibling based on the need to harvest the child's tissue.

The Council does not find that these considerations are sufficient to prohibit pre-embryo splitting for the following reasons:

- (1) It would take many years to determine the outcome of a child and most families want to complete their childbearing within a shorter time.
- (2) The sale of pre-embryos can and should be prohibited.
- (3) The small number of couples who might bear identical siblings solely for purposes of harvesting their tissue does not outweigh the benefits which might be derived from pre-embryo splitting. Additionally, it is not evident that a sibling would have negative psychological or emotional consequences from having acted as an organ or tissue donor. Indeed, the child may derive psychological benefits from having saved the life of a sibling.

To the extent possible, discussion of these issues should be had with gamete providers prior to pre-embryo splitting and freezing so as to inform the prospective parents of possible future ethical dilemmas.

Issued [June 1994](#).

Opinion 2.169 - The Ethical Implications of Xenotransplantation

Xenotransplantation includes any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a non-human animal source or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live non-human animal cells, tissues, or organs. Although xenotransplantation offers a potential source of tissue and organs for medical procedures, research in this area may uncover physical and

psychological conditions that require medical attention. As such, physicians need to be involved in developing and implementing guidelines for continued research. Therefore, the following guidelines are offered for the medical and scientific communities:

- (1) Physicians should encourage education and public discussion of xenotransplantation because of the potential unique risks such procedures pose to individual patients and the public.
- (2) The medical and scientific communities should support oversight for the development of clinical trial protocols and of ongoing xenotransplantation research.
- (3) Given the uncertain risk xenotransplantation poses to society, participants in early clinical trials may have to agree to (a) postoperative measures such as life-long surveillance, disclosure of sexual contacts, autopsy; and (b) a waiver of the traditional right to withdraw from a clinical trial until the risk of late xenozoonoses is reasonably known not to exist. These requirements may continue even if the transplanted tissue is rejected or removed. The informed consent process should include a discussion of the above issues as well as potential risks to third parties and psychological concerns associated with receiving an organ or tissue graft from an animal. Careful attention must be paid to both the content of the consent disclosure and the manner in which consent is obtained.
- (4) It would be ethical to include children and incompetent adults in xenotransplantation research protocols only when the patients are terminally ill and alternative treatments are not available.
- (5) Allocation protocols must be fair and in accordance with Council Opinion 2.03, "Allocation of Limited Medical Resources," which recommends that decisions regarding the allocation of medical resources among patients be based only on ethically appropriate criteria relating to medical need. These criteria include, but are not limited to, the likelihood of benefit, the urgency of need, the change in quality of life, the duration of benefit, and, in some cases, the amount of resources required for treatment.
- (6) Sponsors of xenotransplantation research should assure that adequate funding exists for life-long surveillance and treatment of complications arising from xenotransplantation procedures on research subjects.
- (7) At a minimum, all on-going research should adhere to the Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation, FDA guidelines relating to xenotransplantation, Council Opinion 2.07 "Clinical Research," and any additional precautionary measures believed to minimize potential risks to the public or to patients. It is inappropriate to participate in xenograft procedures outside federal guidelines.

(8) All xenotransplantation research should continue to promote high standards of care and humane treatment of all animals used in research and to apply these standards to the care and treatment of animals used as sources of transplantation material.

Issued June 2001 based on the report “[The Ethical Implications of Xenotransplantation](#),” adopted December 2000.

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JOURNAL DISCUSSION

Living-Donor Grafts for Patients with Hepatocellular Carcinoma

Mohamed Elhassan Akoad, MD

Pomfret EA, Lodge PA, Villamil FG, Siegler M. Should we use living donor grafts for patients with hepatocellular carcinoma? Ethical considerations. *Liver Transpl.* 2011;17 Suppl 2:S128-S132.

Living-donor liver transplantation (LDLT) is a relatively recent surgical innovation that was developed to alleviate the severe shortage of transplantable organs for patients suffering from end-stage liver disease (ESLD). Living donation seriously challenges the medical dictum to “do no harm” because donors are subjected to the risks of surgery for no physical benefit to themselves.

The first successful LDLT was performed in 1987, when a child with ESLD received a left-lateral segment from his parent. Due to the success of LDLT in children it was subsequently extended to adults [1]. In adults, right-lobe grafts are commonly used because they have the larger hepatocyte volume necessary for successful LDLT.

The initial enthusiasm for and success of LDLT in the 1990s led to a proliferation of programs offering living-donor liver transplants, but that number quickly waned due to technical challenges and ethical concerns after a highly publicized donor death in 2002 [2]. The number of LDLT procedures peaked at around 500 cases per year but quickly dropped after 2002 and then stabilized at around 250 cases per year [3]. The risk of donor death after right lobe LDLT has been estimated to be around 0.2-0.5 percent and does not seem to be associated with the transplant center’s level of experience [4].

The benefit of living donation is obvious in countries with limited access to deceased-donor grafts (due to cultural or religious beliefs), but in countries like the United States where this is not an issue, living donation offers patients the possibility of transplantation before they become too sick to benefit or die on the waiting list. While most deceased-donor donations are nondirected, most living-donor donations are directed, so LDLT does not disadvantage patients on the waiting list, and the argument can be made that LDLT should be extended to patients who are not eligible for transplants from deceased donors according to standard allocation criteria.

Since its inception, LDLT has generated extensive ethical discussion because of concerns for donor safety. LDLT as a treatment for hepatocellular carcinoma (HCC) in particular is the subject of some controversy. The ethical principle of respect for patient autonomy coupled with the poor outcomes observed after transplantation in

patients with advanced HCC engendered debate about the utility of LDLT in that case.

In their article “Should We Use Living Donor Graft for Patients with Hepatocellular Carcinoma? Ethical Considerations” [5], Pomfret and colleagues examine three important questions: why is living donation necessary and is it different for patients with hepatocellular carcinoma (HCC)? What is double equipoise, and how is it affected by the diagnosis of HCC? Is paired exchange appropriate if one or both recipients have HCC?

Living Donation and HCC

The authors suggest that since a case of HCC that is within Milan criteria—a single tumor less than 5 cm in diameter or 2-3 lesions with individual diameters less than 3 cm—is an acceptable indication for receiving a deceased-donor liver transplantation, it should also be an acceptable indication for LDLT [6]. Moreover, almost all patients with HCC who receive liver transplants have cirrhosis, and patient with cirrhosis are excellent candidates for LDLT because they often have well-preserved liver function and low natural MELD (model for end-stage liver disease) scores.

The wide regional variability in MELD score-based liver allocation supports the authors’ argument that acceptable risks for donors and recipients may exist in certain areas of the country where the availability of deceased-donor organs is limited. For example, in New England, New York, and California, patients who receive transplants have much higher MELD scores than patients in other areas within the same time zone. This often results in patients “chasing the organ,” moving to different parts of the country in search of liver transplants. The most notable example of this was the late Steve Jobs who temporarily moved from his home in California to a more favorable location for his MELD score in Tennessee.

Because their mortality risk from cancer is greater than from liver failure, patients with HCC receive a priority MELD score that is increased every 3 months as long as their disease remains within Milan criteria limits. In many regions, patients with HCC can receive a deceased-donor liver transplant within 3 months of listing, but in other regions they may wait as long as 9 to 12 months, facing the risk of disease progression and death on the waiting list.

The ethical question is whether it is justifiable to subject a healthy donor to the risk of right-lobe donation if the recipient has a reasonable chance of receiving a deceased-donor organ within a reasonable time frame. Hence, the decision to offer LDLT must be individualized and weighed against regional differences such as waiting time for transplant and risk of the patient’s “dropping out,” which is an euphemism for dying while on the waiting list. For example, a patient with a 2.1-cm lesion who can receive ablative therapy in the form of radiofrequency ablation or transarterial chemoembolization as a bridge to transplantation has a reasonably good chance of receiving a deceased-donor liver transplant (DDLTL), even in regions of the country where the wait for it is longer, with minimal risk of dropping out. It can be

argued that it is not reasonable to subject the donor to a 0.2-0.5 percent mortality risk if the recipient has a high probability of receiving a DDLT.

As physicians, however, it is our responsibility to present both the risks and benefits of the procedure and help patients make informed decisions. Some donor-recipient pairs may choose to proceed since uncertainty about disease progression becomes incapacitating, while others are perfectly comfortable waiting. On the other hand, a patient with more advanced disease who is at risk for exceeding Milan criteria may not have the luxury of waiting and may benefit from a LDLT performed earlier, especially in regions where the wait for DDLT is long.

Because of the inherent donor risk associated with LDLT, there is further debate on whether to proceed with LDLT in patients with advanced HCC that puts them beyond Milan criteria. Pomfret et al. [6] explore why LDLT is a reasonable treatment option for patients whose tumors are slightly beyond Milan criteria. Using the University of California San Francisco (UCSF) criteria, which are more liberal (allowing larger tumors) than Milan criteria, liver transplant recipients did not experience significant increases in recurrence rates or decreases in long-term survival [7]. In many parts of the country, patients whose tumors are only slightly too large for them to qualify under Milan criteria do not receive MELD priority points, and LDLT represents the only realistic option. Expansion of the criteria beyond UCSF's significantly increases the recurrence risk and reduces the likelihood of long-term survival [8]; it is therefore ethically uncertain. The authors explain [6] that in these situations defining what is an acceptable recurrence risk to justify donor risk proved to be more challenging.

A more difficult ethical dilemma arises if a recipient who received a LDLT develops complications that cause graft loss (e.g. hepatic artery thrombosis or small-for-size syndrome) and is in urgent need of a deceased-donor graft for which he or she is not eligible. The authors rightly recommend that "Until extended criteria are adequately defined and accepted, indications for LDLT should be individualized" to minimize the likelihood of this set of circumstances occurring [6].

The current liver organ allocation system for patients with ESLD and HCC, which provides fixed priority points for HCC, does not accurately predict the risk of dropout and advantages HCC patients over non-HCC patients, who are prioritized using a continuous system that is revised over time. Development of a continuous system for HCC patients that incorporates tumor size, grade, alpha-fetoprotein levels, and natural MELD scores that would more accurately predict the drop-out risk and not disadvantage non-HCC patients has been suggested [9]. Such a system would not only be valuable for allocation of deceased donors but also helpful in selection of recipients for LDLT as well.

Double Equipoise and Paired Exchange

The authors offer an incisive analysis of the concept of double equipoise, which refers to the balance between the recipient's survival benefit and the risk of donor

death, and apply it to patients with HCC outside of Milan criteria. Unlike DDLT, in which the risk benefit analysis is restricted to the recipient, double equipoise evaluates the relationship between the recipient's need, the donor's risk, and the recipient's outcome. The authors affirm that these areas need to be explicitly defined and accepted by the donor, the recipient, and the medical and surgical teams [10]. In this model, ethical unacceptability occurs when the risk to the donor is not justified by the predicted minimal benefit to the recipient.

For example, if the recipient has multifocal HCC outside UCSF criteria or has extrahepatic disease in which the recurrence rate is high and long-term survival tends to be poor, risking a donor's life does not seem justified. Currently, there is no consensus on what constitutes an acceptable recurrence rate for advanced HCC or an acceptable donor risk.

The concept of double equipoise calculation means that reducing the risk to the donor may make greater risk to the recipient (of HCC recurrence and lower long-term survival) ethically acceptable. This could conceivably be achieved by using left-lobe grafts, which are smaller than right-lobe grafts, since the donor's risk is proportional to the amount of liver tissue removed. The removal of the left lobes confers significantly lower mortality and morbidity on donors, but left-lobe grafts are more challenging to the recipients because they increase the risk of graft loss due to small-for-size syndrome.

Interestingly, the concept of double equipoise considers each donor-recipient pair as a unit, analyzing whether the specific recipient's benefit justifies the specific donor's risk. Paired exchange, as eloquently suggested by the authors, could swing the pendulum towards ethical acceptability if one member of the recipient-donor pair is exchanged for reasons such as ABO (blood-type) incompatibility [10] or size mismatch. The complexity and logistics of LDLT prevent paired exchange from becoming as widespread as it is in kidney transplantation.

As transplant physicians and surgeons we must judge each case individually and reconcile donor risk and recipient gain. The answers are not always straightforward. When faced with a patient with advanced HCC, the physician's instinctive response is that the likelihood of recurrence poses an unacceptable risk to the living donor. But there are situations in which the benefit derived may justify the risk to a given donor. The case cited by the authors—of a mother of three young children with advanced HCC whose husband is aware of the risks but still committed to providing a graft [10]—is such a situation. To their family, even a short prolongation of survival is beneficial. After being presented with the risks and the potential benefits, donor and recipient should be granted the right to exercise autonomy in making an independent decision.

Conclusion

LDLT is an ethically viable treatment option for patients with ESLD and HCC. This is especially true with the current organ allocation system and the regional

differences in terms of MELD score and waiting times. If and when the organ allocation system becomes more uniform and the regional differences are eliminated, the impetus to perform LDLT will be reduced. Decisions regarding LDLT for advanced HCC should carefully balance donor's risks and recipient's probable outcome. Only when suitable organ substitutes can be generated in the form of xenografts from animals or artificial organ equivalents bioengineered in the lab will LDLT be relegated to surgical history.

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STATE OF THE ART AND SCIENCE

Severe Brain Injury and Organ Solicitation: A Call for Temperance

Joseph J. Fins, MD

Several years ago I resigned from a board position with the local organ procurement organization (OPO) over the status of organ retrieval from those with severe brain injury. I resigned with a heavy heart but a wary brain because I *am* a supporter of organ transplantation. Why else would I have agreed to join the board of an OPO? It was *pro bono* service in the pursuit of a good—the giving of life to patients in dire need of replacement organs in the face of end-stage disease. But there was another set of goods, emerging goods, for a different constituency—some patients with disorders of consciousness—that seemed in opposition to some of the policies pursued by the mainstream organ donation community. I was particularly concerned about patients who were in the minimally conscious state (MCS), a brain state just above the vegetative state.

Disorders of Consciousness: A New Nosology

To put all this into context and avoid nosological confusion, it is best to review some definitions, limiting ourselves to brain injuries that result in a loss of consciousness. Let us start with coma, which is an eyes-closed, self-limited state that finds the patient unresponsive and unarousable. The most serious of comas progress to *brain death*, defined as the irreversible loss of function of the whole brain, including the brain stem and higher cortical functions [1-3].

Comas can also evolve into a *vegetative state* (VS), which, in contrast to a coma, is an eyes-open state of unresponsiveness. Jennett and Plum first described the vegetative state as one of “wakeful unresponsiveness” marked by autonomic brain-stem function [4]. Vegetative patients demonstrate nonpurposeful, autonomic behaviors such as sleep-wake cycles, blinking, eye movements, and even the startle reflex [5]. These patients are not conscious or self-aware. By most definitions, the vegetative state becomes *persistent* once it has lasted for 1 month; it becomes *permanent* 3 months after an *anoxic* injury and 12 months after *traumatic* injury [6, 7].

The minimally conscious state, in contradistinction to VS, is a state of consciousness, although it is episodically and intermittently demonstrated. According to the Aspen Criteria of 2002 [8], MCS patients demonstrate unequivocal, but fluctuating, evidence of awareness of self and the environment. They may say words or phrases and may gesture. They also may show evidence of intention, attention, memory.

Prognostically, reaching MCS before VS becomes permanent is a critical milestone because, once that plateau is reached, the possibility for additional recovery seems to have no expiration date. The timeline is open-ended, with rare recoveries to emergence—defined as the consistent and reproducible recovery of consciousness and an awareness of self, others, and the environment—taking place years or decades later [9].

Organ Retrieval and Recovery from Severe Brain Injury

Federal regulations require that Organ Procurement Organizations (OPOs) be notified of the impending death of potential donors [10]. The timing of this notification can be self-evident: the patient on life support and vasopressor agents that maintain the blood pressure artificially, whose end is inevitable, no matter the intervention. But sometimes, the end is contingent upon decisions about the withholding or withdrawal of life support.

Case in point: what to do about those who have sustained a severe brain injury. Totally dependent upon ventilator support for at least airway protection if not ventilation as well, they can quickly become the imminently dying if a decision is made to withdraw the ventilator. And once such decisions are contemplated, regulations would have it that the OPO be notified about the possibility of what is commonly and euphemistically termed a potential organ *harvest*.

My problem as an OPO board member was that, too often, patients like these were viewed as if they were destined or compelled to die. They were seen as organ donors even before their organs had outlasted a viable body—and brain. As an ethics consultant at an academic medical center, I had seen OPO representatives hover in an ICU, waiting to sweep in—as some intensivists have described it to me—and collect what they viewed as rightly theirs—organs that would have a salutary effect on another human being.

I use the word “hover” deliberately, if a bit provocatively, because that is how families of many brain injury patients viewed it. I know this from interviews with more than 40 families, each with a member who had a disorder of consciousness, who came to Weill Cornell Medical College for enrollment in neuroimaging and EEG studies designed to elucidate mechanisms of recovery. While they were here, we conducted extensive interviews with patients’ surrogates about their experiences with the care system as they made their journey from acute injury on through rehabilitation and chronic care [11].

One of the most powerful scenes, often repeated, occurs early in the course of care, when patients are still in the ICU: surrogates are approached for organ donation. After the patients survive and recover to varying degrees of function, these families still resent what is often described as the predatory behavior of OPO representatives. Many families report zealous attempts at procurement and a near-certainty about their loved one’s prognosis: death was inevitable, ventilators should be withdrawn, and organs should be redirected for some greater good. But with valuable hindsight,

families later ask, how did they know? And how could they have been so wrong, both medically and perhaps ethically?

These are key questions that we need to untangle about the sociology of organ procurement. Why was there such certainty about these brain-injured cases when in fact many recovered, albeit to a level of function most of us would not desire? What was the basis of such prognostic confidence, when the work of scholars like Nicholas Christakis tells us that we are often quite poor at prognostication [12]? How did they *know*?

Brain injury seems to be a special case, constructed by historical and social context, because of how the designation of brain death and the vegetative state came into being. The concept of brain death was a product of the advent of transplantation and the need to procure organs. It is no accident that Christiaan Barnard's first heart transplant [13] and the Harvard Criteria for Brain Death authored by Henry K. Beecher and others [1, 14] date to 1968. Indeed, as the Harvard Criteria were being promulgated [15], Beecher proposed a utilitarian policy for retrieving the organs of those who had lost consciousness to help "those who could be helped" [16]. Here we see the link between the loss of consciousness and the correlative obligation to help others—presumably those who are conscious—through organ retrieval.

But there is a problem with this formulation. Brain-injured patients are, as is self-evident, especially prone to the loss of consciousness, which is generally the end-stage stigma of terminal illness and the prompt for surrogates to put a DNR in place for their loved one [17, 18]. But loss of consciousness might just be the start of a recuperative process for patients with severe brain injury, who begin their journey with a coma, an eyes-closed state of unconsciousness.

Organ retrieval can be, in some cases, what I would call premature harvesting before a patient has had the opportunity to declare himself. Comatose patients who have brain-tissue herniation, or are near herniation with massive edema, might be accurately said to be facing a dire, if not mortal, outcome. Other patients in coma may have the potential for significant recovery. The ethical action, in my view, is to better risk-stratify patients with a favorable prognosis from those with a grim one, recognizing that coma, per se, is not necessarily the harbinger of a fatal outcome.

Although investigative efforts are under way to better understand mechanisms of recovery and prognosticate outcomes for patients with disorders of consciousness, using methodologies like functional neuroimaging [19, 20] and electroencephalography [21], these interventions remain experimental, and sometimes the bedside exam, functional imaging, and EEG can yield discordant results [22, 23]. Thus, it is important to stress that, despite the media hype often occasioned by neuroscience results [24], these methods are not yet ready for clinical use. In many cases it is better to wait and let these patients declare themselves before making a decision to withhold or withdraw care, which is the requisite—and importantly separate—decision on which organ donation is predicated.

Temperance

So let me suggest a modest proposal: temperance in the setting of organ retrieval. By temperance, I mean to invoke the notion of moderation and “rational self-restraint” [25] in soliciting donations. But it is not just about temperance in the sense of moderation. It is also temperance in the context of temporality [26]. I mean to appeal to the temporal flow of recovery, which is charted by a biology we, as yet, do not understand.

One of the tertiary definitions of temperance in the Oxford English Dictionary refers to keeping time, as in music [25]. To offer a metaphor, I would suggest that clinicians also need to keep apace with the rhythms of recovery. Clinicians should of course be sensitive to and respect a patient’s prior wishes about withholding and withdrawing life-sustaining therapy. But when wishes are unclear or have not been expressed, it is also important not to stop a process of recovery before its trajectory can be better known. To do so would be akin to not knowing there was a fourth movement in Beethoven’s Ninth Symphony and abandoning a performance before the chorus sang.

I would propose a moratorium upon solicitation when the outcome is unclear. In these indeterminate cases, I would urge clinicians to see how the patient emerges from the comatose state. How and when that occurs can have prognostic implications that can help surrogates make judgments about ongoing life-support in the wake of any prior wishes.

Although this “time out” may be difficult, even painful, for surrogates, it helps inform the decision process, making it more patient-family-centered [27]. That additional bit of deliberation is morally good for both the patient’s family (the “donative sources”) and any potential recipient of such a gift. That additional element of process might assuage any misgivings or guilt that might accompany the giving, or receipt, of an organ because it helps ensure that the donative act was neither coerced nor forced but rather one of *informed* altruism, a standard for which we should strive, particularly given the recent encroachment of the market into the donative space [28].

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STATE OF THE ART AND SCIENCE

Sham Surgery

Richard J. Rohrer, MD

Those of us who work in transplantation are not prone to existential angst. Heart and liver transplants save lives where no other viable option exists. Kidney transplantation has proven itself time and again to add years and quality to the lives of renal failure patients, and in a highly cost-effective way. Aside from occasional concerns over comorbidities and patient selection, we rarely think twice about offering our services. And yet, humility is a virtue, even for us.

A few years back I was attracted to a review of the book *Charlatan*, by Pope Brock [1]. It recounts the story of a quack surgeon from the 1920s, one John R. Brinkley. His signature operation was testicular xenografting (goat donors, human recipients), making him, I suppose, a pioneer of transplant surgery. The book tells the tale of how he was finally taken down by the legendary Morris Fishbein, editor of the *Journal of the American Medical Association*.

A saga like this leads a thoughtful person to many different considerations. One such consideration for me was how we ever really know what a surgery accomplishes. Surely the claims of individual surgeons and the testimonials of selected patients are inadequate, and they may be positively misleading. Even that staple of the surgery literature, the case series—whether single-center or multi-institutional—commonly suffers from selection bias in design and groupthink in analysis.

The sources of bias in studies of surgery are legion. In addition to the straightforward patient selection bias inherent in most of them, there is a variety of more subtle forms of bias to consider. The Hawthorne effect describes changes in general behavior (and in the care of a control group, if any) that are related to participation in the study rather than to the intervention itself [2]. The Pygmalion effect describes how investigators are predisposed to see the outcome they seek, even if it is objectively absent [3]. The Will Rogers effect (“When the Okies left Oklahoma for California, they raised the average intelligence of both states.”) describes a unique but not uncommon form of allocation bias (i.e., how patients are assigned to diagnostic groups or stages). And publication bias is everywhere; trials with positive outcomes are 3-8 times more likely to be published than trials with negative outcomes [4].

Moving beyond the literature to everyday practice, even more elements of bias come into play. Action bias—“Don’t just stand there, do something”—can be particularly hard to resist [5]. It may take various forms: “Dr. Jones sent me this patient, so she

must want me to operate”; “The procedure may be a bit hard to justify in this patient, but everybody’s doing it”; or even “If I don’t operate on this patient, someone else will.” Provider bias—“If all you have is a hammer, the whole world looks like nails”—naturally influences the specifics of any recommended procedure, particularly in this age of rapidly evolving technology (and individual surgical skill sets that may not have kept pace). And we are disingenuous if we don’t acknowledge the timeless effect of straightforward economic bias in surgical practice. As Rene Descartes said in the seventeenth century, “A man is incapable of understanding any argument that interferes with his revenue.”

Randomized, controlled, double-blind studies go a long way toward answering the question of how we really know what a surgery accomplishes. But an observer of the literature immediately notices a few problems. First, and most conspicuous, there are very few of them, and blinding is difficult. In addition, they are often statistically underpowered, and what’s more, they are rarely repeated by another group for confirmation. But perhaps even more daunting is the fact that the control arm of these studies is usually some other mode of surgery, which is itself untested in the first instance. That is to say, sham-controlled surgical trials are rare.

Placebo-controlled trials are well-known in pharmaceutical studies (though even there, they are not the rule). It is at least easy to conceptualize how a “sugar pill” can be used to create a control arm for a study of, say, a new antihypertensive medication. Sham “placebo” surgery controls (as opposed to sham “bogus” surgery, like goat-testicle transplants) are another matter. The sham control patient would at least need anesthesia and an incision somewhere, and that would seem to be simple enough in principle. But it is highly dependent upon the specific surgery and may not be logically possible. For example, if I want to study arteriovenous fistulae for patients heading onto dialysis, including a sham control group in my study would make no sense, since there is no way for high-volume vessels to spontaneously appear on the arm of a patient who had just a skin incision and nothing more.

Even if a sham control is logically possible, it may not be practical. Though you might plausibly design a sham control for a study of amputation for rest pain (due to ischemia of the lower leg)—one group gets a below-knee amputation, the other just anesthesia and a circumferential incision—it would be impractical to conceal the outcome from the patient, or anyone else for that matter. Finally, even if a sham control group were both logical and practical, it may not be ethical. There will never be a sham control group to evaluate surgery for colon obstruction, since it could never be ethical to leave patients with colons that remain obstructed, not to mention putting them through the risks attendant on anesthesia and the incision. And sham surgery in organ transplant would seem to be equally difficult to justify on ethical grounds.

Furthermore, we surgeons (and proceduralists in general) have a fundamental problem with the null hypothesis that is implicit in a sham-controlled study. We believe in our operations. This is quite natural: we live and breathe in a world where

we actually *do* things to people. When we make errors, they are usually errors of commission, which contrast qualitatively with the errors of omission that are seen among our medical (i.e., nonproceduralist) brethren. When we stick a knife or a needle into a patient, we are carried along by confidence that the risk-benefit calculation for this patient favors action, and the same mindset infuses both pre-op preparation and post-op management. If it were otherwise, we'd risk a kind of psychological inertia approaching paralysis. We are only human, and though we live in the twenty-first century, we have Stone Age brains, which benefit from overriding confidence (captured in the aphorism "often wrong, but never in doubt").

So it should come as no surprise that sham-controlled studies of surgery are rare [6]. In fact, there are only a dozen or so, and most of them involve what might better be described as "minimally invasive procedures" than "traditional surgeries." The classic is a study of internal mammary artery ligation for angina pectoris, by Cobb and colleagues from 1959 [7]. At the time it was thought that ligation of the distal internal mammary arteries might increase collateral blood flow to the ischemic heart. All patients underwent dissection and encircling of the internal mammary arteries, but then subjects were randomized into trial and control groups, and only half had their arteries ligated. The postoperative angina and performance metrics of both groups improved equally. This, of course, led to the conclusion that bilateral internal mammary artery ligation was no better than a sham procedure. But more interesting, in many ways, was the question generated: what was going on with the sham group that they were able to improve at all?

In all, there appear to have been about 15 sham-controlled studies of surgical interventions in the recent literature. Much depends upon how one defines "surgical intervention," of course. I have chosen to include vertebroplasty [8], for example, but to exclude an excellent and illustrative study of acupuncture [9]. There have been sham-controlled studies of arthroscopy for osteoarthritis [10], implantation of dopaminergic neural tissue for Parkinson's disease [11], and transmyocardial laser revascularization for refractory angina [12]. One of particular interest for the general surgery community involved implantation of a gastric stimulator for treatment of obesity. In the SHAPE trial [13], 190 patients underwent laparoscopic placement of a device designed to alter normal gastric function; in half the group, the stimulator was turned on, and in the other half it was left off. Patients and evaluators were blinded. At 12 months the control group had lost 11.7 percent of excess weight, while the treatment group had lost 11.8 percent: no difference between the two groups. Similarly, a sham-controlled study of laparoscopic lysis of adhesions in treatment of pelvic pain showed that both groups improved equally [14].

These studies might be dismissed as just a collection of oddball case types, except for one thing: in all reported sham-controlled studies to date, evidence for benefit of surgery over sham has been lacking. The score is sham 15, intervention 0. Of course this is due in large part to some of the barriers to study described above. But as surgery moves from its historical role—open, ablative procedures for the saving of lives—to its contemporary role, which includes a remarkable percentage of

minimally invasive techniques, with reworking of the native anatomy for the reduction of pain or improvement in quality of life—surely an expanded role for sham-controlled trials is indicated.

And when true sham-controlled studies of surgery can't be performed, we must learn to be creative in seeking the next best thing. For example, Waki and colleagues studied the putative survival benefit of pancreas transplantation in an ingenious but straightforward way [15]. They queried a large transplant database for deceased organ donors who had donated one of their kidneys to a diabetic recipient as part of a simultaneous pancreas-kidney transplant (SPK), and the other kidney to a diabetic recipient as a kidney graft alone—a “sham” (absent pancreas) SPK. The result: patient survival through 10 years was equivalent, indicating that in these patients there is no survival benefit to a pancreas transplant over standard insulin injections (and thereby relegating the potential benefit of pancreas transplantation to quality of life).

Or consider the study comparing open colectomy to laparoscopic colectomy performed by Basse et al [16]. They randomly assigned 60 patients to one of these modes of surgery and, at the conclusion of the case, went to the considerable effort of covering the entire abdomen with a single large bandage. Patients and evaluators were blinded as to the kind of surgery performed. Time until discharge from hospital—the primary endpoint—was the same for both groups.

In short, the sham effect is anything but a wifty notion: it is real, and it is alive and well in surgery today. More surgical procedures should be compared to sham controls, or the closest thing we can devise. The insights gained will help us understand exactly what it is that we accomplish with our procedures, and what it is that the patient actually experiences with surgery [17]. And they will allow us to expeditiously identify procedures of little or no intrinsic merit.

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HEALTH LAW

Reproductive Tissue Transplants Defy Legal and Ethical Categorization

Valarie Blake, JD, MA, and Kavita Shah, MD, MBE

Since its inception in the early part of the twentieth century, organ transplantation has posed ethical and regulatory challenges. How should we allocate a limited supply of life-saving resources? Who should decide? Who should be allowed to donate organs—the living, the dead, prisoners, patients with communicable disease? Organizations like United Network for Organ Sharing (UNOS) and laws like the National Organ Transplant Act (NOTA) provide some guidance, but recent technological advancements in reproductive medicine are creating new dilemmas. The transplantation of reproductive organs (including ovaries, testes, and uteruses) challenges our notion of the very purpose of organ transplantation, its goals, and its outcomes.

The Current State of Reproductive Tissue Transplant

The most successful reproductive tissue transplants to date are ovarian tissue transplants. In 2004, a woman with non-Hodgkins lymphoma, whose ovarian tissue had been removed and frozen before she underwent chemotherapy, became pregnant and gave birth after receiving a transplant of her own ovarian tissue [1]. Ovarian tissue transplants between monozygotic twins and nonidentical sisters have succeeded, making it more probable that transplants from nonrelated donors will someday be possible [2, 3]. The procedure also appears to treat infertility over the long term—one woman gave birth to two children as a result of an ovary transplant, becoming pregnant without assistance in 2007 and through IVF in 2010 [4].

Fertility after testicle transplant was proven possible in 2001, when a man in remission for cancer fathered a child after transplant [5]. Uterus transplant is the least-developed technology, still mainly in the animal phases of research, with some success in mice, dogs, and pigs [6]. A failed attempt in a human occurred in 2002 in Saudi Arabia, but plans are in place to attempt a mother-daughter transplant in Sweden sometime in the spring of 2012 [7, 8].

Reproductive tissue and organ transplants vary in difficulty and demand, depending on the type. All enable greater involvement in and control over reproduction for a wide variety of groups with disease-related or congenital infertility. Testicle transplant receives less attention, both because sperm cryopreserve better than eggs and because male-factor infertility can more easily be resolved with less invasive techniques (like artificial insemination) than female-factor infertilities [9]. However, testicle and other transplants are key in regions where gamete donation (or, in the case of uterus transplant, gestational surrogacy) is illegal.

New Regulatory Challenges Raised by Reproductive Tissue Transplants

While reproductive tissue transplants open a variety of possibilities for the future of infertility treatment, they also pose significant challenges for those regulating the practice of organ transplant.

Applicable laws. Reproductive tissue transplant is unusual in that it embodies elements of both assisted reproductive technology (ART) and organ transplantation, two fields that are treated differently under the law. Organs are regulated by federal rules, mainly the Uniform Anatomical Gift Act (UAGA) and National Organ Transplant Act (NOTA), whereas ART is regulated by the states, whose rules vary widely in their scope, context, and existence. Because reproductive tissue transplant has characteristics of both, it's unclear which rules should apply, and neither body of regulations applies perfectly.

Current organ regulations, for example, do not take into account new concerns raised by reproductive tissue donation, namely the genetic aspect of the donation. That is, while other organ transplants affect only the health and body of the recipient, reproductive tissue transplants affect the offspring of the recipient, as well as the donor and donor's family because of their genetic relationship to the recipient's offspring. Another example is payment. Payment for organ donation is strictly prohibited but payment for donating eggs and sperm is a burgeoning market—will an egg donor be paid if she donates for IVF but not for transplant? How reproductive tissue transplants will be treated depends a great deal on how legislatures classify these procedures in the current legal terrain.

Informed consent. Regulatory classification also has an impact on informed consent to donate organs. To the extent that any of these donations rely on deceased donors, if the UAGA applies, it permits the next of kin to donate organs on behalf of the deceased donor [10]. However, gamete donations raise more significant issues than livers or kidneys because of their ability to create genetic offspring, thus touching upon important legal rights to reproduce (or not). These are decisions that (despite countless hours of badgering at the Thanksgiving table) we typically do not leave to our parents or next-of-kin. Some may question whether deceased individuals have a right to control reproduction, a complex and unsettled legal and ethical question that some states have tackled in posthumous conception cases (where family members have asked to use deceased individuals' gametes to reproduce) [11].

Allocation criteria. United Network for Organ Sharing (UNOS) plays the primary role in determining who will receive organs and in what order for all solid organ transplantation in this country [12]. This method of distribution prioritizes recipients based on three factors: sickest-first, prognosis, and first-come, first-served [13]. Reproductive tissue transplants are not life-saving interventions, so the sickest-first criterion does not apply. If a "greatest need" criterion is applied, would that mean those with the most incurable forms of infertility, those who do not already have children, those closest to reaching the end of their reproductive years, or those who

have expended the greatest resources trying to become pregnant would be prioritized for the transplant?

Prognosis is also difficult to qualify. Reproductive tissue transplants are unlike other organ transplants because they are intended to achieve the short-term result of reproduction and then be removed to avoid the lifelong need for immunosuppression, unlike a liver or a kidney which ideally remains in place until the end of the recipient's life. Medical criteria used to determine organ candidacy, including psychosocial criteria, have thus focused on who can best sustain the organ for the longest period of time [14]. In reproductive tissue transplant, in contrast, the aim for everyone is the same—to maintain the organ long enough to reproduce. In this context, what criteria determine who has a better prognosis?

The Changing Goals of Transplantation

Possibly the most significant difference between reproductive tissue transplants and other organs is reflected in the changing goals of transplantation. Organ transplant has already progressed from being a life-saving procedure to being a quality-of-life intervention. In December 2011, the Department of Health and Human Services proposed rules that would include a broader array of transplants under the purview of the current Organ Procurement and Transplantation Network (the group which regulates UNOS) [15]. The new rule adds mainly “vascularized composite allotransplantation” (or the transplant of multiple tissues and a functional unit), which mainly includes hand and face transplants, to the list of regulated organs. This new proposal shows both an evolving acceptance of these new goals of transplant and a desire to regulate them [16, 17].

Reproductive tissue transplants, however, present even newer issues than hand and face transplants because they are intended not only for quality-of-life improvement but the creation of life as well. This has led scholars to ask when a dangerous and expensive procedure should be permitted [18, 19]. It raises larger societal questions about how we wish to allocate health resources, what the boundaries of medicine and transplant medicine in particular are, and how far we will go in terms of research and individual risk in the pursuit of having children.

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POLICY FORUM

Contemporary Debates over the Acceptability of Kidneys for Donation

Benjamin Hippen, MD

For the last three decades, kidney transplantation has been the preferred approach to renal replacement therapy for the vast majority of patients. The virtue of transplantation lies in the expected conferral of a longer quantity and a better quality of life to recipients than they would have from chronic dialysis.

Advances in the management of hypertension, diabetes, and other contributors to the burdens of cardiovascular morbidity have permitted more of our fellow citizens to live longer, surviving (or even avoiding) what would previously have been a fatal myocardial infarction or cerebrovascular accident, and thus surviving long enough to live with kidney failure. Demand for a transplantable kidney has tracked growth in the number of new patients with kidney failure, and pharmacologic advances have substantially attenuated what were once severe iatrogenic complications of systemic immunosuppression, making transplantation a plausible therapeutic possibility for more patients. But the supply of transplantable kidneys has not kept pace.

Extant Policy Approaches

There have been three non-mutually exclusive policy approaches to addressing the supply-demand problem: (1) increasing supply, (2) reducing demand, and (3) revising the allocation system. Despite aggressive, federally sponsored efforts to increase the supply of organs from deceased donors, growth in supply has come primarily from using more organs from so-called “expanded-criteria” donors (ECD) and donors after circulatory death (DCD). The total number of kidneys procured from standard-criteria (SCD) donors (read: young, healthy donors without comorbidities) has remained flat to falling over the last 5 years [1]. As a result, the total number of kidneys from all deceased donors transplanted in 2009 (7,248) is not substantially higher than in 2006 (7,178) [1]. Over the same interval, the total number of kidneys from living donors has remained stable at between 6,000 and 6,500 kidneys per year [2].

Paired kidney donation and donor “chains” initiated by a volunteer for nondirected living donation are recent, exciting innovations [3], but the total number of organs transplanted from these arrangements each year remains small [4]. Efforts to repeal existing legislation that prohibits policy experiments in remunerating prospective living donors have so far been unsuccessful [5] and are, at any rate, highly controversial.

While reducing demand for kidney transplants has not been thus far successful (prevalence rates of end-stage renal disease—ESRD—continue to rise [6]), some have argued that the total number of candidates on the waiting list substantially overstates the true demand [7-9]. Critics have pointed to the fact that a large fraction of patients on the waiting list are classified as “inactive,” or “status 7” in the parlance of United Network for Organ Sharing (UNOS) and the Organ Procurement and Transplantation Network (OPTN). Candidates listed as status 7 are not able to receive an organ offer but are able to accrue waiting time on the list so that, once “activated,” they can receive organ offers based on time accrued while they were inactive. Some patients listed as status 7 never become active and are ultimately removed from the waiting list. Therefore, status 7 patients represent a “shadow” demand, which tends to inflate (and overdramatize) the true demand for organs.

A candidate may be designated as status 7 for many reasons, candidates may switch back and forth between status 7 and active status with unknown frequency, and different transplant centers have substantially different policies regarding use of the status 7 designation. Patients may be designated as status 7 because of insurance ineligibility, a recent (reversible) illness, or because their renal function remains too good to benefit from transplant but sufficiently low to accrue waiting time. Some centers with large waiting lists and long median waiting times routinely list patients as status 7 after referral and then begin the evaluation process once the candidate has accrued sufficient waiting time to rise close to the top of the center’s list, thus reducing the need for and expense of repeated screening tests over a period of years.

To be sure, some fraction of these patients will never become active candidates and will be removed from the list due to physiologic deterioration or death. But a patient listed as status 7 at a center with a median waiting time that exceeds 5 years may well be a medically viable transplant candidate in the first or the fourth year of status 7 listing, and deteriorate and be removed after 5 years on the list. Far from being an instance of “shadow” demand, attrition of patients listed as status 7 is more plausibly understood as a feature of longer median waiting times to transplantation.

Finally, even if every patient listed as status 7 is not and never was a medically suitable candidate for transplantation, other research has shown that there are an additional 80,000-130,000 patients with ESRD who could theoretically benefit more from transplantation than from dialysis based on demographic information, but are never referred for a transplant evaluation [10]. So even though the waiting list for a kidney now exceeds 90,000 candidates, this may represent less than half of the true number of patients who might benefit from kidney transplantation.

Understanding the fact that efforts to increase the supply of kidneys as well as reduce (or downplay) the growing demand have been unsuccessful is crucial to understanding the key impetus for the third policy approach: revising how kidneys are allocated. Organ allocation from deceased donors is already a zero-sum affair, since any organ allocated to one candidate cannot be allocated to any other who might benefit. But a fixed supply combined with growing demand yields

progressively diminishing returns because more and more candidates will be waiting longer for an organ, which in turn means that more medically suitable candidates will be sicker at the time of transplantation (resulting in worse outcomes) and more medically suitable candidates will become too sick to receive a transplant at all or will die on the waiting list.

The Proposed System

Proponents of changing kidney allocation are animated by the concern that the expanded-criteria allocation system is inefficient because it transplants kidneys of lower quality, which results in higher rates of discard, and wasteful because it allocates kidneys from young and healthy donors to older and sicker recipients. What is proposed instead is a hybrid system comprising accrued waiting time, age-matching between the donor and candidate, and a utility score based on demographic information on donors (the kidney donor profile index or KDPI) and candidates (called the estimated posttransplant survival score or EPTS).

By matching the “best” 20 percent of kidneys (as measured by KDPI) with the “best” candidates (as measured by the EPTS), and by age-matching the donor kidney to within 15 years of the age of the candidate, proponents contend [11] that the new allocation system would substantially increase total life-years accrued from all available organs. However, minutes from the August/September 2011 meeting of the UNOS/OPTN Kidney Committee report conclusions from HHS counsel that age-matching would run afoul of the Age Discrimination Act of 1975 [12]. This means that it is unlikely that explicit age-matching will be a part of any proposed revision, though donor and candidate age will probably be included as surrogate variables for predicting graft and patient survival.

Much of the conversation about the new allocation system begins by granting the premise that the scoring systems employed to match “best organ” to “best candidate” are reliable predictors of prognosis. But, as my colleagues and I have argued in detail elsewhere, there is good reason to think this is not the case [13]. If the scoring system employed in the new allocation system does not fare well as a prognostic tool, then discussing the moral defensibility of such a scoring system is premature. The practical implications of using a scoring system that may generate an incorrect prognosis of graft survival more than 30 to 40 percent of the time must be discussed first.

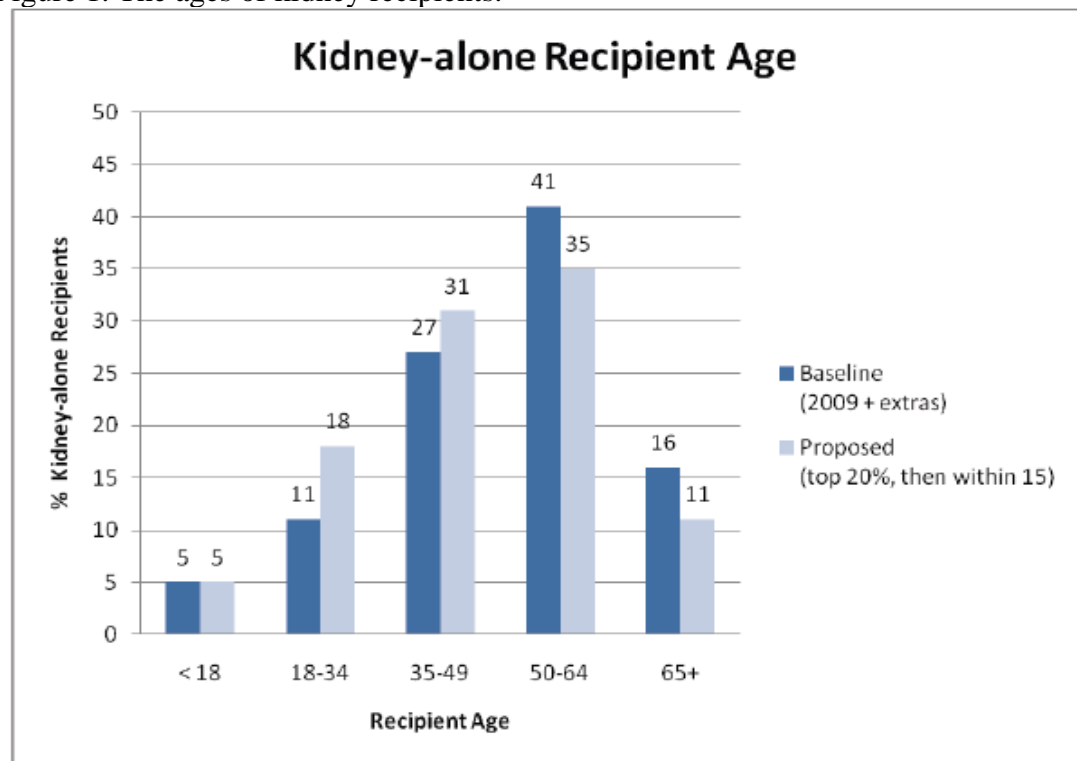
For starters, it is implausible that a scoring system with this degree of prognostic disability will reduce rates of organs deemed unacceptable for transplant. Transplant centers cultivate different institutional attitudes to risk. Some centers are more willing to routinely accept and transplant higher risk kidneys from physiologically marginal donors than others. These are the considered judgments of professionals, and it is implausible that the introduction of KDPI, with these stipulated prognostic limitations, would generate wholesale changes in how centers adjudicate donor risk. In any event, centers are already required to submit parameters for acceptable organ offer to UNOS/OPTN so as to avoid the inefficiency of offering a center organs that

are outside its established risk tolerance [14]. The addition of KDPI to this requirement would only add confusion in instances in which it wasn't otherwise merely redundant.

Proponents of the new allocation system are also motivated by the plight of younger patients on the waiting list, the prospect that these candidates are harmed by longer waiting times, and the potential pressures to accept a kidney of poorer quality and face the need for retransplantation. One might gather that there are legions of young people being added to the list, only to languish. But the waiting list is not evenly distributed across age cohorts.

ESRD is increasingly a disease of aging, and this is reflected both in the rising median age of newly listed candidates and in the facts that two-thirds of candidates listed for transplant are over the age of 50 and only 10 percent of listed candidates are aged 18-34. New additions to the waiting list in 2010 are distributed in roughly the same proportions [15]. So stipulating the general premise that older candidates are more likely to die on the waiting list than younger candidates and that the organ supply is zero-sum, a proposal that prioritizes younger candidates over older candidates will mean that (a) older candidates, who make up most of the waiting list, will have fewer opportunities to receive a transplant from a deceased donor (see figure 1) and (b) because older candidates are less physiologically robust, the result will be more removals from the list due to deterioration and higher rates of death on the waiting list than in the current system.

Figure 1. The ages of kidney recipients.



Proponents of the proposed system respond that this possibility will increase the pressure to use kidneys from more physiologically marginal deceased donors, pointing to the “old-for-old” program employed by the Eurotransplant Senior Program (ESP) as a favorable example. But the outcomes data from ESP suggest a less sanguine lesson. Frei and colleagues [16] reviewed 6-year patient and graft survival comparing three allocation strategies: (a) old-donor kidney to old candidate, (b) old-donor kidney to any-age candidate, and (c) any-age-donor kidney to old candidate. The results showed that old-to-old conferred significantly worse patient survival and worse graft survival than the other allocation strategies.

This should not be a surprise: kidneys from physiologically marginal donors tend to have higher rates of primary nonfunction and delayed graft function and shorter half-lives than kidneys from younger, healthier donors. In the immunosuppressed recipient, these complications confer significant risk for additional complications: infection, debilitation, and death. Old candidates are much less likely to withstand these complications than younger candidates, and so it is unsurprising that older candidates who receive marginal kidneys are more likely to sustain adverse outcomes than younger candidates.

Furthermore, preferentially allocating the “best” deceased donor kidneys to the youngest recipients may have a dampening effect on rates of living donation to young, healthy recipients, a phenomenon observed when pediatric candidates were given preferential access to organs from deceased donors less than 35 years of age [13]. Since most organs from living donors are directly donated to younger recipients in the first place, preferential allocation of deceased-donor organs may have the undesirable effect of depressing total rates of living kidney donation.

Rearranging the Deck Chairs

One hypothesis that explains why the total rate of growth of kidneys procured from deceased donors is flat to falling is that transplant centers are increasingly aware of all this. Virtually all of the growth in the deceased-donor list has come from an increase in kidney procurement from physiologically marginal donors, with a smaller fraction from donors after circulatory death. Centers are held accountable for patient and graft survival rates by UNOS/OPTN, as well as by insurers. While those survival statistics are “risk-adjusted” to account for donor characteristics and candidate comorbidities, what risk-adjustment *really* amounts to is, across all transplant centers, a quiet lowering of expectations for patient and graft survival.

The ongoing disagreement over the merits and flaws of different allocation regimes exposes a deeper, existential question for regulators, insurers, and the transplant community at large. The promises of efficiency and allocating “the right kidney to the right recipient” are based on empirically dubious promises of gains. The transplant community and those it treats would be far better served if the following premise was simply conceded: it actually doesn’t matter overly much whether or not the current allocation system is maintained or a new one is adopted. The fact is, so long as the growth in the organ supply is primarily from lower-quality organs from

deceased donors, we can perform fewer transplants with better outcomes, or more transplants with worse outcomes, but the available data strongly suggest that we really can't promise both more transplants and better outcomes. The transplant community should just admit that *this* is the crucial policy choice.

In practice, the choice between volume and outcomes will probably not be made by changes to OPTN allocation policies, but by the aggregate clinical behavior of individual transplant centers, strongly determined by their attitudes toward risk. And if, as in the past, the Health Resources and Services Administration remains unwilling to grant additional regulatory dispensation for worse reported outcomes from centers with a higher operational risk tolerance, the coming years will see fewer total kidneys procured from deceased donors, and most of that attrition will be from a reduction in the total number of kidneys transplanted from physiologically marginal deceased donors. Centers with conservative risk tolerance will remain conservative, and more centers that are currently less risk-adverse will become skeptical that this approach can be reliably offset by risk adjustments for donor and candidate comorbidities. More centers will make the calculation that by lowering their risk tolerance and doing fewer transplants with better-quality organs (which should more reliably confer better outcomes), they can escape the slings and arrows of additional scrutiny by regulators and insurers. If this comes to pass, we can expect fewer kidney transplants from deceased donors in the near future and more removals from the waiting list due to deterioration or death.

Eventually, it will become obvious that rearranging deck chairs does not yield substantially more places to sit down. The controversies over allocation really represent intellectual exhaustion in the face of a long series of inadequate policy responses to the decade-long trend of the kidney supply increasing only at the expense of organ quality and patient outcomes, exacerbated by a steady growth in demand for organs. The sooner the transplant community understands that we can't allocate our way out of this problem, the better off our patients will be.

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POLICY FORUM

Rationing Livers: The Persistence of Geographic Inequity in Organ Allocation

Bruce C. Vladeck, PhD, Sander Florman, MD, and Jonathan Cooper, JD

The Problem: Rationing by Place of Residence

Whether accurately or not, “rationing” was frequently employed as a term of opprobrium during both the health reform debates and subsequent explosion in political vituperation. But whatever that word’s lingering stigma, there are unquestionably situations—long preceding the Patient Protection and Affordable Care Act and almost certain to persist whether it is fully implemented or not—in which a fundamental imbalance between need and supply makes rationing of some health services inevitable. In such circumstances, some socially acceptable mechanism must be available to insure equitable and justifiable allocation processes. Yet in the case of liver transplantation, an especially dramatic example of the imbalance between need and supply, neither the public nor the private sector has been able to ensure equitable allocation.

Right now, more than 16,000 Americans are awaiting liver transplants, and each year about 10,000 more are determined, as a result of irreversible liver damage, to need one, while for many years the total supply of donated organs has remained relatively steady at about 6,500 [1]. As a nation, we clearly need to do a better job of encouraging organ donation, but that is a very long-run solution.

Reasonable people could well differ on the precise criteria for allocating such a scarce, life-saving resource as donated livers, but it is hard to make a case that the patient’s place of residence should be a criterion. Yet people on liver transplant waiting lists in some major metropolitan areas across the United States are 30 percent less likely than similarly ill people in other communities to receive deceased donor transplants—and, not coincidentally, 30 percent more likely to die while still waiting [1]. In some areas in the United States, death while awaiting a liver transplant is less than 10 percent a year, while in other areas it is more than three times that. This regional variation can be dramatic when comparisons are made between patients from different regions with the same medical priority, as best exemplified by those with cancers confined to the liver that meet well-defined criteria and therefore receive priority for transplantation. In some regions these patients receive transplants within 3 months of being listed, while in another region the wait can exceed 18 months [1].

These geographic disparities are not new. In the mid-1990s, public concerns about equity in access to organ transplantation, notably fuelled by allegations that the retired baseball star Mickey Mantle had received preferential access to a donated

liver—and died just 2 months later—led to public reconsideration of existing practices [2]. United Network for Organ Sharing, a private, nonprofit organization chartered by the federal government with responsibility for overseeing the national transplant enterprise, revised its allocation priorities to prevent “gaming” of waiting lists by deemphasizing the importance of time spent on the list.

UNOS recommended a new process of priority-setting more closely tied to the severity of patients’ illness, but maintained the practice of applying those clinical priorities only within and not *across* the UNOS regions. The 11 regions, which grew up largely as a matter of historical accident and for mostly administrative purposes, vary considerably from one another in population, incidence of end-stage liver disease, and rates of organ procurement. But the proposed revisions appeared to fan, rather than dampen, the controversy.

In response, the Secretary of Health and Human Services appointed a special, ad-hoc review panel to conduct public hearings on the general issue of allocation of donated organs, which thereafter made its recommendations to the secretary in early 1997. Based on the panel’s recommendations, the secretary then promulgated new regulations UNOS would be required to follow in establishing liver allocation policies, including a specific requirement that geographic equity be addressed [3]. In response to complaints about the geographic equity requirements, however, Congress voted to suspend implementation of those regulations and requested that the Institute of Medicine perform a study of the policies contained in the regulations and their likely impact on the transplantation process.

The IOM report, completed in 1999, specifically recommended that existing UNOS policies, which called for a new, quantitative system of setting priorities based on medical criteria, be applied uniformly across geographical areas with populations of roughly nine million, a system that would effectively supersede UNOS’s regional structure [4]. While UNOS has subsequently refined its medical prioritization criteria, livers are still allocated on the basis of medical need within a given UNOS region, producing the discrepancies in waiting times, transplantation rates, and outcomes.

The continuing centrality of the UNOS regions in liver allocation has also fostered a system in which patients with sufficient sophistication and financial resources strategically seek care—and placement on waiting lists—in regions with shorter waiting times and higher transplantation rates than those in which they reside. While allowed by the current rules, this option, of course, is only available to those with access to such resources, adding a significant socioeconomic gradient to location-based disparities. Steve Jobs, a resident of Northern California, received a liver transplant in 2009 in Tennessee [2]. For most people awaiting transplantation, it is simply not practical to reside in another city, often far from their families and support systems, while awaiting a transplantable organ.

Organizational and Political Considerations

Like the Accreditation Council on Graduate Medical Education, the Joint Commission, and literally dozens of other organizations in health care and other sectors of public policy, UNOS is a private, not-for-profit organization that has been delegated an important public function by the federal government, although UNOS, unlike ACGME and the Joint Commission, relies heavily on direct public funding as well. In a nation that has always been suspicious of governmental authority and reluctant to permit governments to exercise discretion in especially sensitive matters, such delegation gives the appearance of taking decisions “out of politics” and putting them in the hands of presumably disinterested, objective authorities.

UNOS is governed by a board of directors comprising representatives of the major “stakeholders” in organ allocation. At least half the board, under UNOS bylaws, must be physicians engaged in transplantation, and another 25 percent must be people who are awaiting or have received transplants or have donated organs and their family members. Other enumerated categories of stakeholders include representatives of local organ procurement organizations, histocompatibility laboratories or their scientific experts, transplant coordinators (generally hospital or medical center employees), nonphysician transplant professionals, and representatives of health care fundraising or advocacy organizations—such as the National Kidney Foundation—and the general public. Critically, most UNOS board members are elected on a regional basis, from within each of the 11 geographic regions around which existing allocation policies are organized. Board seats are partially based on regional representation, despite the threefold variation in population across the UNOS regions [5].

To the extent that interregional equity is a concern in the development and administration of organ allocation policies, UNOS’s bylaws actually reinforce the existing regional structure and the importance of regional interests. And while transplantable organs are a scarce resource, transplant centers are not. Judging by the numbers of transplants performed at many centers, a more rational allocation system would have fewer. With modern preservation capabilities, there is little impediment to a liver traveling to a patient in greater need than a patient in the region where the liver originated. But medical centers feel a variety of pressures to maintain transplant programs for academic and competitive reasons, and many programs are quite lucrative.

At least in the particular form under which it is organized and governed, therefore, UNOS cannot really be said to have taken the politics out of organ allocation. Rather, it has replaced the political conflicts in government with its own internal political divisions. In a situation in which there is a relatively fixed supply of a valued commodity, allocation is what social scientists would describe as a zero-sum game: any change in formula that makes one stakeholder better off will adversely affect the others. When regional representation encompasses wide variation in populations and need for the commodity, moving away from an inequitable status quo is thus extremely difficult.

Conclusion

The transplant community did a good job of addressing the IOM's call for the creation of a disease-severity scoring system (the model for end-stage liver disease or MELD score) to more accurately and fairly assess a patient's medical need for transplantation. While there are some patients whose disease severity is not fully captured by the MELD system, all would acknowledge that it is far more closely tied to objective clinical values than the prior system, which included a number of subjective variables [6]. In addition, per IOM's recommendations, the effect of waiting time on allocation is now minimal (except for patients with the same MELD score), which is definitely another step towards more equitable allocation.

Disappointingly, however, the transplant community has largely ignored the recommendation to eliminate geographic inequities by reorganizing liver distribution into uniform organ allocation areas to ensure broader sharing such that "allocation be based on common medical criteria and not accidents of geography" [4]. In short, over a period of more than a decade in which thousands of lives have been at stake, neither the responsible public nor private institutions have acted to redress these geographic inequities. Instead, as happens so often in the American health care system, rationing takes place in an arbitrary and haphazard way, in which only those with considerable resources are able to escape correctable "accidents of geography."

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POLICY FORUM

Implications of the Affordable Care Act for Kidney Transplantation

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It has been argued that the kidney was the “heart” of antiquity. According to some medical historians, kidneys in the Old Testament symbolized the “core of the person” and thus “the area of greatest vulnerability” [1]. This metaphor of vulnerability is perhaps even more apt in the present day, where the failure of transplanted kidneys symbolizes the core defects of both the existing Medicare system and recent health reform implemented by the Obama administration. This article provides historical perspective on the evolution of coverage for kidney transplant patients and attempts to identify what initiatives would most effectively and efficiently improve their survival.

The Current State Of Access to Posttransplant Care

As of January 24, 2012, in the United States, there were 112,767 waitlist candidates on the various national transplant registries [2]. Of those candidates, 90,563 were waiting for kidneys, but in 2011 only 13,430 kidney transplants were performed [3]. The need for kidneys far outweighs the availability of suitable donor organs, and some postulate that the Patient Protection and Affordable Care Act of 2010 (ACA) may worsen the shortage by eliminating barriers to insurance coverage based on preexisting conditions, lifetime coverage caps, and required periods of pretransplant dialysis [4].

Even more critical from a clinical, economic, and moral perspective is the fact that the additional end-stage renal disease (ESRD) patients now expected to receive transplants by 2014 will be most vulnerable in the posttransplant phase of care. Coverage for pretransplant dialysis and maintenance drugs for ESRD, but not posttransplant care, receives strong support in Washington from large dialysis and pharmaceutical companies, which derive significant profits from dialysis, ESRD drugs, and dialysis-related services [5]. For ESRD patients, dialysis is covered by Medicare for life [6].

For posttransplant care, however, Medicare coverage is limited, providing only 80 percent of the cost of immunosuppressive medications for 36 months after transplantation (for those whose Medicare entitlement is based on ESRD) and no coverage thereafter. Despite the fact that effective and long-term immunosuppression is essential for survival of transplant patients [7], the vast majority are left to fund 20 percent of the cost for the first 3 years of immunosuppressive drugs (\$13,000 to \$15,000 total cost per year per patient) [8], and, for patients under 65 who are not disabled, all of the cost of immunosuppressive drugs thereafter [9].

Not surprisingly, this system leads to noncompliance. Many patients cope with the financial burden by “spreading out” their anti-rejection drugs, taking them less often or not at all [10, 11]. A recent meta-analysis reports that “about 22.6 of 100 adult transplant patients per year fail to take anti-rejection drugs” [12]. If allograft failure occurs due to nonadherence or a patient is considered unable to pay for posttransplant costs, with few exceptions, she is typically not relisted [13, 14]. According to a study focusing on medication nonadherence among transplant patients, nonadherence was more prevalent among kidney recipients than among recipients of other organs and more prevalent in the United States than in Europe [12].

Legislative History

Congress has continually struggled with the tension between supporting low-income patients and controlling the costs of government-funded health care. The legislative history of renal-transplant drug coverage highlights this struggle.

The Social Security Act Amendments of 1965, which created Medicare and Medicaid, initiated medical insurance for seniors, families with dependent children, the blind, and the disabled [15]. At the SSA’s inception, Medicare provided for prescription drugs that were administered in the physician’s office but did not provide coverage for outpatient prescription drugs [14].

In 1972, on the eve of President Richard Nixon’s reelection, after much debate and political pressure to expand health care insurance, amendments were passed that provided increased coverage in specific areas. They specifically designated chronic kidney disease patients “disabled” for the purpose of receiving Medicare coverage but only after at least 3 months of dialysis and only for 12 months after transplantation [16].

Undoubtedly, these amendments were the original and now obviously outdated roots of the notion that posttransplant care benefits should be time-limited. At the time, such a notion was defensible. Dialysis was then a cost-effective and, more importantly, still superior way to extend lives, while kidney transplantation was a risky medical procedure on the frontier of available therapies. In the decades that would follow, however, renal transplantation outpaced dialysis in mortality reduction and overall clinical outcomes [17]. Meanwhile, the number of eligible patients who used dialysis far exceeded expectations, and the ESRD entitlement became quite costly [14].

In the last 3 decades, the dialysis entitlement has remained largely intact while posttransplant entitlements have waxed and waned in small stutters.

- As a response to the increased costs of dialysis, Congress passed an amendment in 1978 extending Medicare posttransplant coverage from 1 year to 3 years; however, this amendment did not cover the cost of outpatient immunosuppressive medications [14].

- In 1984, Congress passed the National Organ Transplant Act of 1984 to ban the sale of organs [18]; extended coverage for immunosuppressive drugs was considered but ultimately left out of the bill, mostly due to funding concerns and political bargaining [14].
- Posttransplant drug coverage gained some traction in the Omnibus Budget Reconciliation Act of 1987 which included Medicare coverage of 80 percent of a kidney transplant recipient's immunosuppressive drug costs (including outpatient immunosuppressive prescription drugs) for 1 year after transplant [14, 19]. This was eventually extended, in 1997, to cover 36 months of immunosuppressive drug costs [9].
- In 2000, Congress extended Medicare coverage of immunosuppressive drug costs to the life of the patient, but only for those who are disabled or over 65. This often leaves those patients most at risk for nonadherence and noncompliance—i.e., younger kidney recipients under 65—uninsured after 3 years [14].

Despite decades of legislative history and clinical data revealing the obvious gaps in posttransplant care entitlements, extending the duration of coverage for immunosuppressive-drug costs was not included in the ACA. In a provocative piece published in 2010 in the *Clinical Journal of the American Society of Nephrology*, Cohen and colleagues assert that “in response to pressure from the corporate dialysis community and their kidney coalition, several members of Congress acted to prevent the patient immunosuppressive provision from being included in the final health care reform package. Some of these opposing voices on Capitol Hill have been generously supported by the large dialysis providers for years” [5].

It is theoretically possible that the ACA's insurance exchanges will include lifetime coverage for immunosuppressive drugs. These exchanges will not be implemented until 2014, however. Moreover, it is not clear exactly what type of coverage will be offered and whether such lifetime coverage will be offered in the lower-priced options, where it is most needed [9].

Cost Savings for the Federal Government

Continuing the current limitations on coverage of posttransplant medications is actually costing the health care system more money in the long term. Studies have shown that it is less costly to continue covering the cost of immunosuppressive drugs for kidney transplant patients after 36 months than it is to cover the costs of resuming dialysis for the same population. For example, a University of Maryland study concluded that it was more cost-effective to continue covering immunosuppressive drugs than it was to pay for dialysis, finding that “the breakeven point was 2.7 years for all of the cases [it] analyzed and for 30 percent of all patients who did not need to be readmitted to the hospital during the year after their transplant, the breakeven point was only 1.7 years” [10]. A study conducted by the Institute of Medicine (IOM) also concluded that lifetime coverage of immunosuppressive drugs would lead to cost savings because it would reduce nonadherence and thereby improve kidney allograft survival, reducing long-term reliance on dialysis [12].

Current Legislation

The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2011, currently pending in committee in both the House and the Senate, would extend coverage of immunosuppressive drugs for kidney transplant patients for the lifetime of the kidney [20, 21]. The bill is bicameral, bipartisan, and supported by the transplant community [22]. As noted by Cohen et al, however, similar attempts have failed in the past, most recently with the proposed Durbin amendment to the ACA [5]. Similar attempts by Congress in 2003 and 2007 to extend lifetime immunosuppressive coverage also failed in the wake of funding concerns and political jockeying [14].

Conclusion

Extending immunosuppressive drug coverage for the lifetime of kidney patients is a cost-effective way for the federal government to increase the value of health care by improving clinical outcomes for those with ESRD while avoiding the costs of resuming dialysis and allograft failure. Low-income kidney transplant patients currently suffer heavy financial burdens and are denied access to transplant relisting because of their inability to pay for critical drugs. There is a clinical, economic, and moral imperative to, at long last, bridge this coverage gap—a gap that lies at the core of effective transplant care and detracts from the movement for comprehensive coverage begun by the Affordable Care Act.

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MEDICINE AND SOCIETY

The Veneer of Altruism

Michele Goodwin, JD, LLM

The United States' organ transplantation system suffers under the weight of its exclusive commitment to altruistic organ procurement. The prohibition against any procurement mechanism's use of "valuable consideration," including specialized exchanges, incentives, and payments, most likely contributes to thousands of unnecessary deaths each year. These deaths are the unfortunate byproducts of our federal legislative commitment to a purely altruistic organ procurement regime. Despite the low supply and extraordinarily high demand for organs, federal organ transplant law remains imbedded in its 1980s time capsule. This article documents several key weaknesses in the current U.S. transplant system. It concludes by advocating for greater flexibility in the organ procurement system, including proposing a federal carve-out to allow states to experiment with innovative programs.

Americans' options for obtaining organs are constrained by federal law. The U.S. model emphasizes altruism over flexibility for historic rather than programmatic reasons. The "valuable consideration" prohibition, which anchors the National Organ Transplant Act (NOTA), imposes a prophylactic ban on the exchange of anything that might resemble emotional, monetary, or psychological value [1, 2].

History of the Current Organ Procurement Structure

U.S. transplant policy promotes altruism at all costs; commitment to this model alone cannot be justified on economic, social, or moral grounds. This inflexible procurement model grew out of an isolated instance of mild historic importance, where federal legislators rushed to create a law without the benefit of forethought and deep contemplation. The policy emerged as a federal response to the uninspiring plans of a lone rogue Virginia doctor, Barry Jacobs [3]. Jacobs had previously been investigated for fraud and as a result lost his license to practice medicine. In his new career, he proposed to broker organs [4].

In a 1983 *Washington Post* interview [5], Jacobs detailed his plan to recruit living organ sellers from developing countries. As a broker, he hoped to earn a few thousand dollars for each transaction. Many human rights activists did not take him seriously, but a few members of Congress galvanized an internal campaign to prohibit any such business plan from taking effect [5]. The result of their efforts is NOTA, passed in 1984 [4], specifically in response to a censured, unlicensed doctor who lacked credibility.

Prior to this time, organ transplantation policy was determined at the local level by states [7]. In 1968, all 50 states adopted the Uniform Anatomical Gift Act (UAGA) [8], signifying that legislators basically agreed on transplant policy. Noticeably, their policies were neutral on the question of incentives, leaving such matters to be addressed on a case-by-case basis at the state level. Indeed, after presenting the model law to their home states for ratification and enactment, legislators sought to work within the spirit of the original draft. Thus, in a radical shift, states that had previously enacted laws to ban payments for organs and body parts—among them Massachusetts, Delaware, Hawaii, Maryland, and New York—*repealed* those regulations [9]. In so doing, they, too, were expressly leaving open the question of incentives, payments, and other forms of valuable consideration, at least for the posthumous disposition of organs and human tissues.

NOTA's Consequences

Despite what might have been the best intentions at the federal level, such as prohibiting black markets or the exploitation of men and women from third-world countries, their rush to legislate has backfired. Noticeably, 30 years later, the government's altruistically-focused policy contributes to the very exploitation of people of color in developing countries it sought to prevent. The U.S. demand for organs spills over into other nations, where individuals' poverty and vulnerability make them the voiceless conspirators in a very dangerous enterprise. Ironically, federal efforts to avoid domestic organ sales now contribute to the international human trafficking in organs. Quite possibly, more organs are trafficked now than had Dr. Jacobs been the most successful businessman on earth [10].

As with any business, Jacobs' enterprise would have been subject to some regulation, and vulnerable to civil liability and criminal penalties for any illegal activities conducted in association with his business. Individuals could have sued Jacobs had he violated contracts, harmed their dignity, or otherwise coerced them. Had he been negligent in the treatment of potential "donors" or recipients, civil law would have been a logical recourse—as well as criminal law. Such forms of private regulation are intended to protect vulnerable individuals from harm by individuals as well as organizations.

There are few domestic disincentives to monitor or police Americans trafficking organs from abroad. Because demand outpaces organ supply, Americans actively participate in black- and grey-market transactions in Asia, Africa, and South America [10]. Frequently, Americans obtain organs from executed political prisoners in China, as well as from destitute men and women in India, Pakistan, South Africa, and Brazil [10]. American patients pay brokers upwards of \$150,000 for kidneys and as much as \$250,000 for hearts [11]. Rather than waiting more than 6 years for a kidney, patients can obtain this vital organ on the black market in less than 8 weeks [12]. These black-market exchanges are the byproducts or outgrowths of an altruistic system that lacks the capacity to adequately meet organ demand. Thus, our "altruistic" procurement regime contributes to an aggressive, overt system of

unregulated, unmonitored, organ markets that undermines the health and dignity of individuals abroad as well as patients in the United States.

Unsurprisingly, NOTA's inflexibility prohibits more than financial payments to donors. Years ago, this policy prohibited organ exchanges, such as daisy and domino chains, from forming because "love" was considered a "valuable consideration" [3]. The irrationality of that type of rule-making is more than obvious. In that context, noble programs like the National Kidney Registry—a not-for-profit organization founded by Garet Hil, whose sophisticated computer programming matches people willing to swap organs for their friends and loved ones [13, 14]—could not exist. In February 2012, the *New York Times* reported on Hil's most recent pairing of more than 60 individuals. With a private, innovative effort, Hil has advanced transplant procurement more than any federal government efforts. However, his program could launch only after Congress revised NOTA's prohibitions to exclude daisy chains [3].

Other programs suffered, failed, or could not launch because of NOTA's strict proscriptions. U.S. organ procurement policy discouraged the Pennsylvania legislature from pursuing a burial benefit program [15], an effort designed to ease the costs of funeral and hospital expenses for families that chose to donate their deceased relative's organs. The Pennsylvania legislature invested in the effort for nearly a decade prior to conceding that federal law could lead to the incarceration of potential participants, including administrators at hospitals who accepted a payment for medical bills or the relatives that donated organs.

Indeed, the valuable-consideration clause in NOTA operates even at the most innocuous or frivolous level, meaning that receiving a cup of coffee, slice of bread, or movie ticket in exchange for donating a kidney violates the law [16]. Criminal penalties attach to any violation of the law—and the consequences are quite severe: a \$50,000 fine and incarceration up to five years [17].

The Altruistic System Operates At Maximum Capacity

Many are harmed by the valuable consideration rule, but who benefits? Arguably, no one; the proscription is overinclusive in prohibiting well-meaning programs that involve no financial exchanges and chilling innovation, and it is underinclusive in tolerating markets for babies, ova, sperm, embryos, and commercialized cell lines and human tissues. Successful organ recipients sometimes register at multiple locations to increase their odds of receiving an organ. Such tenacity takes more than will, but also the type of financial resources often out of reach for poorer Americans. In addition, the waiting time on the lists is so lengthy that health deterioration and becoming too sick for a transplant are associated risks of the U.S. transplant model. These issues dominate the "real-life" concerns of patients and their families.

Much has changed since NOTA's enactment in 1984. Beyond a doubt, some of this has been positive, including improvements in surgical technology, the enhancement of immunosuppressive medications, and more sophisticated data-collection and

sharing mechanisms. These technological advancements (along with a host of others) enhance the transplant process and ultimately save lives.

However, negative externalities dominate many key aspects of contemporary transplant policy. In the 28 years since NOTA's passage, the demand for organs has not kept pace with supply. In the U.S., thousands die each year waiting for organs. About 7,000 patients die each year after interminable waits on transplant lists [18]. They are not the only patients who suffer under the unbearable weight of an enormously constrained transplant system.

Currently, more than 113,000 Americans wait for organs, but it is likely fewer than 13,000 people in the United States will agree to become organ donors this year [19]. This gap between supply and demand manifests most perniciously in the kidney-transplant waitlist; more than 90,000 patients wait for kidneys [20]. Even that figure misrepresents the true number of people who could benefit from receiving a healthy kidney: nearly 500,000 Americans receive dialysis treatments [2], and many will never be counseled about the option to receive a kidney.

Therefore, the number of deaths on the waitlist provides an incomplete account of the devastating implications of our current transplant policy. Peeling back the veneer of altruism reveals other troubling aspects of the current altruistic organ procurement regime. For example, many other patients who never had access to transplant waitlists die each year; these unfortunate men and women were tethered to dialysis machines several days per week for hours at a time. Some patients describe that process as a death sentence or akin to being medically imprisoned [13].

Burning, bloating, infections, low blood pressure, fatigue, and nausea commonly result from dialysis treatments. Presently, about 500,000 Americans endure this reality [2]. Patients bravely endure these side effects not because dialysis cures the underlying disease—the treatment does not—but because this weekly, if not daily, process keeps them alive. Of these patients, most never made the kidney transplant waitlist because they were too sick, too old, too poor, too uneducated, or simply unable to convince doctors that they were “suitable” for an organ transplant. Some dialysis patients receive organs, but that group represents a tiny fraction of the overall population on dialysis. In reality, rationing is a necessary effect of the U.S. organ transplant policy; too few organs in the supply chain inevitably leads to pernicious forms of rationing and lengthy waitlist queues.

The U.S. kidney transplantation regime particularly disserves African Americans. Blacks wait longer than any other group for kidneys [21], they suffer the highest death rate while on the transplant list [21], and they are more frequently kicked off the list than any other ethnic population [22]. Government explanations for these discrepancies and disparities are inadequate [22]. Bureaucrats frequently point to low donation rates among African Americans as the chief reason why they fare so poorly on the back end [22]. In other words, if more organs from African Americans came into the system, then more organs would come out—or at least it would improve the

odds of better HLA “matching” for African Americans. The argument is not illogical on its face. However, it must be understood that the federal transplant system provides only one, poorly planned route into organ donation—altruism; all others are blocked. This affects everyone, not only African Americans.

Federal Funding Bears Little Relationship To Promoting Organ Transplants and Raises Costs

The federal government provides unlimited spending for only one treatment of kidney disease: dialysis [23]. Dialysis does not cure end-stage renal disease or other diseases associated with kidney failure. Federal funds are not allocated toward underwriting daisy chains, despite immediate cost savings. Neither does the federal government offer states financial incentives to create innovative organ-sharing programs. In short, the government has committed its funding primarily toward an important but less-than-ideal solution.

Thus, Americans pay for our antiquated organ procurement policies in key ways. First, Americans pay with their lives; many waitlist candidates and dialysis patients die each year from otherwise treatable diseases. Second, family members suffer the collateral effects of the lengthy waitlist process and the need for caregivers for dialysis patients—some family members stop working to care for their relatives, while others work more to compensate for income loss due to their partners’ disability. Third, the financial costs associated with treating kidney disease take up about 6-7 percent of the Medicare budget [24]. In other words, taxpayers fund dialysis treatments. For each dialysis patient, federal expenditures can range from \$60,000-\$90,000 per year [25]. The Government Accountability Office (GAO) estimates that federal spending for kidney disease costs taxpayers more than \$30 billion per year [26]. Each patient removed from dialysis and given a transplant saves taxpayers \$500,000 to \$1 million per year [27].

On inspection, serious problems emerge with an “altruism at all costs” organ-procurement model, including the senseless loss of life. At a cost of \$30 billion per year, federal expenditures should bear some relationship to the number of lives saved, not simply those put on dialysis.

Moving Forward

The question of how to enhance a system beyond its capacity into one that self-sustains and thrives has defied law makers for nearly 3 decades. Their decision making is beset with challenges, not only from patient-consumers demanding life-sustaining treatments but also from the desire to balance competing political, ethical, medical and social interests.

Exclusive reliance on the present altruistic organ procurement process in the U.S., in light of alternatives, undermines the very purpose of volunteerism and noncoercion by fueling living-donor markets in developing countries. Other options, including directed donations, nonfinancial incentives, financial incentives, job-protection programs, and presumed consent, deserve meaningful consideration. Each of these

measures involves risks and must be judged according to what benefits it would bring in light of the burdens experienced or values compromised.

To move forward, states must be released from the shackles put in place by NOTA. The veneer of altruism does not cover preexisting commercial relationships in human biological material, including corporate sales of human tissue, tendons, bones, and heart valves at enormous profit. The human-tissue industry grosses billions of dollars each year with mild regulation from the Food and Drug Administration [28, 29]. Commercial bio-banks buy, sell, trade, and research human biologics unfettered by NOTA's proscription [30].

On the other hand, the reproduction market successfully commercializes human biologics while maintaining and valuing human dignity. Built into that system are sets of local standards that minimize coercion and exploitation, while promoting healthy biological exchanges. Courts are appropriately utilized to settle disputes when they occur. Ironically, this industry bypasses federal regulation and oversight even when some modest standards might be advisable to reduce dependence on courts to settle disputes. Unburdened by federal intervention, men and women exchange ova, sperm and embryos and rent wombs to create families. When considered, the inflexible federal policy that proscribes all valuable consideration in the organ realm cannot be justified in light of the government's tolerance of other nonregulated human biological exchanges, most of which do not save lives.

How should the U.S. move forward? The first significant step in relieving organ scarcity involves allowing states to engage in monitored, approved experimentation. These efforts can take place if the federal government permits states to waive out of NOTA. The waiver process is not new; states waive out of federal regulation through an administrative process. Most recently, President Barack Obama announced plans to allow states to waive out of the education regulation No Child Left Behind [31]. Waivers are not provided in lieu of state action on a given issue. Rather, waivers allow states to attempt to achieve federal goals through novel, innovative, untested programs. As a general matter, states with waivers propose meeting federal goals at reduced costs and with maximized participation.

Solutions for the organ shortage in the U.S. are well within reach. With leadership at the highest levels of government, the U.S. can relieve organ demand. As Congress approaches the thirtieth anniversary of the passage of NOTA, it would be wise to revisit the law in light of social acceptance of innovation in the human biologic realm. The introduction of a waiver allowance would permit states like Pennsylvania to introduce dynamic, lifesaving programs. A second step should be the allocation of federal dollars to support programs that increase the number of transplants performed each year and remove patients from dialysis, like the National Kidney Registry. Other efforts should include financially supporting states that launch innovative organ-sharing programs. A final step should involve the repeal of NOTA's valuable-consideration clause, which has outlasted its purpose and no longer protects

vulnerable individuals from the reach of desperate Americans who need kidneys. A better tailored response is needed to reduce human trafficking and save lives.

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HISTORY OF MEDICINE

The Ethics of Organ Transplantation: A Brief History

Albert R. Jonsen, PhD

Organ transplantation is certainly one of the “miracles” of modern medicine. The impossible dream of replacing a dead or dying vital organ, such as a kidney or a heart, with a living one became a reality on December 23, 1954, when Drs. Joseph Murray and John Merrill of Peter Bent Brigham Hospital transplanted a kidney from one monozygotic twin to another [1]. Rejection was prevented by their genetic similarity, and the recipient lived another 8 years. Many years of experimental transplants, mostly on animals and occasionally on humans, led to this miraculous moment of success. Many obstacles remained, particularly the problems of transplanting organs between persons who were not genetically identical. Still, the era of transplantation had begun and was everywhere hailed as an extraordinary leap in medicine and surgery [1].

Yet, almost immediately, ethical problems were noticed lurking in the miracle. Dr. Murray himself, acknowledging that he had given a “great deal of soul searching to these problems,” reflected on the ethical problem of taking an organ from a healthy person. He contended that, “as physicians motivated and educated to make sick people well, we make a basic qualitative shift in our aims when we risk the health of a well person, no matter how pure our motives” [2]. Dr. Tom Starzl remarked in a 1967 special issue of *The Annals of Internal Medicine* that, recognizing these multiple problems, he had asked Dr. Chauncey Leake, one of the early medical ethicists, to devote a chapter to them in his forthcoming book [3]. In 1966, a major conference, sponsored by Ciba Foundation, was held in London to review the ethical problems of transplantation. Most of the leading transplanters and researchers, as well as scholars in the law, were present [4].

What were the ethical problems that troubled the leading transplanters? First, the problem on Dr. Murray’s conscience—invading a healthy body to obtain an organ for another—was most obvious. But beyond that, how were kidneys to be obtained? If from a related living donor, how could consent be obtained without coercion? If from an unrelated donor (should that become possible), should there be compensation? If from a dead donor, with what clinical evidence of death? As transplant became more efficient, how should recipients be fairly selected? How should sufficient numbers of organs be harvested to meet the need? The literature and the conferences raised these issues, acknowledged that they were ethically and legally problematic [5], but did not go far toward what Dr. Starzl called “a sturdy framework that is ethical, practical and efficiently policed” [3].

Kidney transplantation was proceeding clinically and scientifically when a new miracle—the miracle of Capetown—occurred. On December 3, 1967, Dr. Christiaan Barnard transplanted a still-beating heart into Louis Washkansky. Washkansky lived for 18 days; a few weeks later, Barnard tried again. He gave a new heart to Philip Blaiberg, who lived 594 days. Media coverage of these two transplants was worldwide and enthusiastic. Blaiberg was pictured cavorting on the beach [6].

Heart transplantation not only startled the world, it raised the same ethical questions as kidney transplant, only in a louder register. Removal of a kidney from a living donor was partially justified by the fact that kidneys are paired organs; a person can live with only one. But removal of a viable heart definitely ends the life of its source. So the debate over the definition of death was revived: is it possible to assert that a person whose brain has ceased functioning is dead?

This question had been asked prior to the organ transplantation era, when advances in pulmonary support made it possible to sustain major organ functioning after what appeared to be persistent coma. By the time of the Ciba Transplantation Conference in 1966, transplanters had realized the importance of the question for their work: under what clinical conditions could a heart be removed from a person? In 1968, a report from Harvard Medical School made a bold attempt to redefine death [7]. The report had the “primary purpose of defining irreversible coma as a new criterion for death... [because] obsolete criteria for definition of death can lead to controversy in obtaining organs for transplantation” [8]. It did not, however, “define” death but listed a series of neurological signs, such as unresponsiveness, lack of movement or breathing, no reflexes, and, as confirmation, a flat encephalogram, that evidenced irreversible coma.

The Harvard Report, although widely accepted, did not, in fact, settle the question. It was not clear that it had distinguished between persistent vegetative state and death: it was simply designating that persistent vegetative state should be called death and treated as such. A vigorous debate arose among ethicists and legal scholars. Several notorious cases, such as that of Karen Ann Quinlan (1975) [9] agitated the question even more.

Finally, the U.S. Congress requested the President’s Commission on the Study of Ethics in Medicine (1979-1982) to study the question. The commission framed a uniform definition of death that included both the traditional cardiopulmonary and the brain criteria: “An individual who has sustained either (1) irreversible cessation of circulatory and respiratory function, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead” [10]. The report provided a more extensive and precise set of clinical criteria to identify the irreversible cessation of brain stem function. This unitary definition was subsequently adopted as the legal definition in all states [11]. Thus, the route was cleared to obtain organs from persons whose vital functions were sustained by artificial means but who were dead by brain-stem criteria. In the future, however, lay new questions about this practice, such as the controversial but now generally accepted “non-beating heart donation,”

in which a terminally ill person is removed from life support and organs immediately excised.

The debate over death by brain criteria did not halt progress in clinical transplantation, however. but another problem did: the failure of heart transplantation to prolong life. After the first South African transplants in 1967 and 1968, transplants were performed around the world; by June 1970, only 10 survivors could be counted among 160 transplant recipients [12]. Gradually, enthusiasm waned, but the conviction remained that, with improved procedures and selection of patients, as well as more powerful immunosuppressive drugs, heart transplant would emerge as a truly life-sustaining intervention.

The transplant community returned to research, leaving only one major transplant center, at Stanford University, under the direction of Dr. Norman Shumway [12], which proceeded very cautiously. By the mid-1970s, surgeons were again confident enough to return to clinical transplantation [12].

This pause represents a genuine ethical action: those who were performing the “miracle” voluntarily ceased, until they were sure that their miracle was not merely a public relations event but a true boon to patients. Throughout the history of transplantation, similar pauses, though less dramatic, have attended new ventures, lung and liver transplants, in particular. The pause to reconsider techniques and selection of subjects realizes the most ancient ethical imperatives of medicine: be of benefit and do no harm.

Over all these ethical issues looms a major factor: the scarcity of organs. Whatever the source of organs, many fewer organs are available than patients who await them. In 1984, Congress enacted the National Organ Transplant Act, which established a task force on organ transplantation to examine the ethical, social, and economic aspects of organ procurement. In that year, 200,000 persons were declared dead using brain criteria; organs were obtained from only 2,000, while the need for kidneys, hearts, and lungs was estimated to be in the range of 50,000 potential beneficiaries [13].

The task force affirmed two principles that did not increase the supply of organs, namely, that no financial compensation could be given for organs or to organ donors (except for medical costs), and that organs must always be donated, that is, explicitly granted by the donor, either living or before death. These two principles characterize the American transplant ethos. In some other nations, financial compensation is not prohibited and organs can be “harvested” from the dead without permission. Still, the task force insisted that “organs are donated in a spirit of altruism and volunteerism and constitute a national resource to be used for the common good” [14]. It considered these principles essential to prevent commercialization of organs and exploitation of the healthy poor and to promote equality in organ distribution.

The supply of organs remains the most persistent problem in the field of organ transplantation. The National Organ Transplantation Act [15] established a national system for identification of transplantable organs and fair distribution to recipients on the basis of medical need. Even within the explicit criteria of this system, it remains necessary to evaluate each patient for suitability. Since this evaluation includes the ability to comply with the transplant regimen, there is much room for clinician bias.

The act also encouraged systems to promote donation, such as donor identification cards and widespread advertising. Still, the supply of organs remains far short of need. At the same time, new challenges arise, such as “organ tourism,” in which patients travel to nations where organs are, for various reasons, more available. Though services in other countries are often excellent, they are sometimes deficient, and, in both cases, patients return to the United States and re-enter our already burdened system.

This evolution of the ethics of organ transplantation shows that this extraordinary step in the history of medicine has a special feature: unlike other medical advances, this one necessarily involves not only a physician and a patient but also another party, the donor, and the organ itself. The organ is a precious resource which, if not efficiently used, is lost to another potential recipient. It is this complex network of patient, donor, and organ that makes transplantation unique.

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MEDICAL NARRATIVE

Liver Transplantation: The Illusion of Choice

Carol Panetta Zazula, RN, BSN, CCTN

They stood at my nurses' station, two men, fiftyish, physically unrelated, yet brothers in disease. Their skin color might be mistaken for a tan with a yellow cast or they might have the glow of yellow jaundice to skin and sclera. I have seen skins tainted grey; others a shade of green no human should be, but those patients are unable to stand at my station. Their arms exhibit muscle loss, always a stark contrast to the oversized, sometimes enormous abdomens, taut and shiny with ascites. Fluid waves and shifts in the body, causing legs swollen with edema, shortness of breath from pressure on the diaphragm, and scrotums sometimes the size of a grapefruit. The thin white feeding tube snakes from nares, another line on sallow complexions, a nutritional necessity for these men with no appetite. Loose and plentiful daily bowel movements are the side effects of the drug that keeps the brain lucid. Then there are the coagulopathies, those at risk of bleeding out at any time. Yes, these are some of my patients waiting for their only option: a liver transplant.

My patients so sick, so at risk for infection, bleeding, kidney failure, and encephalopathy, and they must await another's death so that they may live. The longer one is on the transplant list the greater one's chances for walking along the long yellow road. The end of the road has no choice at all: liver or death.

Who gets a coveted spot on the transplant list, who doesn't, and how does ethics guide us and our patients in the process? There are many tests to be passed to be considered for transplant. In addition to an EKG, chest x-ray, pulmonary function test, abdominal CT, doppler echocardiogram, bone-density test, endoscopy, flex/sigmoidoscopy, and labs upon labs, there are the evaluations: dental, nutritional, psychological, surgical, and psychosocial. It is with these and other measures that we assess fitness to wait on the transplant list and survive major surgery.

You must also have family and friends to get a liver; that is, you must have a reason to live for a liver transplant. And these wives, husbands, mothers, fathers, and siblings will be crucial to your posttransplant course. Sometimes after the transplant there are months of feeling ill in addition to the many follow-up appointments, and boy will you need someone to walk this road with you. Alcohol can no longer be part of your life. You must have a brain that works reasonably well, so that the hundred-page binder of pre- and post-transplant instructions can be read and understood. You must have the ability to show up and follow the rules; be unable to do this and you will not be listed.

All the patients' test results and evaluations are presented to a committee of doctors, nurses, social workers, psychologists, and others to decide who gets an opportunity to wait for a healthy organ with their blood type. Some patients may be de-listed and some—due to infection or other conditions—may be made inactive.

The last such committee meeting I attended had 33 people in the room. The atmosphere is always earnest and a bit somber. We bring our own knowledge, practices, professional opinions, and, at times, personal biases to the table. We who are human, able to distinguish right and wrong, determine placement on the lists leading to a liver and life. Hoping for a good outcome, we weigh patients' information and each other's comments carefully. We want to be fair. Who will take good care of that scarce item, a liver, one made possible through death. Do we choose to list those who don't meet all the criteria so that they may hope and pray that a liver becomes available?

Who gets this scarce commodity is greatly scrutinized, as it should be. But when something is scarce and an imperfect human is in need of it, allotment and choice can have shades within shades of grey. Many of those awaiting a liver transplant are alcoholics. A question many wrestle with is, if your last drink was 6 months ago, have you taken actions that will allow you to live your life alcohol-free after the transplant? Some stopped drinking only because they became too sick to drink. That may have been 2, 6, 10 months ago. When they feel better posttransplant, then what? There is a small percentage that falls back to drinking, something they think made things better in the past. Knowing all that has transpired in order for the patient to have a new liver, we transplant professionals are greatly saddened by this choice; a transplanted liver is not meant to process alcohol, and forcing it to do so can be harmful.

There is a way to skip all of this process and it is called fulminant liver failure, a condition that puts you right at the top of the list. You could have been to China and picked up the wrong parasite. Maybe you picked the wrong mushroom to harvest; the death's cap mushroom is deadly to your liver. Then there is the person who attempts suicide with acetaminophen. This patient tries our souls. For reasons I cannot fathom, there are those who seek to end their lives with this seemingly benign over-the-counter drug. Many times, the desired outcome, death, is not obtained—just a dead liver or one that will not support life. Because many of these people are young, we in the field want to give back to them the life they have thrown away. So they get a new liver and a new life, but at what cost to them? They have no idea of the payment expected on the other side: countless follow-up appointments and labs and a different state of health for the rest of their lives. Each of these scenarios, right or wrong, causes the list to grow just that much longer for others waiting. See paragraph one.

What about the incarcerated? Although they aren't often able to meet the requirements, it happens. Do we need to know their crime or when they will be released in order to get them on the list? Is it ethical to suggest to patients of means that they move to Florida, that land of car, boat, and motorcycle accidents generating

a bounty of organs. Do you try to list that 52-year-old-man, one with a wife and 3-year-old, who has drunk great empty spaces in his frontal cortex?

If being morbidly obese can cause many postsurgery complications, should the obese be unable to get listed? What about the person unable to stay on a low-salt diet, demonstrating an inability to be compliant at this point in his life? And just how well must one's brain work to earn a place on the list?

The philosopher and psychologist William James wrote, "An act has no ethical quality whatever unless it be chosen out of several all equally possible" [1]. For our patients, there may be no higher truth. Yet we in the field of transplantation are required to make choices: who has or has not met the requirements, list or not, now or later. We choose and our patients take a chance. The chance is to continue in this world.

I must be able to believe in the process and trust in the members of the committee. Sometimes being able to give a patient another chapter in life's book, perhaps an opportunity for some redemption, is enough. Yes, this is an imperfect system. Yet we come together, medical professionals working within a system of moral judgment and standards in an open environment and choose who should be listed for liver transplantation. My patients, glowing and starving and swollen, rely on us to choose wisely. So as I care for my patients I give them their medicine, I give them a smile, I adjust a pillow and I say, "I hope you get a liver soon."

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OP-ED

The Limits of Altruism: Selecting Living Donors

Richard B. Freeman Jr., MD

If altruism had no limits, wouldn't the world be a better place? Most certainly this is true, so how could this truth possibly conflict with one of the major teachings of medicine, *primum no nocere*, or "do no harm"? Merriam-Webster's dictionary defines altruism as: "unselfish regard for or devotion to the welfare of others" [1]. What does the physician do if this "unselfish regard for devotion to others" potentially jeopardizes the health of his or her patient? And even more perplexing, how does the physician advise his or her patient when that patient is considering whether to be a living donor? In this situation, the living donor is accepting harm with the only possible benefit accruing to someone else. And, in the sorting out of these questions, which takes priority: the physician's paternalistic idea of what would be best for the patient or respect for the autonomy of the potential donor's right to self-determination? The first successful human organ transplantation, performed in 1954 using a living donor, raised all of these questions and, as living donation has expanded over the years, these questions have only become more prominent and important to ponder.

Altruism can be characterized as a motivation at the level of the individual. This should be seen as distinct from a moral obligation, such as an obligation to follow a religious doctrine or execute duty to one's country, that one assumes by belonging to a group. Altruism, therefore, is a manifestation of individual autonomy. Graham Bell writes that "in the science of ethology (the study of animal behavior), and more generally in the study of social evolution, altruism refers to behavior by an individual that increases the fitness of another individual while decreasing the fitness of the actor" [2]. In this sense, altruism involves some form of sacrifice or acceptance of risk on the part of the altruistic. So, at what point does it become acceptable to subordinate patient autonomy to medical paternalism when the "actor" is willing to accept "decreased fitness" for the benefit of someone else? In other words, when does extreme altruism become pure foolhardiness, and who is responsible for making that distinction? This is the dilemma in the case of living-donor transplantation, when the living donor undertakes a surgical risk for the benefit of another.

There is no escaping the fact that the surgery to remove the transplantable graft carries a risk even when the prospective donor is in excellent health. The short-term mortality risk for living kidney donors is roughly the same as that for any patient undergoing general anesthesia—in the range of 0.031 percent [3]. For living liver donors this risk has been estimated to be in the 1 in 200 range. The most recent studies suggest that, over the long term, living kidney donors have the same life

expectancy as members of the general population [3], although they may have more protein in their urine than healthy people with two kidneys [4]. There are no good long-term statistics summarizing the outcome for living donors of non-renal grafts.

But does risk automatically imply “harm”? We expose patients to all kinds of risks everyday for presumed benefits. Moreover, people willingly assume risks in their everyday lives, often much greater than those imposed by donor surgery, that have little or no direct benefit to their health [5]. The risk that the harms from kidney donation will occur is very small compared with many risks we all face in everyday life. We readily accept that the risks of surgery are justifiable when the individual being asked to accept the risk can expect a reasonable chance of receiving at least as much benefit. The principle of altruism as outlined above concludes then, that it is acceptable for an individual to choose to assume a risk of harm and “decreased fitness” in order to help someone else.

But how much benefit is the recipient of an altruistic donation likely to receive, and does the donor receive any benefit? There is ample evidence that recipients of living donor kidneys receive more benefit in terms of life-years after transplant than either patients who receive deceased-donor transplants or those who remain on dialysis [6] and that this benefit is even greater if the living-donor transplant is performed before the patient starts dialysis [7]. When questioned about the benefits they derive from their experience, almost all living donors report an improved sense of well-being, and there is evidence that their quality of life is at least as good as that of the general population many years after the donation procedure [8].

Based on the experience to date, at least for living-donor renal transplantation (for which we have the most long-term data), the harm imposed on the donor by the surgery is balanced by the benefit the recipient gains, and the process does not appear to impose an undue burden on the donor. Thus, if both the donor and recipient are informed about the risks of the surgery, the long-term consequences of the donation, and an estimate of the factors that can impact the success of the transplant, living donation as it has been practiced historically does not seem to stretch the limits of acceptable altruism.

Moreover, even though living donation does violate medicine’s “do no harm” dictum in the strictest sense, one can argue that any surgical procedure causes harm by virtue of the trauma that surgery inflicts. Long ago surgeons decided that a relativistic interpretation of *primum non nocere* is acceptable if benefit is to be expected. Strict adherence to the “do no harm” principle also imposes a degree of medical paternalism that may violate patients’ autonomy. A.J. Cronin argued in a recent article that

the motives for participating in living-donor kidney transplantation are likely to be many and varied. Undoubtedly, living donors are exposed to risk. However, individual autonomous agents are entitled to take risks and their individual choice to participate in donation is

legitimate. Restricting the risks that autonomous agents may freely run on the basis that this is legitimate paternalism because it might conflict with a clinician's responsibility to "do no harm" is not compelling grounds for arguing that living kidney donation should be prohibited or become much more restricted [9].

Patient autonomy and altruistic motivation clearly should have limits, however. For example, it is well accepted that older patients have higher risks for complications and death following surgery than younger patients. Moreover, it is well understood that renal function deteriorates with age, so kidneys from older donors provide less renal function to their recipients. Thus, is the harm so increased and benefit so diminished when older living donors are considered that physicians should advise against such transplants? Several reports indicate that older living donors do not necessarily face more significant short-term risks and that the transplanted kidneys' short-term function is acceptable, although long-term follow up for the older donors and the recipients of their kidneys is lacking [10].

More recently, living donors with mild hypertension (usually defined as no more than one medication for treatment) have been used as kidney donors. The available evidence suggests that there is no increased harm to these donors and that the transplanted kidney function is similar to that of living-donor grafts retrieved from normotensive donors [11]. The evidence that obese kidney donors carry increased risk for complications and death in the long term is more worrisome. Obesity alone apparently confers an increased risk for the development of renal disease, but it is unknown whether this is accelerated in patients with only one kidney [12, 13].

If we accept that living donation is an altruistic decision that does not violate the "do no harm" maxim when "harm" is weighed against benefit, then living donation should not be limited to instances in which there is a preexisting relationship between the donor and recipient. This has provided justification for the expansion of living donation to include spouses, genetically unrelated donors, and even strangers either donating to other individuals or participating in paired donation or living-donor chains [14]. If the potential harm to the donor remains at the baseline, then, in the truest sense of altruism, it should not matter whether the benefit of the donation accrues to someone who is known to the donor or not. However, if donors are coerced, either by psychological or monetary means, the individual voluntarism of altruism is violated and all of the ethical rationale for living donation becomes suspect [15].

If individual autonomy is to be the highest priority, is *any* risk a fully informed donor is willing to take acceptable? To answer that question, risks must be considered in two categories; (1) risks the donor assumes relative to the expected benefits and (2) risks that the *recipient* would have to accept were the donor's intent to donate strictly observed. Consider the obese person mentioned above. The amount of harm he or she assumes is unknown but choosing to be a donor could increase his or her risk of needing lifelong dialysis. One could argue that the benefit in freeing the recipient

from dialysis is equal to or less than the harm of imposing an uncertain increased risk of dialysis on the obese donor.

For example, an obese 35-year-old mother wishing to donate to her 10-year-old daughter to spare her imminent dialysis, and all of the growth retardation and developmental problems children with renal failure endure, may have extreme motivation to donate to her child. Assuming that the mother is well informed of all of the risks and benefits, should medical paternalism prevent that mother from exerting her altruistic autonomy even if the mortality risk from the donor surgery may increase the risk that her child may lose a parent in the process? We exert much less paternalism in justifying sending parents into combat where arguably less altruism (a duty to country) is in play. It is difficult to argue that medical paternalism should assume more priority in the case of the maternal donor.

On the other hand, medical paternalism may be justifiable in the case where the outcome of the transplant could be jeopardized by unrestrained donor autonomy. For example, a brother known to carry hepatitis C virus or HIV may want to exert his autonomy by being allowed to donate his kidney to his sibling. This may be an extremely well-matched transplant but, because the recipient will acquire a new, potentially fatal, viral infection through the transplant, medical paternalism should take priority here to prevent a high likelihood of harm to the recipient, even if the donor's autonomy is violated. This case puts respect for autonomy and paternalistic beneficence in direct conflict. Does the prospective recipient have the right to know that the possibility for a transplant exists? Should the doctor even mention it? Suppose both donor and recipient, fully informed, want the transplant to go forward. Is the doctor obligated to follow through if he or she believes the risk to the recipient outweighs the benefit and that the recipient's diminished benefit may not justify the harm to the donor?

The current culture comes down on the medical paternalism side here, with most transplant clinicians likely to not move this forward. In fact, a difficult situation arises where the donor's privacy (regarding disease status) must be maintained when informing the recipient of the reasons why a transplant from the brother is not feasible. Moreover, federal regulations essentially mandate medical paternalism toward HIV-infected donors; the intentional use of organs from HIV-infected donors for transplantation is prohibited [16].

A more nuanced situation occurs when, for example, an adult child wants to donate to an older parent whose life expectancy is significantly less than the survival time of the transplanted kidney. In this case it may be more difficult to show that the recipient will gain a benefit in terms of life years gained from the transplant. However, both the donor and the recipient may gain significant psychological or quality-of-life benefits that may be difficult to equate with the potential physical harms. Here, as in all cases of living donation, careful assessment of real and perceived benefits is critical. What do the donor and recipient believe they will gain

in all the multidimensions of health, perception of health, quality of life, emotional well-being, or survival?

Living donor transplantation does impose limits on altruism because more than one individual is involved. An altruistic act, including the assumption of some risk by the “actor,” is the primary foundation for organ transplantation. However, unlimited altruism must be balanced with consideration of the risks and benefits, and all of the actors must understand them before embarking on any course of action. Often, these risks and benefits are not well documented or appreciated by the physicians who are facilitating the process. But all risks and benefits must be thoroughly understood and appreciated as a restraint on overexuberant medical paternalism. Allowing one individual to accept some risk in the name of altruism when there is little chance for benefit or significant chance for harm, no matter how difficult it may be to measure these, is still adequate justification for a paternalistic response from the physicians involved.

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Suggested Readings and Resources

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