

Human Organ Transplantation in the U.S. – Crossing New Lines?

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Successful human organ transplantation is one of the great achievements of the medical profession in the past half-century. Unfortunately, the track record of medical ethicists in confronting the myriad of ethical issues involving human organ transplantation, and of the medical profession itself in self-regulating its participation in the procurement of organs, is less than stellar. Recent articles¹ in the medical literature indicate that things could get a lot worse in the near future as physicians continue to push to increase the supply of available solid organs for pediatric and adult patients needing heart and kidney transplants.²

The Scope of the Problem

Since 1995 more than 85,000 U.S. citizens have died waiting for a solid transplant organ,³ and the current waiting list in the U.S. is close to 100,000.⁴ Perhaps the only thing everyone – patients, transplant surgeons, hospital and transplant program administrators, and state and federal officials – agrees on is that there is an inadequate supply of acceptable good-quality healthy solid organs (e.g. kidney, liver, lung, pancreas, heart) to meet current demand in the United States.⁵ As a result, it is not uncommon for patients to spend prolonged periods of time on organ transplant waiting lists. Invariably, and inevitably, some patients die while waiting to receive a transplant.⁶ In 2007 more than 6,000 people died while waiting to receive an organ transplant.⁷

All parties might also agree that the primary reason for this state of affairs in the United States is the fact that our solid organ donation system, whether from a cadaver or a living person, is purely voluntary.⁸ Our current system is also non-random in the sense that individuals who have magnanimous friends or relatives have a distinct advantage as potential recipients.⁹ Wealthier individuals also have the option of “opting out” of the U.S. system completely and securing a needed solid organ quickly by becoming medical

¹ Mark M. Boucek, Christine Mashburn, Susan M. Dunn, et. al., *Pediatric Heart Transplantation after Declaration of Circulatory Death*, 359 N. ENGL. J. MED. 709 (2008) [hereafter Boucek].

² James L. Bernat, *The Boundaries of Organ Donation after Circulatory Deaths*, 359 N. ENGL. J. MED. 669 (2008).

³ The Associated Press, *N.J. licenses to require organ donation decision. First law of its kind asks residents to make a choice at time of renewal*, July 23, 2008, available at <http://www.msnbc.msn.com/id/25816523/print/1/displaymode/1098/> (last accessed August 6, 2008)[hereafter New Jersey law].

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ David Orentlicher, Mary Anne Bobinski, and Mark A. Hall, *BIOETHICS AND PUBLIC HEALTH LAW* (2nd Ed. 2008).

⁸ Neal R. Barshes, Carl S. Hacker, Richard B. Freeman, Jr., John M Vierling, and John A. Goss, *Justice, Administrative Law, and the Transplant Clinician: The Ethical and Legislative Basis of a National Policy on Donor Liver Allocation*, 23 THE JOURNAL OF CONTEMPORARY HEALTH LAW AND POLICY (2007).

⁹ *Id.*

tourists and traveling overseas to a foreign country where their currency will buy priority organ transplantation with a negligible increase in risk of complications.¹⁰

Three questions immediately come up. First, is there a “problem” with organ transplantation which requires that the current system be changed, or should the relative scarcity of medical resources be accepted as a fact of life in the U.S. and the current system preserved? This is a normative question. Either one accepts that a significant shortage of organs is acceptable or one doesn’t; there is little point in reforming the system unless one accepts that a relative shortage of transplantable organs is a problem, and not everyone agrees that there is a “problem” with the current organ transplant system in the U.S.¹¹ Second, what are the various new proposals for “fixing” our current under-supply of solid organs for transplantation for infants and adults? Lastly, which of these new proposals are acceptable, and which should be rejected?

The Current U.S. Regulatory Framework

The regulation of solid organ transplantation from both cadavers and healthy living donors was formally removed from the jurisdiction of the United States Food and Drug Administration (FDA) by Congress with the passage of the National Organ Transplantation Act (NOTA).¹² This legislation established the framework for whole organ recovery and allocation which operates today. Prior to passage of this Act, there was some controversy as to whether FDA had authority to regulate the marketing of human organs. Although transplantation of human organs began in the 1960’s, the regulatory oversight lagged behind the medical practice for decades, and it was not until 1983 that Congress formally asked FDA to address its authority under existing law to oversee whole organ transplantation.¹³

The most important provisions of NOTA were that it¹⁴ (1) provided federal funding for regional federal procurement agencies; (2) established a national organ procurement and transplantation network (OPTN) to manage the procurement and distribution of solid donor organs; (3) mandated funding of transplant-related medication and surgical transplant procedures by Medicaid/Medicare; (4) established a task force to formally study organ transplant allocation problems; and (5) specifically prohibited the sale of donor organs for transplantation though the ban does not apply to blood, sperm or ova.

¹⁰ Bruce Patsner, *Medical Tourism: A Serious Business Undergoing Serious Change*, University of Houston Law Center, Health Law Perspectives January 2008, available at <http://www.law.uh.edu/healthlaw/perspectives/homepage.asp> (last accessed August 18, 2008).

¹¹ JoNel Aleccia, *Dislosing organ transplant risks: Now or later?* MSNBC Health News June 25, 2008, available at <http://www.msnbc.msn.com/id/25354022/print/1/displaymode/1098/> (last accessed June 25, 2008). “This proposal (allowing patients to decide in advance whether they’re willing to take substandard organs, including those at risk for infectious disease such as HIV or hepatitis C) is a solution in search of a problem”, said Dr. Benjamin Hippen, a transplant surgeon on the UNOS ethics committee.

¹² NATIONAL ORGAN TRANSPLANTATION ACT, Pub. L. 98-607, 98 Stat. 2339 (1984), codified as amended at 42 U.S.C. §§ 273-274 (2000) [hereafter NOTA].

¹³ Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman, *Human (Tissue) Transplants. Regulatory Authority*, CHAPTER VI BIOLOGICS: VACCINES, BLOOD, TISSUE TRANSPLANTS, in *FOOD AND DRUG LAW* (3rd ed. 2008).

¹⁴ NOTA, *supra* note 14.

The solid organ donor program is purely voluntary, both for living and cadaveric organ transplantation.

Acceptable New Approaches to Correct “The Problem”

Because of the medical and surgical risks to the donor, even if negligible, there is more controversy surrounding donation of organs by living persons. In addition to the need for effective donor screening to rule out psychopathology, most of these transplants are limited to situations in which the donor and recipient are either relatives or have some personal relationship.¹⁵ These donations are governed by each state’s version of the Revised Uniform Anatomical Gift Act.¹⁶ Agreeing to donate organs and tissues after death is much less controversial.

Recent proposals to overcome the inadequate supply of solid human organs for transplantation differ significantly in approach but all focus on the supply side of the solid organ transplantation equation. There are currently no proposals to decrease demand for solid organ transplants by further narrowing the eligibility criteria used to select recipients for donor organs.

One new approach focuses on increasing the supply only of good quality organs from donors in the United States. Within this general category are three very different approaches directed towards cadaver organ donation. The first, taken by the State of New Jersey, is a proposed new law known as the ‘New Jersey Hero Act’ which requires that all New Jersey residents seeking driver’s licenses be required to make a decision about cadaveric organ donation as part of the licensing process.¹⁷ The law also would make the state the first to incorporate mandatory organ donation education into the curriculum of public high schools.¹⁸ Organ donation selection has been a part of the driver’s license application process in multiple states for many years, though traditionally the “checkbox” may be ignored. The New Jersey proposal is unique in that it is a mandatory selection.

The second approach to increase the number of cadaver organ donations by simply paying individuals money to provide an incentive for them to donate organs for transplantation after they have died. This is the proposal which has recently been advocated by some U.S. transplant surgeons frustrated by the paucity of available organs for donation.¹⁹ Some physicians, both here²⁰ and abroad,²¹ have tentatively endorsed formally studying this approach as a way of going beyond our current altruism-only system. However, this proposal immediately raises two real-world concerns: (1) the

¹⁵ Orentlicher, *supra* note 8 p. 358-359.

¹⁶ *Id.* See also REVISED UNIFORM ANATOMICAL GIFT ACT, 8A U.L.A. 1 (Supp. 2007).

¹⁷ New Jersey law, *supra* note 10.

¹⁸ *Id.*

¹⁹ JoNel Aleccia, *Docs push for cash-for-organ studies. Medical group wants to go beyond altruism to motivate cadaver donors*, MSNBC June 25, 2008, available at <http://www.msnbc.msn.com/id/25356966/print/1/displaymode/1098/> (last accessed June 26, 2008).

²⁰ Arthur Matas, *Should we pay donors to increase the supply of organs for transplantation? Yes*, 336 BR. MED. J. 1342 (2008).

²¹ Fiona Goodlee, *Editor’s Choice. Is it time to pilot paying for organs?*, 336 BR. MED. J. 14 (2008).

prospect of even modest payments leading economically disadvantaged families to withhold vital information about the decedent's behavior (e.g. high-risk sexual activities) which might otherwise lead to rejection of the use for transplantation;²² and (2) a very real fear of quickly going down a slippery slope to paying for living organs. In the absence of firm governmental regulation of a payment for living organs program, there is the possibility that such a system would be vulnerable to coercion, black market trading both within and across national borders.²³ The current U.S. system of allocating solid organs for transplantation would have to be modified in order to make this proposed change a realistic and fair one, as under current law the sale of vital organs for donation is prohibited²⁴ although an argument could be made that the law was intended to apply only to living person, not cadaveric, donation.

Unacceptable New Proposals and Trends

A third recent proposal is to increase supply by lowering the criteria for what constitutes a quality acceptable organ. This would allow those individuals willing to trade the uncertainty of undefined infectious disease risk factors from certain donors for the certainty of having to wait less time to receive a transplant.²⁵ This disturbing proposal is bothersome on multiple levels. For one, there is the simple fact that willingly and knowingly transplanting a potentially diseased solid organ which has not undergone the standardized infectious disease screening for HIV and hepatitis may be grotesquely below acceptable standards of medical care as well as in violation of multiple state laws. Just as importantly, there is a clear coercive element to the informed consent process resulting from proposals such as this. Given the time pressures patients with end-stage organ failure have waiting for a transplantable organ, it may be difficult if not impossible to accurately convey the actual risk of a particular transplant to a desperately ill patient. Equally bothersome is the apparent willingness of renowned medical ethicists to seriously consider such a proposal simply because there is a waiting list for organ transplants,²⁶ and the fact that risk-disclosure practices of transplantation programs are unknown and unregulated with regard to organs other than kidneys.²⁷

Patients and their guardians have every reason to fear the willingness of physicians and transplant surgeons to push the standards boundary. A recent policy enacted by Denver Children's Hospital allowed the organ donation process to begin in two infants after only seventy five seconds of observation following cessation of cardiopulmonary

²² *Id.*

²³ Jeremy Chapman, *Should We Pay for Donor Organs? No*, 336 BR. MED. J. 1343 (2008).

²⁴ NOTA, *supra* note 14.

²⁵ Scott D. Halpern, Abraham Shaked, Richard D. Hasz & Arthur L. Caplan, *Informing Candidates for Solid-Organ Transplantation about Donor Risk Factors*, 358 N. ENGL. J. MED. 2832 (2008).

²⁶ This proposal has been advocated by the same medical ethicist who was involved in the Jesse Geisinger death at the University of Pennsylvania Medical School. The preventable death of this otherwise healthy young man in a Phase I gene therapy trial raised a host of issues revolving around what was clearly inadequate informed consent.

²⁷ Halpern, *supra* note 21.

resuscitation.²⁸ Although this decision may be within what has emerged as a consensus within the medical profession that infant hearts have never been reported to have restarted on their own (“auto-resuscitate”) after two minutes of asystole,²⁹ there is no definitive medical evidence to support this figure as defining an irreversible loss of function. The Institute of Medicine has repetitively pointed out that significant uncertainty exists in this area.³⁰ There is clearly a risk that the rush to minimize organ damage may result in an unacceptable change to the accepted time frame for what is labeled the “dead donor rule.” This rule appears in the laws of every state, and holds that organs necessary for life (e.g. the heart, entire liver, or both lungs) cannot be removed for transplantation from a person unless the person is dead.³¹

Foreign Experience with Less Regulation and Paying Donors for Organs

Then there is the issue of obtaining solid organs for transplantation from foreign donors. The regulation of organ transplantation differs among different countries; in some countries in Asia in particular there is significantly less regulation, and a much greater trend towards considering paying living donors for their organs.³² In part, this is because of the shortage of solid organs for transplantation in the West and the ability and willingness of Westerners to pay for foreign organs. Unfortunately, there is evidence that this process tends to enrich foreign transplant surgeons at the expense of indigent citizens they are under no obligation to provide long-term care for.³³ And, there is no evidence that a similar race to the bottom would not occur should the U.S. adopt a similar policy. Even in the U.S. a policy of paying living donors for their organs would likely discriminate against the least educated and most economically disadvantaged, and likely result in more black market activity not less.

Where Things Are Headed

It is unclear why the issue of relative scarcity of transplantable organs in the U.S., and the plethora of proposals to correct a health policy issue which may or may not need correcting, has occurred now. No one argues with the generally beneficent nature of the desire to provide patients needing organ transplantation. The problem is that when physicians and medical ethicists decide to push the envelope on standards, both organ

²⁸ Boucke, *supra* note 2. For kidney donations only, the United Network for Organ Sharing (UNOS) has a policy which states the prospective kidney transplant recipients must designate whether they would accept organs from expanded-criteria donors before they are putting on the waiting list.

²⁹ UNIVERSITY OF PITTSBURGH MEDICAL CENTER, *Policy and procedure manual: management of terminally ill patients who may become organ donors after death*, 3 KENNEDY INST. ETHICS J A1-A15 (1993).

³⁰ Gregory D. Curfman, Stephen Morrissey, and Jeffrey M. Drazen, *Cardiac Transplantation in Infants*, 359 N. ENGL. J. MED. 749 (2008).

³¹ Orentlicher, *supra* note 8 p.367.

³² The Associated Press, *Singapore may pay donors for kidneys. Officials to study allowing poor to trade organ for money to bolster supply*, July 21, 2008, available at <http://www.msnbc.msn.com/id/25784563/print/1/displaymode/1098/> (last accessed July 23, 2008).

³³ M A Noorami, *Commercial transplantation in Pakistan*, 336 BR. MED. J. 1343 (2008).

donors and organ recipients may suffer despite everyone's best intentions, given the current regulatory state of affairs.

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<http://www.law.uh.edu/healthlaw/perspectives/homepage.asp>