

INTERIM REPORT OF THE OPTN/UNOS ETHICS COMMITTEE
December 7, 2009
Chicago, IL

Michael Shapiro, M.D., Chair
Alexandra Glazier, J.D., MPH, Vice-Chair

The following report represents the Ethics Committee's deliberations and discussions at its in person meeting held on December 7, 2009:

1. Public Comment Proposal – Proposed Requirement to inform living donors of the prohibition against valuable consideration. Dr. Shapiro reminded the Committee of some background events that occurred prompting the development of this proposal. The Living Donor Committee felt that there should be something in policy to require that donors and recipients were aware that it was not legal to participate in such behavior. This

It was asked why there is no similar requirement for the recipients? It was understood that this was being approached in two stages: first to address the donor and follow up requirements will be suggested for the recipient.

It was noted that there is only one case of an alleged violation of NOTA and that a single case may not be adequate grounds to develop policy. It was suggested to delay supporting this proposal until there is more scientific evidence. It was noted that this proposal isn't preventative and will not stop rulebreakers. The second requirement in the proposal has questionable value.

It appears that this appears to be a requirement to provide cover to the members. The Committee generally believed that the requirements should be the same for donor and recipients.

It was offered that Region 4 discussed this proposal and unanimously rejected this proposal. There are many rules and laws which are not required to be disclosed and understood by donors and recipients.

This is an attempt to get one of the elements of informed consent into the bylaws. The organization will be able to say it is doing its best, if this proposal is passed. However, this proposal will have no effect on those patients who are determined to donate and have been coached to respond to concerns from the transplant team.

The Committee evaluated the pros and cons of the proposal. One of the reasons for the proposed requirement is to inform someone who did not know that it was against the law and the second reason is to aid law enforcement in the prosecution of a potential offender.

The benefit of this language might be to assist the transplant programs with the right questions to ask when screening donors and recipients prior to a living directed donation.

The Committee discussed the concept of valuable consideration since that term is specifically

used in NOTA and in the proposal, and would prefer a clearer definition of valuable consideration. The Committee was seriously concerned about requirement to inform patients about the definition of valuable consideration. It was asked whether an educational tool, perhaps online, should be prepared to help OPOs and physicians with this concept. Such a tool may address the types of questions that were asked by patients to try to develop uniformity among responses to common questions.

The Committee did not have any specific ethical concerns with the proposed policy. The Committee believes that the requirements in Paragraph 7 for both Kidney and Liver living donor transplantation to require informing donors of the prohibition is ethically appropriate.

With respect to documenting that the patient understands the disclosure, this is problematic. Documentation of a patient's understanding is always problematic. It was suggested that this disclosure is far simpler than obtaining informed consent of surgical issues.

The Committee feels strongly that the same requirements should apply to both donors and recipients.

The Committee generally supports the proposal and would like to communicate its concerns to the Living Donor Committee.

2. Restatement of Principles of Allocation White Paper. Dr. Shapiro recounted the procedural status of this proposal, which has been in process for several years. The Ethics Committee was originally charged with revisiting prior Ethics Committee Statements and White Papers. After much work and revisions, the Committee proposed several versions of an updated Restatement of Principles of Allocation of Human Organs. Most recently, the Committee proposed revisions to be considered by the Board of Directors at its June 2009 meeting. Representatives of HRSA had concerns about the proposal and asked that the proposal not be presented to the Board of Directors. Dr. Shapiro has been working to communicate with OPTN leadership and HRSA.

It was suggested that this paper should be published independently without the endorsement of the OPTN. By the next meeting in March 2010, whether this goes to the Board, this remains OPTN/UNOS work-product and those identifiers should be removed.

Dr. Shapiro indicated that we will continue to work with leadership to determine the concerns and address those appropriately.

The concerns generally are that HRSA is concerned that there is another document that may compete with the OPTN Final Rule. It was noted that the 1991 white paper was created and approved prior to the development of the OPTN Final Rule. HRSA was concerned that any such document from the Ethics Committee comports with and reflects the OPTN Final Rule. There was concern as to whether a revision of the 1991 White Paper is the proper approach as the Final Rule on which it should be based did not exist at the time. Section 121.8 of the Final Rule is very specific regarding policies of equitable allocation and states 8 principles allocation policies

"shall" be based upon. It is felt that any contemporary allocation white paper must discuss and focus on these 8 principles in relation to the overarching ethical principles. Basically the concern is that rather than continuing on the present direction, a document should be written taking more into consideration the specifics of the Final Rule.

It was asked whether there would be opportunities to revise the paper again. Once a path forward was determined, there would be opportunities to revise and fine tune the paper as appropriate.

3. Kidney Allocation System (KAS) and LYFT (Life Years Following Transplant). Dr. Shapiro gave some comments about the status about efforts to develop a revised kidney allocation system. It was noted that public forums at meetings are not particularly effective methods to obtain feedback from the patient population.

Dr. Shapiro reviewed with the Committee the presentation given by Dr. Kenneth Andreoni, Chair of the Kidney Transplantation Committee given at the recent meeting of the Board of Directors in Orlando, Florida.

4. Concept for a National Pancreas Allocation System. Dr. Shapiro reviewed some of the concepts on the allocation of pancreata. Pancreata were allocated like other extrarenal organs. In Region 1 in 1988, when you came to the top of the pancreas list, you also got a kidney with the pancreas. Process was changed to require that the pancreas list had to get to the top of the kidney list before the patient received the simultaneous pancreas and kidney (SPK).

The Pancreas Transplantation Committee (Pancreas Committee) requested feedback for potential changes to policy regarding options to modify the national pancreas allocation system. The Pancreas Committee is considering proposing:

1. Combining candidates on the waiting list for a kidney-pancreas and pancreas-alone on a solitary list;
2. Development of more specific listing criteria for SPK waiting list candidates (e.g., on dialysis or having a GFR or CrCl < 20 mL/min, a minimum C-peptide threshold in consideration with the HgbA1c level); and
3. Having kidney allocation for SPK candidates meeting appropriate listing criteria follow the pancreas and precede kidney paybacks and pediatric and adult kidney-alone recipients.

Currently, pancreas allocation policy (Policy 3.8) allows OPOs several choices on pancreas (PA) allocation priority with respect to diabetic candidates.

- o The candidates can be listed on separate or combined SPK / PA waiting lists,
- o The kidney may be allocated to SPK or kidney alone (KI) recipients.

It was noted that the only deceased donors from whom you can get a pancreas are very healthy deceased donors. The pancreas is a harder organ to obtain and there are fewer of them available.

If the kidney follows the pancreas, in 36 months only about 10% of the patients are still waiting.

It was asked about the impact of multi-visceral transplants are on the pancreas lists. The Committee reviewed the simulation modeling results requested by the Pancreas Committee.

It was asked whether a diabetic would ever not want a SPK? A diabetic would likely always prefer a SPK unless they are too sick to transplant. The Committee reviewed materials regarding concepts proposed by the Pancreas Committee for a national pancreas allocation system. Concerns were raised that a particular disease would be getting priority for the healthiest kidneys.

It was asked about the effect of kidney paybacks on the pancreas system. If one sends and SPK out of the DSA, would that generate a payback for the kidney? Under the current system, yes it does. Under the proposed system, it would depend on whether the payback system will be eliminated under the proposed revisions to the kidney allocation system. Dr. Shapiro explained the concept of paybacks in allocation policy for the benefit of the new and public members on the Committee.

Concerns were shared about the impact on pediatric kidney allocation because the younger healthier donors who donate a kidney-pancreas may divert kidneys to other donors that might have otherwise been allocated to a pediatric donor.

The Ethics Committee provides the following feedback for the Pancreas Transplantation Committee:

- The Ethics Committee applauds the effort to standardize the policy nationally;
- The Committee appreciates the development of minimum criteria for the kidney side so that the SPK is not a mechanism to “skip” the list; and
- It will be important as the policy is further developed to understand the implications of the effect of this policy on the qualitative impact of allocating younger donor kidneys to the SPK and the impact of this on the kidney waiting list.

5. Ethical Considerations of Certain Procedures to Facilitate DCD Donation. Dr. Shapiro reminded the Committee of its mandate not to opine on individual cases and seek to discern ethical principles applicable to the national network. With that framework, Dr. Shapiro recounted a scenario regarding an ALS patient who wanted to become an organ donor. He was on ventilation and wanted to withdraw care and die under circumstances to permit a controlled DCD recovery.

The primary question was whether an individual should be intubated at home and then transported to the hospital where the care could be removed and the patient allowed to expire. Thus, the intubation procedure was solely to permit the patient to become a DCD donor. The Committee discussed the role and the appropriate length of time between the withdrawal of respiratory support and the progression to cardiac death.

This scenario presents a good example of first person consent and a patient specifically selecting their end of life care.

The informed consent process would have to contain a discussion between the length of time of intubation and the probability of becoming an organ donor. The longer the delay, the less likely that the patient would become a successful organ donor.

First person and informed consent for DCD needs to be viewed in the framework for autonomy for end of life care decision. This is unique because there was a specific request by the patient/prospective donor to be put on a ventilator for purposes of becoming a DCD donor.

6. DCD – Declaration of Death Protocols. Dr. Shapiro recounted prior deliberations of the Committee from October 2008. Based on recently reported DCD pediatric cases, the Committee discussed Donation after Cardiac Death and ECMO Issues at its October 2008. The Committee reviewed articles regarding a pediatric death protocol where the pediatric donor organs were recovered beginning only 75 seconds following the declaration of death. The Report of the National Conference on Donation after Cardiac Death recommended a period of two minutes following declaration of cardiac death prior to commencing organ recovery in order to confirm that there was no autoresuscitation.

At the time, the Committee developed the following proposal for consideration by the Board of Directors:

RESOLVED, that it is ethically acceptable and appropriate to recover organs after cardiac death is pronounced in both adult and pediatric patients, with consent and in accordance with the “dead donor rule.” Death should be established using current empirical data and standards established by the Institute of Medicine (IOM) and the Report of the National Conference on Donation after Cardiac Death. Further scientific investigation in adult and pediatric populations should be conducted to determine more precisely the minimum time needed to ensure the permanent cessation of circulatory function in the donor.

The Committee discussed the declaration of death process and at what point a person is declared dead. The Committee discussed the Uniform Declaration of Death Act and the distinction of this proposal where a time limit is necessary for a DCD donor. Need to focus on the fact that there is a lethal condition and a withdrawal of support. There is a need to be clear about the dead donor rule.

Upon review by OPTN leadership, there were concerns that this proposal might be interpreted as the OPTN prescribing medical practice and the Committee was asked to reconsider this proposal. It was suggested striking the language regarding specific standards in the above resolution.

It was also recommended to add language to describe specific standard. After additional discussion, by a vote of 18 for, 0 against, and 0 abstentions, the following proposal is recommended for consideration by the Board of Directors:

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in accordance with the “dead donor rule.” Death should be established using current empirical data and accepted medical standards ~~established by the Institute of Medicine (IOM) and the Report of the National Conference on Donation after Cardiac Death.~~ Further scientific investigation in adult and pediatric populations should be conducted to determine more precisely the minimum time needed to ensure the permanent cessation of circulatory function in the donor.

7. Uncontrolled DCD and Rapid Organ Recovery. This item was initially planned to discuss ethical issues regarding Uncontrolled DCD (UDCD) potential resulting in either a statement of support for the 2006 IOM recommendation that OPOs consider pilot programs in UDCD or alternately, that it is premature and then the Committee could consider outlining a path forward for the OPTN to encourage UDCD. Dr. James DuBois was expected to direct this discussion and unexpectedly became unavailable for the Committee meeting. It was agreed to defer this issue until a later meeting at which Dr. DuBois was available.

Related to uncontrolled DCD organ recovery, Bernard Kozlovsky, M.D., explained that there are two grants available from HRSA to increase organ procurement.

It was suggested that there is not enough data for the Committee to be able to comment on this topic. It was asked whether this was a presumed-consent or a first person consent situation? It was noted that this would be a first person consent based upon registered organ donors.

Dr. DuBois also suggested that the Committee discuss the standardization of protocols. There are articles that clearly document wide variations in the practice of determining brain death and determining death in the context of DCD. It was suggested that the current degree of variation is problematic and poses a threat to trust in the transplant system. Given that there have been a few widely publicized cases of "recovery from brain death," it was suggested that there might be efforts aimed at fostering greater protocol uniformity.

8. Public Solicitation Subcommittee. Rachel Mackey, Subcommittee Chair was recognized to present a report. At the April 2009 meeting of the Ethics Committee, the Committee reviewed prior resolutions and position statements regarding public solicitation of living donors, reviewed the ASTS statement on living directed donation, and a memo from former OPTN/UNOS President on the OPTN website regarding public solicitation. A subcommittee was formed to review the present memos and statements and compile a consolidated position. Members include Richard Demme, Rachel Mackey, and Elisa Gordon. Dr. Robert Sade volunteered to assist with this subcommittee. The Subcommittee work is in its early stages and suggest the following key points:

1. Living donation in the United States has traditionally been conducted between donor-recipient pairs with long-standing emotional relationships or biological linkages. Absent a meaningful relationship, prospective living donors are encouraged to allow their organs to be allocated according to the principles of equitable organ allocation developed by the Organ Procurement and Transplantation Network.

2. Directed donation to strangers is a recent development that has come under increasing scrutiny. Although it respects autonomous decision-making, it challenges ethical concerns about equity in the fair distribution of organs. In the context of directed donation to strangers, relationships between donor-recipient pairs may have resulted from direct or non-direct solicitation by the recipient. The solicitation may have been to family members, friends, acquaintances or strangers and may have been done directly or indirectly through community groups or via internet websites. Solicitation for living donation raises the ethical concern about financial incentives for donating and voluntariness.
3. Transplant centers need to continuously evaluate the new relationships between recipients and donors along with new developments in communication methods available to facilitate such relationships.
4. Public solicitations of living donor organs cannot be regulated or restricted in the United States as long as no felonious or illegal activity is involved (i.e. no party knowingly acquires, receives or otherwise transfers any human organ for valuable consideration for use in human transplantation). In other words, the ways in which relationships are developed in society with respect to directed living donation cannot be regulated or restricted.
5. There are ethical grounds to proceed with directed living donation transplants as long as the motivation is based in altruism and there are well defined safeguards regarding informed consent and evaluation in the transplant centers performing them that insure safety for the donor, the recipient, the transplant center and the community.
6. At all stages of the evaluation and transplantation process, the donor is as legitimately considered to be a patient as the transplant recipient, and thus should be afforded the same level of care and the same protections against undue risks.
7. The evaluation and/or determination of eligibility of potential living donors will continue to be the responsibility of the physicians, surgeons, allied health professionals and living donor programs involved with the donors.
8. Transplant centers vary in their approach to live donation, and each center has developed acceptance criteria that are reflective of its philosophy for providing live donor transplantation. These criteria may range from accepting only known relatives or those with close emotional ties, to approving transplants from non-directed donors or those with only distant relationships.
9. Transplant centers and professional transplant organizations work to developing guidelines for procedures and practices to best assure that these types of transplants

proceed with maximum safety, and it is ultimately the transplant center, utilizing ethical principles that underscore established standards of care for the donor and recipient, to develop and apply the criteria for the medical and psychosocial acceptance for live donor transplantation at that center.

10. We do, however, continue to philosophically oppose marketed programs designed to match living donors with recipients when they requiring payment for participation, as they exploit vulnerable populations (i.e., donors, transplant candidates, etc.) and subverts the equitable allocation of organs for transplantation. This includes our previously stated philosophical opposition to matchingdonors.com. However, those programs facilitating matches between prospective living donors and recipients that do not require payment (e.g., Craig's list) do not subvert the equitable allocation of organs for transplantation and are thus ethically acceptable.

Additional points were made that living donors do not gain any physical improvement from the procedure so the only benefit to the living donor must be psychological.

9. Paired Donation Issues: Dr. Shapiro and the Committee discussed recent correspondence from HRSA regarding the Kidney Paired Donation Pilot Project. In 2006, HRSA directed the OPTN to develop policies regarding living organ donors and living organ donor recipient for the equitable allocation of living donor organs consistent with the OPTN Final Rule. HRSA considers the living donor paired match process to be organ allocation and as such, must follow the OPTN Final Rule.

It was noted that the Final Rule was written and published in 2000 and the directive to develop living donor policies and guidelines was published in 2006. Policies for the allocation of living donor organs might be considered differently from policies for the allocation of deceased donor organs.

Policies for living donation should be separate. Autonomy should be the primary principal with living donation and justice should be the primary principal of allocation regarding deceased donors.

There needs to be consideration of donor autonomy as the central principal of living donation and this principal is deemphasized in the OPTN Final Rule.

HRSA believes that the matching of kidney donors and recipients constitutes organ allocation. It was noted that §121.8 of the OPTN Final Rule specifically applies to "cadaveric" donation.

There were also concerns that there are not OPTN policies and bylaws for living donor organ allocation. The immediate issue is whether §121.8 addresses the important ethical principals that it should address for living donation. The consensus of the committee is that §121.8 does not contain all of the ethical principals that apply to living donation.

It was suggested to draft a paper explaining the ethical principals for living donation that should be included in the policy development of living donor policies.

In an attempt to provide helpful information to inform development of living donor policies, it was suggested that the OPTN Final Rule may be incomplete with respect to living donation.

The Committee agreed that it will draft a relatively short letter to OPTN/UNOS leadership outlining the concerns of the Committee before this topic is referred to the committees to draft living donor policies.

11. Removal of Financial Disincentives for Organ Donation Subcommittee. The Committee discussed the status of this Subcommittee and determined that the utility of this Subcommittee has diminished. The Committee agreed to suspend this Committee and will review the materials on Financial Incentives on the Committee SharePoint site.

12. Stewardship/Ownership Subcommittee. The Committee discussed the status of this Subcommittee and determined that the utility of this Subcommittee has diminished. The Committee agreed to suspend this Committee and will review the materials on stewardship/ownership of organ on the Committee SharePoint site.

Adjourn: 3:30 p.m.

**Attendance at the Ethics Committee Meeting
December 7, 2009
Chicago, IL**

Committee Members Attending:

Michael Shapiro, M.D.	Chair
Alexandra K. Glazier, J.D., M.P.H.	Vice-Chair
Matthew G. Nuhn, M.D.	Region 1
Melissa J. Doniger, J.D.	Region 2
Natalie G. Murray, M.D.	Region 4
Randolph L. Schaffer, III, M.D.	Region 5
Pasala Ravichandran, M.D.	Region 6
Bargav M. Mistry, M.D.	Region 7
Lauris C. Kaldjian, M.D., Ph.D.	Region 8 (by telephone)
Richard Demme, M.D.	Region 9
Amy Pope-Harman, M.D.	Region 10
Robert M. Sade, M.D.	Region 11
Jack Berry	At Large
Ronald E. Domen, M.D.	At Large
James M. DuBois, Ph.D, DSc	At Large
Liz Lehr, BSN, MHA	At Large
Rachel Mackey	At Large
Daniel J. Lebovitz, M.D.	At Large (by telephone)
Liz Lehr, BSN, MHA	At Large
Lainie F. Ross, M.D., Ph.D.	At Large
Dane Sommer, D.Min., BCC	At Large
Bernard Koslovsky, M.D.	HRSA, <i>Ex officio</i>

Board Liaisons

Mark C. Norquist

UNOS Staff:

Jason P. Livingston, Esq.	UNOS
Gloria Taylor	UNOS

SRTR Staff:

Erik Roys	SRTR
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Unable to attend

Alison Silva, RN, BSN, CCTC	Region 3
Elisa J. Gordon, Ph.D., MPH	At Large
James M. Dubois, Ph.D., DSc	At Large
Kevin E. C. Meyers, M.D.	At Large