

**OPTN/UNOS Ethics Committee
Report To The Board Of Directors
November 8-9, 2010
St. Louis, Missouri**

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee is evaluating the current organizational positions on public solicitation for living and deceased donor organs. (Item 2, Page3)
- The Committee will collaborate with the Ad Hoc International Relations Committee to review present policies on the transplantation of non-resident aliens. (Item 3, Page 5)
- The Committee reviewed and provided feedback to the OPO and Organ Availability Committees on their jointly proposed modifications to model elements for DCD protocols. (Item 4, Page 5)
- The Committee reviewed materials for rapid organ recovery/uncontrolled DCD to develop ethical guidelines for the development of uncontrolled DCD protocols. (Item 7, Page 7)

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**Michael Shapiro, M.D., Chair
Alexandra Glazier, MPH, JD, Vice Chair**

The following report describes the deliberations of the OPTN/UNOS Ethics Committee at its meeting in Chicago, Illinois on September 26-27, 2010:

1. Review of Annual Committee Goals. Alexandra Glazier, Vice-Chair welcomed the Committee and reviewed the meeting agenda. The approved goals for the Ethics Committee for 2010-11 include the following:

- 1) Review positions, statements, and documents currently in development by the Committee taking perspectives included in NOTA and the Final Rule into account and complete the proposed revisions to the white paper, "General Principles for Allocating Human Organs."
- 2) Examine potential ethical issues that should be considered by the Liver and Intestinal Organ Transplantation Committee in the process of developing changes to liver allocation.
- 3) Examine potential ethical issues that should be considered by the Living Donor Committee in developing new policies regarding living donation.
- 4) Examine potential ethical issues that should be considered by the Kidney Paired Donation workgroup in developing permanent policies regarding kidney paired donation.
- 5) Review previous positions and white papers posted on the UNOS and OPTN web sites and recommend to the Board whether any should be updated by the Committee or archived.

It was noted that with respect to Goal 1, the Board of Directors approved the paper entitled, "Ethical Principles to be Considered in the Allocation of Human Organs" at its June 2010 meeting. To address Goal 5, the Committee reviewed a consolidated summary document of past actions and positions taken by the Committee and the Board of Directors on a wide range of transplantation-related topics. The Committee began efforts to prioritize the Committee's review of existing white papers and position papers

2. Public Solicitation Subcommittee. In support of Goal 5, the Committee had formed a Subcommittee to evaluate the prior positions that the OPTN/UNOS had adopted with respect to public solicitation of organs from deceased donors and from living donors. The Public Solicitation Subcommittee met by conference call on September 10, 2010. **Exhibit A.** The Committee discussed a draft document that had been discussed but not adopted by the Public Solicitation Subcommittee. In summary, after extensive discussion, the Committee agreed that the current positions of the OPTN are not sufficient, but the Committee did not reach a consensus on modifications appropriate position.

It was asked whether the goal is to update the organizational positions to reflect the differences between solicitation for live donors and solicitation for deceased donors.

With respect to the existing position statement, concerns were shared about the implication that the only thing that the OPTN/UNOS philosophically opposes is the requirement of payment for participation in the matching service. There are other things that could make a solicitation inequitable other than the requirement of payment - nor should we automatically endorse any solicitation that doesn't require

payment for participation in the program.

Additional concerns were noted about means of public solicitation that require technological savvy such as through social networking, internet-based matching services, and other internet solicitations. While a particular method of solicitation may be legal, it may not be a good thing for transplantation. As an alternative position, it was suggested that even though a certain form of solicitation may be legal, the organization could still state that it deplors the act.

It was noted that some transplant programs routinely advise their patients to go out and seek a living donor based on the results of living donation and significant waiting times in certain DSAs, particularly for certain diabetics awaiting a kidney transplant.

During the evening session, Rachel Mackey offered to prepare a restated position for further discussion by the Committee. During the second day of the meeting, the Committee considered the document attached as **Exhibit B**.

There was further discussion about the various points in the draft position paper. Currently, the document discusses directed donation of deceased donors, directed donation of living donor organs, and public solicitation. It was noted that there are ethically acceptable principles that support solicitation and directed donation, including patient autonomy and maximizing utility.

The Committee recognizes that certain people who may advertise in media such as on a billboard may be more likely to receive a directed donor organ for a variety of subjective criteria such as appearance and fame.

The Committee also discussed the implications of a public solicitation that results in a match with an unrelated altruistic living donor. It was asked whether there are unique evaluation processes that need to be applied differently for unrelated altruistic donors. The psychosocial evaluation should be the same or very similar for both related and unrelated living donors. If a psychiatrist needs to interrogate donor motives, that process should be consistent for any living donor. There is a significant risk of coercion for related living donors.

It was acknowledged that much of the concerns about public solicitation include the potential for an increased risk of donors accepting payment for their donor organ.

In an effort to distill the draft position into a more workable document, the following draft position was offered and discussed by a Committee member:

The Board recognizes that methods and media for public solicitation of living donor organs have proliferated. Although public solicitation cannot be regulated or restricted by law as long as no illegal activity is involved, not all legal methods and media for public solicitation are ethical. The Board continues to philosophically oppose public solicitations for living donors that exploit vulnerable populations and/or subvert the equitable allocation of organs. Some of the ethical factors that should be evaluated related to potential living donor pairs that resulted from public solicitation include coercion, informed consent, or illegal payments for organs.

Recognizing a continued lack of consensus, the Subcommittee will consider the comments of the full Committee and prepare a document for consideration by the Committee at its next meeting.

3. Consideration of 5% Limitation of Transplants of Non-resident Aliens. Dr. Shapiro recounted to the Committee the origin of the limitations on non-resident alien transplantation. Dr. Gabriel Danovitch, Committee member and Chair of the Ad Hoc International Relations Committee, has requested collaboration with the Ethics Committee to review the current 5% Rule. Dr. Shapiro also recounted that the UNOS Board of Directors has adopted the Principles set forth in the Declaration of Istanbul but not the entire document. One of the Principles of the Declaration include that a nation should not transplant non-resident aliens if it would impact the nation's ability to transplant its own citizens.

Dr. Shapiro highlighted that we generally condemn patients who travel overseas to receive transplants and then return to the United States for their follow up care. It was also noted that there is not a reciprocal condemnation of non-resident aliens travelling to the United States to receive an organ transplant. It was noted that cultural differences may drive certain individuals to seek a transplant in another country. For example, deceased donation is virtually non-existent in Japan such that the only realistic option is to travel to another country to seek a transplant. It was suggested that those countries that have transplant programs should make a contribution to help those countries where, for whatever reason, transplant is not available. It was noted that that transplant centers will accept donor organs from non-resident aliens.

It was asked how many transplant centers exceed the 5% threshold.

It was offered that the Committee could recommend that the 5% rule be eliminated and take the position that it is inappropriate to transplant non-residents until there is a surplus of organs, consistent with the Principles of the Declaration of Istanbul. The Committee looks forward to the opportunity to work with the Ad Hoc International Relations Committee on this topic.

4. Review of Draft Public Comment Proposal for DCD Model Elements. The Committee was asked by the OPO and Organ Availability Committees to provide advance feedback on a proposal prior to being distributed for public comment. The Committee reviewed the draft public comment document to provide appropriate ethics-related feedback on DCD Model Elements being considered by the OPO and Organ Availability Committees. The Ethics Committee recommends a number of modifications to the proposal language, which are set forth in red tracked changes in **Exhibit C**.

The Committee provides the following specific responses to questions from OPO and Organ Availability Committees:

1. General comments:

- “Candidate” is a defined term in the OPTN Final Rule and should not be used anywhere in the model elements in the interest of consistency and to avoid confusion;
- There is no meaningful distinction between a Medicare participating “hospital” and a “critical access” hospital so long as it has a ventilator and operating room;
- All OPOs are required to have a DCD protocol and all of the OPOs presently have such a protocol;
- The language regarding the “legal next of kin” is somewhat awkward and the Committee suggests the following alternate language for Section D.1.:
“For all purposes, the patient is the appropriate person to make decisions for themselves regarding their end of life care including the withdrawal of life sustaining care and the decision to be an organ donor. If the patient is unable to make those decisions, the legal next of kin is the appropriate decision maker.”
- For section E., the Committee recommends the following additional requirement that the protocol address the presence/non-presence of the donor's next of kin during the withdrawal of life sustaining care:

“The protocol should address the presence of the potential donor’s legal next of kin during the withdrawal of life sustaining medical treatment/support. “

- Proposed Section F.4 appears to be substantially the same as Section F.2; and
- The Committee recommends a substitute for Section F.4 as follows:
“Testing to confirm the absence of circulation (e.g. intra-arterial monitoring or Doppler study) should be performed in accordance with the hospital’s DCDD protocol to assure the patient’s legal next of kin and the hospital professional staff that the patient is dead.”

2. With respect to the terminology change from DCD to DCDD, the Committee understands the intent of the change however, “DCDD” is a more confusing title. It was noted that this change in designation would require transplant hospitals and OPOs to change established policies and protocols to reflect the new terminology. The name change may be confusing for hospitals and may give the impression that the transplant community is less comfortable with the DCD concept. The Committee suggests maintaining the DCD initials but changing to “circulatory” instead of “cardiac” death.

5. Discussion of SRTR Contractor Change. HRSA explained that there will be a three month overlap for the transition to the new SRTR contractor. In the context of kidney allocation policy development, all of the modeling work has been done with KPSAM; it was asked whether the computer simulation model belong to the SRTR Contractor or to HRSA? With the absence of a model, does the OPTN still have access to the model? How will there be a comparison from new model to old results? Will old model be licensed to new SRTR? There were also questions raised about the donor risk models. Due to the very recent announcement of the change in the SRTR Contractor, answers to these questions were not available at the time of the meeting.

6. Review of Kidney Allocation System. Consistent with its longstanding Committee goal, the Committee reviewed the most recent regional presentation on the development of a kidney allocation system. The Committee also is charged with reviewing the ethical implications of living donor policy development. The Committee noted that the best data set on living donors may not accurately reflect the population of the country or reflect the demographics of the kidney waiting list.

The Committee wanted to discuss the issues of geography and its effects on the waiting list. It was suggested that improvements to geographic distribution will be the best way to improve the efficiency of the national transplantation system. Anecdotal evidence of significant variances in waiting time was shared. It was suggested that transplant centers that perform a large number of transplants have an interest in maintaining the system and their current volumes of transplant.

The OPTN Final Rule was referenced and requires that organ allocation policies should not be based on a candidate’s place of listing and should seek to allocate organs over as broad an area as feasible.

The Kidney Transplantation Committee had sought years ago to make incremental positive changes rather than take on every issue related to kidney allocation at the same time. It was noted that those incremental changes have not been implemented such that it may be appropriate to consider the other issues that have been deferred including geography. The ultimate goal should be that a patient should have an equal opportunity to receive an organ regardless of location, which will require broader sharing.

It was asked why waiting times are so different in geographic areas? It was offered that renal disease has different rates of occurrence depending on population characteristics. If donation rates are consistent but the incidence of disease varies, then wait times will vary. Donation rates and donor eligibility vary by

geography. It was agreed that the OPTN/UNOS should gather more detail about candidates and their attributes and their ability to get an organ.

The Committee will communicate its concerns regarding geography to the Kidney Transplantation Committee.

7. Rapid Organ Recovery/Uncontrolled Donation after Cardiac Death (DCD). The Committee reviewed materials related to uncontrolled DCD and began considering ethical guidelines for the development of uncontrolled DCD protocols. Dr. DuBois provided an overview of the topic and suggested that it is appropriate to consider formally because the practice is already being done in different areas using varying protocols. Some studies suggest that rapid organ recovery could lead to 22,000 additional potential deceased donors. Three rapid organ recovery protocols were shared with the Committee and the elements of those protocols were discussed.

Many logistical as well as ethical issues are raised with rapid organ recovery. There was some concern about the accuracy of the number of potential additional donors.

It was noted that some states promote this activity by having laws that permit organ perfusion of a deceased potential donor prior to obtaining consent. This practice would be easier to promote in a country with an opt-out system instead of an opt-in system like the United States. With respect to an appropriate uniform standard, the Committee could recommend a position that organ preservation measures should be applied only in the presence of an affirmative donor designation.

The Committee was particularly concerned about the issue of consent – whether first person consent or from the donor’s next of kin. The Committee discussed some of the methods for designating intent to be an organ donor in donor registries. Consent is not as large of a concern ethically with first person consent laws and donor registries however, the declaration of death is significantly problematic.

There is little support for using ECMO and whether it the use of ECMO is ethically acceptable in the uncontrolled DCD context. It is unknown whether ECMO will help kidney or liver graft functions. Uncontrolled DCD kidneys are no different from controlled DCD kidneys, which are essentially the same as deceased donor kidneys by neurologic death.

The Committee, and the protocols it reviewed agreed that there is a need for a clear transition from patient to donor. For this transition, a hands off period is essential, especially for staff that are involved in treating the patient.

It was noted that patients are consistently concerned that if they are a designated donor, they may not receive the best resuscitative efforts. One of the major hypotheses was that the public would share that concern however, evidence suggest that the community already believes that this is the way donations are accomplished.

It was also asked why this is not the *status quo* rather than the exception if it could provide thousands more transplantable organs?

The Committee then discussed an appropriate path forward. It was suggested that the Committee could draft a lengthy white paper or more expeditiously prepare a shorter statement in support.

A subcommittee of Amy Pope-Harman, Alexandra Glazier, Dane Sommer, James Dubois, Rachel Mackey, and Richard Demme, will prepare a position for the Committee to consider at a later date.

8. Liver Allocation Forum Update – Goal 2 for the Committee is to examine potential ethical issues that should be considered by the Liver and Intestinal Organ Transplantation Committee (Liver Committee) in the process of developing changes to liver allocation. As this is a new area of work for the Committee, Natalie Murray, M.D. was asked to update the Committee on the liver forum led by the Liver Committee.

Under the MELD system, the liver allocation policy was developed to include objective criteria. At the forum, the issue of geography and its impact on allocation was discussed and there was very brief discussion of allocation by distance with concentric circles around the donor. There was discussion about the Share 15 proposal, which requires livers to be shared regionally with MELD scores higher than 15. Modeling with tiered thresholds was discussed and also the application nationally of the Share 15 proposal. There were also proposals to look at serum sodium as an indicator of mortality and to include that as an element in the allocation system although there were concerns that serum sodium is too easily manipulated.

It was suggested to ask a representative of the Liver Committee to give a presentation to the Ethics Committee on liver allocation issues at a future meeting date.

The Committee will communicate with the Liver Committee to expressing support for a national Share 15 proposal and similarly to kidney allocation, concerns that liver allocation policy should be modified to address the geographic disparities in liver allocation.

**Attendance at the Ethics Committee Meeting
September 26-27, 2010
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
Peter Reese, M.D.	Region 2
Natalie G. Murray, M.D.	Region 4
Gabriel M. Danovitch, MB, LRCP, MRCS	Region 5
Lisa Florence, M.D.	Region 6
Bargav M. Mistry, M.D.	Region 7
Deborah B. Adey, M.D.	Region 9
Amy Pope-Harman, M.D.	Region 10
Jack Berry	At Large
Richard Demme, M.D.	At Large
James M. DuBois, Ph.D, DSc	At Large
Kay Kendall, MSW, LISW	At Large
Liz Lehr, BSN, MHA	At Large
Rachel Mackey	At Large
Liz Lehr, BSN, MHA	At Large
Lainie F. Ross, M.D., Ph.D.	At Large
Dane Sommer, D.Min., BCC	At Large
Robert M. Veatch, Ph.D.	At Large
Teresa M. Beigay, Ph.D.	HRSA, <i>ex officio</i>

UNOS Staff:

Jason P. Livingston, Esq.	UNOS
Gloria Taylor	UNOS

Unable to attend

Carlos F. Zayas, M.D.	Region 3
Gabriel M. Danovitch, MB, LRCP, MRCS	Region 5
Erik Schadde, M.D.	Region 8
Robert M. Sade, M.D.	Region 11
Ronald E. Domen, M.D.	At Large