

**OPTN/UNOS Ethics Committee
Report to the Board of Directors
June 25-26, 2012
Richmond, VA**

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee worked with the Ad Hoc International Relations Committee to propose modifications to Policy 6.0 (Transplantation of Non-Resident Aliens), which will be presented to the Board of Directors for consideration at this June 2012 meeting. The briefing paper and proposal are included in the report of the Ad Hoc International Relations Committee to the Board of Directors. The proposed changes include: 1) technical edits to Policy 6; 2) removal of the audit policy that provides for the OPTN to review transplants of organs from deceased donor non-resident aliens if the transplant rate at a given program exceeds 5% annually; 3) new citizenship definitions for citizenship categories approved by the Board in June, 2011; 4) a policy that provides for the OPTN to review listings and transplants of non-US citizens/non-US residents; and, 5) the new requirement that the OPTN provide transplant-by-citizenship data to the public. (Item 1, Page 2)

**OPTN/UNOS Ethics Committee
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**Alexandra Glazier, MPH, JD, Chair
Peter Reese, MD, Vice-Chair**

The following represents the deliberations of the OPTN/UNOS Ethics Committee at its joint meeting with the Ad Hoc International Relations Committee by teleconference on March 21, 2012, and its meeting in Chicago, Illinois on April 2, 2012:

1. Proposed Revisions to Policy 6.0 (Transplantation of Non-Resident Aliens) – On March 21, 2012, the Ad Hoc International Relations Committee and the Ethics Committee (Committees) met jointly by telephone and internet to discuss comments submitted by the public, OPTN/UNOS Committees, and the OPTN/UNOS Regions about the revisions to Policy 6 (Transplantation of Non-Resident Aliens). The Committees received the opportunity to evaluate these comments and during this meeting, discussed select policy revisions proposed by the Committees’ leadership to address the comments submitted. The following were the primary issues raised by those who reviewed the policy revisions during the comment cycle (9/16/2012 to 12/23/2012).

- **Issue I: Retain Language about Valuable Consideration** - The revisions to Policy 6, distributed for public comment in September 2011, deleted language about valuable consideration. This language was part of the “ethical practices” policy section. Concerns were raised that the removal of the policy altogether, especially language about valuable consideration, may not be prudent. Removing this language may suggest that the OPTN is not concerned about the illegal exchange of valuable consideration in organ transplantation.
- **Issue II: Modify the Organ Export Policy** - It was suggested that the policy should define “exhausting the match run.”
- **Issue III: Modify the Residency Definitions** - How is residency best reported? Current residency definitions may place transplant programs in a position of sorting through immigration information.
- **Issue IV: Modify Language in the Nondiscrimination in Organ Allocation Policy** - During the public comment cycle, UNOS staff reviewed this policy and recommended editorial suggestions.
- **Issue V: Modify the Proposed Audit Policy** - Various comments were submitted about the proposed audit policy; they were mostly supportive of the suggested changes. Concerns were expressed that the proposed audit policy was the first step in making it a policy violation to transplant non-residents. There were concerns that the proposed policy lacked an explanation about the audit process, leaving the transplant community wary of the proposed audit. The review itself may be burdensome to the transplant centers. If a review was to occur, perhaps the submission of data should be voluntary. The proposed audit policy may give too much oversight to the Ad Hoc International Relations Committee. Some suggested retaining the greater than 5% audit trigger policy, because it sets a concrete threshold by which transplant programs can decide when to stop listing or

transplanting non-residents during a given calendar year. Because of this perceived “limit” some suggested that the greater than 5% audit trigger policy may better achieve the goal of reducing transplant tourism in the US than the proposed audit policy, which has no limit to the number of non-residents that may be transplanted. Some responders suggested edits to the proposed audit policy language; while others suggested that the proposed policy focus only on data collection.

- **Issue VI: Modify Proposed Reporting Policy** – It was suggested that the OPTN should focus on collection of the data, and that the OPTN should report all data, not just data about those non US citizens who traveled to the US for transplant. The policy must continue to ensure that individually identifiable patient data remain private. It was asked to better define how the data will be handled.
- **Issue VII: Define Ad Hoc Deceased Donor Organ Import** - UNOS staff reviewed the policy and suggested that an ad hoc deceased donor organ import be defined.

The Committees discussed further policy modifications to address each issue described above. During this discussion, the Committees agreed to include the following policy text changes in the final version of Policy 6 that will be submitted to the Board of Directors for its consideration in June 2012:

- *Include language that recovery or transplantation of an organ for valuable consideration is not legal in the United States.* Policy 6.4.4 (Ethical Practices) currently includes the valuable consideration concept. Proposed revisions to Policy 6 struck Policy 6.4.4 in its entirety, because it: 1) is illegal to recover and transplant organs for valuable consideration and a Member’s violation in this area would involve other federal agencies, so it may not be necessary to continue to include this concept in policy; 2) makes no mention that Members may not import a living donor who has valuable consideration; 3) contradicts Policy 12.6 (Center Acceptance of Living Donor Organs) that requires recovery of living donor organs for transplant in the United States to occur only at Member transplant centers; and, 4) includes but does not define the phrases “ethical practices” and “practices which might discredit the transplant community.” A definition of “ethical practices” and “practices which discredit the transplant community” would be subjective and arbitrary, leading to inconsistent interpretations of this phrase over time. A few comments from the public, however, suggested retention of the valuable consideration concept in Policy 6.4.4.

Legal prohibition to recover or transplant organs due to valuable consideration, however, is not restricted to the recovery of organs from or transplants of non-resident aliens. The foreign status of an organ procured for transplant is not relevant, because OPTN Members must not procure or transplant an organ for valuable consideration. Therefore, Policy 1.1 (Obligation to the National Organ Transplantation Act) includes only the valuable consideration concept from Policy 6.4.4.

- *Edit the proposed organ export policy* - The proposed and post-public comment revisions to the export policy continue to allow living donor organs to be exported, however, a recent question posed by a community member has created a project for the Ad Hoc International Relations Committee and the Living Donor Committee to determine if policy should continue to enable living donor organs to be exported.
- *Edit the definition of non-US citizen/US resident and non-US citizen/non-US resident* - The Committees edited the definitions of non-US citizen/US resident and non-US citizen/non-US resident for clarity.
- *Revise the proposed audit policy (See Issues V and VI; Proposed Policies 6.3 and 6.3.1)*- The proposed revisions to Policy 6.3 include the following modifications: 1) remove the term “audit” from the policy’s title; 2) Instruct the Ad Hoc International Relations Committee to review all citizenship data submitted per board-approved modification of data entry introduced March 2012 3) remove the term “justification” regarding listing or transplantation of a non-resident non-citizen; and, 4) allow the Ad Hoc International Relations Committee to request that transplant programs voluntarily provide additional data related to their listings or transplants of non-resident aliens. In making these revisions the Committees avoided any mandatory reporting requirements over and above that which are already in place while retaining the ability to review and analyze data regarding the listing and transplantation of non-citizen non-residents. The Ad Hoc International Committee will provide an annual report of the listings and transplants of non-residents publicly available (with patient data blinded).

The proposed review of non-resident listings or transplants as a policy path will provide a significant degree of transparency to the American public regarding the number of individuals who travel to the United States for transplant. This information may guide future policy considerations. The Committees rejected the suggestion to retain the “greater than 5%” audit policy since this policy is widely misunderstood, does not provide transparency and, in some transplant programs, prevents foreign nationals in need of transplants from being listed.

- *Define “ad hoc import” of deceased donors* - The Committees, per request from UNOS staff members, defined “ad hoc” deceased donor organ import.

The proposed policy modifications presented below include post-public comment changes to policy text, based on the discussion described above. Text with double underlines (example) and double strikeouts (~~example~~) denotes changes proposed by the Committees after the public comment cycle. The Committees voted in favor of the following modification for submission to the Board of Directors: 24-supported; 0-opposed; and, 0-abstained.

1.0 Member Rights and Obligations

The Organ Procurement and Transplantation Network (OPTN) is a private non-profit entity that has an expertise in organ procurement and transplantation. The purposes for which the OPTN is organized are detailed in the OPTN Charter. Membership in the Corporation is voluntary; rights and obligations of Members of the OPTN are set forth in the OPTN Bylaws and in OPTN Policies adopted by the OPTN Board of Directors.

OPTN Policies govern the various areas of OPTN operations. Amendments and additions to OPTN Policies are adopted by the Board of Directors and may be incorporated into the Bylaws. Policy Amendments and additions are binding upon OPTN Members after adoption by the Board of Directors and after notice to Members, whether or not such amendments and additions are incorporated into the Bylaws. Copies of OPTN Policies are distributed to Members upon request, and policy updates are available subsequent to adoption of policy changes.

By accepting membership in the OPTN, each Member agrees to be bound by all provisions of the OPTN Charter, Bylaws, and Policies, including amendments thereto. A Member who does not comply with such provisions will be afforded the appropriate due process as described in the OPTN Bylaws.

The Membership application and review process is set forth in the OPTN Bylaws. Permanent Standing Committees and Ad Hoc Committees, develop OPTN Policies and propose such Policies, amendments, and additions for consideration and adoption by the Board of Directors. All OPTN Members are invited and encouraged to participate in OPTN activities through OPTN committee service and through consultation with OPTN Committee Members and members of the Board of Directors.

1.1 Obligation to the National Organ Transplantation Act

An OPTN member may not knowingly permit donation, recovery, or transplantation of deceased or living donor organs for valuable consideration.

- 3.2.1.4 Prohibition for Organ Offers to Non-Members.** ~~Members shall not provide organs to non-member transplant centers except to transplant centers in foreign countries as described in Policy 6.4 (Exportation and Importation of Organs – Developmental Status). Members can only share organs with Members or countries. However, Members may only export deceased donor organs outside of the United States after a well documented and verifiable effort, coordinated through the Organ Center, has been made to hospitals in foreign countries after having offered offer these organs to all potential recipients on match runs. Prior to exporting deceased donor organs, Members must submit the organ export verification form to the OPTN Contractor contractor prior to exporting deceased donor organs.~~

6.0 Deceased Donor Organ Transplantation of Non-US Residents/Non-US Citizens, and the Importation of Deceased Donor Organs from Foreign Sources

6.1 Definitions. The following definitions apply to this policy:

- 6.1.1 Non-US Citizen/US Resident** – A person who is not a non-citizen of the United States, who is present in the United States, and for whom the United States is the primary place of residence.
- 6.1.2 Non-US Citizen/Non-US Resident** – A person who is not a non-citizen of the United States and for whom the United States is not the primary place of residence.

6.2 Guidelines. Any member transplant center that places a non-US citizen/non-US resident on its waiting list shall adhere to the following guidelines:

6.2.1 Nondiscrimination in Organ Allocation. Selection from the waiting list of non-US citizen/non-US resident candidates for transplantation shall be based on the same allocation policies (Section 3.0) mandated by the Board of Directors for selection of candidates who are citizens or residents. Deceased donor organ allocation to candidates for transplantation shall not differ on the basis of a candidate's citizenship or residency status in the US. Such selection Allocation shall not be influenced by favoritism or discrimination based on political influence, national origin, race, sex, religion, or financial status.

6.2.2 Referrals. Members shall not enter into formal contractual arrangements with foreign agencies or governments for the transplantation of non-US residents/non-US citizens in the United States. Members may negotiate the terms and conditions under which any individual candidate would be treated with the understanding that each candidate must be referred on a case-by-case and physician-to-physician basis.

6.3 ~~Audit~~ Review and Reporting of Non-US Citizens/Non-US Residents Listings and Transplants. As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and, at its discretion, audit all member transplant center activities pertaining to transplantation of non-US residents/non-US citizens. At member transplant centers where non-US residents/non-US citizens are listed for transplant, the Ad Hoc International Relations Committee shall review the circumstance and justification for listing any non-US resident/non-US citizen traveling to the United States for transplant. The Ad Hoc International Relations Committee will review all citizenship data submitted to the OPTN Contractor. The Ad Hoc International Relations Committee may request that Member transplant centers voluntarily provide additional information about listings or transplants of non-US citizens/non-US residents.

6.3.1 Transparency in Reporting Listings and Transplants of Non-US Citizens/Non-US Residents. The Ad Hoc International Relations Committee shall prepare and provide public access to an annual report of ~~member~~ Member transplant center activities related to the listings and transplantation of non-US citizens/non-US residents.

6.4 Importation of Deceased Donor Organs from Foreign Sources. Members may import deceased donor organs from foreign sources, and in doing so, must adhere to the related policies below.

6.4.1 Formal Deceased Donor Organ Import Agreement. Upon approval by the Board of Directors, a Member may enter into formal, deceased donor organ import agreement with a foreign entity. Each formal agreement cannot exceed two years in duration. A Member that wishes to enter into a formal, deceased donor organ import agreement with a foreign entity must submit a proposal to the Ad Hoc International Relations Committee for review. The proposed deceased donor organ import agreement must:

- 1) Describe the basis for the agreement.
- 2) Describe the expected benefits to the foreign and domestic participants.
- 3) Include credentials of the foreign entity.
- 4) State the number and type of deceased donor organs anticipated for import.
- 5) Outline a plan for reporting the results of the agreement.
- 6) Include a requirement for the donor organization to submit documentation certifying the ~~informed consent~~ authorization of the donor or his or her legal representative.
- 7) Include a requirement for the donor organization to submit documentation certifying that the donor has met the met brain death or donation after ~~cardiac~~ circulatory death (DCD) protocols that are in compliance with recognized US standards for domestic organ procurement.
- 8) Include a requirement for the donor organization to submit documentation of the donor's ABO.

The Ad Hoc International Relations Committee will review each formal agreement every two years.

Each organ imported through a formal agreement must adhere to the requirements listed in 6.4.1.1.

6.4.1.1 Requirements for Importing Deceased Donor Organs through a Formal Agreement. The Member importing any deceased donor organ from a foreign entity must:

- Report the event within 72 hours to the Organ Center.
- Allocate the organ using the Match System, ~~and~~ in accordance with the allocation policy for that organ.
- Provide the minimum required information about the foreign deceased donor organ, as specified in Policies 2 (Minimum Procurement Standards for an Organ Procurement Organization (OPO), 3.5.9 (Minimum Information/ Tissue for Kidney Offer), 3.6.9 (Minimum Information for Liver Offers), 3.7.12 (Minimum Information for Thoracic Organ Offers, and 3.8.2 (Required Information).
- Comply with the ABO verification requirements in Policies 2 and 3.2.4 (Match System Access).
- Evaluate the organ for transmissible diseases as specified in Policy 4 (Identification of Transmissible Diseases in Organ Recipients).
- Verify that the foreign entity is authorized as a transplant center or organ procurement program by an appropriate agency of its national government.
- Obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

6.4.2 Ad-Hoc Deceased Donor Organs Imported from outside of the United States. A Member may import a deceased donor organ recovered outside of the United States without a formal agreement (6.4.1). An ad-hoc imported of a deceased donor organ must meet all the requirements in 6.4.1.1. Except, the The Member must notify the Organ Center immediately so that the OPTN contractor Contractor can allocate the organ using the Match System, and in accordance with the allocation policy for that organ.

If the The Member importing the organ is an OPO, in addition to the requirements listed above, the OPO must provide the following to the OPTN contractor:

- Documentation certifying that the donor has met brain death or donation after ~~cardiac~~ circulatory death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement;
- Documentation from the donor organization certifying the ~~informed consent~~ authorization of the donor or his or her legal representative; and,
- Documentation from the donor organization verifying the donor's ABO.

The Ad Hoc International Relations Committee will review the circumstances of each deceased donor organ imported without a formal agreement. ~~each Ad-Hoc deceased donor import~~

At its meeting on April 2, the Committee reviewed the final proposal resulting from the modifications agreed upon at the March 21 conference call, and offered no additional comments.

2. Review of Proposals Released for Public Comment – At its April 2012 meeting, the Committee reviewed proposals that were scheduled to be distributed for public comment on March 16, 2012, and provided the following ethics-related feedback to the sponsoring committees:

1. *Proposal to Clarify Priority Status for Prior Living Organ Donors who later Require a Kidney Transplant (Kidney Transplantation Committee).* The Committee discussed the intent of the proposal. It was asked whether the same rationale that supports the initial priority for prior living donors supports the continued priority for retransplant. It was noted that the 4 additional points is roughly the equivalent of 4 years of waiting time for a kidney transplant. The local priority is more important because it elevates the prior living donor above all local candidates except zero antigen mismatches. The approved OPTN/UNOS position is that prior transplantation, in and of itself, should not exclude a patient from being considered for a repeat transplant. However, the policies are unclear as to the applicability of priority for multiple successive retransplants for prior living kidney donors. It was suggested that the priority makes sense for the first kidney transplant but not necessarily for the second or subsequent kidneys. They were not patients previously suffering from renal failure, and those individuals should get the same priority as similarly situated patients. It was asked why the reason for the second transplant is necessarily different from the first? The continued priority for prior living donors makes sense and is supported by the principles of fairness. The award of priority is functionally a reward to the living donor for good behavior for the benefits given to the living donor recipients. It would help if the underlying principle is better defined. Rewarding good behavior may not be an accurate

description, but rather, recognition of the uncompensated risk voluntarily undertaken by the living donor. After additional discussion, the Ethics Committee unanimously supported the proposal. The Committee would also consider granting priority for living donors of other organs, and where the living donor experiences native organ failure. The Committee also discussed the potential matching of priority benefit for organ type, i.e. should there be a liver benefit for a living kidney donor if the prior living donor experiences liver failure? Under the same principles that support the priority for kidney allocation, there should be consideration to grant priority for living donors of other organs. The Living Donor Committee is encouraged to articulate the rationale supporting the policy. If the complications are directly related to the donation event then the priority for that organ type is appropriate.

2. *Proposal to Establish Kidney Paired Donation (KPD) Policy (Kidney Transplantation Committee)*. The Committee determined that there were no ethical issues in this proposal requiring comment.
3. *Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD Program) (Kidney Transplantation Committee)*. The Committee determined that there were no ethical issues in this proposal requiring comment.
4. *Proposal to Allow Transplant Centers to Place Liver Candidates with HCC Exceptions on 'HCC Hold' Without Loss of Accumulated MELD Exception Score (Liver and Intestinal Transplantation Committee)*. The Committee determined that there were no ethical issues in this proposal requiring comment.
5. *Proposal to Revise the Lung Allocation Score System (Thoracic Organ Transplantation Committee)*. The Committee determined that there were no ethical issues in this proposal requiring comment.
6. *Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors (Living Donor Committee)*. The Committee determined that there were no ethical issues in this proposal requiring comment.
7. *Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal (Operations and Safety Committee (OSC))*. The Committee determined that there were no ethical issues in this proposal requiring comment.
8. *Proposal to Require Documentation of Second Unique Identifier (OPO Committee)*. The Committee determined that there were no ethical issues in this proposal requiring comment.
9. *Proposed Changes to the Donation after Cardiac Death (DCD) Model Elements (OPO Committee)*. Robert Hunter, UNOS Staff liaison to the OPO Committee, joined the meeting by telephone and gave a presentation to the Committee regarding the OPO Committee proposal to update and make required the DCD Protocol Model Elements. Mr. Hunter explained the proposed changes to the DCD Model Elements, and that the proposal will now convert these into "Requirements."

The first issue discussed by the Committee involves the change from cardiac death to circulatory death. This change is based on the Uniform Determination of Death Act (UDDA) definition, which defines "death" by cardiac criteria as the irreversible cessation of circulatory or pulmonary functions. It was agreed that the change to circulatory is appropriate, and that it is a good change because it makes the terminology of the bylaws and the community consistent with the UDDA. It

is potentially problematic that literature suggests that DCD donors do not have the *irreversible* cessation of circulatory function but rather the *permanent* cessation of circulatory function. The proposed language confirms that DCD describes death as the irreversible cessation of circulatory function, while a contrary interpretation exists. The Committee believes that it is appropriate to make this change in terminology. When the heart not working regardless of electrical activity, then circulation has ceased and death may still be declared according to state and hospital policies. It is consistent with the law to use this language but the Committee acknowledges that it does not answer all of the potential ethical questions as to when death occurs.

The second issue was about the terminology of withdrawal of medical treatment/support. The Committee offered no comments.

The third question involved the use of the term “disease” in the list of conditions that would permit valid first person consent. The Committee offered no comments about the use of the term “disease.”

The Committee discussed the issue of when donor families were contacted about the potential for DCD donation. Families have expressed concerns that they feel like they have little or no control of the end of life care decisions for their loved ones. One of the options available is organ donation. When first person consent is emphasized, the family role in donation is minimized. First person consent is similar to an advanced medical directive. It was noted that by being on a donor registry, it is not clear that a donor has any idea to what is involved in donation, and how that decision intersects with end of life care decisions.

With respect to the extent of authorization, what is the extent of the consent given when a donor is entered into a registry? The registry indicates an individual’s consent to donate organs, but not consent to all end of life care decisions. What does the public have in mind with respect to first person consent reflected in a donor registry? There was extensive discussion about donors who give first person consent to donation but not to all of the potential procedures that could be performed to maintain a potential donor after death has been declared.

Consent is appropriate for screening tests pre-mortem. While the patient is still alive, normal informed consent practices are still required. A potential donor would likely not want any of the screening tests to jeopardize the patient’s ability to become a DCD donor, and this would be an appropriate disclosure during the informed consent process.

It was asked when should DCD discussion be raised: before; during; or after discussion of withdrawal of care?

The Committee remains concerned that there is not clarity as to where the boundaries of first person authorization in terms of DCD practice recognizing that there is a legal component granting donation after death, and that there is a medical component of practice that must occur pre-mortem. The Ethics Committee does not agree with the OPO approaching the family prior to decision to withdraw treatment or support. The Committee has general concerns that there is a lack of clarity of the boundaries/scope of first person authorization. For example, there is a need to be clear which tests can be fairly included within the authorization given when a person is entered in a donor registry.

It was noted that it is ethically inappropriate to make the OPTN the arbiter on how to describe circulatory death. There is an absence of consensus about the appropriate time period of asystole.

The requirements are clear that the OPO staff have no role in the end of life care yet it was suggested that it is a common practice that it is not the patient's physician who obtains consent for certain procedures performed to maintain the viability of the donor organs. The Committee agrees that the evaluation of the suitability for DCD may ethically occur pre-mortem.

10. *Proposal to Update Data Release Policies (Policy Oversight Committee)*. The Committee determined that there was no ethical issues in this proposal requiring comment.

3. Vascular Composite Allografts (VCA) – The U.S. Department of Health and Human Services issued a notice in the Federal Register indicating its intent to designate Vascular Composite Allografts (VCA) to be organs and within the purview of the OPTN. If this determination is made, the OPTN will need to develop policies for the equitable allocation and distribution of VCAs as well as policies for VCA transplant program requirements, physician and surgeon requirements, data collection and follow-up, monitoring, as well as assessments of how to finance the oversight required for a new area of responsibility. Consistent with a goal previously assigned by the Executive Committee, the Committee intends to assist the policy writing committees at early states in VCA policy development to identify and discuss potential ethical issues related to the policy topics.

Ms. Glazier gave the Committee a presentation on the proposed nine-part definition of a VCA in order to be considered an “organ.” The definition is designed to give maximum future flexibility for additional VCAs that may become subjects of transplantation.

Committee leadership prepared a broad outline of subject areas for potential policy development and determined that several areas were more operational in nature, and thus did not require ethical input such as physician/surgeon criteria. The Committee will be able to provide the most assistance with allocation and matching criteria. It was noted that there are many more criteria to be used in VCA matching than with traditional solid organs. The Department of Defense has been providing significant support for VCA transplantation and there may be a potentially significant number of potential VCA candidates who are veterans.

With respect to matching, it was noted that the existing face transplants have not been zero antigen mismatches. The Committee discussed whether there is there any insight into the VCA scarcity issue? NEOB has only approached families who have already said yes to donation and the conversion rate has been very good. Given the more stringent requirements for face matching, will the demand for face transplants always be less than the supply?

The Committee also discussed authorization considerations unique to VCAs. For prospective VCA donors registered in donor registries, even if the consent is legally sufficient, is such authorization ethically sufficient? For faces, confidentiality will always remain a concern. The success of a face transplant is whether the public appearance is acceptable, which may involve recreating the likeness of the donor.

Based on experiences with other organ transplants, we have a sense of what the equity component of VCA allocation policy might look like but there is an uneven understanding of what VCA utility measures might look like. It could likely take years to collect meaningful sufficient data and measurements. Graft survival is one measure but functionality is another likely measure of utility, especially in the case of limbs.

A subcommittee was formed to work on applying the principles of organ allocation to VCA transplantation. The subcommittee consists of Alexandra Glazier; Richard Demme; and Lisa Florence.

4. Committee Feedback and Planning – The Committee also briefly discussed the Committee Project Evaluation tools and the process to obtain Executive Committee approval for specific projects. Each committee is required to submit project forms to the POC and the executive Committee to ensure that each project is coordinated with the OPTN annual and strategic goals. The Committee believes that it can best inform the policy development process through earlier involvement with the traditional policymaking committees. The Committee reviewed the complete list of approved Committee projects and identified areas that it believes could benefit from early input from the Ethics Committee.

Uncontrolled DCD (UDCD) Protocol Model Elements. Alexandra Glazier and Robert Truog agreed to work with the OPO Committee to assist with their proposed new project to survey UDCD protocols to develop model elements to be included in UDCD protocols.

Kidney Allocation System Development. The following individuals offered to work with the Kidney Committee and provide ongoing monitoring of the developments with the kidney allocation system: Carlos Zayas; Deborah Adey; Mark Fox; and Robert Veatch.

Joint Pediatric Thoracic Group on Pediatric Heart Allocation. Dr. Manuel Rodriguez-Davalos agreed to seek opportunities for the Ethics Committee to provide early feedback to the Joint Pediatric Thoracic Group on Pediatric Heart Allocation.

5. Multi Organ Transplantation – Dr. Peter Reese, Vice Chair, gave an overview to the Committee about the challenges of multi organ transplantation. Lifesaving organs are heart, lung, and liver, and for which there is no replacement therapy. The Policy Oversight Committee (POC) is beginning work to address multi organ allocation and has submitted a memorandum to the several committees including the Ethics Committee with preliminary questions to consider. See Exhibit A. The POC posed the following questions to the Committees to assist its work:

- 1) For those committees with minimum listing criteria: Do you think the minimum listing criteria issues are resolved for your organ and if so, what are the important principles that were used to get there?
- 2) Are there organ combinations for which minimum listing criteria do not exist but should?
- 3) In order to minimize unnecessary multi-organ transplants, are there adjustments needed to the allocation system that will ensure a candidate who does not receive multiple organs (due to failure to meet minimal listing criteria) could get appropriate priority if subsequent to the transplant of the primary organ he/she develops failure of the second organ?
- 4) Are there logistical issues regarding waiting list management surrounding multi-organ listing and transplant that need to be addressed?
- 5) Are there procurement issues that could be addressed in this process?
- 6) If the concept of lifesaving organ is removed, are there key ethical principles your committee feels should be included in a framework for allocating the second organ based on a balance between equity and utility.

It was noted that the existing policy for multi organ transplantation is vague, incomplete, and sometimes conflicting. Selection of whether a multi organ allocation happens often depends on a single OPO staff person. The OPTN needs to understand what is done presently, and then determine what should be done with multi-organ transplant candidates. The Committee has not previously entertained discussions of

multi organ transplantation. Dr. Reese will lead a workgroup and try to develop a document on how to apply the principles of organ allocation in a multi organ transplant framework.

The Committee continued to discuss the issue and asked if there are multiple organs, should they be used to save more candidates rather than fewer, which is a strictly utilitarian view of allocation. Is this type of allocation fair?

The Committee believes that there is probably consensus around minimal listing criteria for multi-organ transplant candidates. Does the present system “privilege” this class of patients with a safety net?

There needs to be additional discussion, and development of the equity and utility tradeoffs on multiple organ transplant cases. We do not presently know how to balance those ethical values. It was noted that some multi organ candidates are waiting for multiple organs because they did not receive a single organ transplant in time to prevent the subsequent organ failure.

Some general questions for the work group to address include: Why is multi organ given priority; and what is the rationale for the ordering of the priorities for competing multi organ candidates? There has not been a thoughtful position on why multi organ allocation is given priority from an ethical principles standpoint. The goal is to develop a product that will be helpful to the Policy Oversight Committee (POC). In addition to Dr. Reese, Lisa Florence; Daniel Bruggemeyer; and Scott Biggins will assist in the development of a response to the POC.

6. Kidney Allocation System – Lainie Ross, MD, was invited to give a presentation of a proposed kidney allocation system, which was developed with Robert Veatch, Sommer Gentry; J. Richard Thistlethwaite and William Parker. Dr. Ross described the current proposed kidney allocation concepts as put forth by the Kidney Committee, as well as the concerns identified by the HHS Office of Civil Rights. A copy of her presentation is attached as Exhibit B.

There is the current system, the age matching proposal as suggested by the Kidney Committee, and a model promoted by Dr. Ross of Equal Opportunity supplemented by Fair Innings (EOFI). From an equity perspective, the current system is fair but is still subject to geographic disparities, which is a weakness that is shared by all of the proposals. In the age matching proposal, the elderly will get far fewer kidneys given the current mismatch of donor and candidate age. Dr. Ross requested the Ethics Committee to insist that any changes to deceased donor kidney allocation give serious attention to equity as well as utility.

There needs to be specific indicators of equity and the EOFI proposal includes two indicators: fair innings and equal opportunity. The Fair Innings approach also promotes efficiency.

It was asked what the effects would be on African American population and diabetics. In particular, what populations would be disadvantaged by the change from the current system to the EOFI proposal? It was suggested that younger patients are more disadvantaged by the current system.

Dr. Ross will give a similar presentation of this system to the Kidney Transplantation Committee at its next meeting.

It was asked how does this responds to the disadvantages in the baseline condition, inequities based on race, geography, and time waiting? Geographic disparities will continue to exist so long as there is a preference for local first allocation.

The next steps would be to request that this proposed system is modeled by the OPTN and then fine tuned for potential inclusion as a national kidney allocation policy. The specific request will be posed to the Kidney Transplantation Committee to use some of its analytic resources to review and evaluate this EOFI proposal.

After the presentation, the group discussed what might be an appropriate path forward. It was shared that in the earlier iterations of the kidney system proposals that equity was much more central to the earlier discussions of the kidney allocation system (KAS) discussions.

It was suggested that the Ethics Committee could share with the Kidney Transplantation Committee that there are no ethical concerns with proceeding with modeling the EOFI proposal. Geography remains a concern in all of the kidney allocation models proposed to date.

The Committee approved the following recommendation which will be transmitted to the Kidney Transplantation Committee:

The Ethics Committee remains concerned that geographical disparities, as a primary inequity, are not being addressed in the current proposal or the Equal Opportunity supplemented by Fair Innings (EOFI) proposal. The Committee does not specifically endorse any proposal, and believes that EOFI appropriately balances efficiency and equity considerations, and we encourage the Kidney Allocation Committee to consider allocating modeling resources to better understand the potential consequences of this approach.

7. Recognize Outgoing Committee Members – Ms. Glazier recognized the members of the Committee whose terms were expiring in June 2012 and thanked them for their service to the Ethics Committee.

Ethics Committee			
Name	Position	March 21, 2012 Teleconference	April 2, 2012 Chicago, Illinois
Alexandra K. Glazier	Chair	X	X
Peter Reese, MD	Vice-Chair	X	X
Manuel Rodriguez-Davalos, MD	Region 1		X
Peter Reese, MD	Region 2	X	X
Carlos F Zayas, MD	Region 3	X	X
Mark Fox, MD, PHD, MPH	Region 4	X	X
Daniel Bruggemeyer, MS	Region 5	X	X
Lisa S Florence, MD	Region 6	X	X
Bhargav M Mistry, MD	Region 7		
Scott Biggins	Region 8		X
Antonio DiCarlo, MD	Region 9	X	
Amy Pope-Harman, MD	Region 10	X	
Robert Sade, MD	Region 11		
Michael E. Shapiro, MD	Immediate Past Chair	X	
Jack Berry	At Large	X	
Kay Kendall, MSW, LISW	At Large	X	X
Robert Veatch, MD	At Large	X	X
Liz Lehr, BSN, MHA	At Large	X	X
Robert Truog, MD	At Large		X
Richard Demme, MD	At Large		X
Isabel Stenzel-Byrnes, MSW	At Large	X	
Deborah Adey, MD	At Large	X	X
Keren Ledin, PhD	At Large	X	X
Teresa Beigay, DrPH	Ex Officio – HRSA		
Bernie Kozlovsky, MD	Ex Officio – HRSA	X	X
James Bowman	Ex Officio – HRSA		
Maryam Valapour, MD	SRTR	X	X
Lainie Ross, MD	Guest		X
William Parker, MD	Guest		X
J. Richard Thistlethwaite, MD	Guest		X
Jason P. Livingston	UNOS Staff – Liaison	X	X
Gloria Taylor	UNOS Staff	X	X
Leigh Kades	UNOS Staff	X	X
Robert Hunter	UNOS Staff		X by phone
Deanna Parker	UNOS Staff		X by phone