

**OPTN/UNOS Ethics Committee
Meeting Minutes
October 2, 2017
Richmond, VA**

**Elisa Gordon, PhD, MPH, Chair
Keren Ladin, PhD, Vice Chair**

Introduction

The Ethics Committee met in Richmond, Virginia on October 2, 2017 to discuss the following agenda items:

1. Opening Remarks
2. Living Organ Donation by Persons with Certain Fatal Disease who Meet the Criteria to be Living Donors
3. White Papers in Development
4. Report on Equity in Access Measuring and Monitoring Equitable Access in Kidney Transplantation
5. Proposed New Projects
6. Discussion Items
7. New Business

The following is a summary of the Committee's discussions.

1. Opening Remarks

The Chair opened the meeting. She welcomed new and returning Committee members. She reviewed the Committee charge which follows: The Ethics Committee considers ethical issues related to organ procurement, distribution, allocation, and transplantation. The committee considers the broader implications presented by such issues and does not consider any individual patient's issues or disputes. It also makes recommendations to the Board of Directors regarding emerging ethical issues in the national transplant network. The goal of the committee's work is to ensure that OPTN policies and activities are consistent with accepted ethical principles.

Summary of discussion:

UNOS' Chief Executive Officer joined the meeting and welcomed Committee members. He provided an overview on the development of the new strategic plan which will reevaluate how resources for projects will be allocated. He stated that all Committees will be asked to consider how they add value and contribute to UNOS/OPTN. He reviewed recent events concerning the white paper addressing financial incentives for living organ donation which the Executive Committee of the Board had not approved for public comment. He explained that the white paper may have been outside the scope of the Ethics Committee because it addressed amending the National Organ Transplant Act (NOTA). A Health Resources Services Administration (HRSA) representative attending the meeting commented that the Committee should address problems, but it would be problematic if the Committee made recommendations on how other parts of the government should change to address problems.

Next steps:

UNOS and HRSA are currently in discussions to define the scope of OPTN Committees.

2. Living Organ Donation by Persons with Certain Fatal Disease who Meet the Criteria to be Living Donors

The white paper was on the consent agenda for regional meeting. Only the Living Donor Committee and the Membership and Professional Standards Committee have provided feedback indicating concerns with the white paper. Public comment from the transplant professional societies is expected but has not been received at this time.

Summary of discussion:

The Committee reviewed responses received during public comment. Of note, the Living Donor Committee was concerned that it might be compelled to modify policy to facilitate living donation by persons with certain fatal diseases. Additionally, the Living Donor Committee opined that the white paper underestimated the complexity of what could need to be considered for the informed consent and psychosocial and medical evaluation of potential donors with certain fatal diseases.

A member asked if stakeholder groups had been contacted to provide feedback on the white paper. The Committee liaison contacted the Amyotrophic Lateral Sclerosis and Muscular Dystrophy organizations requesting feedback on the white paper.

Some public comments questioned if organ donation by persons with certain fatal disease might reduce the number of organs available for transplant suggesting that more organs could be obtained through deceased donation versus living donation. The Committee did not agree with this premise because most patients with certain fatal diseases would not experience brain death and consequently would not be candidates for deceased organ donation.

Some public comments addressed how to evaluate the level of risk to potential donors with certain fatal diseases. Members commented that the Ethics Committee should provide an ethical analysis of organ donation by persons with certain fatal diseases. The Committee agreed that determining the appropriate level of risk was outside the scope of this white paper. The paper clearly proposes that living donation should only be considered if both the potential donor and the transplant center mutually agree that the level of risk would be acceptable. A member commented that the level of risk may be less for potential donors with a short life expectancy due to progression of their fatal disease.

The Committee discussed and ultimately supported removing any content regarding living donation prior to physician assisted suicide from the white paper. The Committee determined that the content on physician assisted suicide distracted from the main focus of the white paper. This topic could be reconsidered in the future if it becomes legal in more states.

Committee members discussed the importance of honoring the autonomy of the potential donor rather than focusing on protecting the transplant hospital involved in evaluating the potential donor.

Next steps:

Committee leadership will revise the white paper based on public comment and contact the Living Donor and Membership and Professional Standards Committees to address their concerns. The Committee will contact Not Dead Yet to address their concerns submitted during public comment.

3. White Papers in Development

Manipulation of Therapeutic Strategies to Advance Candidate Priority Status

Summary of discussion:

The title of this white paper has changed several times. The workgroup addressing this white paper determined the focus of the project should be limited to therapeutic manipulations that are not medically necessary. A member opined that it would be unethical to use therapeutic manipulations that increase risk to the candidate without benefit. The white paper will address the ethical principles that should be considered before engaging in therapeutic manipulations to increase a candidate's priority for transplant. Emotional bonds between the candidate and the provider may cause the practitioner to act locally rather than globally. Gaming is a zero sum game. Reducing the wait time for one candidate increases the wait time for another candidate. The white paper will not recommend increased surveillance or policy changes.

A member questioned the benefit of the white paper if it does not lead to policy changes. The white paper could cause members to stop and think about their actions. The OPTN has not previously addressed this topic, therefore some members may not understand that their actions may not be ethical. The white paper may or may not discourage this activity, but at a minimum it could encourage institutional dialogue.

The Committee discussed the prevalence of this problem. Members opined that this is a common problem. Providers may feel forced to take whatever action is needed to increase their patient's access to transplant because the problem is so widespread. A member commented that therapeutic manipulation to increase a patient's status for transplant results in "cheating" other high priority transplant candidates.

Next steps:

The work group will update the current draft to address feedback from the Committee. A draft of the white paper will be sent to other Committees for pre-public comment feedback.

Ethical Considerations for First Person Authorization in the Context of Donation after Circulatory Determination of Death

Summary of discussion:

The lead author provided an update on the development of this white paper. Early in the development of this white paper the work group spent a lot of time trying to address practical and operational considerations. As work on the white paper continued the work group decided the white paper should have a very limited scope and its focus should be limited to an ethical analysis.

Next steps:

The work group will meet to finalize the white paper and will plan to submit it for spring 2018 public comment.

4. Report on Equity in Access Measuring and Monitoring Equitable Access in Kidney Transplantation

Summary of discussion:

A staff member from the UNOS Research Department joined the meeting to provide an update on equity in access for kidney transplantation following implementation of the new kidney allocation system (KAS).

Key findings included:

1. Disparities in access to transplant have decreased post-KAS, suggesting KAS increased equity in kidney allocation
2. This improvement was primarily driven by reduced disparities across the CPRA spectrum, as well as by DSA
3. Remaining disparities are largely attributable to candidate differences in DSA of listing, CPRA, and ABO.

5. Proposed New Projects

Committee members were asked to complete and submit a new committee project form in advance of this meeting.

Summary of discussion:

The author of each new proposed project provided a brief overview of their project. Proposed project titles included:

- Eligibility of Intellectually Disabled Individuals for Transplant
- Organ Transplantation in Undocumented Migrants to the United States
- Stipends to Living Donors from Medicare Funding
- Spending Time with Patients on Dialysis

Next steps:

The Committee will consider these proposed projects during future meetings.

6. Discussion Items

Summary of discussion:

The Committee supported revising an existing white paper titled *General Consideration in Assessment of Transplant Candidacy* to address people with intellectual disabilities.

The Committee will resume work on a white paper addressing multi organ allocation.

The Committee developed four white papers that were last reviewed in 2014. These papers must be reviewed before 2019. The Committee plans to review each of the four white papers to determine if the papers are still accurate and relevant or if the white paper may need modifications.

Next steps:

7. New Business

The Chair announced that the Committee is tentatively scheduled to meet on April 9, 2018 at the Chicago O'Hare Hilton. Members were asked to advise Committee leadership if they have a conflict with the proposed date for the next in-person meeting.

The meeting was adjourned.

8. Other Significant Items

During the lunch break, Committee members toured the National Donor Memorial and were offered an opportunity to visit the UNOS Organ Center.

Upcoming Meeting

- October, 2017