OPTN/UNOS Ethics Committee
Meeting Minutes
April 3, 2017
Chicago, IL

Peter Reese, MD, Chair
Elisa Gordon, PhD, Vice Chair

Introduction

The Ethics Committee met in Chicago, IL on 04/03/2017 to discuss the following agenda items:

1. Opening Remarks
2. Policy Oversight Committee Update
3. Status of Current Projects
4. Drug Overdose Deaths in Organ Donation
5. Acknowledge Members Ending Their Term of Service on the Committee
6. Discussion Items
7. New Business
8. White Paper Work Group Break Outs

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

1. Opening Remarks

Summary of discussion:

The Ethics Committee (the Committee) Chair opened the meeting. He encouraged everyone to participate because all perspectives are important. He welcomed the HRSA representative who was participating remotely and welcomed UNOS' Director of Policy. He announced that a current member of the Committee had been elected to join the OPTN/UNOS Board as a Patient/Family Affairs Representative.

The Chair reviewed the Committee's charge:

> *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.*

The Committee liaison demonstrated how to access and use the new OPTN Archive to search for resources.

Next, the Chair introduced an ice breaker activity. Members were asked to briefly re-introduce themselves and two answer two questions. What is your favorite movie? What is one fact about you that most people don't know (e.g. a skill, hidden talent or interest)?

2. Policy Oversight Committee Update

Summary of discussion:

The vice Chair provided a Policy Oversight Committee (POC) update. She explained why the POC reviews projects which included to:

- Assign the project to the correct primary strategic goal (1-5)
- Continue to work towards alignment of the project portfolio with the OPTN Strategic Plan
- Prioritize resources
- Ensure collaboration with key stakeholders and provide feedback to sponsoring committees
- Make a recommendation to the Executive Committee

The vice Chair reviewed the strategic plan and provided an update on the current strategic alignment. She reviewed a list of recent projects approved by the POC and provided information on how the POC reviews and scores proposed projects. In February, the POC approved a new project for the Committee, requested by the OPTN President, and entitled White Paper Addressing the Escalation of Treatment for the Purpose of Advancing a Patient's Status on the Waitlist.

3. Status of Current Projects

Summary of discussion:

Financial Incentives for Organ Donation

The Chair explained that this white paper had been released for spring 2017 public comment but was subsequently removed from public comment due to concerns from some members of the government and the Organ Procurement Organization (OPO) community. There was concern that the white paper was calling for amendments to North American Organ Transplant Act (NOTA). The white paper proposed pilot studies to determine if financial incentives might increase the number of organs available for transplant. The paper acknowledged that NOTA would need to be modified to allow such pilot studies to occur. Additionally, there was some confusion regarding if the white paper was suggesting a pilot study for living donation, deceased donation or both categories of donation.

The Chair explained that the paper has been revised to clarify recommendations regarding a possible pilot study and to clarify the paper is addressing possible financial incentives for living donation.

Next steps:

Prepare final version of this white paper and send it to UNOS leadership and to OPO representatives for review. This white paper should be distributed for public comment in July, 2017.

Honoring First Person Consent and Extending First Person Consent to Include DCD

The lead author led a discussion on the development and status of this white paper. She explained that she agreed to lead the development of this white paper but was unfamiliar with the problems OPOs experience with honoring first person consent. Consequently, she did not know how to frame the problem and how the paper should flow.

A member who leads an OPO explained that most OPO's will proceed to recover organs for potential organ donors who meet brain death criteria and who gave prior first person consent regardless of possible objections by family members. If the patient meets brain death criteria, the OPO has a legal right to procure organs, but if the potential donor has not been declared brain dead it can be problematic. Problems can arise if a potential donor has documented first person consent but does not meet brain death criteria and if the family is not supportive of organ donation. The OPO is prohibited from touching a patient until the patient is declared dead.

The member questioned if there are any differences in how patients who are declared brain dead and Donation after Cardiac Death (DCD) patients would be handled? A member cautioned against considering brain death and DCD differently and recommended against suggesting two different types of deaths may be occurring.

In general Committee members opined that if the potential donor is listed in the donor registry their support for organ donation should be honored. If the family objects, the OPO should make every attempt to gain family support, but if family will not give authorization for organ donation the OPO should proceed with organ recovery. The potential donor's wishes should prevail even if the family remains opposed to organ donation. In such cases, the OPO is asking the family for support but the OPO is not asking the family for permission.

A member commented that family support is important for the medical management of the potential donor. If the family is not supportive, the medical staff involved in the care of the potential donor may not be supportive.

Committee members supported developing a position statement rather than a white paper to address honoring first person consent. Members opined that it could be helpful to have a position statement from the OTPN Ethics Committee in support of honoring first person consent even if the family may object.

Next steps:

Prepare final version of this white paper and send it to the OPO Committee or to the OPO representatives for review. This position statement should be ready for public comment in July, 2017.

Guidance Regarding Organ Donation by Competent Terminally Ill Donors

The lead author led a discussion on the development and status of this white paper.

Committee members were asked to comment on several unresolved issues with the white paper. Members were asked if the white paper should address physician assisted suicide (PAS). A member recommended that PAS should be addressed because it is currently allowed in six states. One member commented that he works with an OPO in an area where PAS is allowed and the OPO is considering how to handle potential donors after PAS. If a potential donor lives in a jurisdiction that has approved PAS then organ donation should be an option. Members commented that it should be important to address the use of life support and code status for potential donors with certain terminal illnesses who may want PAS. In general, members supported the concept of organ donation prior to PAS. A member commented that there could be opposition for religious organizations and disability advocates.

The Committee discussed how the paper should address potential donors with high spinal cord injuries. Specifically, the Committee discussed if there should be a requirement for a waiting period to allow time for helonic adaptation. A member commented that there are no required waiting periods for living donors in existing OTPN policy and suggested the same rules or conditions should apply to patients with high spinal cord injuries.

Next steps:

Prepare a final version of this white paper and send it the Living Donor Committee, and Operations and Safety Committees for review and feedback prior to public comment. This white paper should be ready for public comment in July, 2017.

White Paper Addressing the Escalation of Treatment for the Purpose of Advancing a Patient's Status on the Transplant

The lead author led a discussion on the development and status of this white paper. This white paper is being called the "gaming" white paper for short. The work group developing this white paper has had two previous meetings by conference call. The work group has had some difficulty defining gaming. What's the difference between escalation of care to benefit the patient versus gaming the system? A member suggested that gaming could be defined as practice with the intent to deceive or practice that is clearly outside the professional standard and recognized by the institution. Clear cut examples of gaming could include taking diuretics to raise MELD score or adding vasopressors to increase allocation score, and the use of inotropes without invasive monitoring. Multi listing is a form of a transplant candidate gaming the allocation system that is not prohibited.

A member asked if gaming is a physician autonomy issue or a patient autonomy issue. A member suggested that most patients defer to their doctors so a transplant candidate may not know that gaming may occur. It could be important to comment that organ supply and demand issue contribute to gaming. Is it wrong for a physician to do whatever possible to get an organ transplant for their patient? Advocating for your patient needs to be balanced with advocating for all patients. Gaming is an equity issue. If gaming occurs to advantage one transplant candidate it disadvantages another transplant candidate. A member suggested that if the physician is the steward of an organ they have a duty to ensure it is allocated appropriately. A member suggested that there should be social science research that addresses if physicians have difficulty responding to the general need of the public versus the needs of their patient.

The Committee discussed the prevalence of gaming. A member suggested it is hard to measure gaming because it is an activity that the transplant community will want to hide. The Membership and Professional Standards Committee does not specifically monitor programs for potential gaming. Members suggested that the OPTN should study the prevalence of gaming through data collection, random audits or by providing a whistle blower hot line. Members suggested that the increased use of electronic medical records should make audits and identifying potential gaming of the allocation system easier. A member recounted published reports regarding gaming in Germany that resulted in some physicians going to prison and a drop in donation rates in subsequent years.

A member commented that any allocation that is subject to gaming is not a good allocation system. Liver and heart allocation may be more subject to gaming. Allocation systems work best when the criteria are widely understood and verifiable. The Committee briefly discussed "safeguarding" and what measure could be used to reduce gaming.

Committee leadership suggested reframing this issue as an equity problem. Gaming is wrong, physicians have a duty to all candidates on the waiting list.

Next steps:

Involve members of the Thoracic Committee in this project. Prepare final version of this white paper for review by other Committees prior to public comment. This white paper should be ready for public comment in July, 2017.

4. Drug Overdose Deaths in Organ Donation

A member of the UNOS Research department joined the meeting via web conference to lead a presentation entitled Drug Overdose Deaths in Organ Donation.

She reported recent data revealing that 129 people per day are dying from opioid abuse or overdoses. These deaths have contributed to an increase in organ donors (12.6%) whose

deaths are related to drug abuse. Regions 1, 2, 9 and 10 had the highest percentage of donor deaths related to drug abuse.

These deaths tend to involve younger potential organ donors with few comorbidities but typically are considered higher risk donors. Organs from these donors, and especially kidneys, are underutilized and may be discarded due to concerns with potential disease transmission. The risk of dying while a candidate is on the waitlist is much higher than the risk of disease transmission from a higher risk donor.

OPTN collects data on drug related deaths through the Deceased Donor Registration (DDR) form but it does not capture details on the type or dosage of the drug.

DonorNet® captures some information but it does not collect the details on the type or dosage of the drug, the history or duration of drug use, and it does not collect how recently the history of drug use occurred.

A member questioned why some Regions have lower reported deaths. Some deaths might not be correctly categorized as drug overdoses. Some EMS may be using narcan.

5. Acknowledge Members Ending Their Term of Service on the Committee

Summary of discussion:

The Committee Chair acknowledged several Committee members who will end their term of service on June 30, 2017. These members received certificates.

The vice Chair announced the name of the new vice Chair for the 2017-2018 Committee cycle.

The Chair of the Committee was acknowledged for seven years of service on the Ethics Committee. The Chair received a plaque acknowledging this past service.

6. Discussion Items

Summary of discussion:

The Committee briefly discussed and supported revising an existing white paper entitled General Consideration in the Assessment of Transplant Candidacy to address transplant candidates with intellectual disabilities.

7. New Business

Summary of discussion:

The Committee's fall in-person meeting is scheduled for October 2, 2017 at UNOS in Richmond, VA. This will be the first time the Committee has met in Richmond.

8. White Paper Work Group Break Outs

Summary of discussion:

The Committee split into workgroups to continue work on three white papers under development for the next public comment period:

- Honoring First Person Consent and Extending First Person Consent to Include DCD
- Guidance Regarding Organ Donation by Competent Terminally Ill Donors
- White Paper Addressing the Escalation of Treatment for the Purpose of Advancing a Patient's Status on the Transplant

At the conclusion of the break out period the lead author of each white paper provided a brief report on their progress and next planned steps to finalize the white papers.

The meeting was adjourned.

Upcoming Meeting

- May 18, 2017