

**OPTN Ethics Committee
Meeting Minutes
October 15, 2019
Chicago, IL**

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

Introduction

The OPTN Ethics Committee met in Chicago, IL on October 15, 2019 to discuss the following agenda items:

1. Review Committee Charge
2. Social Media Project Update
3. Review of Spring 2020 Projects
4. OPTN Strategic Goals
5. POC Update and Thematic Brainstorm
6. Ethics Project Guidelines
7. Brainstorm New Projects

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

1. Review Committee Charge

The Committee reviewed, discussed and voted on their Committee Charge.

Summary of discussion:

All OPTN Committees were tasked to review and make suggested revisions to update their respective Committee charges. The Committee was asked to review their revised charge before coming to a vote to pass to the OPTN Board for review.

A member asked if there was a Committee that takes on individual patient issues or disputes. UNOS staff clarified that as far as individual patient issues, the Membership and Professional Standards Committee (MPSC) reviews those types of cases. Additionally, the Ad Hoc Disease Transmission Advisory Committee (DTAC) do case reviews.

The Vice Chair stated that the scope of the OPTN Ethics Committee does not pertain to performing case reviews. HRSA staff added that there are other routes for complaints and issues to go through. UNOS has a good process to address those concerns.

A member stated that the word "donation" is not included in the first sentence and asked if this was intended to be inclusive by using the term "procurement". The Committee agreed with this change and included the term "donation" to the first sentence of the Committee Charge.

Another member stated that the Committee charge does not include language to the broader aspirations/goals of the committee. The Committee Chair asked if the other Committee charges include an aspirational goal. UNOS staff stated that most Committees have focused on their purview of the OPTN, not necessarily the goals of the Committee.

The Committee reworded the first sentence of the charge to include, “The Ethics Committee aims to inform the policies and practices of the OPTN related to organ donation, procurement, distribution, allocation, and transplantation so they are consistent with ethical principles.”

The Committee Chair called for a vote. The Committee unanimously approved the revised Committee charge.

Next steps:

- The Committee charge will be submitted to the OPTN Board for review and approval during their December meeting.

2. Social Media Project Update

The Committee received an update on the Living Donor Committee’s project regarding social media use by candidates to solicit donations or potentially find living donors.

Summary of discussion:

The Committee reviewed the outline of the Social Media (SoMe) project:

- Social media usage survey and current best practices query for transplant centers
- White paper group for transplant center guidance
- Practical toolkit development with social media guidance materials for transplant center use

A social media survey was developed to evaluate the variations among transplant programs in the country. The Committee reviewed the results of the survey.

A member stated that in reference to looking at the data from the social media referrals, this information can be assessed further to see what communications are being done to get that many referrals. The Committee Vice Chair asked if the referrals were in regards to people who otherwise the candidate does not know. The presenter clarified that there was not a formal definition for social media referral.

Another member asked what the definition was for social media. The presenter stated that social media refers to Facebook, Instagram, paid websites, commercials and billboards and anything else that was considered a globally speaking social media solicitation.

The Vice Chair stated that looking at the data, it is hard to determine if the donors are a result of social media or if the donors were planning to donate anyway. The presenter replied that the project did not specifically define whether the donations observed were due to social media or through other means.

Another member asked if the issue of patient access had come up. Not everyone uses or has access to social media and/or computers. The presenter confirmed that there were specific questions on the survey to gauge that. This project is geared to be guidance for OPTN members. It will not be a policy, but rather a resource for transplant programs to use.

A member asked what type of feedback is the Ethics Committee being asked to weigh in on. Another member stated that at this point, there are no right or wrong answers. The project is trying to determine if there are common best practices. The member continued that the OPTN should come out with a strong opinion one way or another. By coming out with a guidance document it appears that this would be saying that the OPTN supports the use of social media.

UNOS staff clarified that the guidance would be a project sponsored by the OPTN Living Donor Committee. The OPTN is not making a decision one way or another. If transplant centers use social

media then they have a resource to provide additional information. The Vice Chair added that the role of the Ethics committee is to determine if this project is consistent to ethical principles.

A member stated that this could be dependent on how centers feel about non-directed donation. Each center has different opinions. Some centers will only do family member living donations and not the non-directed donation. How would this information be utilized? It appears that this information is more of a tool that is used for a much broader ethical question.

The Committee Chair stated that the Ethics Committee has a white paper addressing non-directed organ donation that was last updated in 2015. The Committee could discuss reviewing and updating this white paper as a future project.

A member stated that without being prescriptive, it may be appropriate to say formally to transplant programs that they need to have an approach for providing equity and defining how they use social media.

Another member asked if any factors such as socio-economic status (SES) and access to social media were considered? The presenter stated that the project had not gotten that far and that it is mostly to see how the transplant centers currently use social media.

A member stated that there should be guidance included on how to use social media and/or economical resources for those of lower SES status.

Another member asked that as social media becomes more prevalent, are transplant centers eventually going to get overburdened following up on all of the social media requests? The presenter clarified that this information is part of the data that is being collected, and could be found in more detail in the complete data set.

Next steps:

- The Ethics Committee will provide some questions in relation to how the project pertains to ethical principles to the Living Donor Committee.

3. Review of Spring 2020 Projects

The Committee reviewed upcoming projects that are under consideration for Spring 2020 and Fall 2020 public comment.

Summary of discussion:

The Committee reviewed and provided their feedback on the following upcoming projects:

Review of DCD Policy (Organ Procurement Organization (OPO) Committee)

The OPO Committee is working on a project to review and Revise the policy language of *Policy 2.16: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols* in order to give OPOs and donor hospitals more flexibility to include donation discussion as part of end of life discussions. The project has not been presented or voted on by the Policy Oversight Committee (POC), but a workgroup has resumed to begin discussing the project. The proposed plan was for the Committee to be updated and provide their feedback on the proposed policy language during their development.

A member stated that the problem is the process. The time limit for expiration is arbitrarily set. Data should be used to determine what length of time is ethically correct. Being able to utilize all DCD donors could really help impact the waitlist.

The Committee Chair highlighted two white papers that the Ethics Committee worked on in the past. There may be an opportunity to update this information and provide insight on this project.

A member asked if it would be possible to have Ethics Committee members join the workgroup. The Committee Chair stated that the involvement of the Committee would be helpful and encouraged members to reach out to UNOS staff if interested in joining the workgroup to provide further input.

Modifications to Pediatric Heart Allocation

It was identified that many of the extensions made were among candidates with congenital heart diseases and cardiomyopathy. Cardiomyopathy is a broad term and conditions vary for these candidates by age. This project wishes to provide guidance on cardiomyopathy among pediatric patients. Currently, the Thoracic Committee is developing a guidance document. The proposed plan was for the Committee to provide feedback during public comment.

There were no additional comments from the Committee.

Living Donor & Vascularized Composite Allografts (VCA) Committee Project

Both the Living Donor and Vascular Composite Allograft (VCA) Committees will be working on two separate projects:

- Living Donor Committee: Re-evaluation of Policy 14
- VCA Committee: Modifications of the Living Donor Registration (LDR) form and the Living Donor Follow-up (LDF) form to modify data for VCA (for uterus)

The project is currently in the Idea phase with the plan of going to the POC in January or February. There has been acknowledgement that an ethics perspective is important in this project. As the workgroup forms, the Ethics Committee will be asked to volunteer 1-2 members for each workgroup.

There were no additional comments from the Committee.

Update to VCA Transplant Outcomes Data Collection

The VCA Committee is developing a proposal to collect follow up information of children born by uterus recipients. The proposal would modify the Transplant Recipient Registration (TRR) form and the Transplant Recipient Follow-up (TRF) form. The proposed plan was for the Committee to receive updates and provide feedback during the development of this project.

There were no additional comments from the Committee.

SES Status and Access to Transplant

The Minority Affairs Committee (MAC) is developing a data collection proposal to begin collecting some of the significant data regarding transplant candidates socioeconomic status in order to better understand the issue of potential disparate access for individuals with low socio-economic background. The proposed plan was for the Ethics Committee to provide feedback during public comment.

The Committee Chair voiced some concerns about this data collection effort. There is already a lot of published data on this topic over the years. What is new that would help advance this knowledge?

The Vice Chair stated that a lot of modeling on potential implications regarding changes in policies in allocation, presents a gap. It is modeled, but there is not good data in the UNOS database.

A member asked if there were any subjective measures in terms of access. As a dataset marker, this type of variable has a lot of implications for variability from who is being asked (individual vs. transplant program). In putting the dataset together, there needs to be a sense of what are the reasons for getting listed, not getting the data after they are listed.

The member continued that there is a huge amount of data that looks at the complexity and multi-layering of socio-demographic factors. If some of these factors are inadvertently being discredited, there will be a superficial glance of the issue.

Another member stated that this also presents an issue of excluding the patients who don't get listed or referred and should be a population that the Committee analyzes. There needs to be a clear reason for what the data collected will be used for.

Next steps:

- Committee members will be updated on the progression of the featured upcoming projects and any additional involvement needed.

4. OPTN Strategic Goals

The Committee reviewed the OPTN Strategic goals, and project guidelines in preparation for the afternoon project brainstorming session.

Summary of discussion:

The Committee Chair provided an overview of the OPTN Strategic Goals to members.

A member asked if the previous white papers that the Ethics Committee worked on previously are in alignment with the strategic goals. The Committee Chair stated that when the papers were being written they were aligned with the strategic goals at that given time, as the Strategic Goals shift every three years.

UNOS staff clarified that the OPTN Strategic Goals are broader than just policy projects. Within the strategic goals, there are things beyond policy projects that the OPTN targets.

The Committee Chair clarified that the Ethics Committee do not write policy proposals. The Committee writes white papers and there may be some educational guidance materials that the Committee would be asked to weigh in on.

There were no additional comments.

5. POC Update & Thematic Brainstorm

The Vice Chair provided a Policy Oversight Committee (POC) update to members.

Summary of discussion:

Members reviewed the new structure of the POC and proposed strategic policy priorities. Under this new initiative, the POC selected the following themes:

- Continuous distribution
- More efficient donor/recipient matching to increase utilization

- Improved equity for multi-organ and single organ candidates

Committee members were asked to think about these themes when brainstorming project ideas and what ethical issues could the Committee provide guidance on.

A member asked if the Committees would focus on each theme one at a time or if all three themes would be open at the same time. UNOS staff clarified that the themes would be staggered. Since most of the themes are extensive, it will take more than a year to work on projects.

The member continued by asking that in regards to the theme of more efficient donor/recipient matching to increase utilization, is this discussing deceased donors or does it include living donors as well? UNOS staff clarified that this theme would be in regards to deceased donors and it is more in reference to the offer system rather than the referral. Living donors would be considered for future project themes and ideas.

Another member asked if there was a standardized process in selecting the themes. UNOS staff clarified that the POC discussed their criteria for forming project themes. POC leadership then discussed their proposed themes with Board leadership to get their feedback. There were reviews of current literature, current projects by OPTN Committees, and discussions among the transplant community to come up with a list of themes. Those themes were then discussed and voted on by the POC.

Next steps:

- The Committee will continue to share ideas as they brainstorm project ideas.

6. Ethics Project Guidelines

The Committee Chair reviewed the Ethics Committee project guidelines.

Summary of discussion:

A member asked if there was rationale in the guidelines beginning with what should not be done rather than what the Committee should focus their efforts on. The Committee Chair stated that the project guidelines is not a formal document and that these guidelines was more of getting ideas out on how best to outline future projects.

Next steps:

- The Committee will use these guidelines as they brainstorm on new project ideas.

7. Brainstorm New Projects

The Committee brainstormed and discussed new Committee project ideas.

Summary of discussion:

The Committee discussed new project ideas they discussed during their small groups. Each group presented their top project ideas the Committee consolidated the list of project ideas by the following strategic goals:

Increase the number of transplants:

- DCD Heart Procurement: There are two main approaches to how DCD hearts can be recovered. If you reanimate the heart, is the patient still dead?
- Ex Vivo pumping: This is currently not addressed by OPTN policy. At what level should this be applied?

- Ethical Relevance of Statistically Driven Outcomes: Discussing ethical relevance of the outcomes being measured and what may be the better marker to use in driving decisions.
 - The Vice Chair suggested that from an Ethical standpoint, it may be best to select the ethical relevance that should be focused on. Rather than addressing which statistics should be focused on, the Committee should address the ethical principles of using certain statistics.

Promote living donor and transplant recipient safety

- Patients being informed about covert factors in organ donation & transplant: how much should these patients be guided on listing practices, aggressive surgeons and acceptance criteria that have been established by centers. How should patients match themselves to certain centers without knowing this information?
- Transparency of Long-Term Outcomes as an ethical responsibility to living donors: Acknowledging the ethical responsibility to demonstrate a transparent message of the long term outcomes of being a living donor. This should be a broader community message on long term outcomes.
- Outcomes and safety considerations for living donors beyond 2 years (informed consent framework), improving transplant outcomes by operationalizing education post-transplant (resources (multi-sources) to recipients to have better outcomes/longevity), and patients being informed of covert factors in donation and transplantation.
- Ethical framework for uterine transplantation: focus on patient safety and follow up on the children born from uterus recipients.
- Vaccinating and Non Vaccinating Pediatric Transplant Recipients: States vary in their policies regarding non-vaccinated patients. Centers do not have policies regarding non-vaccinated patients and not a center driven contraindication. The challenges of this is that non-vaccinated pediatric patients will come to these centers with other pediatric patients who are immunosuppressed. The ethical implications of this should be addressed.
- Informing living donors of APOL1 genetic testing

Provide equity in access to transplants

- Potential Outcome Measures to Utilization: Addressing transplantation of higher risk recipients and declines of higher risk donors by centers. Additionally, discussion on the socio-economic disparities that are present in the referral evaluation to wait listing and access.
- Social media – access (living donation)
- SES disparities – referral evaluation to wait listing and access
- Re-writing Criteria for Transplantation (CAT)

Multiple Organ Transplantation (MOT)

- Multi-organ transplants in relation to pediatric patients: Establishing priority for pancreas pediatric candidates.

Additional Project Ideas:

- Mismatch of UNOS Strategic Goals vs the major Ethical Principles and how best do they match up?

- The Committee had discussed this project before and agreed that it would be best to draft a memo to the OPTN Board of Directors as they will be looking to update strategic goals next year.
- Current listing criteria of heart candidates (potential collaboration with the Thoracic Committee):
The new policies are very stringent and are limiting the number of people who have access to transplant. Addressing this could help cut down on the number of exceptions and will increase the efficiency of the system.
 - Currently, the Thoracic Committee is working on reviewing Status 2 exceptions and criteria. The Committee voiced interest in being updated as this project develops to review and provide feedback.

The Committee took a ballot vote on their top three project selections from the list they developed. The votes will be tallied and the top project ideas will be discussed by the Committee in further detail during their next meeting.

Next steps:

- The Committee votes will be tallied to determine the top project ideas that the Committee will discuss in further detail during their next meeting.

Upcoming Meetings

- November 21, 2019
- December 19, 2019

Attendance

- **Committee Members**
 - Elisa Gordon
 - Keren Ladin
 - Mahwish Ahmed
 - Randee Bloom
 - Ashton Chen
 - John Entwistle
 - Andrew Flescher
 - Amy Friedman
 - Roshan George
 - Tania Lyons
 - Richard Sharp
 - Catherine Vascik
 - Jeffrey Cooper
 - Glenn Cohen
 - Colleen Reed
 - Robert Veatch
 - Michael Davis
 - Giuliano Testa
- **HRSA Representative**
 - Jim Bowman
- **SRTR Representative**
 - Bryn Thompson
- **UNOS Staff**
 - Joann White
 - Ross Walton
 - Craig Connors
 - James Alcorn
 - Lindsay Larkin
- **Other Attendees**
 - Lisette Theriot