

OPTN Executive Committee

Meeting Summary

April 16, 2024

Webex

Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, Chair

Introduction

The OPTN Executive Committee met via Webex teleconference on 04/16/2024 to discuss the following agenda item:

1. Welcome and Announcements
 - a. eGFR Monitoring Update
2. Ethics Committee Xenotransplantation Memo
3. New Projects from the Policy Oversight Committee*
4. Code of Conduct Work Group Public Comment Proposal*
5. Membership and Professional Standards Committee and Peer Review

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

1. Welcome and Announcements

Dianne LaPointe Rudow, Chair of the Executive Committee, welcomed the committee to the meeting and presented the agenda. Dr. LaPointe Rudow provided an update on incorporating the OPTN and the impact of incorporation on the OPTN Board of Directors. Dr. LaPointe Rudow presented an update on eGFR monitoring currently being done by the MPSC. The most recent update detailed that on March 29, the MPSC reviewed cases and determined next steps for the programs being monitored. She shared that 45 of the 56 programs inquiries were closed with no action as they were found to have implemented the policy appropriately. 11 of the 56 programs will receive feedback from the MPSC to re-review their patients and submit this information to the OPTN in 45 days.

Summary of Discussion:

The committee discussed whether it would be appropriate for the OPTN Vice President of Patient and Donor Affairs to send a letter to members on the impact of eGFR modifications. The committee discussed whether there are best practices that have been identified throughout the eGFR wait time modification work that can be used to educate the entire community moving forward. The committee discussed resources available to members, including a toolkit, webinars, and other OPTN resources.

2. Ethics Committee Xenotransplantation Memo

Andrew Flescher, Chair of the Ethics Committee, presented a memo on xenotransplantation drafted by the Ethics Committee. Dr. Flescher shared that the Ethics Committee is interested in exploring considerations involved in xenotransplantation and noted that some aspects of xenotransplantation clinical trial eligibility and enrollment could impact participant and waitlisted candidate access to deceased donor transplants. He noted that these questions are within the scope of the OPTN and NOTA as the memo evaluates allograft waitlist status, timing, and priority of xenograft recipients. Dr. Flescher explained that the Ethics Committee is seeking approval on the approach of exploring questions further in a white paper.

Dr. Flescher shared that the main questions raised in the memo were:

1. Should eligibility to participate in xenotransplant clinical trial impact the eligibility for timing a patient's initial waitlisting for a deceased donor allograft?
2. Should patients who receive a xenotransplant remain on the allograft waiting list?
3. How should prior receipt of a xenotransplant affect eligibility to be listed for a subsequent deceased donor organ?
4. Should former clinical trial participants with a failed xenograft receive special consideration for subsequent receipt of a deceased donor organ?

Summary of Discussion:

The committee suggested the Ethics Committee share the memo with HRSA as a formal recommendation on behalf of the OPTN. The committee also asked that HRSA consider the memo in approving the Ethics Committee's continued efforts in evaluating the practice of xenotransplantation. The committee discussed the importance of considering the impact that xenotransplantation will have on allograft transplantation in the near future. A representative from HRSA shared that HRSA planned to send a letter to the OPTN President from HRSA on xenotransplantation. The committee decided that the OPTN should wait to receive the letter from HRSA before sending the memo from the Ethics Committee to HRSA.

Next Steps:

The OPTN will wait for HRSA to send their letter to the OPTN President on xenotransplantation before sharing the memo on xenotransplantation from the Ethics Committee. Once the letter is received from HRSA, Dr. LaPointe Rudow shared that she would discuss the contents of HRSA's letter with Ethics Leadership.

3. New Projects from the Policy Oversight Committee*

Jennifer Prinz, Chair of the Policy Oversight Committee (POC), presented two new projects from the POC. Ms. Prinz presented a project from the Histocompatibility Committee to Reduce HLA Critical Discrepancies and Require Reporting to the OPTN and she presented a project from the Ethics Committee on an Ethical Analysis of Allocating Organs Out of Sequence.

Ms. Prinz explained that the purpose of the project from the Histocompatibility Committee to Reduce HLA Critical Discrepancies and Require Reporting to the OPTN is to allow for additional review to determine if any quality steps are required to improve laboratory performance, to collect data on causes of HLA critical discrepancies to inform future policy development, and to disseminate best practices on how to reduce critical discrepancies at each step of the analytical process. Ms. Prinz presented the key metrics of the project, strategic plan alignment, benefit score, a summary of POC's discussion, and their recommendation to the Executive Committee.

Ms. Prinz then presented a white paper from the Ethics Committee on the Ethical Analysis of Allocating Organs Out of Sequence. Ms. Prinz explained that the Ethics Committee is looking to explore the ethical underpinnings of rescue pathways and associated implications for appropriate use. She noted that the white paper will analyze rescue pathways, with the balance of utility, autonomy, respect for persons, and equity in mind. Ms. Prinz presented a summary of the POC's discussion and their recommendation to the Executive Committee on the project.

Summary of Discussion:

While discussing the new project from the Histocompatibility Committee, the Executive Committee discussed the resource needs associated with the project and how these are factored into the project's

benefit score and the OPTN project portfolio. A committee member asked whether this project would pertain to living donors. Ms. Prinz explained that the project does extend to living donors.

When discussing the new project from the Ethics Committee, the Executive Committee discussed whether there should be a more detailed timeline presented with the project instead of the estimated timeline of when the project would go to the Board of Directors for consideration. The committee discussed the title of the proposal and conversed on whether or not the title should include the term “allocations out of sequence”. The committee approved the project and deferred to the Ethics Committee on the semantics associated with the project and project title.

Vote:

The Executive Committee approved the initiation of the projects from the Policy Oversight Committee (POC):

- Reduce HLA Critical Discrepancies and Require Reporting to the OPTN (Histocompatibility)
- Ethical Analysis of Allocation Organs Out of Sequence (Ethics)

4. Code of Conduct Work Group Public Comment Proposal*

Contractor staff presented the proposal to Establish Code of Conduct and Whistleblower Protection Bylaws from an Executive Committee Work Group. They shared that the purpose of the proposal is to document existing practices that encourage participation in the OPTN, to establish processes and protections for anyone to raise concerns with the OPTN, and to document process for reviewing and addressing potential violations of law, ethics, or regulations.

Contractor staff shared that the proposal includes a set of bylaw changes and a proposed code of conduct. They noted that the proposed changes to OPTN bylaws are high-level changes and are binding requirements, whereas the code of conduct is more specific but is easier to modify as necessary.

Contractor staff shared changes that have been made to the proposal since the Executive Committee last received an update on the project. They shared that changes to the OPTN bylaws are focused in the following areas: requirements that the OPTN Compliance Officer be a part of the OPTN Board of Directors, members to sign the OPTN Code of Conduct before they begin their volunteer service, code of conduct complaints be reported to the Board of Directors on a quarterly basis, and a volunteer’s use of their position or title in conjunction with a scientific or professional article. Contractor staff shared that changes to the code of conduct since the Executive Committee’s last meeting include amendments to committee member attendance at regional meetings and including a provision on self-policing and asking volunteers to act in their best judgment when considering conflicts of interest, whether such conflicts are disclosed to the OPTN or not.

Contractor staff shared that the rationale behind the proposal is to clarify protections and emphasis that the OPTN welcomes and encourages different viewpoints, and to clarify expectations for conduct as a volunteer of the OPTN. Contractor staff presented implementation considerations and shared that the proposal would have no impact on transplant centers, but all OPTN volunteers will be required to sign the OPTN Code of Conduct annually.

Summary of Discussion:

The committee discussed the changes in attendance for committee members at regional meetings and noted that participating virtually in a regional meeting was considered as attendance.

The committee discussed the proposal’s inclusion of noting OPTN titles in professional publications and editorials and discussed why the work group thought this was important to include. The committee also

discussed whether the work group should consider including provisions in the code of conduct for volunteers that publish opinion pieces and whether there needed to be provisions in place for these kinds of publications.

Vote:

The committee unanimously approved the following:

RESOLVED, the OPTN Executive Committee approves distributing the proposed Establish Code of Conduct and Whistleblower Protection Bylaws proposal for special public comment from April 17, 2024 to May 17, 2024.

Next Steps:

The proposal to Establish Code of Conduct and Whistleblower Protection Bylaws will go out for public comment. The committee will then consider the feedback received during public comment.

5. Membership & Professional Standards Committee and Peer Review

Dr. Maureen McBride, OPTN Executive Director, shared background on the Membership & Professional Standards Committee (MPSC) peer review process. She shared how the peer review process is conducted and how the confidentiality of the peer review process is imperative to the integrity of the process. Dr. McBride addressed questions that had been received from Executive Committee members recently on how the Executive Committee is involved in the peer review process and why the MPSC conducts their reviews in a confidential process. Committee members noted that they have no knowledge of these incidents, unless they are brought to the committee or the Board for a formal decision, and wondered whether this was a best practice. Dr. McBride shared that the peer review process is kept strictly confidential to everyone, including the Board, to ensure the integrity of the process and to ensure there are no biased opinions in the chance that the Board is asked to make a decision on a member's status in the future.

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Ginny McBride
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Melissa McQueen
 - Richard Formica
 - Valinda Jones
 - Wendy Garrison
- **HRSA Representatives**
 - Aite Aigbe
 - Adrienne Goodrich-Doctor
 - Jennifer Brock
- **UNOS Staff**
 - Anna Messmer
 - Betsy Warnick
 - Courtney Jett
 - Dale Smith
 - Jacqui O'Keefe
 - James Alcorn
 - Julie Nolan
 - Kaitlin Swanner
 - Kieran McMahan
 - Krissy Laurie
 - Maureen McBride
 - Morgan Jupe
 - Shandie Covington
 - Susan Tlusty
 - Susie Sprinson
- **Other Attendees**
 - Andrew Flescher
 - Jennifer Prinz
 - John Lunz
 - Sanjay Kulkarni