

**OPTN Executive Committee
Meeting Summary
January 16, 2024
Webex**

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

Introduction

The OPTN Executive Committee met via Webex teleconference on 1/16/2024 to discuss the following agenda item:

1. Winter 2024 Public Comment Items*
2. New Projects from the Policy Oversight Committee (POC)*
3. eGFR Update
4. Closed Session

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

1. Winter 2024 Public Comment Items*

Erika Lease, Vice-Chair of the Policy Oversight Committee (POC), presented the recommended slate of proposals for Winter 2024 Public Comment. Dr. Lease explained that the POC reviewed these proposals and recommended them to the Executive Committee for release for public comment:

- Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection
- Update on Continuous Distribution of Hearts
- Update Post-Transplant Histocompatibility Data Collection
- Modify Effect of Acceptance Policy
- Concepts for Modifying Multi-Organ Policies
- Refit Kidney Donor Profile Index without Race and Hepatitis C Virus
- Standardize Six Minute Walk for Lung Allocation
- Clarify Requirements for Pronouncement of Death
- Standardize the Patient Safety Contact and Reduce Duplicate Reporting
- National Liver Review Board (NLRB) Updates Related to Transplant Oncology
- Promote Efficiency of Lung Allocation
- OPTN Strategic Plan 2024-2027

A representative from HRSA explained why they do not recommend the OPTN send the Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection concept paper from the Membership and Professional Standards Committee (MPSC) out for winter 2024 public comment. They explained that a directive is imminent from the Secretary of Health and Human Services (HHS) which will request the OPTN to collect data on donor potential. The representative explained that there is significant overlap between the data the secretarial directive will request and the data the concept paper will suggest the OPTN request. The HRSA representative noted that HRSA will be attending all OPTN Regional Meetings this cycle and explaining the directive to members. The secretarial directive will allow for public comment through the Office of Management and Budget (OMB). The representative from HRSA stated that they recommend the concept paper be withdrawn from public comment and be revisited once the secretarial directive has been issued.

Dr. Lease presented how each public comment item aligns to the current OPTN Strategic Plan and the technical implementation estimate of each.

Summary of Discussion:

The committee discussed that the data that may be requested in the secretarial directive and the data included in the concept paper have a significant amount of overlap, but the data included in the concept paper is more extensive. A representative from HRSA was asked whether HRSA is still interested in the feedback they requested from the MPSC and the Data Advisory Committee (DAC) on the directive. The representative from HRSA stated that these committees can submit their feedback through the OMB public comment process. HRSA was asked to provide more detail on the timeline of the directive, and a representative explained that the directive is imminent, they plan to have the data incorporated into the next OPTN data collection package, and the directive will be incorporated into the OPTN by fall 2024.

The committee discussed how the Final Rule allows the Secretary of HHS to direct the OPTN in the data collection process. A representative from HRSA explained that this data directive is due to the Centers for Medicare and Medicaid Services (CMS) informing HRSA that the data currently being collected by organ procurement organizations (OPOs) is insufficient. They also stated that the data collected through the directive will be shared with CMS and may be used for their own purposes. The OPTN Executive Director, Dr. Maureen McBride, shared that the OPTN has been working closely with HRSA throughout this process. She noted that the directive represents a significant change in direction, not only for the MPSC, but for resources.

A representative from HRSA stated that HRSA may be supportive of a revised concept paper from the MPSC in the future, after the secretarial directive. They noted that HRSA is not supportive of the concept paper during the winter 2024 public comment cycle because it conflicts with the secretarial directive. An attendee asked how having an item out for public comment conflicts with the secretarial directive, as they are two separate processes. A committee member suggested that the Executive Committee wait for the secretarial directive to be issued, and then analyze the data that will be collected by the secretarial directive compared to the data that would be collected based on proposed concept paper. Another committee member suggested that the Executive Committee wait for the secretarial directive to be issued, and then if directive has not been issued by a predetermined timeframe, then the Executive Committee will revisit the public comment item.

The Committee Chair suggested that the MPSC comment on the secretarial directive when it is out for public comment through the OMB. The Chair suggested the Executive Committee revisit the concept paper from the MPSC on March 1, 2024 to allow the committee ample amount of time to review the secretarial directive that is expected to be published at the end of January 2024.

Vote:

The OPTN Executive Committee unanimously approved the following items for Winter 2024 public comment:

- Update on Continuous Distribution of Hearts
- Update Post-Transplant Histocompatibility Data Collection
- Modify Effect of Acceptance Policy
- Concepts for Modifying Multi-Organ Policies
- Refit Kidney Donor Profile Index without Race and Hepatitis C Virus
- Standardize Six Minute Walk for Lung Allocation
- Clarify Requirements for Pronouncement of Death
- Standardize the Patient Safety Contact and Reduce Duplicate Reporting

- National Liver Review Board (NLRB) Updates Related to Transplant Oncology
- Promote Efficiency of Lung Allocation
- OPTN Strategic Plan 2024-2027

Due to the impending secretarial directive and feedback from HRSA, the Executive Committee unanimously declined to release the concept paper from the MPSC on Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection. The committee unanimously approved the following resolution to decline the public comment proposal from the MPSC:

RESOLVED, that due to the January 16, 2024, email to OPTN Leadership from HRSA advising that the Secretary of Health and Human Services will imminently direct the OPTN to collect certain data on deceased donor referrals from donor hospitals, and that there is potential confusion for the transplant community if the OPTN distributes for public comment the *OPTN Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection*, the OPTN Executive Committee postpones the *Concepts* paper at this time. The Executive Committee will revisit the paper on March 1, 2024 or upon receipt of the directive.

2. New Projects from the Policy Oversight Committee (POC)*

Erika Lease, Chair of the Policy Oversight Committee (POC), presented two new projects. Dr. Lease presented a proposed White Paper on Examining Ethical Considerations in Access to Living Donation from the Ethics Committee. She shared that the purpose of the project is to analyze ethical implications of equitable access to becoming a living donor. She shared that the project would explore the importance of living donation to the OPTN and transplant community, varied access to becoming a living donor and how to address this, and the differences between providing incentives and removing disincentives. Dr. Lease shared that the analysis from the committee will consider the issues using the principles of utility, equity, and autonomy. She shared that the project would focus on equity in access to living donation to promote greater rates of living donation, as it related to utility.

Dr. Lease shared the other projects the Ethics Committee is currently collaborating on, what OPTN Committees may collaborate on the whiter paper, how the white paper aligns with the strategic plan, the expected technical implementation resources, and the benefit score. Dr. Lease shared the POC's analysis of the white paper and noted that the committee noted their concerns around clarity with the white paper, specifically regarding the complexity of the project.

Summary of Discussion:

Dr. LaPointe Rudow shared that she recently spoke with the Chair of the Living Donor Committee and asked the Living Donor Committee to assess what projects they can bring before the Board in June 2024 to enhance living donation. She suggested that the Executive Committee pause on approving the white paper from the Ethics Committee until the Living Donor Committee brings forward their project ideas in June.

The committee discussed whether the white paper was the best use of the OPTN's resources and whether there were other initiatives the Ethics Committee should be focusing on. A committee member commented that it is not within the OPTN's purview to discuss incentives as it pertains to living donation. Contractor staff noted that the white paper would focus on removing disincentives and not on incentives for living donation. A committee member commented that removing disincentives to living donation is not controversial, so a white paper would not be necessary to explore this. The committee discussed whether an ethical analysis pertaining to equity and removing disincentives from living donation would lead the government to support adding living donor incentives to the OPTN's purview. A representative from HRSA commented that if there is an ethical analysis that identified equity issues in

access to living donation, then this would help further support the activities pertaining to living donation.

A committee member commented that if the Ethics Committee does continue to work on this white paper, then the Patient Affairs Committee should collaborate on the project. A committee member suggested that the topic be explored from both a policy perspective and an ethical perspective. Another committee member agreed with Dr. LaPointe Rudow's earlier statement that the white paper be tabled at this time.

Vote:

The committee declined the project proposal from the Ethics Committee on a White Paper on Examining Ethical Considerations in Access to Living Donation.

New Project: Centralized Reporting of Stored Extra Vessels

Dr. Lease presented a project from the Operations and Safety Committee (OSC) on Centralize Reporting of Stored Extra Vessels. Dr. Lease shared that the project is based on a referral from the MPSC to re-evaluate extra vessel policy, specifically for the OSC to address the 14-day extra vessel storage timeframe as stated in *OPTN Policy 16.6.B: Extra Vessel Storage*. She shared that the committee reviewed and decided to begin with a concept paper that would outline the topic, provide recommendations, and solicit feedback. The project would focus on defining or recommending extra vessel storage time periods, analyze Hepatitis C and B requirements, analyze OPO practices and processes for extra vessels, understand the impact on living donor or re-transplant, discuss packaging and labeling requirements, and review the tracking or sharing of extra vessels. Dr. Lease also shared the collaborating committees, strategic plan alignment, technical resources, and the benefit score.

Summary of Discussion:

The committee discussed whether this project was something the OSC should be focusing on, or if there are other projects for the OSC that align with the work of the Expedious Task Force. The committee discussed that the use of OPTN resources should focus on efficiency, and that the POC and the Executive Committee should focus on approving projects that are the best use of the OPTN's resources.

The committee discussed why the project was a concept paper and not a policy proposal. Dr. Lease shared that the committee wanted a concept paper to gather more evidence and input from the community to understand the entirety of the issue before issuing a policy proposal. The committee discussed the process of storing vessels and how this process differs across member types.

Vote:

The committee declined the project proposal on Centralized Reporting of Stored Extra Vessels from the Operations and Safety Committee (OSC).

3. eGFR Update

Dianne LaPointe Rudow, Chair of the Executive Committee, presented an update to the committee on eGFR waiting time modifications that were due on January 4, 2024. Dr. LaPointe Rudow shared that as of January 4, 2024, all centers had submitted their attestations to modify waiting times for candidates affected by race-inclusive eGFR calculations. She shared that HRSA has asked for the OPTN to review the modifications submitted by centers close to the deadline that included no modifications to their waiting lists. Dr. LaPointe Rudow shared the number of programs that this would include, the size of their programs, and the number of Black kidney candidates at each program. A representative from HRSA

shared that HRSA would like to review these members' attestations to ensure no patients are being disadvantaged.

At the end of the discussion, the committee agreed that they would direct the MPSC on next steps.

Summary of Discussion:

The committee discussed whether the MPSC could review member attestations and report back to the Executive Committee on their findings and recommendations. A committee member suggested that instead of reviewing these specific centers, the MPSC could review centers' attestations whose waitlist saw a low percentage of modifications made to their waitlists. They suggested the Executive Committee follow a procedure to ensure consistency on which attestations they are auditing.

Another committee member commented that there was some confusion throughout the community on whether members should measure patients that were pre-emptive to the waitlist, and some situations of not modifying a patient's wait time could have been done by mistake.

The Chair of the MPSC, Zoe Stewart Lewis, shared that the MPSC will discuss the process on how the OPTN can audit members perform at their next meeting.

4. Closed Session

The committee met in a closed session.

The meeting was adjourned.

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Ginny McBride
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Manish Gandhi
 - Melissa McQueen
 - Richard Formica
 - Valinda Jones
 - Wendy Garrison
- **HRSA Representatives**
 - Christopher McLaughlin
 - Frank Holloman
- **UNOS Staff**
 - Alicia Hennie
 - Anna Messmer
 - Cole Fox
 - Dale Smith
 - Jacqui O'Keefe
 - Julie Nolan
 - Kieran McMahan
 - Krissy Laurie
 - Lindsay Larkin
 - Liz Robbins Callahan
 - Maureen McBride
 - Michael Ghaffari
 - Morgan Jupe
 - Nadine Hoffman
 - Roger Brown
 - Ryan Ehrensberger
 - Sharon Shepherd
 - Susan Tlusty
 - Susie Sprinson
 - Tony Ponsiglione
- **Other external attendees**
 - Erika Lease
 - Rick Hasz
 - Zoe Stewart Lewis