OPTN Executive Committee
Meeting Summary
February 20, 2024
Webex

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

Introduction

The OPTN Executive Committee met via Webex teleconference on 02/20/2024 to discuss the following agenda items:

1. Expedited Placement Variance Special Public Comment Review
2. Updates from the Chair
    a. Expeditious Task Force: Securing Commitments
    b. eGFR Monitoring
    c. HRSA Data Directive
    d. Executive Committee Work Groups
3. Updated Summaries of Evidence & Updated Pathogens of Special Interest from DTAC*

1. Expedited Placement Variance Special Public Comment Review

Dianne LaPointe Rudow, Chair of the Executive Committee, provided an update on the Expedited Placement Variance Proposal. Dr. LaPointe Rudow shared that the community suggested various changes to the proposal during the special public comment period, and the community has requested clarifications and more details on the proposal.

Dr. LaPointe Rudow shared feedback from the community included request for more details, questions on how individual protocols would be reviewed, questions around equity, questions about the length of the public comment period, questions about whether protocols would be concurrent or sequential, questions about the drivers of utilization, questions on what organs are eligible, how geographic differences would be considered, and questions about plans to monitor member compliance.

Dr. LaPointe Rudow explained that next steps will include making clarifications within the proposal. The committee will work with the Expeditious Task Force to identify potential future protocols, update the Board on public comment feedback, and host a public town hall in March.

Summary of Discussion:

Committee members discussed the importance of emphasizing that these variances are experiments, and that equity and utility are not mutually exclusive. The committee discussed that it is important for the variances to be tested in consistent ways, and noted that some of the criticism was around misunderstanding. Dr. LaPointe Rudow noted that each plan-do-study-act (PDSA) must have a plan for assessing the results, including the unintended consequences, and this information will be included in the proposal. A representative from HRSA agreed that this information should be included so the community is aware of the process. The representative also suggested that the final document include information about the public comment process for PDSAs.

2. Updates from the Chair

Dr. LaPointe Rudow shared updates with the committee on the Expeditious Task Force, eGFR monitoring, the Health and Human Services (HHS) Data Directive, and the two Executive Committee Work Groups: code of conduct and prioritization.

Expeditious Task Force:

Dr. LaPointe Rudow shared an update on the work of the Expeditious Task Force. She explained that the Task Force is currently creating a work group to help secure commitments throughout the community. She explained that the Task Force and the OPTN can try and create changes throughout the system, but unless there are commitments from the community, then the goals and bold aims of the task force are not going to be achieved. Dr. LaPointe Rudow shared that the task force is hosting a "Transplant Growth Collaborative" where senior leaders from hospitals will be invited to hear from speakers on behalf of the task force. She noted that during these events they will discuss opportunities and barriers to growth, effective practices, and seek specific commitments from attendees. She shared that the work group is seeking OPTN support for these member-hosted events.

Ginny McBride, Executive Committee member and Expeditious Task Force member, noted that the OPO community is incredibly interested in and excited about this work. She shared that the support of national participants, such as the OPTN President, is very important. She noted that the task force hopes to utilize information from these first two events to secure more commitments throughout the community.

Summary of Discussion:

A representative from HRSA asked how these events would be funded. Dr. LaPointe Rudow shared that the only expense the OPTN would incur would be travel expenses for the task force members to attend the events. She shared that as the work continues, the task force may reevaluate funding needs from the OPTN.

eGFR Monitoring:

Dr. LaPointe Rudow shared an eGFR monitoring update. She shared that at HRSA and the Executive Committee's request, the Membership and Professional Standards Committee (MPSC) has discussed and developed a plan to further inquire with kidney programs who submitted an attestation without submitting any or few eGFR wait time modifications. Dr. LaPointe Rudow shared that the MPSC sent letters of inquiry to programs who had Black/African American candidates registered but submitted modifications for fewer than 20% of those candidates. She explained that programs will have 30 days to respond, and all responses are due by March 8. Once responses are received, the MPSC will review the information and determine next steps.

Summary of Discussion:

Committee members discussed feedback from community members who were asked to complete these attestations. A committee member suggested that the OPTN consider how eGFR monitoring is being messaged to the community to ensure that the purpose of the monitoring is not misunderstood. A representative from HRSA suggested that the OPTN send a community update on eGFR monitoring.

HRSA Data Directive:

Dr. LaPointe Rudow provided an update on the Data Directive from HHS that the OPTN received on February 5, 2024. Dr. LaPointe Rudow shared that an initial OPTN communication was sent and that the OPTN met with HRSA on February 14 about the directive. She shared that HRSA requested staff to

provide input on two pre-waitlist forms, aligned with the Data Advisory Committee's (DAC) feedback and form instructions. HHS also requested OPTN staff provide a ventilated patient form that would combine the two drafted forms HRSA provided. The OPTN is requested to provide information on the forms by February 21.

Dr. LaPointe Rudow shared that the OPTN expects the 60-day federal notice to be posted in spring 2024. She explained that a collective OPTN response will be drafted and finalized by the Executive Committee.

Dr. LaPointe Rudow explained that based on community feedback, HRSA is encouraged to provide timely information on next steps and opportunities for engagement. She noted that the DAC chairs received feedback from the community that some of the messaging is confusing, and although HRSA has been presenting information on the directive during regional meetings, the community is unfamiliar with the HHS data directive approach. Dr. LaPointe Rudow shared that it is important for the OPTN to provide information to the community on how the public can comment, and that the OPTN should provide an assessment of the directive. Dr. LaPointe Rudow shared that after the 60-day comment period on the federal register, the Executive Committee will discuss next steps on revisiting the MPSC's concept paper on "Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection."

Summary of Discussion:

A representative from HRSA shared that recommendations from OPTN committees are being considered for the data directive.

Executive Committee Work Groups:

Dr. LaPointe Rudow presented an update on two Executive Committee Work Groups: the Code of Conduct Work Group and the Prioritization Work Group. Dr. LaPointe Rudow shared the project plan for the Code of Conduct Work Group and the progress the group has made. She shared that the work group has discussed volunteer responsibilities and requirements for public statements to include in the code of conduct. She shared that during their next meeting, the work group will finalize provisions and discuss enforcement options and processes.

Dr. LaPointe Rudow provided an update on the Prioritization Work Group. She shared the problem statement the work group is considering, the goal of the work group, and the timeline of the work group's plan. Andrea Tietjen, Chair of the Prioritization Work Group, commented on the work that the group has been focusing on, including analyzing the current process and ensuring that the current prioritization process is the best it can be and is transparent. Ms. Tietjen stated that much of the work group's focus will be around refining the process, communicating what the process is, and having objective tools to demonstrate a thoughtful review. Ms. Tietjen shared that the work group hopes to strengthen oversight throughout the prioritization process to ensure that the OPTN is utilizing its resources in the most efficient way possible.

Summary of Discussion:

A committee member commented that the work of the prioritization work group is key to the future of the OPTN. A committee member commented that at the end of the prioritization work group's efforts, they hope the Policy Oversight Committee (POC) and the Board will have increased alignment.

3. Updated Summaries of Evidence & Updated Pathogens of Special Interest from DTAC*

Presentation Summary:

Dr. Lara Danziger-Isakov, Chair of the Disease Transmission Advisory Committee (DTAC), presented two updated summaries of evidence and an updated pathogens of special interest document on behalf of the committee.

Dr. Danziger-Isakov presented the updated Mpox Summary of Evidence, explaining that the committee reviews the summary of evidence annually. Dr. Danziger-Isakov shared that the document contains information on the background of Mpox, routes of transmission, viral detection and infectivity, screening considerations for donors, testing considerations, and the safety of OPOs, recovery teams, and transplant programs. She shared that updates to the summary of evidence include case numbers to show an increase in cases reported in the United States, the CDC's recommendation for a vaccine, and a "Screening Considerations: Decease Donors" section.

Summary of Discussion:

There were no questions or comments from the committee.

Vote:

The committee approved the following resolution:

> **RESOLVED**, that the updated Summary of Evidence on Mpox, as set forth in the materials distributed, is hereby approved, effective immediately.

Presentation Summary:

Dr. Danziger-Isakov presented an update on the SARS-CoV-2 summary of evidence on behalf of the committee. She shared that the DTAC has updated the summary of evidence on SARS-CoV-2 donor evaluation and testing, as well as organ recovery from donors with a history of COVID-19. Dr. Danziger-Isakov shared that updates to the summary of evidence include:

- Removing the definitions for mild COVID-19, severe COVID-19, and resolved COVID-19,
- Removing the omicron subvariant information,
- Updates to "SARS-CoV-2 Deceased Donor Evaluation Testing" section to simplify CDC recommendations for healthcare personnel during COVID-19 pandemic, revise the number of donors identified as having negative URT but positive LRT SARS-CoV-2 tests, and remove FDA notification on potential false positive and false negative results associated with certain SARS-CoV-2 testing platforms;
- Updates to "Deceased Donors for Non-Lung Transplants" section
- Adds recent analysis of lung transplantation performed in the United States between January 2020 and June 2022
- Adds literature pertaining to SARS-CoV-2 infection, COVID-19 and timing of elective surgery,
- Updates "Timing of Transplant for Recipients with a History of COVID-19 or Incidental Test Positivity at the Time of Organ Offer" section that adds a recent case series that describes transplanting patients with positive SARS-CoV-2 testing at the time of organ offer, and adds another case series describing two successful lung transplant procedures performed on recipients with positive nasopharyngeal SARS-CoV-2 PCRs at the time of transplantation and unclear timing of infection onset.

Summary of Discussion:

There were no questions or comments from the committee.

Vote:

The committee approved the following resolution:

RESOLVED, that the updated Summary of Evidence on SARS-CoV-2, as set forth in the materials distributed, is hereby approved, effective immediately.

Presentation Summary:

Dr. Danziger-Isakov presented the updated Pathogens of Special Interest on behalf of the committee. She shared that OPTN Policy 15.4 requires OPOs to report post-procurement positive results from the pathogens of special interest list to the OPTN through the patient safety portal. Dr. Danziger-Isakov noted that OPOs are required to report all other post-procurement positive results to the transplant hospital and transplant hospitals are required to report all suspected donor-derived transmissions to the OPTN patient safety portal, not just those on the pathogens of special interest list. She noted that OPTN Policy required the DTAC to review the pathogens of special interest annually.

Dr. Danziger-Isakov explained that the recommended change to the document is to add candida auris.

Summary of Discussion:

A committee member asked how the community will be updated on the changes to the documents. Dr. Danziger-Isakov shared that there will be communication with the community and the documents will be available on the OPTN website.

Vote:

The committee approved the following resolution:

RESOLVED, that the updated Pathogens of Special Interest, as set forth in the materials distributed, is hereby approved, effective immediately.

Dr. LaPointe Rudow concluded the meeting by informing the committee that a Transition Work Group would be created to assess recommendations from the Board of Directors on how the OPTN Board should proceed with the changes and transitions in the OPTN contract.

The meeting adjourned.

Attendance

- **Committee Members**
  - Andrea Tietjen
  - Dianne LaPointe Rudow
  - Ginny McBride
  - Jerry McCauley
  - Jim Sharrock
  - Linda Cendales
  - Manish Gandhi
  - Melissa McQueen
  - Richard Formica
  - Wendy Garrison
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Christopher McLaughlin
  - Frank Holloman
- **UNOS Staff**
  - Ann-Marie Leary
  - Anna Messmer
  - Dale Smith
  - Jacqui O'Keefe
  - James Alcorn
  - Julie Nolan
  - Krissy Laurie
  - Liz Robbins Callahan
  - Maureen McBride
  - Michael Ghaffari
  - Morgan Jupe
  - Nadine Hoffman
  - Rebecca Murdock
  - Susie Sprinson
- **Other Attendees**
  - Lara Danziger-Isakov