OPTN Executive Committee
Meeting Summary
February 21, 2023
Webex

Jerry McCauley, MD, MPH, FACP, Chair

Introduction

The OPTN Executive Committee met via Cisco Webex Meetings teleconference on 02/21/2023 to discuss the following agenda items:

1. New Project from the Policy Oversight Committee (POC)*
2. Updates on the Multi-Organ Transplantation Committee Composition*
3. Updated Mpox Summary of Evidence from the Disease Transmission Advisory Committee (DTAC)*
4. Updated SARS-CoV-2 Summary of Evidence from DTAC*
5. Updated Pathogens of Special Interest from DTAC*
6. Letter to HRSA Regarding Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) HOPE Act Recommendations*

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

1. New Project from the Policy Oversight Committee (POC)*

Dr. Nicole Turgeon, Chair of the Policy Oversight Committee (POC), presented a new project sponsored by the Ad Hoc International Relations Committee (AHIRC), Best Practices for Managing International Living Donation in the United States. The guidance document seeks to provide information to transplant programs on how to effectively and efficiently manage international living donors in the United States. Dr. Turgeon noted that the evaluation process is resource-intensive and presents transplant programs with barriers when evaluating international living donors. AHIRC aims to provide programs with recommendations on how to address the obstacles within the evaluation process.

Dr. Turgeon explained that the POC suggested the addition of a collaborator from the Ethics Committee and suggested that as follow-up, AHIRC include metrics that show an increase in international living donors.

Summary of discussion:

A committee member voiced support for the project and noted the difficulty of obtaining a visa for a potential living donor. They thought this would be a great opportunity to facilitate more transplants and ensure donor safety. Dr. Turgeon noted that the POC felt comfortable with the project and wanted the Ethics Committee involved as a precaution. A representative from HRSA thought that the biggest hurdle these donors will face are issues with immigration. They commented that they wanted to ensure donors stayed for the allotted time their visa permitted. Dr. Turgeon responded that this feedback was also provided by the POC. Dr. Turgeon said they would provide this feedback to the AHIRC.

Vote:

The Executive Committee approved the initiation of the new project on Best Practices for Managing International Living Donation in the United States from the Policy

Oversight Committee.

2. Updates to the Multi-Organ Transplantation (MOT) Committee Composition*

Ms. Lisa Stocks, Chair of the Multi-Organ Transplantation (MOT) Committee, presented the proposed updates on behalf of the MOT. The committee proposed a change in the committee dissolution date from June 30, 2024 to June 30, 2026. The committee is currently involved in multiple projects, including continuous distribution, that will extend beyond June 30, 2024. The committee also proposed to remove the committee membership cap of 18 members.

Summary of Discussion:

A committee member asked if there are any skillsets the committee is currently looking to add. Ms. Stocks responded that the committee has been conscious of having a pediatric representative on the committee, along with an intestine representative. The committee has liver representatives but would like a member that is more specialized in intestines. The Executive Committee member asked that a pancreas representative also serve on the committee. Ms. Stocks commented that while there are representatives with pancreas experience on the committee, they could consider increasing the number of pancreas representatives on the MOT to ensure these representatives focus solely on pancreas.

A committee member asked why the MOT had a limit on the number of committee members. Ms. Stocks explained that the MOT would like to extend the number of members past eighteen to ensure there are members that fulfill the different perspectives the committee needs. A committee member voiced their support of the idea of eliminating the cap to ensure that the appropriate perspectives are represented on the committee.

Vote:

The Executive Committee approved that the Ad Hoc Multi-Organ Transplantation Committee, set to dissolve on June 30, 2024, shall instead be dissolved on June 30, 2026. The Executive Committee further approved that the Ad Hoc Multi-Organ Transplantation Committee's membership cap of 18 members, instituted on April 26, 2021, shall be removed, effective immediately.

3. Updated Mpox Summary of Evidence from the Disease Transmission Advisory Committee (DTAC)*

Dr. Stephanie Pouch, Vice Chair of the Disease Transmission Advisory Committee (DTAC), presented an updated summary of evidence on behalf of the committee. This updated summary of evidence addressed requests made by HRSA, OPTN members, and stakeholder organizations. The updated document also reflects collaboration from multiple organizations including the Centers for Disease Control and Prevention, and the Food and Drug Administration.

The revisions in the paper include changing the name from Monkeypox to Mpox, updating case numbers to show a decline in cases, the addition of vaccine effectiveness, the addition of recent studies examining sample collection from multiple body sites, and updating the document annually.

Summary of Discussion:

A committee member asked how DTAC planned to approach Mpox if it were to become less prevalent in the future, or how they would handle other epidemics in the future that eventually disappear. They asked if the committee considered having a summary document for these types of diseases instead of having one document per virus. Dr. Pouch concurred that the committee could move towards having a generalized document. Dr. Pouch commented that the committee has seen the value of this summary of evidence, along with the SARS-CoV-2 summary of evidence, to provide updates to the transplant community as the epidemics or pandemics evolve. A committee member reminded the group that there

was some frustration throughout the transplant patient community over communication surrounding COVID-19 and they voiced their support for acting swiftly and updating the documents as needed.

Vote:

The Executive Committee voted approved the updated Summary of Evidence on Mpox, effective immediately.

4. Updated SARS-CoV-2 Summary of Evidence from DTAC*

Dr. Stephanie Pouch, Vice Chair of the Disease Transmission Advisory Committee (DTAC), presented an updated summary of evidence on SARS-CoV-2. The purpose of the summary of evidence is to analyze the effect of SARS-CoV-2 on donor evaluation and testing, and the effect on organ recovery from donors with a history of COVID-19. There were multiple updates to the summary of evidence including the addition of the Omicron subvariant, the addition of metrics on the success of required lower respiratory SARS-CoV-2 testing for lung donors, the removal of a 21-day horizon for recency of infection, and there were updates made to the considerations for living donor surgery. The summary of evidence also reiterated points the document has stated before including the iteration to continue screening lung donors and modification to the 90-day suggestion of reinfection. The document also suggests the committee update the document annually, or sooner if necessary.

Summary of Discussion:

A committee member asked if the DTAC thought updating the document annually was frequent enough. Dr. Pouch responded that annually seems reasonable given what the community is seeing in terms of epidemiology and outcomes, as well as the data related to outcomes. Dr. Pouch commented that the committee continues to monitor the situation and the committee could update the document if any of the evolving data changed.

Vote:

The Executive Committee approved the updated Summary of Evidence on SARS-CoV2, effective immediately.

5. Updated Pathogens of Special Interest from DTAC*

Stephanie Pouch, Vice Chair of the Disease Transmission Advisory Committee (DTAC), presented the updated pathogens of special interest on behalf of the committee. OPTN Policy requires the DTAC to review the list of pathogens at least annually. 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.

The suggested changes to the document include the removal of all language related to post-transplant recipient reporting requirements and instead have this incorporated into existing education on recipient reporting. The document also suggested adding a brief introduction to explain the use of the document, classifying diseases into categories and include both the common and scientific names, and clarify language around inclusion/exclusion requirements to make it consistent throughout.

The committee recommends the addition of Blastomyces, Mpox, and CVB3 (previously in the “other” category for Acute Flaccis Myelitis). The committee also suggests modification in reporting requirements for Amoebas, Histoplasmosis, and HBV.

Summary of Discussion:

A committee member clarified that reporting pathogens is currently voluntary, to which Dr. Pouch explained that these specific pathogens must be reported if they are detected in any post recovery test

results by OPOs. The committee member then asked if they knew what percentage of these pathogens were being reported. Dr. Pouch responded that there should be a 100% report rate of pathogens in order to adhere to OPTN Policy. Another committee member commented that with their experience in OPOs, that this reporting is a standard policy requirement and OPOs are audited on these results during their site surveys, so they would expect reporting to be close to 100%.

Vote:

The Executive Committee approved the updated Pathogens of Special Interest Document, effective immediately.

6. Letter to HRSA Regarding Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) HOPE Act Recommendations*

Stephanie Pouch, Vice Chair of the Disease Transmission Advisory Committee (DTAC), briefed the committee on a second letter the DTAC wrote to the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) on the OPTN's recommendations on the HOPE Act.

On November 8, 2022 the OPTN initially submitted a letter to the ACBTSA with the OPTN's recommendations. In December 2022, HRSA responded to the OPTN's letter and asked for more information and some clarification on the OPTN's recommendations. The letter presented to the committee, from the DTAC serves as clarification on the OPTN's prior recommendations to the (ACBTSA) and the role that the OPTN would play within these HOPE Act recommendations.

In the clarifying letter, the OPTN stated their concern for the suggestion of new data collection and monitoring for non-kidney and non-liver HOPE Act transplants. The OPTN asks for clarity on who would be responsible for the data collection burden and expressed their concern on what an OPTN "organ specific variance" entails. The letter also expresses the organization's concern with the 15-month timeline to implement the proposed monitoring and proposed data collection. Asking the OPTN to implement within 15-months when this would require public comment, board approval, OMB approval and IT implementation is not an appropriate timeline.

Summary of Discussion:

A committee member commented that they do not understand how kidney and liver were separated from heart and lung in the HOPE Act because immunosuppression across organs is quite similar. They thought that having the OPTN taking on the role of a research organization was not in the OPTN's scope of work, nor is it included in the OPTN Contract. The committee member stated that they would like to start performing HIV-positive kidney and liver transplants outside of a research position, but they also don't want to increase the burden on the OPTN to try and meet the expectations for the non-kidney, non-liver recipients. They asked how they could perform these transplants while also collecting the data that is being asked for non-kidney, non-liver HIV-positive transplants. Dr. Pouch reiterated that in the OPTN's response to HRSA, they advocated for keeping non-kidney, non-liver transplants under the NIH research criteria. A representative from HRSA commented that when it came to splitting the kidney and liver from non-kidney, non-liver transplants it came down to data. There was sufficient data for kidney and liver HIV-positive transplants, but the ACBTSA did not think there was sufficient data for non-kidney, non-liver organs. The committee member was not surprised at the lack of data for non-kidney, non-liver transplants because of the research requirements that are set in place for organizations that want to perform these transplants. They said that if members have to continue with trials, then this could result in a small number of transplants. They commented that they did not believe the ACBTSA appreciated the commonality between transplant recipients' immunosuppression, heart therapy, and the benefit that this could result in.

David Klassen, UNOS Chief Medical Officer, commented that the research requirement for non-kidney, non-liver HIV-positive transplants poses a significant barrier to increasing transplants with HIV-positive organs. With the research requirement, only two heart transplant centers have been able to perform these surgeries and these requirements have created a significant barrier in advancing this area of transplant. He commented that if the research requirement is maintained, then these transplants will not occur, and if they do occur then they will be one-off situations and will not lead to any meaningful data. He believes eliminating the research criteria for all organs is the appropriate pathway forward, with minimal risks, and aligns with the OPTN's recommendations to the Secretary in their initial letter sent on November 8, 2022. A committee member agreed with Dr. Klassen that having non-kidney, non-liver operate under a research requirement would continue to hinder the progress of these transplants for smaller programs across the country. They also stated that requiring the OPTN manage that research would be a huge undertaking for the OPTN.

Vote:

The vote for this item was administered via email due to loss of quorum. After email consideration and vote, the Executive Committee voted unanimously approved the OPTN's letter to HRSA on recommendations for the Advisory Committee on Blood and Tissue Safety Availability to the HHS Secretary, including non-substantive edits subject to the OPTN President's review.

The meeting adjourned.

Attendance

- **Committee Members**
  - Annette Jackson
  - Bradley Kornfeld
  - Jeff Orlowski
  - Jerry McCauley
  - Linda Cendales
  - Matthew Cooper
  - Valinda Jones
- **HRSA Representatives**
  - Frank Holloman
  - Shannon Taitt
- **UNOS Staff**
  - Alex Tulchinsky
  - Anna Messmer
  - Cole Fox
  - Courtney Jett
  - Dale Smith
  - David Klassen
  - Jacqui O'Keefe
  - Maureen McBride
  - Morgan Jupe
  - Rebecca Murdock
  - Susan Tlusty
  - Tamika Watkins
  - Taylor Livelli
  - Tony Ponsiglione
- **Other Attendees**
  - Lisa Stocks
  - Nicole Turgeon
  - Stephanie Pouch