

## **OPTN Executive Committee**

### **Meeting Summary**

**August 19, 2022**

**Conference Call**

**Jerry McCauley, MD, MPH, FACP, Chair**

### **Introduction**

The OPTN Executive Committee met via Cisco Webex Meetings teleconference on 08/19/2022 to discuss the following agenda items:

1. New Project from the Policy Oversight Committee (POC)\*
2. Updated SARS CoV-2 Summary of Evidence\* and Monkeypox Summary of Evidence
3. OPTN Response to CMS CLIA Proposed Rule\*
4. OPTN Response to Systems of Record Notice (SORN)
5. NASEM Report Overview

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

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

Nicole Turgeon, Chair of the Policy Oversight Committee (POC), presented a new project from the Histocompatibility Committee to Review and Update OPTN Histocompatibility Guidance and Policy with Current Practice. Dr. Turgeon presented the POC's analysis around the project and noted any current policy or guidance the project could affect. The project plans to update histocompatibility-related guidance and policies to ensure accuracy, relevancy, and clarity around multiple topics. The topics that will be updated are lab reviews of HLA reports, deceased donor HLA typing, candidate HLA typing, candidate antibody screening, physical crossmatching, virtual crossmatching, and the preservation of excess specimens.

#### Summary of discussion:

A committee member commented that the guidance documents parallel current guidance set forth by the OPTN and noted that they did not think this was a significant change. The committee member highlighted the importance of working towards the same goal to make sure that the OPTN is working with outside agencies in a non-redundant manner. Dr. Turgeon shared that the project would go out for public comment to receive more feedback from the community.

Another committee member emphasized the difference between a committee producing guidance documents as compared with policy. The committee member reminded the group that policy is binding. The member urged the POC to be use caution when moving from guidance to policy. Dr. Turgeon appreciated the feedback and assured them that the current project is a guidance document and if it were ever to become policy, it would go back to the POC for consideration.

#### Vote:

The committee unanimously approved the project from the POC.

## **2. Updated SARS CoV-2 Summary of Evidence and Monkeypox Summary of Evidence\***

Stephanie Pouch, Vice Chair of the Ad Hoc Disease Transmission Advisory Committee (DTAC), presented the updated SARS CoV-2 Summary of Evidence. Dr. Pouch explained that the DTAC has continued to review and update the summary of evidence on a quarterly basis. The two updates to this summary of evidence include current publication references on SARS-CoV-2 positive organ utilization and there is a new section on Omicron subvariants BA.4 and BA.5.

Dr. Pouch shared that the DTAC is developing a Monkeypox Summary of Evidence. The committee has collaborated with other organizations, such as the CDC and FDA, to produce a comprehensive summary of evidence. When the summary is complete, it will be distributed to the committee for a vote via email.

### Summary of discussion:

A committee member asked how much engagement the SARS CoV-2 Summary of Evidence has received since it was first made available to the community. UNOS Staff shared that the document has been viewed 779 times.

### Vote:

The committee unanimously approved the updated SARS CoV-2 Summary of Evidence.

### Next steps:

DTAC will meet August 22<sup>nd</sup> to vote on the Monkeypox Summary of Evidence and once that summary is approved by DTAC, the summary of evidence will be circulated to the Executive Committee for an email vote.

## **3. OPTN Response to CMS Clinical Laboratory Improvement Amendments Proposed Rule\***

Gerald Morris, Vice Chair of the Histocompatibility Committee, presented a response to be submitted to CMS on behalf of the OPTN. The response was in reference to a proposed rule “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories”. In the proposed OPTN response they were supportive of allowing virtual crossmatching and recommended other miscellaneous changes. These recommendations addressed sample drawings for crossmatching (especially for pediatric patients), suggested use the term “immunologic assessment” instead of “test”, and to clarify that donor testing must be performed using molecular methods.

### Summary of discussion:

A committee member asked for clarification on the reconsideration for pediatric candidates. Dr. Morris explained the difficulty of drawing samples for pediatric candidates, to which the committee member suggested guidance stating that pediatric tests do not have to be done on the day of transplant. Another committee member added their sentiments that this is true for all patients. Dr. Morris agreed and explained that response focuses on pediatric patients.

A committee member asked about the parameters of drawing samples. Dr. Morris explained that the Histocompatibility Committee decided this was a clinical judgment. The committee wanted to provide guidance to the community and not advocate for a strict rule. A committee member agreed with the Histocompatibility Committee that it is important for the guidance not to be overly restrictive. A committee member voiced support for the proposed statement.

### Vote:

The Executive Committee unanimously voted to approve the OPTN Response to the CMS Proposed Rule 3326-P. The letter was submitted to the Federal Register.

#### **4. OPTN Response to System of Records Notice (SORN)**

Nadine Hoffman, Director of Data Governance, presented on the OPTN System of Records Notice (SORN). SORN is a required notice for all government agencies under the Privacy Act and details information contained in the records, legal authority for collecting and maintaining the records, how records are used, routine uses, and whether any records are exempt from certain Privacy Act requirements. Changes were most recently made on August 1<sup>st</sup> when HRSA posted the changes on the Federal Register. Ms. Hoffman detailed the changes to the SORN and how they could affect the OPTN.

Most of the changes were expected by the OPTN and are positive changes within the transplant system. The proposed comment from the OPTN will share support for the substantive changes outlined in the SORN and plans to address the benefits of data sharing with healthcare professionals providing clinical care. The Executive Committee will receive a copy of the letter upon completion and will be asked to vote on the response via email.

##### Summary of discussion:

A committee member asked for more explanation on the categories of the individual sections within the document. Ms. Hoffman explained that the changes deal specifically with the Privacy Act and is why the categories are outlined in the SORN. She said that the categories serve as a clarification. HRSA noted that while these policies typically apply to living individuals, deceased donors fall under the Final Rule.

##### Next steps:

Once the response is complete, the Executive Committee will receive a copy of the statement and will be asked to vote on the response via email.

#### **5. NASEM Report Overview**

James Alcorn, Senior Policy Strategist, provided an overview of what actions the OPTN is taking that align with the recommendations from National Academies of Science, Engineering, and Medicine (NASEM) Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System. Mr. Alcorn presented projects OPTN Committees are working on that address various recommendations and how the work aligns with the OPTN Strategic Plan.

Mr. Alcorn focused on three categories of recommendations: to improve equity, to use more donated organs, and to improve the system and system performance. Mr. Alcorn detailed the work the OPTN has completed since these recommendations were published such as implementing a race-neutral eGFR calculation to improve equity and the changes made to MELD calculations to address sex-based disparities. Mr. Alcorn also noted ongoing and future projects that align with the report's recommendations.

##### Summary of discussion:

A committee member asked about the recommendation from the NASEM Report to eliminate preemptive listing or accruing waiting time before a patient starts dialysis to try to improve equity for kidney patients. The committee member disapproved of this recommendation and noted that listing patients sooner and having them accrue wait time is a best practice. The committee discussed opportunities to be proactive with community education on common errors made by histocompatibility labs. The OPTN will continue to keep the committee up to date on projects aligned with the NASEM report.

Next steps:

OPTN Committees are actively reviewing recommendations from the NASEM Report to identify where their work or new projects may coincide with these recommendations. The Policy Oversight Committee (POC) will be prioritizing potential committee projects in the future to address recommendations.

**Upcoming Meetings**

- September 19, 2022
- October 26, 2022
- December 4, 2022

## Attendance

- **Committee Members**
  - Annette Jackson
  - Dianne LaPointe Rudow
  - Jeff Orłowski
  - Jerry McCauley
  - Jim Sharrock
  - Linda Cendales
  - Lloyd Ratner
  - Matt Cooper
  - Valinda Jones
- **HRSA Representatives**
  - Frank Holloman
  - Shannon Taitt
- **SRTR Staff**
  - Ajay Israni
  - Jon Snyder
- **UNOS Staff**
  - Alex Tulchinsky
  - Cole Fox
  - Courtney Jett
  - Delaney Nilles
  - Isaac Hager
  - Jacqui O'Keefe
  - James Alcorn
  - Jason Livingston
  - Laura Schmitt
  - Leonyce Moses
  - Maureen McBride
  - Morgan Jupe
  - Nadine Hoffman
  - Ryan Ehrensberger
  - Steve Harms
  - Susie Sprinson
  - Tina Rhoades
- **Other Attendees**
  - Gerald Morris
  - Nicole Turgeon
  - Stephanie Pouch