

## **OPTN Operations and Safety Committee**

### **Meeting Summary**

**June 27, 2024**

**Conference Call**

**Alden Doyle, MD, MPH, Chair**

**Kim Koontz, MPH, Vice Chair**

### **Introduction**

The OPTN Operations and Safety Committee (“Committee,” “OSC”) met via WebEx teleconference on 6/27/2024 to discuss the following agenda items:

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

1. Update: Re-evaluation of Deceased Donor Testing Requirements
2. Task Force Update: Late Declines Discovery Project
3. Outgoing Members Recognition

#### **1. Update: Re-evaluation of Deceased Donor Testing Requirements**

A call for volunteers will be sent out to form a Workgroup to begin work on the project. The Committee will continue discussions in the development of this project once approved.

### Presentation Summary:

The Committee was provided with an update on the progress of the *Re-evaluation of Deceased Donor Testing Requirements* project. The Committee’s project was reviewed by the OPTN Policy Oversight Committee (POC) and the OPTN Executive Committee with some feedback provided for consideration. The Committee was made aware that a call for volunteers will be sent out to identified stakeholders to form a Workgroup to begin work on the project.

### Summary of Discussion:

A HRSA representative recommended that the Committee refer to the Public Health Service (PHS) guidelines during the review of the deceased donor testing requirement policies.<sup>1</sup> The guidelines, developed by the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), and Food and Drug Administration (FDA) include requirements related to donor testing. It was recommended that the Committee refer to these guidelines to ensure any modifications proposed align with the established guidelines. Staff responded that this point was brought up previously in Committee discussions and was also mentioned in the project outline. The Committee plans to refer to the PHS guidelines and have also identified the OPTN Histocompatibility and Ad hoc Diseased Transmission Advisory Committees as stakeholders to consult on any potential testing requirements reviewed that may relate to the guidelines.

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<sup>1</sup> Seem, DL, Lee, I, Umscheid, CA, Kuehnert, MJ, "United States Public Health Service. PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation," Public Health Reports 128, no. 4 (2013): 247-343.

The Vice Chair reported the feedback from the POC and Executive Committee were supportive of the project and noted that POC recommended re-evaluation of the proposed key metrics for the project. The question posed by the POC related to the key metrics was in reference to the time an offer is sent out and time to get to an acceptance versus (vs) provisional yes. It was recommended that the Committee review the key metrics again and determine if any modifications are needed during the development of the project.

Next Steps:

A call for volunteers will be sent out to form a Workgroup to begin work on the project. The Committee will continue discussions in the development of this project once approved.

**2. Task Force Update: Late Declines Discovery Project**

The Committee will be updated on the progress of the Late Declines Discovery project and provide feedback as needed.

Presentation Summary:

The Committee received an update of the OPTN Expeditious Task Force's (Task Force) Late Declines Discovery project. Currently, there is not a standard definition for late declines, nor an understanding of how often late declines occur. The Task Force hopes to learn more about the reasons behind these declines, as well as finding ways to improve the system through standardization with a voluntary improvement approach through surveys and rapid plan-do-study-act (PDSA) assessments.

The project's first phase (discovery) recently ended. The first phase included the participation of twelve organ procurement organizations (OPOs) who provided feedback on cases of late declines. The data is currently under review; the Committee reviewed preliminary results and will receive a more extensive report of the data collected during an upcoming meeting. A summary of the findings of phase 1 of the project is as follows:

- OPOs used their own definitions for late declines to submit reports
- OPOs reported 211 instances of late declines (48% of reports were livers)
  - Primary Reasons: **Recipient Status, Organ Quality, and Donor History**
- OPOs submitted 11 instances of surgical damage; four of which led to non-use
- One transportation-related report; organ was able to be transplanted

The second phase of the project (refined iteration) will be conducted July – August 2024. The second phase of the project will refine definitions and determine consensus for the late decline, surgical damage and transportation. The feedback during this second iteration will also be refined to obtain more granular details.

Post- Phase 2 of the project will be focused on identifying effective practices currently in place and exploring areas of opportunities to develop effective practices. OPTN Committees and stakeholders will be provided summaries of these findings and recommendations and a webinar or town hall will be facilitated to report out to the broader community and allow the opportunity for dialogue and feedback.

Summary of Discussion:

A member asked if there was a definition for late declines. Staff responded by stating that there is currently not a standardized definition for late declines. From the first phase of the project, it was discovered there was variation in how late declines are defined across OPOs. One of the purposes of this

project is to gather information that would inform the development of a standardized definition for late declines.

The member continued by asking if the new policy requirements related to OPOs acceptance of one organ at a time and how this may impact this project.<sup>2</sup> Staff clarified that the cohort for the first phase of the project predated the implementation of the policy to limit organ offer acceptance to one. Now that the policy is in place, the second phase of the project will give more detail of the impact as it relates to late declines.

Next Steps:

The Committee will be updated on the progress of the Late Declines Discovery project and provide feedback as needed.

**3. Outgoing Members Recognition**

No discussion or action items.
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Presentation Summary:

Outgoing members were recognized for their service on the Committee.

Summary of Discussion:

There were no comments or questions. The meeting was adjourned.

**Upcoming Meetings**

- July 25, 2024 (Teleconference)

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<sup>2</sup> *Modify Organ Offer Acceptance Limit*. OPTN Organ Procurement Organization Committee. July 2023.

## Attendance

- **Committee Members**
  - Kim Koontz
  - Anja DiCesaro
  - Annemarie Lucas
  - Anne Krueger
  - Andy Bonham
  - Jami Gleason
  - Jennifer Smith
  - Megan Roberts
  - Sarah Koohmaraie
  - Nicole Toran
  - Snehal Patel
  - Steven Potter
  - Mony Fraer
- **HRSA Representatives**
  - Marilyn Levi
  - Shelley Tims Grant
  - Penni McMahan
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Joann White
  - Betsy Gans
  - Kaitlin Swanner
  - Kayla Temple
  - Kerrie Masten
  - Laura Schmitt
- **Other Attendees**
  - Bridget Dewees
  - Amanda Bailey
  - Elizabeth Shipman