

## **OPTN Operations and Safety Committee**

### **Meeting Summary**

**April 25, 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 4/25/2024 to discuss the following agenda items:

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

1. Update: Late Declines Discovery Project
2. Review and Discussion: Organ Chain of Custody (OPTN Membership and Professional Standards Committee (MPSC) Project Idea Referral)
3. Follow up: New Project Ideas

#### **1. 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 a presentation on the OPTN Task Force’s (Task Force) Late Declines Discovery project. Currently, there is no standard definition for late declines, nor an understanding of how often late declines occur. The Task Force hopes to learn more about the reasons for late 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 Committee reviewed an outline of the survey that includes questions related to timing of late declines, details of those specific cases, and impacts. The aforementioned survey also includes asking organ procurement organization (OPO) definitions and uses for declines, surgical damages, transportation-related events, and policies and procedures surrounding these events.

At the end of this first iteration of the study, the data would be shared with the Committee; the Committee would provide feedback to help define further iterations of the study and inform potential Committee projects.

#### Summary of Discussion:

The Committee Chair agreed with the Committee helping to monitor data and providing feedback through the progression of this study. The Committee Chair added that this data will give more insight into the day-to-day operations related to the recent topics of the Committee’s work.

The Committee Vice Chair affirmed interest in taking on this work. A member mentioned that this project is important from an OPO perspective because of the extra steps taken by OPOs when late declines happen.

The presenter mentioned that quality improvement is important when applying this data. It was noted that this survey may have some question overlap with other reporting done by OPOs, but this factor may help fill in information gaps.

A member asked how duplicate reporting (patient safety portal versus this study) is being promoted for OPOs. The presenter clarified that the survey and patient portals are two separate prompts for information.

Next Steps:

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

**2. Review and Discussion: Organ Chain of Custody (MPSC Project Idea Referral)**

**The Committee recommends gathering additional information by combining efforts in the Late Declines Discovery project. The Committee will monitor the data collected to better inform next steps.**

Presentation Summary:

The Committee reviewed a project idea referred by the MPSC that proposes establishing chain of custody requirements for all OPTN members involved in organ and vessel transportations to prevent issues related to an increase in cold ischemic time (CIT), organ declines, and delayed cross matching.

Committee leadership recommended rolling this project into data collection efforts for late turndowns and transportation events to gather more information to further inform the Committee.

Summary of Discussion:

The Committee discussed proceeding with the project, as well as the urgency of the project. The Committee Chair found this to be an important project, but raised questions on how this data may be gathered. The Committee Vice Chair stated that combining transportation and chain of custody together into the PDSA previously discussed is reasonable because of their similarities and connection in organ allocation logistics.

A member agreed with data collection being a good first step for the project and asked if the Committee had the bandwidth to work on this project. The Committee reviewed a list of new and currently active projects; staff confirmed said that the Committee does have the bandwidth for this project.

Next Steps:

The Committee recommends gathering additional information by combining efforts in the late declines discovery project. The Committee will monitor the data collected to better inform next steps.

**3. Follow up: New Project Ideas**

**The Committee finalized the outline for the Re-evaluating Deceased Donor Testing requirements project. Staff will develop a project form that will be submitted for the review by the OPTN Policy Oversight Committee (POC) and OPTN Executive Committee.**

**In the interim, Committee members will reach out to their respective hospitals/organizations to get feedback from their colleagues about concerns that can be evaluated in the project. Outreach will also include the OPO, Transplant Administrators and Transplant Coordinators Committees.**

### Presentation Summary:

The Committee reviewed and finalized the outline for a project that would re-evaluate donor testing requirements. The project seeks to identify necessary deceased donor testing requirements and propose modifications. This project will align with the strategic goals of the current goal of increasing the number of transplants and future outlook/goal of optimizing organ use. Efficiency will also be centered regarding the project modifications.

### Summary of Discussion:

The Committee Vice Chair agreed that donor testing requirements should be re-evaluated for relevancy. Staff asked for clarification on the focus of the project and if this included living donor testing. The Committee Chair responded that for the purposes of this project, deceased donors should be evaluated first; there may be potential for a second iteration of this project that addresses re-evaluating living donor testing requirements.

The Committee agreed with the outline of conducting a comprehensive review of deceased donor testing requirements, being cognizant of Public Health Service (PHS) guidelines and Food and Drug Administration (FDA) regulations while reviewing/making recommendations. The Committee also discussed reviewing and auditing *Guidance on Requested Deceased Donor Information*<sup>1</sup> to ensure alignment with any proposed policy modifications and provide updates as necessary. Staff asked the Committee their thoughts on stakeholders to collaborate with on this project. The Committee discussed and identified the following Committees:

- Histocompatibility Committee
- Disease Transmission Advisory Committee (DTAC)
- Organ Procurement Organization (OPO) Committee
- Membership and Professional Standards Committee (MPSC)
- Transplant Coordinators Committee (TCC)
- Transplant Administrators Committee (TAC)

The Committee Chair recommended including the following organ specific Committees: Kidney, Pancreas, Liver and Intestines, Heart. The Committee agreed to include those policies that are organ specific in their comprehensive review of the deceased donor testing requirement policies except for the lung deceased donor testing requirements. The Committee was made aware that the OPTN Lung Transplantation Committee were addressing this policy in a separate project.

The Committee agreed with the project outline. Staff provided an overview of next steps – a project form would be developed which would be submitted to the OPTN Policy Oversight Committee (POC) for their review. If approved, the project would then go to the OPTN Executive Committee for review and approval before the Committee can move forward with the project.

The Committee was tasked in gathering additional information from colleagues at their respective hospitals/organizations to identify concerns that the Committee should consider as follows:

- For OPOs: What testing is the most challenging to obtain?
- For transplant programs: What test results are needed/are you waiting for to better inform a decision on an organ offer?

---

<sup>1</sup> *Guidance on Requested Deceased Donor Information*. OPTN Organ Procurement Organization Committee, June 2018.

The Committee Chair suggested also gathering additional feedback from the following Committees: OPO, Transplant Administrators, Transplant Coordinators.

The Committee will report on their findings at the upcoming Committee meeting on May 23<sup>rd</sup>. There were no further comments or questions.

The meeting was adjourned.

Next Steps:

- Committee members will reach out to their respective hospitals/organizations to get feedback from their colleagues about concerns that can be evaluated in the project. Outreach will also include the OPO, Transplant Administrators and Transplant Coordinators Committees.
- Staff will develop a project form that will include the project outline as discussed. The project form will be submitted to the POC for review/approval. If approved, the project would then go to the OPTN Executive Committee for review and approval before the Committee can move forward with the project.

**Upcoming Meetings**

- May 23, 2024 (Teleconference)
- June 27, 2024 (Teleconference)

## Attendance

- **Committee Members**
  - Alden Doyle
  - Kim Koontz
  - Andy Bonham
  - Anne Krueger
  - Annemarie Lucas
  - Jami Gleason
  - Jennifer Smith
  - Jillian Wojtowicz
  - Kaitlyn Fitzgerald
  - Megan Roberts
  - Sarah Koohmaraie
  - Norihisa Shigemura
  - Snehal Patel
  - Mony Fraer
- **HRSA Representatives**
  - Shelley Tims Grant
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Aileen Corrigan-Nunez
  - Beth Overacre
  - Betsy Gans
  - Cass McCharen
  - Kaitlin Swanner
  - Kate Breitbeil
  - Kayla Temple
  - Kerrie Masten
- **Other Attendees**
  - Bridget Dewees
  - Amanda Bailey
  - Elizabeth Shipman