OPTN Operations and Safety Committee
Meeting Summary
January 25, 2024
Conference Call

Alden Doyle, MD, MPH, Chair
Kim Koontz, MPH, Vice Chair

Introduction

The OPTN Operations and Safety Committee (henceforth the Committee) met via Citrix GoTo teleconference on 1/25/2024 to discuss the following agenda items:

1. Special Public Comment Presentation: Expedited Placement Variance
2. Review and Discussion: Transportation Events Data Collection
3. Overview: In Person Meeting and Pre-Work Assignments

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

1. Special Public Comment Presentation: Expedited Placement Variance

Summary of Presentation:

The Committee received a presentation on the OPTN Executive Committee's *Expedited Placement Variance* proposal.

Summary of Discussion:

The Committee voiced support for the proposal and provided some questions and feedback for consideration. A Committee member asked how long it would take to test an individual variation. Staff responded that this would be dependent on various factors such as how many members sign up, what kidneys are being allocated out of sequence, etc. Staff also added that the more members who sign up with variance ideas, the more data that can be collected and the more rapidly protocols can be tested.

The member then asked if the protocols would be run concurrently or sequentially. Staff stated that there were different opinions on the approaches on this and that it will depend on the protocols that are received to determine which approach would be taken.

The member continued by asking if the OPTN Expeditious Task Force had a goal for the amount of protocols that would be tested during the time the variance is in place. Staff responded that it was known to be a minimum of two, but it is expected that there will be multiple protocols received. If it is found that a protocol works well early on, policy may be developed quickly from there. The member then asked if an OPO were to sign up for a variance, does this mean an organ procurement organization (OPO) is committed to trying out a variance no matter what it is regardless of implications for themselves, or signing up for the opportunity to be involved in variances that they still get an option for? Staff replied that this had been raised up to leadership and welcome additional feedback on ways to structure this.

The member noted that OPOs are currently under high scrutiny and cautioned that OPOs not having the opportunity evaluate the impact of success on their organ placement that a variance would have would

be detrimental. The Committee suggested there being some room for that willingness or there would be challenges to have members sign up for this effort.

Next Steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

2. Review and Discussion: Transportation Events Data Collection

The Committee reviewed and discussed a project referral (by the OPTN Membership and Professional Standards Committee (MPSC) related to data collection of transportation events.

Summary of Presentation:

Background: The MPSC had a proposal titled "Required Reporting of Patient Safety Events" in which they proposed requiring submission of various transportation events to the Patient Safety Portal. Many of the comments expressed an interest in data collection on transportation issues to evaluate causes of delay and the consequences of delay beyond non-use or the intended candidate not receiving a transplant. The MPSC concluded transportation events could not be adequately collected/evaluated through the Patient Safety Portal.

Purpose/Proposal: The MPSC referred this project idea to the Committee that would evaluate causes of delay and the consequences of delay beyond non-use or the intended candidate not receiving a transplant referred this project idea with The Committee and the OPTN Data Advisory Committee were identified as co-sponsors to review and provide a recommendation on the suggested project idea.

Summary of Discussion:

A member asked how this data collection aligned with the Committee's responsibility and charge, specific to transportation events that don't result in a non-transplant. The Vice Chair stated that transportation could represent an operational component to allocation. There would be a need to determine the scope of the project and that there is a need to further define the scope of this project if this were a project the Committee would like to move forward with.

Another member stated that there has been a lot of public scrutiny and asked that if there was not a baseline to report out, is it the Committee's due diligence to respond to the public that this is something that the Committee would monitor and report? The member suggested that it would be beneficial to be able to respond with real data.

A member asked how transport was being defined and if it included other factors such as packaging and labeling. The member continued by stating they experienced an incident the night before and submitted a Patient Safety Event. Upon review of the Patient Safety Event form, the member noted that the form did not include the details needed and asked if the Committee may be able to augment the already existing process to obtain that level of detail.

Another member commented that the data would be interesting to have once the Committee defines what should be considered and the transportation that ultimately impacts the use of an organ. For sentinel events, for example, how often does that happen? From regional meeting discussions, it is apparent that programs are encountering transportation issues; transplant programs also have issues with access to quick and efficient transportation which can impact organ recovery. It is a significant enough problem, and the impact is so significant that it would be beneficial to collect the data. The member continued by commenting that this is operational but was uncertain on if this were a project that Committee should work on or if it should be a self-reported effort, but ultimately suggested that it

is important enough to keep as a project idea as it seems that organs are being lost on account of transportation issues. If there is data that could be shown that would support future legislation and transplant/donation, it would be good to have this information.

The MPSC representative stated that in Public Comment the MPSC received feedback that the "organ did not arrive when expected" was vague and didn't capture scale. The MPSC agreed with this feedback and determined that the Patient Safety Portal was not the appropriate place for that information to be housed. The MPSC felt it would be appropriate for instances leading to non-use and non-utilization to have a place where investigators can look at it and better understand where the broader failure occurred. For other transportation events and other impacts of transportation on organ transplant that still resulted in a transplant, MPSC didn't feel the Patient Safety portal was the right place to report these instances, nor did they feel they were the subject matter experts to monitor these types of cases. The MPSC decided to move forward with board proposal with two transportation events and remove the "organ did not arrive when expected".

A member asked if the Patient Affairs Committee was consulted. Staff responded that at this time, the Committee and the OPTN Data Advisory Committee had been consulted as they were listed as co-sponsors for the project referral. The member clarified that there had been discussions related to the obstacles that have come up recently and wanting to have a baseline of where patients think.

The Vice Chair summarized that the Committee is interested in the project but would like to evaluate any data that may be available to determine how the Committee may propose to move forward with this project. Additionally, the Committee would recommend consulting with the OPTN Patient Affairs Committee for additional perspective and feedback.

Next steps:

Staff will gather additional information that has currently been collected on transportation to share with the Committee to review. The Committee will develop a recommendation on next steps once more information becomes available.

3. Overview: In Person Meeting and Pre-Work Assignments

The Committee was given an overview of the agenda and pre-work for the upcoming in person meeting.

Summary of Presentation:

The OPTN Operations and Safety Committee's in person meeting will be held on Wednesday, February 7th in Richmond, VA. The Committee was provided a preview of the agenda that included the following:

- Offer Filters Update
- Public Comment presentations
  - Promote Efficiency of Lung Allocation
  - Concepts for Modifying MOT Policies request for feedback
  - 2024-2027 Strategic Plan
- Discussion/Breakout Groups: New Project Ideas

An outline of the pre-work and group assignments would be distributed to the Committee members after the call.

Summary of Discussion:

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

Upcoming Meetings

- February 7, 2024 (in person)
- March 28, 2024 (teleconference)

Attendance

- **Committee Members**
  - Kim Koontz
  - Anja DiCesaro
  - Anne Krueger
  - Annmarie Lucas
  - Julie Bergin
  - Jami Gleason
  - Jennifer Smith
  - Jillian Wojtowicz
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Betsy Gans
  - Carlos Martinez
  - Cass McCharen
  - Kayla Temple
  - James Alcorn
  - Kaitlin Swanner
  - Kerrie Masten
  - Laura Schmitt