

**OPTN Operations and Safety Committee
Meeting Summary
October 26, 2023
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 10/26/2023 to discuss the following agenda items:

1. Housekeeping/Updates
2. Vice Chair Nomination and Selection Process
3. Post- Public Comment Review and Follow Up: Deceased Donor Support Therapy Data Collection
4. Overview/Discussion: Standardize the Patient Safety Contact and Duplicate Reporting proposal

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

1. Housekeeping/Updates

Decision: The Committee will be provided with updates. The Committee will discuss the Centralized Reporting of Extra Vessels project further during their November call.

Summary of Presentation:

The Committee was provided an update on the project idea referrals as follows:

- Centralized Reporting of Extra Vessels
 - Status: Further discussion by Committee needed to:
 - Sequence projects
 - Develop project outline
- Organ Labeling Clarification
 - Status: Gathering additional information to determine next steps (policy vs. label change)
 - If label change, will need to determine if impacted by OMB process
- Introduce Pre/Post Transfusion Field
 - Status: Identify active (data collection) project this effort could combine with

Summary of Discussion:

There were no questions or comments.

Next Steps:

The Committee will be provided with updates. The Committee will discuss the Centralized Reporting of Extra Vessels project further during their November call.

2. Vice Chair Nomination and Selection Process

Decision: A call for nominations will be sent out to the Committee as well Committee members of the past five years. Members are encouraged to apply if interested in the Vice Chair role.

Summary of Presentation:

The Committee reviewed the Vice Chair Nomination and Selection process that included an overview of the following:

- Nomination and Selection Goals
 - Increase transparency in the selection process
 - Inform committee of nomination and selection process
 - VC vacancy is announced in the annual call for nominations
 - Promote inclusiveness
 - Full committee and others participate in the nomination process for VC selection
 - Full committee participates in the selection process
 - Thorough review and vetting of VC candidates
 - Interested individuals submit an updated volunteer interest form, personal statement, agree to responsibilities, and meet qualifications
 - Final candidates go through a formal interview process
- Vice Chair Nomination and Selection Process
 - Call for interest: Current committee members and alumni from past 5 years
 - Candidates must meet qualifications in the VC job description and commit to responsibilities
 - If there are more than 4 candidates, candidate information is sent to current committee members to select top 4 candidates
 - Top 4 candidates are interviewed by current chair and/or vice-chair
 - Two finalists are recommended to the OPTN President-Elect for final appointment
- Timeline
 - After this meeting: look for “call for interest email”
 - November: Committee selects top candidates (if more than 4 applicants)
 - December: Leadership and support staff hold interviews with candidates
 - January: Two finalists are submitted to OPTN Vice President, Rich Formica, for final appointment
- Vice Chair Qualifications
 - Service on an OPTN committee within the last 5 years
 - A history of full engagement and participation
 - Knowledge of the OPTN policy development process
 - Ability to cultivate relationships and build consensus
 - A collaborative approach to leading projects and building consensus.
 - Experience in meeting facilitation
 - Systems thinker
 - Leadership acumen
 - Experience as a leader of an OPTN subcommittee or working group, preferred
 - Ability to make a 5-7 year commitment to the OPTN/UNOS
- Preferred Qualifications for Vice Chair
 - Transplant Clinician

Summary of Discussion:

A member asked if patient members can apply. Staff confirmed that any members from the past five years are eligible to apply for the Vice Chair position.

Next Steps:

A call for nominations will be sent out to the Committee as well Committee members of the past five years. Members are encouraged to apply if interested in the Vice Chair position.

3. Post- Public Comment Review and Follow Up: Deceased Donor Support Therapy Data Collection

The Committee reviewed, discussed and came to a vote on post- public comment modifications to the Committee's *Deceased Donor Support Therapy Data Collection* proposal.

Decision: The Committee approved post- public comment modifications will be included in the *Deceased Donor Support Therapy Data Collection* proposal that will go the Board for review and vote during the December 2023 Board meeting.

Summary of Presentation:

The Committee reviewed and discussed the following modifications to the *Deceased Donor Support Therapy Data Collection* proposal:

- *Rewording/clarifying Parent field question* - public comment suggested that data collection incorporates instances where donor is transferred to another hospital; time of admission would be collecting a subset of this information.
 - **Modification:** Parent field question would read, "Were any support therapies initiated?". Additional text includes a note to specify that this includes support therapies initiated from the earliest time of admission to time of cross clamp and would be inclusive of any hospital transfers.
- *Addition of support therapy options* – public comment suggested have to be in alignment of including broad categories of donor support therapies, inhaled therapies should be used (rather than nitric oxide, which is a type of inhaled therapy). Additionally, public comment suggested the inclusion of more granular/specific options within each support therapy options and recommended adding other types of dialysis such as intermittent hemodialysis (iHD), and peritoneal dialysis (PD). Another member suggested the addition of sustained low efficiency dialysis (SLED).
 - **Modification:** The Committee reviewed these comments and agreed to extend the list of support therapy options by adding iHD, PD and SLED as suggested; the support therapies were further modified to categorize each option as follows:
- *Data Definition Modifications/Additions*
 - **Modification:** Data definitions were updated to reflect the modifications made to the support therapy options
- *Removal Ongoing until cross-clamp option* - This option may become a default and not provide accurate data (different process from what is being collected).
 - **Recommendation:** Remove this option. The end date and time fields will be optional in the Donor Data and Matching System but will be required for final data submission in the Data System for the OPTN.
- *Clarification of begin and end date/time fields* – Ensure the start and end date/time fields account for scenarios where a therapy may begin and end on the same day as cross-clamp, but before the actual time of cross-clamp.

- **Modification:** Begin date and End date field description would read, “Start date and time must be before cross-clamp date and time” and “End date and time must be before cross-clamp date and time”, respectively.

Summary of Discussion:

Staff clarified, in regard to the proposed modification to removing the “ongoing until cross clamp” option, in the donor record, the end date and time field is optional if unknown at that point and time, but it would be a required field in the Data System for the OPTN.

A member stated that there may be a number of users putting in the cross clamp date and time for the end date. This change could create additional work for members if the actual date and time is cross clamp. This may ultimately lead to cross clamp being the appropriate answer.

Staff clarified that most data that is submitted to the OPTN Donor Data and Matching System is not entered manually, but instead by the import process. It was believed that most integrators would be importing data rather than using the checkbox. Additionally, the use of the checkbox would require processes needing to be built into the system if the checkbox were added. If the end data and time is the cross clamp date and time, there could be a display to show this.

The member replied that if the majority of the end time observed is cross clamp date and time, a checkbox may be preferential than manual entry. The member voiced support in the proposed modification (removal of the “ongoing until cross clamp” option), but wanted to bring awareness to potential challenges with this change.

The Committee was called to a vote on the post- public comment modifications to the *Deceased Donor Support Therapy Data Collection* proposal as discussed. The Committee voted as follows:

- 12 – Support
- 0 – Abstain
- 0 – Oppose

Next steps:

The Committee approved post- public comment modifications will be included in the upcoming *Deceased Donor Support Therapy Data Collection* briefing paper that will go the Board for review and vote during the December 2023 Board meeting.

4. Overview/Discussion: Standardize the Patient Safety Contact and Duplicate Reporting proposal

The Committee reviewed the OPTN Ad hoc Disease Transmission Advisory Committee’s *Standardize the Patient Safety Contact and Duplicate Reporting* proposal.

Decision: The Committee will follow up with any additional feedback to the sponsoring Committee.

Summary of Discussion:

A member commented on consulting with their program’s staff who would have more insight on this topic to get additional feedback to share. Another member voiced in agreement in having further discussion with their program’s staff as well.

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

Next steps:

The Committee will follow up with any additional feedback to the sponsoring Committee.

Upcoming Meetings

- November 30, 2023 (teleconference)

Attendance

- **Committee Members**
 - Kimberly Koontz
 - Anja DiCesaro
 - Anne Krueger
 - Annemarie Lucas
 - Laurel Avery
 - Jennifer Smith
 - Julie Bergin
 - Kaitlyn Fitzgerald
 - Sarah Koohmaraie
 - Norihisa Shigemura
 - Stephanie Little
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Avery Cook
- **UNOS Staff**
 - Joann White
 - Betsy Gans
 - Kerrie Masten
 - Tamika Watkins
 - Laura Schmitt
 - Lauren Mooney
- **Other Attendees**
 - Stephanie Pouch