

OPTN Lung Transplantation Committee

Meeting Summary

March 10, 2021

Conference Call

Erika Lease, MD, Chair

Marie Budev, DO, Vice Chair

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 03/10/2021 to discuss the following agenda items:

1. Governance and Authority of the OPTN
2. Key Personnel Requirements Revision Project
3. 2021-2024 OPTN Strategic Plan Public Comment
4. Update to Refusal Codes Project

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

1. Governance and Authority of the OPTN

UNOS staff gave a presentation outlining the National Organ Transplant Act (NOTA), the Final Rule, the OPTN contract, OPTN Policies and Bylaws, and how each relates to governance and authority. This was to help the Committee members understand how the four governing structures impact their role while serving on the Committee.

2. Key Personnel Requirements Revision Project

A Membership and Professional Standards Committee (MPSC) representative presented on the public comment request for feedback on Key Personnel Requirements. The presentation covered an outline of proposed changes to update and streamline current requirements for primary surgeons and physicians for transplant programs. The MPSC is requesting Committee feedback on the following topics: a conditional pathway option for programs experience an unanticipated vacancy of a primary surgeon or physician, a pathway option for former primary surgeons and physicians who have not served in the role for 10 plus years, a viable option for foreign equivalency, and defining key personnel being "on-site" as a requirement.

Summary of discussion:

The Committee noted that individuals that meet requirements for the current fellowship pathways for primary surgeon and physician may not encompass the knowledge base needed to lead a transplant program, especially regarding knowledge of the OPTN. Also, the Committee discussed that roles and training programs can have variation in relation to the responsibility and knowledge of OPTN requirements and that should be considered. The Committee felt positively about the goal of the more broad pathways being proposed which aim to alleviate overall experience concerns and barriers.

Next steps:

The Committee was encouraged to provide comments on the MPSC's request for feedback via the OPTN public comment website by March 23, 2021.

3. 2021-2024 OPTN Strategic Plan Public Comment

UNOS staff presented an overview of the 2021-2024 OPTN Strategic Plan that outlined the new OPTN strategic goals and requested the Committee's feedback for this public comment item.

Next steps:

The Committee was encouraged to provide feedback via the OPTN public comment website for the strategic plan by March 23, 2021.

4. Update to Refusal Code Project

UNOS staff provided an overview of the refusal code update project and requested feedback from the Committee. This project aims to update refusal codes to improve areas such as data quality, real-time offer decision making, and to gain better understanding of organ refusals. This project intends to incorporate community feedback on the current refusal codes which includes that the current codes are too vague, confusing, and that they are outdated with a majority of the last updates being in 2004. The project includes eight proposed refusal code categories: Candidate Specific Reasons, Crossmatch Related Reasons, Disease Transmission Risk, Donor and Candidate Matching, Donor Specific Reasons, Logistics, Organ Specific Reasons, and Other. Committee feedback is important because the proposed categories and codes can be tailored to show only what is relevant to each organ type.

Summary of discussion:

Disease Transmission Risk

The Vice Chair asked if there should be more granularity on the "Positive infectious disease screening test: HCV, HBV, CMV, etc." code since this can vary between organ types and centers. She clarified by asking if there would be in interest from a data standpoint to collect which infectious disease specifically caused the refusal. UNOS staff added that they have already received feedback to add a free text field to this code to gather that information and the Vice Chair explained that this would be helpful for the centers to see what is happening in their fields. This was supported by the Committee. A member noted that a free text field may also be beneficial for the "Donor infection/positive culture" code but another member explained that unfortunately free text boxes make it difficult to gather meaningful data. UNOS staff suggested that both check boxes and a free text box could be incorporated. The Committee supported adding check boxes for the more common infectious diseases and cultured bodily fluids in addition to the free text field since there are many different possibilities. UNOS staff asked for feedback for the infections that would be in the check boxes and a member expressed a need for both viral and bacterial meningitis. A member asked if these codes would only incorporate infectious disease or would they include disorders like idiopathic thrombocytopenic purpura (ITP) where transmission of antigens or antibodies is possible and could lead to detrimental outcomes. UNOS staff mentioned that this may be incorporated already in the organ specific refusal codes, but encouraged feedback if the Committee felt it was not sufficiently covered. The Vice Chair suggested splitting the "PHS (Public Health Service) risk criteria or social history" code and UNOS staff stated they have been getting feedback to make it two separate categories and the Chair supported that idea.

Donor and Candidate Matching

The Committee discussed the relevance of the "Donor size – weight" code for lung offers. The Committee considered the need for the weight code in pediatric candidates and also instances where a donor after cardiac death (DCD) is extremely obese and procurement would take too long. UNOS staff suggested leaving this code if there are any circumstances where that code may be used and the Committee supported keeping the code for lung. A member asked how these codes would be reflected

in Heart/Lung offers and UNOS staff explained that all relevant refusal reasons would be shown for each organ in the event of multi-organ offers.

Donor Specific Reasons

The Committee discussed the option for adding more granular options for donor cause of death information since that can affect lung offer acceptance. The Vice Chair specified that the modality of death in a donor can affect outcomes and drive refusals so having that information would be helpful. UNOS staff stated that this information would be housed in DonorNet® and cause of death is filled out when a donor is added and noted that this information may not make sense with a refusal code. A member stated that they did not approve of the specify boxes because it does not provide clear information, but supported the use of those boxes for donor specific reasons such as cancer, history of smoking, emphysema, and asthma. UNOS staff mentioned that many of those would be captured with organ specific reasons and that the social history code would capture smoking history and members agreed, but would opt for putting malignancy with donor specific reasons. A member asked if the “Prolonged downtime/CPR” code is relevant for lung and other members agreed that it would be rare, but there may be instances that it would be used.

Logistics

The Committee discussed the nuance between the “Resource time constraint (OPO, TXC, Donor Hospital, etc.)” and “Transplant team or facility availability” codes and UNOS staff clarified that resource time constraint would refer to scenarios when the logistics between an organ procurement organization (OPO) and transplant center do not align and the transplant team code would be instances where the surgeon is unavailable for example. A member expressed it may be challenging to get members to use those codes because the use may be seen as a red flag for the program but saw the value in leaving it as is. UNOS staff mentioned that the codes were intended to be more general than the current codes to avoid raising red flags and finger pointing.

Organ Specific Reasons

The Chair asked if there was a need to specify imaging for lung which likely falls under the “Unsatisfactory organ specific test results” code but imaging can be pertinent to lung offers. The Chair noted that the “Unsatisfactory organ specific test results” code may potentially end up as a catch-all code and UNOS staff said it has been suggested to add a free text field to collect information and once a list of reasons has been generated the code can be updated to reflect the list. The Chair also asked if there was going to be an option to pick more than one code. UNOS staff said up to two reasons can be selected for refusal, and the Chair suggested rethinking that since it can be multiple reasons that all add up to a refusal. UNOS staff stated that adding a multi-select option would put the project out an additional two plus years, but that they will revisit this topic approximately a year after implementation to evaluate the addition of multi-select refusal codes. A member suggested adding more granularity to the “Organ preservation (pumping issue, not pumped, etc.)” code since this was a topic included in the OPTN strategic goal of increasing transplants presented earlier in the meeting to have that data for review. UNOS staff asked for examples of items that would be included to capture that information and the member stated that the organ no longer being viable after pumping and pump waivers not granted by the OPO should be included.

Next steps:

The Committee was encouraged to provide feedback via the OPTN public comment website for the strategic plan by March 23, 2021.

Upcoming Meetings

- March 18, 2021 (Committee)
- March 25, 2021 (Committee)
- March 31 & April 1, 2021 (Committee)

Attendance

- **Committee Members**
 - Erika Lease, Chair
 - Marie Budev, Vice Chair
 - Alan Betensley
 - Whitney Brown
 - Cynthia Gries
 - Julia Klesny-Tait
 - Jasleen Kukreja
 - Denny Lyu
 - Nirmal Sharma
 - Kelly Willenberg
 - Kenneth McCurry
 - Michael Mulligan
 - Staci Carter
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katie Audette
 - Melissa Skeans
 - Maryam Valapour
 - Andrew Wey
- **UNOS Staff**
 - James Alcorn
 - Julia Chipko
 - Rebecca Goff
 - Elizabeth Miller
 - Janis Rosenberg
 - Susan Tlusty
 - Sara Rose Wells
 - Karen Williams
 - Adel Husayni
 - Krissy Laurie
 - Sally Aungier
 - Sharon Shepherd
 - Sarah Konigsburg
 - Rebecca Murdock
- **Other Attendees**
 - Clifford Miles