OPTN Organ Procurement Organization Committee
Meeting Summary
February 27, 2025
Conference Call

PJ Geraghty, MBA, CPTC, Chair
Lori Markham, RN, MSN, CCRN, Vice Chair

Introduction

The OPTN Organ Procurement Organization Committee (the Committee) met via WebEx teleconference on 02/27/2025 to discuss the following agenda items:

1. Normothermic Regional Perfusion (NRP) Guidance Document - Update
2. Clarify Requirements for Reporting a Potential Disease Transmission
3. Modify Lung Donor Data Collection
4. Establish Comprehensive Multi-Organ Allocation Policy
5. OPTN Allocation Out of Sequence Practices
6. Donation After Circulatory Death (DCD) Policy and Machine Perfusion Work Group Updates

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

1. NRP Guidance Document - Update

Presentation Summary

Project Timeline

September 26th - Executive Committee directive for Operations and Safety Committee to establish requirements for standardized practice in the use of NRP.

October 24th and November 7th - Committee met and developed recommendations for consideration (policy, guidance, data collection)

December 2nd - Board of Directors meeting

December 12th - Report out to Executive Committee

Guidance Document Development

The Operations and Safety Committee consulted with the following OPTN Committees and subject matter experts who have extensive experience in NRP.

- Lung Transplantation
- Vascularized Composite Allograft Transplantation
- Patient Affairs
- Policy Oversight
- Membership and Professional Standards (MPSC)
- Organ Procurement Organization (OPO)
- Heart Transplantation

- Liver and Intestinal Organ Transplantation

Purpose

This guidance provides OPOs and transplant programs with operational considerations to promote the standardization of processes related to the use of NRP in organ procurement. The guidance includes recommendations that identify key personnel and address various processes such as communication, technical standards, credentialing, and date reporting.

HRSA has requested that the voting on the NRP guidance document be paused.

Summary of Discussion:

No decisions were made regarding this agenda item.

There was no discussion regarding this agenda item.

Next steps:

There are no next steps regarding this agenda item.

2. Clarify Requirements for Reporting a Potential Disease Transmission

Presentation Summary

Purpose of Proposal

Clarify transplant program requirements for reporting a potential donor-derived disease transmission event (PDDTE).

- Referral from the OPTN MPSC to define an unexpected PDDTE and clarify lung reporting requirements.
- Differentiate between unexpected and expected PDDTE to determine reporting requirements.
- Distinguish between colonization of an organism vs. a donor-derived infection in the respiratory tract to clarify sick and non-sick lung reporting requirements.

Proposal

The proposal will define a potential unexpected transmission event as a pathogen, disease, or malignancy not known in the donor at the time of cross-clamp. This definition aims to establish a specific time in the donation process when an event is no longer considered an expected event and deemed reportable to the OPO and the OPTN Improving Patient Safety Portal.

This proposal will also distinguish between and identify reporting requirements for sick and non-sick lung recipients. Distinction will allow identification of when there is colonization of an organism (nonstick) vs when there is a donor-derived infection (sick) discovered in the respiratory tract. Sick lung recipients are defined as those with an organism isolated from the respiratory tract or other site that directly contributes to the lung recipient's illness based on the clinical judgement of the treating physician or team. All other lungs not meeting these criteria are considered non-sick lung recipients. Only organisms on the Pathogens of Special Interest list should be reported for non-sick lung recipients.

Summary of Discussion:

No decisions were made regarding this agenda item.

One Committee member asked if there were any plans to change the OPTN policy that requires OPOs to report anything that is reported to them by a recipient center which results in double reporting. The speaker informed the Committee that this was being addressed in another policy proposal that is awaiting implementation.

Next steps:

There are no next steps regarding this agenda item.

3. Modify Lung Donor Data Collection

Presentation Summary

Diagnostic Testing

Tests listed under diagnostic testing include Angiography, Bronchoscopy, Cardiac Catheterization, Chest X-Ray, Computed Tomography (CT)/Magnetic Resonance Imaging (MRI), Echocardiograms, Electrocardiogram (EKG)s, Ultrasounds, Other specify.

The proposal would require OPOs to enter the status of the following tests to run a lung match:

- Bronchoscopy
- Chest CT Scan
- Either an echocardiogram or right heart catheterization

The tests do not need to be completed to run a match run. The OPO can list the test status as Completed, Pending, or Unable to complete. If the status is Unable to complete a reason must be provided.

Chest x-rays are still required to run a match, as under current requirements.

Information regarding diagnostic tests would be reported in the donor summary in the OPTN Donor Data and Matching System.

Upcoming Implementation

A button to bypass Bilateral and Other Lung is due to be implemented on March 26th, 2025. This will allow OPOs to bypass all the bilateral candidates on the match run at once, as well as any candidate who needs a lung of the opposing laterality, once a single lung has been placed.

Summary of Discussion:

No decisions were made regarding this agenda item.

A Committee member noted that this proposal places an additional burden on OPOs by requiring electronic testing information to be entered which can interrupt the workflow of donor management and organ allocation and that this requirement will not resolve the need for back-and-forth communication between OPOs and transplant centers regarding diagnostic testing unless there is a way to electronically push the information to transplant centers. The Chair reminded the Committee that ideally these tests should be completed before making offers to avoid this situation.

Another Committee member asked if the test status would show up in the OPTN Donor Data and Matching System if the OPO entered the information into their electronic records management system. The Speaker said that it would transfer over to the OPTN Donor Data and Matching System. Another

member asked if there was a not done option for diagnostic testing. The Speaker said there is an unable to complete status option which requires a reason if selected.

Next steps:

There are no next steps regarding this agenda item.

4. Establish Comprehensive Multi-Organ Allocation Policy

Presentation Summary

The upcoming policy proposal aims to promote equity in access to transplant among multi- and single-organ candidates to facilitate consistent and efficient allocation. It will standardize the order in which OPOs allocate organs across match runs for highly prioritized candidate groups by using multi-organ allocation tables. The OPOs will enter donor information, run the applicable matches, and the system will generate a donor-specific allocation plan based on the applicable allocation table.

Summary of Discussion:

No decisions were made regarding this agenda item.

The Committee felt that the IT system needs to provide notifications of when an OPO operator needs to switch between the multiple match runs to reduce potential errors and that there needs to be some kind of warning system for if an OPO operator attempts to make an offer on an incorrect match run.

The Committee supports a policy for multi-organ allocation provided it is clear and easy to follow to ensure compliance. The Committee felt that policy would ensure the multi-organ allocation process is trackable, enforceable, and consistent. The Committee agreed that the OPOs should still retain a degree of latitude when allocating certain organs in the event of extenuating circumstances, provided the deviation is well documented.

Next steps:

There are no next steps regarding this agenda item.

5. OPTN Allocation Out of Sequence Practices

Presentation Summary

On February 21, 2025, HRSA published a letter directing the OPTN to create a plan to complete a number of tasks related to allocation out of sequence practices (AOOS) by March 21, 2025. The letter and other communications associated with the initial critical comment are publicly available on the OPTN website. The OPTN is developing the next steps in response to the directive and more information will be shared as it becomes available.

Summary of Discussion:

No decisions were made regarding this agenda item.

There was no discussion regarding this agenda item.

Next steps:

There are no next steps regarding this agenda item.

6. DCD Policy and Machine Perfusion Work Group Updates

Presentation Summary

Machine Perfusion/NRP Data Collection Project Update

The workgroup for machine perfusion and NRP is made up of members from the OPTN Data Advisory (DAC), Heart, Kidney, Liver/Intestine, Lung, Ops and Safety, Pancreas, and Transplant Coordinator Committees. They started in September 2024 and anticipate the proposal will go out for public comment in August 2025 then go to the Board of Directors in December 2025.

The goal of this project is to add data elements to assist with organ offer acceptance practices and outcomes analysis by defining and structuring new data collection to apply to evolving modalities. Currently most of the NRP data elements have been reviewed and the workgroup is beginning to review the machine perfusion data elements.

DCD Policy Review Project Update

The workgroup for DCD policy review is made up of members from the OPTN OPO, Liver, Kidney, Ops and Safety, MPSC, and Ethics Committees. They started work in December 2024 and anticipate the proposal will go out for public comment in August 2025 then go to the Board of Directors in December 2025.

The purpose of this project is to review DCD policies to ensure they are relevant and align with current practice. Currently their discussions center on the timing of family discussion for organ donation. Current policy states that "prior to the OPO initiating any discussion with the legal next-of-kin about organ donation for a potential DCD donor, the OPO must confirm that the legal next-of-kin has elected to withdraw life sustaining medical treatment. The workgroup remains divided on the need to amend this policy.

Summary of Discussion:

No decisions were made regarding this agenda item.

One Committee member noted that blood products used in machine perfusion have been an increasing concern and that the fields for blood products are less than sufficient for multiple reasons. The Chair noted that the workgroup could add some information about blood products use in the machine perfusion process.

Next steps:

- Consider adding blood products used in data elements collected for machine perfusion.

Upcoming Meeting

- March 27, 2025

Attendance

- **Committee Members**
  - PJ Geraghty
  - Ann Rayburn
  - Clint Hostetler
  - Dan DiSante
  - Doug Butler
  - Donna Smith
  - Greg Veenendaal
  - Judy Storfjell
  - Lee Nolen
  - Kerri Jones
  - Rachel Markoski
  - Shane Oakley
  - Sharyn Sawczak
  - Stephen Gray
  - Kerri Jones
  - Theresa Daly

- **SRTR Staff**
  - Jon Miller
  - Katie Siegert

- **HRSA Staff**
  - Brianna Doby

- **UNOS Staff**
  - Matt Cafarella
  - Cole Fox
  - Susan Tlusty
  - Joann White
  - Kelley Poff
  - Tamika Watkins
  - Sarah Roache
  - Holly Sobczak
  - Ethan Studenic
  - Alina Martinez
  - Houlder Hudgins
  - Kevin Daub
  -
- **Other**
  - Kimberly Koontz
  - Lisa Stocks
  - Stephanie Pouch