OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
April 10, 2025
Conference Call

Stephanie Pouch, MD, MS, Chair
Rachel Miller, MD, Vice Chair

Introduction

The OPTN Ad Hoc Disease Transmission Advisory Committee (the Committee) met via WebEx teleconference on 04/10/2025 to discuss the following agenda items:

1. Public Comment Feedback: Clarify Requirements for Reporting a Potential Disease Transmission
2. Review Policy Language: Clarify Requirements for Reporting a Potential Disease Transmission
3. Review of Pathogens of Special Interest (POSI) List
4. HOPE Act Update
5. Project Update & Vote: Require West Nile Virus Seasonal Testing
6. Presentation: Update Data Collection to Align with U.S Public Health Service (PHS) Guideline, 2020

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

1. Public Comment Feedback: Clarify Requirements for Reporting a Potential Disease Transmission

The Committee reviewed public comment feedback on the proposal titled *"Clarify Requirements for Reporting a Potential Disease Transmission,"* which was released during the Winter 2025 public comment cycle. The Committee was asked to consider whether any changes to the proposed policy language were warranted based on the feedback received.

Data summary:

- Most responses were from regional meetings and OPTN Committees, including:
  - Organ Procurement Organization Committee
  - Membership & Professional Standards Committee
  - Lung Committee
  - Patient Affairs Committee
- Additional feedback was received from transplant programs and stakeholder organizations.
- The common themes identified during public comment included:
  - Clarify an unexpected transmission event definition and
  - Clarify a sick lung recipient definition.

Summary of discussion:

Decision #1: The Committee agreed to use the **time of cross-clamp** as the standardized point at which a disease transmission event is no longer considered *expected*. Additionally, the Committee decided **not to define a specific timeframe** for when an event is no longer considered *donor-derived*,

Decision #2: The Committee agreed to replace the terms sick and non-sick with clinical evidence of infection and clinical evidence of colonization.

The Chair commented that there are two primary areas for discussion based on the feedback received. The first involves whether the definition of unexpected potential transmission should be modified and if a timeframe should be identified for when an event is no longer considered donor-derived, and whether alternative terminology should be used to refer to lung recipients who are sick and non-sick. She noted that during public comment, feedback supported the use of the time of cross clamp as the timeframe for when an event is no longer considered expected, as it provides a standardized timepoint for transplant programs to decide whether or not they were aware of a donor's has a pathogen, disease, or malignancy.

She also mentioned that public comments raised questions about the approximate timeframe for when a transplant program should no longer report a potential disease transmission event - whether it should be within 30 days, six months, or another period. She acknowledged the difficulty in defining a specific time window, noting that while most donor disease transmissions occur early post-transplant, some may occur late post-transplant. Imposing a strict timeframe for reporting may result in missing the opportunity to identify important disease transmissions.

Members agreed that it's challenging to define a specific point in time when an event is no longer considered donor-derived. There was consensus to proceed with the time of cross-clamp to delineate an unexpected event from an expected event, without incorporating a specific time frame into policy.

The Chair inquired whether the Committee supports using alternative language to refer to lung recipients, rather than using the terminology 'sick' and 'non-sick' to refer to lung recipients. She referenced public comment feedback, noting that, for example, a patient on

Based on public comment feedback, she noted that if a patient is on extracorporeal membrane oxygenation (ECMO), they may be considered sick. This ambiguous terminology can complicate categorizing a recipient accurately based on these terms. From a patient centered standpoint, the Committee considered using patient-friendly language, such as symptomatic and asymptomatic, while underscoring that there is substantial concern that the disease transmission is donor-derived.

One member suggested using clinical terms like "colonization" and "infection," which are commonly used in practice. However, the Chair expressed caution, particularly in the context of identifying malignancy transmissions, and noted some hesitation around using those terms too broadly. Another member highlighted a concern raised during public comment: if a lung recipient develops pneumonia and a pathogen is identified on the pathogen of special interest (POSI) list, but the transplant program believes the illness is not donor-derived, is reporting still required? There was concern that this could lead to unnecessary reporting and administrative burden, even when donor transmission is not suspected.

In response, the Chair clarified that colonization with a pathogen on the POSI list would still warrant reporting. The Vice Chair added that the pathogens on the POSI list are of public health significance, and even if a case is ultimately determined not to be donor-derived, it remains important to report and investigate such findings. Members emphasized that while the POSI list is currently used by OPOs, the proposed policy changes would extend its use to transplant programs. Specifically, transplant programs would be required to report a POSI-listed pathogen in lung recipients in cases of colonization without clinical signs of infection.

A member asked whether a pathogen, disease, or malignancy that is *not* donor-derived is still required to be reported under the proposed policy. The Chair clarified that the policy language should specify

that lung transplant centers are required to report cases where the recipient shows evidence of infection that is *suspected* to be donor-derived. The member then posed a scenario: if a patient develops pneumonia 2–3 weeks post-transplant, and the transplant program identifies a pathogen from the POSI list but does *not* believe it is donor-derived, is reporting still required? Another member responded that if the pathogen is on the POSI list, then yes—it must be reported. If it is *not* on the POSI list, then reporting is not required.

Another member clarified that transplant programs are required to report any pathogen listed on the POSI list, regardless of whether it is causing clinical disease in the lung recipient.

The Chair added that, to avoid labeling the lung recipient as "infected" or "sick," the policy language should instead state that reporting is required when there is clinical evidence of infection, based on the clinical judgment of the treating physician or care team, and there is substantial concern that the pathogen, disease, or malignancy may be donor-derived.

Members continued to discuss ways to refine and clarify the policy language to ensure it is presented in a clear and consistent format.

Next steps:

The policy language will be revised based on the Committee's feedback and will be brought forward for a vote at an upcoming meeting.

2. Review of Policy Language: Clarify Requirements for Reporting a Potential Disease Transmission

The Committee reviewed and provided feedback on the policy language for Clarifying Requirements for Reporting a Potential Disease Transmission.

Summary of discussion:

No decisions were made for this agenda item.

Staff commented on the proposed strikethrough of the word *"potential"* in the policy language. He explained that the term *"potential"* should remain in the policy to account for suspected transmissions, especially in cases where test results are inconclusive. Removing the word could create confusion in such scenarios. The Chair agreed, noting that the standard terminology used by the Committee for referring to a potential donor-derived disease transmission event (PDDTE) includes the word *"potential."* Another member concurred, emphasizing that including *"potential"* reinforces the idea that reporting should not be delayed until a test result is confirmed.

Regarding the proposed section title for OPTN Policy 15.5.B: *Transplant Program Requirements for Reporting Discovery of Unexpected Recipient Disease or Malignancy*, a member asked if the word disease encompasses a pathogen. The Chair responded that the title should be broadened to clarify that transplant programs are required to report the discovery of any *pathogen, disease, or malignancy*. She explained that while some pathogens can cause disease, not all pathogens are associated with a disease. Therefore, to more accurately reflect the reporting requirements, the section title should be updated to explicitly include instances where a pathogen is identified, even in the absence of disease.

Regarding the terminology used to refer to lung recipients, members suggested avoiding the term infected to describe lung recipients, to ensure patient-centered language. One member emphasized that the focus should instead be on whether the organism is identified as a *pathogen* or *colonizer*. Members suggested using a language such a "lung recipient with clinical evidence of infection" to maintain clinical accuracy while being sensitive to how patients are described. Additionally, the Vice Chair noted that the

wording to reflect situations where there is substantial concern that the pathogen, disease, or malignancy may be donor-derived.

Another member noted that, based on the way the policy language is currently structured, it is important to ensure that transplant programs clearly understand their reporting obligations for lung recipients who are not sick. programs will be required to report the presence of any pathogen listed on the POSI list in cases where a lung recipient shows evidence of *colonization* but does not exhibit clinical signs of infection.

Next steps:

The policy language will be revised based on the Committee's feedback and will be reviewed and voted on at an upcoming meeting.

3. **Review of the Pathogen of Special Interest (POSI) List**

The Committee reviewed the *Pathogens of Special Interest (POSI)* list, which is updated annually. This list includes pathogens known to cause severe illness and is currently used by Organ Procurement Organizations (OPOs) for reporting purposes, as outlined in OPTN Policy 15.4.A. Under the proposed policy changes, lung transplant programs will also be required to use the POSI list and report identified pathogens in accordance with OPTN Policy 15.5.B. The Committee was asked to consider whether any additional pathogens should be included as part of the annual review.

Summary of discussion:

No decisions were made for this agenda item.

The Chair explained that the following pathogens were added to the POSI list:

- Mollicutes
- Oropouche Virus
- CRE definition

No additional pathogens were identified to be included in the list. Staff noted that the POSI list should apply to both OPOs and lung transplant programs for reporting purposes. The Committee did not propose any pathogens to include in the POSI list.

Next steps:

The POSI list will be updated to include language specifying that it is intended for use by both OPOs and lung transplant programs once the list is officially approved. The Committee will review and vote on the revised language at an upcoming meeting

3. Hope Act Update

The Committee received an update that the *Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates* proposal is currently out for a special public comment cycle, running from March 21 to April 22, 2025. To date, public feedback has been generally supportive of the proposed policy changes. The proposal has also been presented to several OPTN Committees, including the Transplant Administration, Liver, and Patient Affairs Committees, with presentations to additional committees still pending. A follow-up communication will be sent to the community to remind stakeholders that the proposal is open for public comment and to encourage further feedback.

Summary of discussion:

No decisions were made about this agenda item.

There was no further discussion.

4. Project Update & Vote: Require West Nile Virus Seasonal

The Committee heard a project update on *Require West Nile Virus Seasonal Testing for Donors*. This project is a request from the Center for Disease Control and Prevention (CDC) to consider West Nile Virus (WNV) testing requirements consistent with the CDC and food and Drug Administration. The purpose of the project is to improve patient safety for recipients by minimizing the risk of donor disease transmission and deaths related to WNV. The project proposes a specific timeframe for recommending WNV testing for all donors.

WNV, primarily spread by Culex mosquitoes, is the leading cause of arboviral disease. It poses significant health risks, particularly high morbidity and mortality rates among organ transplant recipients, and can be transmitted through organ transplants and blood transfusions. WNV is seasonal, with most cases occurring from summer to fall. While most infected individuals do not show symptoms, there is no specific treatment or vaccine for WNV.

The Committee was asked: Does the Committee support sending the project, *Require West Nile Virus Seasonal Testing for Donors to the OPTN Executive Committee for approval for the summer 2025 public comment cycle?*

Data summary:

The proposed policy language includes the following key points:

- **Mandatory WNV Testing**: Requires testing for both living and deceased donors.
- **Seasonal Timeframe**: Specifies the seasonal period for WNV.
- **Testing Requirements**: Details the specific tests to be used for WNV detection in donors.
- **Testing and Results Timeline**: Identifies when testing should occur and when results should be obtained.

The following sections of the OPTN Policy have been updated with the proposed language:

- **OPTN Policy 2.9**: Required Deceased Donor Infectious Disease Testing
- **OPTN Policy 14.4**: Medical Evaluation Requirements for Living Donors

Summary of discussion:

Decision #1: The Committee approved of the policy language and supported sending the project to the OPTN Executive Committee for approval for the summer 2025 public comment cycle.

The Chair highlighted that the proposed policy language would be the minimum acceptable requirements if it were adopted by policy. While some OPOs currently test for WNV year-round, the proposed policy specifies a *seasonal testing timeframe*. Therefore, the seasonal requirement would serve as the baseline standard, allowing OPOs to exceed it if they choose.

A member raised a concern about the proposed requirement for living donors, which states that transplant programs must test potential donors for WNV within seven days prior to organ recovery. He noted that some centers rely on external laboratories for testing, and the seven-day window could present logistical challenges. Members agreed and recommended including a specific question in the public comment materials to gather community feedback on whether the seven-day timeframe is feasible or should be adjusted.

The Committee voted on the proposed policy language and whether to advance the project to the Executive Committee for final approval for inclusion in the Summer 2025 public comment cycle.

Vote: Support: 13 Abstain: 0 Oppose: 0

5. Presentation: Update Data Collection to Align with U.S Public Health Service (PHS) Guideline, 2020

The Committee heard a presentation on the 1-year monitoring report to update Data Collection to Align with U.S Public Health Service (PHS) Guidelines.

- OPTN Policy was updated to align with the updated PHS Guideline for assessing solid organ donors for HIV, HBV, and HCV infection on March 1, 2021.
- Specific risk criteria that donors meant to be reported as having PHS risk factors were not specifically collected on the DDR form, and that information about donor risk criteria could be submitted on multiple text fields, making it difficult to analyze trends for donors that met risk criteria outlined in the PHS Guidelines.
- To address this, discrete fields to capture which specific PHS risk criteria donors were met were added into the OPTN Computer System on September 14, 2023.

Summary of discussion:

No decisions were made for this agenda item

The Chair asked whether the differences observed in utilization and non-use rates were statistically significant. The presenter responded that statistical significance was not assessed in this report. The Vice Chair then inquired about the next steps—specifically, what will be done with the data and how the Committee will move forward. The presenter explained that the policy will continue to be monitored for a total of two years. The Chair added that, ideally, the data will help improve understanding as the PHS guidelines are updated in the future, particularly in identifying which factors may increase the risk of disease transmission.

Upcoming Meetings

- April 28, 2025
- May 6, 2025

Attendance

- **Committee Members**
  - Anna Hughart
  - Stephanie Pouch
  - Oyedele Adeyi
  - Cindy Fisher
  - Gabriel Maine
  - Gerald Berry
  - Rachel Miller
  - Dong Lee
  - Tanvi Sharma
  - Shirish Huprikar
  - Fernanda Silveira
  - Riki Graves
  - Jas Kaur
  - Lara Danziger-Isakov
- **HRSA Representatives**
  - Brianna Doby
- **CDC Representatives**
  - Kelsey McDavid
  - David McCormick
  - Carolyn Gould
  - Isabel Griffin
  - Ian Kracalik
- **UNOS Staff**
  - Tamika Watkins
  - Cole Fox
  - Andrew Klein
  - Sandy Bartal
  - Dzhuliyana Handarova
  - Logan Saxer
- **FDA Representatives**
  - Irma Sison
  - Hanh Khuu