

**OPTN Ad Hoc Disease Transmission Advisory Committee  
Requirements for Communicating Transplant Disease Transmission Workgroup  
Meeting Summary  
September 17, 2024  
Conference Call**

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

## **Introduction**

The Requirements for Communicating Transplant Disease Transmission Workgroup (the Workgroup) met via WebEx teleconference on 09/17/2024 to discuss the following agenda items:

1. Review: Reporting Requirements Guidance Document

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

## **Review: Reporting Requirements Guidance Document**

The Workgroup reviewed the Guidance for Reporting Potential Donor-Derived Disease Transmission Events (PDDTE) guidance document and provided edits and feedback to align with the proposed reporting requirements policy language. This guidance document was last updated in 2014 and is being updated to align with the proposed reporting requirement policy language slated for the January 2025 public comment cycle.

### Data summary:

Summary of changes made to the Guidance for Reporting Potential Donor-Derived Disease Transmission Events (PDDTE):

- Clarify the purpose of reporting a PDDTE
- Clarify reporting requirements for Organ Procurement Organizations (OPO) and transplant programs to align with the proposed policy changes.
- Include a proposed definition of a sick lung recipient
- Include a proposed definition of a non-sick lung recipient
- Include transplant program reporting requirement algorithm

### Summary of discussion:

This was not an agenda item that required a decision

A member voiced concerns about the proposed definition of a sick and non-sick lung recipient and differentiating what needs to be reported. She explained that the problem is that programs may be required to report any organisms not included on the Pathogens of Special Interest (POSI) list if the lung recipient is sick, even if there is no concern that it is donor-derived. The proposed definition of a sick lung recipient does not clarify when an event should be reported. She suggested updating the sick lung recipient definition to include a timeframe or language to indicate reporting should occur when there is substantial concern that it is donor-derived related.

The Chair noted that clarifying these definitions is critical and stated that the proposed definition of sick lung recipient allows flexibility for the physician or treating team to determine if the organism contributes to the lung recipient's illness. The member replied that the definition does not include a specific timeframe for when reporting should occur for lung recipients. Another member commented that in previous workgroup meetings, the workgroup considered specifying a time period to define a sick lung recipient; however, there were challenges with identifying a specific time period. Another member noted that the definition does not include a timeframe, which may continue to lead to over or underreporting.

The Vice-Chair asked if the proposed definition is clarified enough to minimize events reported of colonizing organisms. A member replied yes and expressed concerns about the proposed definition of sick lung recipient and what needs to be reported. She inquired at what point programs should not have to report a pathogen if the recipient has an infection and there's no concern that it's donor-related but instead related to the recipient's critical illness. She noted that lung transplant programs may be confused because the proposed language does not set a clear boundary for when programs will not need to report an infection when there is no concern that it is donor-derived.

Another member agreed and stated that this could be confusing because the definition does not include a timeframe. He suggested that programs should not be punished for under or over-reporting and emphasized that this is a challenging term to define and set parameters around.

Regarding OPO reporting requirements, a member noted that the OPO reporting requirements section of the guidance document should include the OPOs' obligations to complete and submit the Potential Disease Transmission Report (PDTR) Form as outlined in OPTN Policy 15.4.C: *Host OPO Requirements for Post-Reporting Follow-Up* when they are notified of a PDDTE.

Next steps:

Staff and DTAC leadership will discuss the next steps for the Workgroup project.

**Upcoming Meeting**

- TBD

## Attendance

- **Workgroup Members**
  - Stephanie Pouch
  - Rachel Miller
  - Anja DiCesaro
  - Brian Keller
  - Chris Curran
  - Emily Blumberg
  - Erika Lease
  - Kaitlyn Fitzgerald
  - Stephen Gray
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
- **UNOS Staff**
  - Tamika Watkins
  - Cole Foz
  - Houlder Hudgins
  - Sandy Bartal
- **Other Attendees**