

**OPTN Ad Hoc Disease Transmission Advisory Committee
Requirements for Communicating Transplant Disease Transmission Workgroup
Meeting Summary
August 27, 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 08/27/2024 to discuss the following agenda items:

1. Review Draft Policy Language

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

1. Review Draft Policy Language

The Workgroup reviewed and provided feedback on the draft policy language to clarify reporting requirements for transplant programs. The policy language was revised based on the feedback from the [7/23 workgroup meeting](#), including:

- Policy language should account for reporting requirements for non-sick lung recipients.
- Structuring the reporting requirements in a clear concise format.

Summary of discussion:

Decision #1: There was consensus among the Workgroup to further clarify the rationale for differentiating between sick and non-sick lung recipients in the policy language.

Decision #2: The Workgroup agreed to send the policy language to the sponsoring Committee.

The Chair asked if the policy language was clear, specifically inquiring about the unexpected disease or malignancy from donor specimen testing. She noted that a question was raised in earlier meetings about whether donor specimen testing should be clarified to include testing of donor tissue and other donor specimens. Another member commented that sometimes there are concerns about disease transmission that may not be from the donor specimens but instead from the recipient. She commented that it may be helpful to have guidance around these circumstances. She also raised concerns about confusion about which member type is responsible for reporting potential donor-derived transmission events (PDDTE) and to whom. The Chair replied that the proposed language addresses when the transplant program is required to report PDDTE and where it needs to be reported.

Regarding reporting requirements for non-sick lung recipients, a member inquired if respiratory tract testing is the only type of testing that should be considered. Another member explained that the policy language aims to address the issue that most lung recipients have multiple occasions where bronchoalveolar lavage (BAL) specimens are collected, not because there is concern for infection but instead as part of a routine process. She elaborated that it would be anticipated that if a lung recipient were getting a blood or urine culture, it would be done because there is a specific concern for the

patient, and they would be considered unwell. However, when a lung recipient is getting a respiratory tract sample, it is part of a panel of things that are done when a patient may be undergoing a routine bronchoscopy to do surveillance for rejection, not infection.

The Vice-Chair added that many lung centers obtain post-transplant specimens to determine if the culture has mycoplasma, Ureaplasma, etc. She further commented that the Workgroup is considering adding mollicutes to the [Pathogens of Special Interest List](#) (POSI) to clarify reporting requirements and ensure that the information is publicly shared in the context of single lung transplantation.

A member inquired if the policy language should differentiate between sick and non-sick lung recipients. Staff noted that there is an opportunity to differentiate between sick and non-sick lung recipients in the public comment proposal document and in the guidance document that the Workgroup will update as part of the efforts to clarify reporting requirements.

Another member asked if the policy language includes language about the responsibilities to notify the other transplant programs that have received organs from the same donor. Staff replied that OPO reporting requirements are outlined in OPTN Policy 15.4: *Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions*.

Another member commented that it would be helpful to further clarify sick and non-sick lung recipients' reporting requirements as much as possible in the policy language. She voiced concerns that if the reporting requirements are further clarified in the guidance document instead of the policy language, the document may not be referred to much post-implementation, especially if the community forgets that the document is publicly published. On the other hand, policy is binding, serves as the source of truth, and is often referenced over guidance documents. A member replied that the Workgroup had discussed lung recipients' reporting requirements numerous times in previous meetings and felt comfortable with moving forward with defining lung recipient reporting requirements, and further clarification and defining of these reporting requirements would not allow the flexibility that transplant programs need to determine if the specific event should be reported. Another member agreed with the comment and stated that if the policy language does not justify differentiating between sick and non-sick lung recipients, years from now, the community may be confused about why sick and non-sick lung recipients reporting requirements are separated. He suggested differentiating between sick and non-sick lung recipients within the policy language, not just the guidance document and public comment proposal. The Workgroup supported this change.

Does the Workgroup support sending the proposed policy language to the sponsoring committee (DTAC)

Support: 9 Abstain: 0 Oppose: 0

Next steps:

The proposed policy language will be reviewed and voted on by the sponsoring Committee. The Workgroup group will begin updating the Guidance for Reporting Potential Donor-Derived Disease Transmission Events (PDDTE).

Upcoming Meeting

- September 17, 2024

Attendance

- **Workgroup Members**
 - Stephanie Pouch
 - Rachel Miller
 - Lara Danziger-Isakov
 - Anja DiCesaro
 - Brian Keller
 - Dong Lee
 - Emily Blumberg
 - Anna Hughart-Smith
 - Kaitlyn Fitzgerald
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
- **UNOS Staff**
 - Tamika Watkins
 - Alex Carmack
 - Cole Fox
 - Houlder Hudgins
 - Logan Saxer
 - Sandy Bartal
 - Sara Langham
- **Other Attendees**