

**OPTN Ad Hoc Disease Transmission Advisory Committee
Requirements for Communicating Transplant Disease Transmission Workgroup
Meeting Summary
April 26, 2024
Conference Call**

**Lara Danziger-Isakov, MD, Chair
Stephanie Pouch, Vice Chair**

Introduction

The Requirements for Communicating Transplant Disease Transmission Workgroup (the Workgroup) met via Webex teleconference on 04/26/2024 to discuss the following agenda items:

1. Project Recap
2. Review Proposed Definitions
3. Review Reporting Requirements Flow Chart

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

Project Recap

The Workgroup heard a recap of the [4/2/2024](#) Workgroup meeting. This project is a referral from the Membership and Professional Standards Committee (MPSC), which asked the Workgroup to update and clarify policy by defining unexpected disease transmission in policy. This is due to inquiries received by the MPSC regarding what organisms should be reported to the OPTN and the timeframe in which the unanticipated organisms should be reported. During this meeting, the Workgroup agreed that unexpected disease transmission should be defined in policy.

Additionally, the workgroup also discussed identifying reporting requirements for lung transplants. This is important to address because reporting requirements for lungs are unclear and can lead to inconsistent reporting.

Summary of discussion:

There was no further discussion.

Review Proposed Definitions

The Workgroup reviewed proposed definitions for unexpected disease transmission. The Workgroup was asked to determine a timeframe that can be included in the definition to help determine a specific time for when an event should be considered unexpected.

Summary of discussion:

The workgroup considered various timeframes to determine when an event should be regarded as unexpected.

A member noted that sometimes only partial information is available before transplanting the recipient, and then additional information is received before transplanting the organ. She further stated that determining when an expected or unexpected disease transmission occurs may be challenging to

incorporate into policy. She inquired if defining unexpected disease transmission could be incorporated into a guidance document instead. The Chair agreed and commented that an unexpected transmission is when the program receives new information that was not anticipated and may affect the recipient's care.

The Working Group discussed particular situations to account for a time period in the donation process to determine when an event should be considered an expected disease transmission. The Chair stated that deciding on a time to delineate expected from unexpected disease transmission is essential. For example, if after the organ has been removed from the donor and implanted into the recipient, the chest cavity has been closed, additional donor information was received, and the recipient ultimately becomes ill, should that be considered unexpected disease transmission? Another member replied that it should be regarded as unexpected disease transmission. She stated that the timeframe that should be used for defining unexpected disease transmission is when an organ has been accepted, procured, and the organ is at the transplant center.

While members supported using the time of anastomosis as a time frame, another member expressed concern about using it. She explained that information received at the start of anastomosis is too late to be considered expected because the native organ may have been removed from the recipient. Another member voiced that donor information received at the time of the recipient's skin incision should be considered when identifying a timeframe.

Members expressed concerns with using at the time of skin incision for the timeframe. Members expressed that the time of skin incision will vary across centers and inadvertently miss the opportunity to mitigate events in other transplant recipients. A member suggested using a timeframe relative to when the organ was procured.

Some members suggested using post-procurement as a time period to delineate expected versus unexpected disease transmissions. A member voiced concerns about using post-procurement as a time period because there are instances where the organ does not immediately get transplanted once it's been procured. The Chair commented that accounting for every situation in which an unexpected transmission may occur is challenging. A member stated that clamp time could be used to define unexpected because it's the easiest and most known time before the organ is transplanted into the recipient.

Members highlighted that, from a patient safety perspective, this project will expedite the communication between OPOs and transplant centers. This will ensure that any information that could potentially impact the recipient is communicated promptly so that there is an opportunity to mitigate any risks and prevent other recipients from having complications.

Members agreed that by choosing a timeframe related to the donor side, all programs would have the same starting point, which removes the variability of when an organ is transplanted after it has been procured. In this case, every organ is on the same timeframe of what was known or not known at that specific starting point, so anything beyond the starting point would impact all organs and, therefore, be reported as unexpected. A member agreed and added that the timeframe should be donor-based rather than recipient-based.

Next steps:

The Workgroup will continue to discuss and define unexpected disease transmission.

Review Reporting Requirement Flow Chart

The Workgroup reviewed the transplant program reporting requirements flow chart, which outlines the reporting requirements for when a transplant program performs testing on the donor organ sample or the transplant recipient and to whom the information should be reported.

Summary of discussion:

There was no further discussion.

Next steps:

The Workgroup will continue to review and discuss the reporting requirements flow chart and identify a reporting requirements pathway for lung transplants.

Upcoming Meeting

- May 7, 2024

Attendance

- **Workgroup Members**
 - Lara Danziger-Isakov
 - Stephanie Pouch
 - Rachel Miller
 - Erika Lease
 - Stephen Gray
 - Kaitlyn Fitzgerald
 - Dong Lee
 - Anna Hughart-Smith
 - Laurel Avery
 - Emily Blumberg
 - Brian Keller

- **HRSA Representatives**
 - James Bowman

- **UNOS Staff**
 - Tamika Watkins
 - Leah Nunez
 - Houlder Hudgins
 - Sandy Bartal
 - Logan Saxer
 - Susan Tlusty
 - Sara Langham
 - Joel Newman