

OPTN Ad Hoc Disease Transmission Advisory Committee
Requirements for Communicating Transplant Disease Transmission Workgroup
Meeting Summary
March 5, 2024
Conference Call

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

Introduction

The Requirements for Communicating Transplant Disease Transmission Workgroup met via Webex teleconference on 03/05/2024 to discuss the following agenda items:

1. Background, Purpose, & Workgroup goal

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

1. Background, Purpose, & Workgroup goal

OPTN Policy 15.5.A Transplant Program Requirements for Post-Transplant Discovery of Donor Disease or Malignancy and Policy and 15.5.B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy require transplant programs to communicate and report post-transplant diseases. However, OPTN policy does not define or specify requirements for reporting unexpected disease transmission events.

The Ad Hoc Disease Transmission Advisory Committee (DTAC) received a referral from the OPTN Membership & Professional Standard Committee (MPSC) expressing the need to update and clarify Policy 15.5.A and 15.5.B. The MPSC received inquiries from transplant programs regarding what organisms should be reported and the timeframe in which the events should be reported. This includes requirements for lung transplantation, since lungs are not sterile, and there is often colonization of the organisms instead of infection. Therefore, the Workgroup will collaborate to clarify transplant program requirements for reporting and communicating disease and malignancy to the OPTN Improving Patient Safety Portal.

The DTAC proposes a phased approach to the project. Phase 1 would propose clarifications to Policy 15.5.A and 15.5.B; ideally, policy clarifications will be submitted for public comment in July 2024. Phase 2 would introduce a secondary component that aims to improve the structure and efficiency of the 45-day follow-up process as the current process is burdensome to the OPTN contractor and transplant programs alike. Phase 2 involves an IT component and will be discussed in detail at a later stage; the Workgroup plans to submit this portion of the project for public comment in January 2025.

Summary of discussion:

Regarding the lung-specific considerations, the Chair explained that the recipient transplant program may directly collect a lung specimen before transplantation and current policy does not state what should be reported if colonization of an organism is found. Members also discussed defining the point at which colonization on the lung would no longer be considered donor-derived.

A Workgroup member emphasized the need to build in education on what constitutes a reportable event. The Chair noted that organ procurement organizations have models that indicate which

pathogens of special interest should be reported and the Workgroup may consider adopting these models. The Chair agreed that more education at multiple levels to ensure compliance with policy will be important.

Next steps:

On March 18, 2024, the OPTN Policy Oversight Committee (POC) will review the project and vote to determine whether it will move forward in the policy development process.

Upcoming Meeting

- April 2, 2024

Attendance

- **Workgroup Members**
 - Lara Danziger-Isakov
 - Stephanie Pouch
 - Rachel Miller
 - Michael Ison
 - Emily Blumberg
 - Laurel Avery
 - Stephen Gray
 - Anna Hughart-Smith
 - Brian Keller
 - Anja DiCesaro
 - Lee Nolen
 - Dong Lee
 - Kaitlyn Fitzgerald
- **HRSA Representatives**
 - James Bowman
- **UNOS Staff**
 - Tamika Watkins
 - Leah Nunez
 - Sandy Bartal
 - Logan Saxer
 - Susan Tlusty
 - Sara Langham
 - Cole Fox