

# OPTN Ad Hoc Disease Transmission Advisory Committee Requirements for Communicating Transplant Disease Transmission Workgroup Meeting Summary May 7, 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 05/07/2024 to discuss the following agenda items:

1. Project Discussion

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

#### 1. Project Discussion

On <u>April 26, 2024</u>, the Workgroup decided that expected and unexpected potential donor-derived disease should be delineated by a specific donor-related event during the donation process. 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.

The Workgroup considered whether the following statements clarify when an organism should be reported to the OPTN:

- Transplant program testing of <u>donor</u> specimen <u>prior to anastomosis</u> that reveals a pathogen <u>known in the donor prior to cross clamp</u> is considered <u>expected</u>.
- Transplant program testing of <u>donor</u> specimen <u>prior to anastomosis</u> that reveals a pathogen <u>not</u> <u>known in the donor prior to cross clamp</u> is considered <u>unexpected</u>.
- Transplant program testing <u>after anastomosis</u> that reveals a pathogen <u>known in the donor prior</u> <u>to cross clamp</u> is considered <u>expected</u>.
- Transplant program testing <u>after anastomosis</u> that reveals a pathogen <u>unknown in the donor</u> <u>prior to cross clamp</u> is considered <u>unexpected</u>.

#### Summary of discussion:

The Workgroup recommended using cross clamp as the defining event to differentiate between expected and unexpected disease transmission events for reporting to the OPTN.

The Workgroup recommended using anastomosis as the defining event to distinguish donor testing and recipient testing of the organ being donated.

The workgroup recommended using the timeframe between anastomosis and cross clamp to define unexpected disease transmission.

The Workgroup recommended using cross clamp as the defining event to differentiate between expected and unexpected possibility of donor-derived disease. The Workgroup also recommended using anastomosis as the defining event to distinguish donor testing and recipient testing of the organ being donated. Cross clamp and anastomosis are clearly defined events in the donation process; the importance of using unambiguous timepoints to reduce policy misinterpretation was emphasized. Additionally, cross clamp and anastomosis are captured in the OPTN Computer system, which was deemed preferable from a monitoring standpoint.

One member recommended using before and after organ offer acceptance to delineate expected and unexpected disease transmission. The member explained that offer acceptance is typically when the transplant team reviews offer details and decides if infectious disease or malignancy clinicians are needed. There was a concern that using offer acceptance would overly burden the OPTN reporting system.

Although members agreed the statements above captured most potential transmission events, it was reiterated that a carve out is needed for unexpected lung recipient results indicating the possibility of donor-derived disease. After briefly reviewing a refined version of the transplant program reporting requirements flow chart, members discussed that it may be helpful to clarify what constitutes a sick versus not sick lung recipient for the purposes of transplant program reporting requirements.

## Next steps:

The Workgroup will review policy language for unexpected disease transmission. The Workgroup will continue to discuss the reporting requirements algorithm.

# **Upcoming Meeting**

• TBD

#### Attendance

## • Workgroup Members

- o Lara Danziger-Isakov
- o Stephanie Pouch
- o Rachel Miller
- o Michael Ison
- o Emily Blumberg
- o Stephen Gray
- o Brian Keller
- o Anja DiCesaro
- o Lee Nolen
- o Dong Lee
- o Kaitlyn Fitzgerald
- **HRSA Representatives** 
  - Kala Rochelle
- UNOS Staff

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- o Tamika Watkins
- o Leah Nunez
- o Sandy Bartal
- o Logan Saxer
- o Susan Tlusty
- o Emily Womble
- o Sara Langham
- o Cole Fox
- Houlder Hudgins