

**OPTN Ad Hoc Disease Transmission Advisory Committee
HIV Positive vs. HIV Infected Workgroup
Meeting Summary
October 24, 2023
Conference Call**

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

Introduction

The OPTN HIV positive vs. HIV infected Workgroup (the Workgroup) met via Webex teleconference on 10/24/2023 to discuss the following agenda items:

1. Review Public Comment Feedback on Concept Paper

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

1. Review Public Comment Feedback on Concept Paper

The Workgroup reviewed feedback on the public comment concept paper, [Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV Positive Results](#), that went out for the Summer 2023 public comment cycle. This concept paper aims to gather relevant data to consider the creation of an algorithm that would account for situations where a donor may have a positive Human Immunodeficiency Virus (HIV) test but is not infected with HIV. Most public comment feedback was received from transplant programs and Organ Procurement Organizations (OPOs). The following themes were identified:

- Suggest clarifying between HIV-positive and HIV infected.
- Overall support for the algorithm.
- Clear guidelines for confirmatory testing
 - Request for precise protocols and definitions for ensuring a donor is truly negative.
- Time and availability of confirmatory testing
 - Proving a donor is not infected with HIV despite having a positive test takes multiple confirmatory tests that not all OPOs can obtain in a timely fashion.
- Utilization of HIV-positive organs
 - It is essential to consider whether discrepant test results for HIV will impact non-use of organs.

Based on the feedback gathered from the concept paper, the Committee was asked how they would like to move forward.

Summary of discussion:

Decision #1: There was consensus among the Workgroup to not proceed with an algorithm at this time; however, this will be an ongoing discussion.

CDC staff inquired how the algorithm would be developed. She stated that based on the public comment feedback, the community is supportive of an algorithm, but it’s also essential to have scientific data that would demonstrate that the algorithm truly works, which may be a challenge.

The presenter explained that this project was a referral from the Membership Professional Standards Committee (MPSC) because there was sentiment that an algorithm may also be helpful for their review. Also, there is limited infectious disease physician staff that supports the MPSC.

Another member inquired about the number of reported cases of human immunodeficiency virus (HIV) positive results, but the donor was considered not infected with HIV that has been reviewed by MPSC and how they've been resolved.

The presenter asked if there was a way to provide clarity on HIV-positive versus HIV infected. A member explained that being infected with HIV is a clinical decision that transplant programs take the responsibility of making. There may be opportunities to amend Organ Procurement Transplantation Network (OPTN) policy to align better with using the term infected with HIV.

The Chair commented that the scope of the problem is limited but still potentially impactful. She noted that if the Workgroup decided to update the OPTN policy to include HIV infected, then it would ultimately depend on the community to develop their own concept of what they consider infected versus not infected, which may present challenges. There would not be any reliable resources, such as an algorithm for the community to determine what is considered HIV infected; this may put patients at a higher risk unintentionally. The Vice-Chair recommended that this project could be revisited later after updates are made to the HIV organ policy equity (HOPE) act variance. There was consensus that now is not the right time to proceed with an algorithm.

The Chair asked if there was anything the Workgroup could do to support the MPSC when they receive these referrals. A member responded that it might be helpful to provide the community with a statement of why this is not the right time and the challenges with creating an algorithm and to acknowledge that it is an ongoing discussion.

Next steps:

The project will go to the OPTN Board of Directors in December 2023

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
 - Lara Danziger-Isakov
 - Stephanie Pouch
 - Dong Lee
 - Emily Blumberg
- **HRSA Representatives**
 - First Name Last Name
- **SRTR Staff**
 - First Name Last Name
- **CDC Staff**
 - Isabel Griffin
 - Sridhar Basavaraju
 - Pallavi Annambhotla
- **FDA Staff**
 - Brychan Clark
- **UNOS Staff**
 - Tamika Watkins
 - Taylor Livelli
 - Cole Fox
 - Laura Schmitt
 - Leah Nunez
 - Sara Langham
 - David Klassen
 - Susan Tlusty
- **Other Attendees**
 - Jonah Odium
 - Michelle Owen