

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

September 5, 2023

Conference Call

Lara Danziger-Isakov, MD, MPH, Chair

Stephanie Pouch, MD, MS, Vice Chair

Introduction

The OPTN Ad Hoc Disease Transmission Advisory Committee (the Committee) met via Webex teleconference on 09/05/2023 to discuss the following agenda items:

1. Activities of CBER's Tissue Safety Team
2. Public Comment Feedback
3. Continuous Distribution Updates

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

1. Activities of CBER's Tissue Safety Team

The Committee heard a presentation on the activities of CBER's Tissue Safety Team.

Data summary:

- FDA's regulatory authority is based on the risk of communicable disease transmission.
- The scope of the 21 Code of Federal Regulations (CFR) part 1271 regulations applies to manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps).
- There are a variety of HCT/P types manufactured by multiple industries.
- Adverse reaction reporting to FDA, investigation, and follow-up is required/
- FDA tracks adverse reaction reports and checks compliance by manufacturers.
- Experience identifies a lack of cooperation from hospitals and end-user physicians when investigating an adverse reaction involving HCT/P.

Summary of discussion:

There were no decisions made by the Committee.

There were no further discussions.

2. Public Comment Feedback

The Committee reviewed public comment feedback on the [Clarification of OPO and Living Donor Recovery Hospital Requirements from Organ Donors with HIV Positive Test Results](#) and [Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation](#).

Clarification of OPO and Living Donor Recovery Hospital Requirements from Organ Donors with HIV-Positive Test Results

The Transplant Coordinator Committee (TCC) suggested clarifying “infected with HIV” and “HIV positive”- there needs to be more clarification, as these two things are different. The Organ Procurement Organization (OPO) Committee supports the development of an algorithm to distinguish between a donor with HIV infection and a donor with a positive HIV test who is not thought to be infected.

- Data gathered by the concept paper on how often OPOs encounter a donor with a positive HIV test that is not thought to be infected included:
 - One donor a year
 - Five donors during the pandemic
 - One donor in the last five years
- General public feedback included:
 - Suggest clarifying between HIV infected donor and a donor with a positive HIV test that may not be infected.
 - Support for the algorithm as it will help safely allocate organs from false positive HIV donors via the match run
- Regional Meeting feedback included:
 - Support for the algorithm if testing can be done quickly and efficiently and not delay placement further since this is such a small, rare occurrence now
 - Sentiment that having precise protocols and definitions for ensuring a donor is truly negative is critical. Additionally, ensuring precise recipient follow-up to demonstrate no transmission is also necessary
 - Support but request to ensure that laboratories, especially smaller labs, can perform follow-up confirmatory testing required by the algorithm

Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation

The TCC and OPO Committees supported the revisions to this guidance document. Feedback from regional meetings to date included:

- Testing should remain optional unless seasons and geographic endemic risk are high
- There is need to utilize the OPTN Computer System for communication regarding OPO and transplant program information sharing
 - Uniform Donor Risk Assessment Interview (UDRAI) questioning does not indicate additional criteria to facilitate further testing
 - The Committee should examine test availability and cost
 - Confusion on the guidance document being required by OPTN policy

Summary of discussion:

There were no decisions made by the Committee.

Regarding the public comment feedback data, the Vice Chair asked over what time frame the OPO noted that there were five donors during the pandemic with a fourth positive HIV test result for a SARS-CoV-2 positive donor. The presenter clarified that the incidence was related to an HIV-positive donor who was not thought to be HIV infected. So far, in the responses collected for whether the fourth-generation HIV

test has led to a positive SARS-CoV-2 nucleic acid amplification test (NAAT), the presenter replied that no one has reported that they have encountered this.

A member asked if the feedback received was relevant to all endemic infections. The presenter responded that the input received is relevant to the guidance document, which will have interim guidance until [Improve Deceased Donor Evaluation for Endemic Diseases](#) is implemented. Another member asked for clarification on the comment about uniform donor risk assessment interview UDRAI questioning, which does not indicate additional criteria to facilitate further testing. The presenter clarified that the guidance document references other endemic diseases, such as histoplasmosis and coccidioidomycosis. There are concerns about the challenge to obtain answers to the UDRAI questions and to know when a donor truly has risk factors for those endemic diseases.

Next steps:

The Committee will review final feedback during the in-person meeting and determine post public comment changes for *Recognizing Seasonal and Geographically Endemic Infections in Organ Donors*.

3. Continuous Distribution Updates

The Committee heard an update on the progress of Continuous Distribution for the OPTN Liver and Intestinal Transplantation and Heart Transplantation Committees.

Summary of discussion:

There were no decisions made by the Committee.

The Chair noted that there should be awareness of issues related to endemic infections being possible outside of the usual areas based on broader organ sharing. She encouraged OPTN committees to consider and be aware of educational needs related to potential infection and transmission in broader organ-sharing. Members agreed with this sentiment.

Next steps:

The Committee will provide feedback to the OPTN Liver and Intestinal Transplantation and Heart Transplantation Committees to be posted to the OPTN website.

Upcoming Meeting

- September 21, 2023, in-person, 8:30 am-2:30 pm ET

Attendance

- **Committee Members**
 - Stephanie Pouch
 - Sarah Taimur
 - Patrick Wood
 - Cind Fisher
 - Michelle Kittelson
 - Lara Danziger-Isakov
 - Gerald Berry
 - Dong Lee
 - Riki Graves
 - Maheen Abidi
 - Sam Ho
 - Rachel Miller
 - Tanvi Sharma
 - Anna Hughart-Smith
 - Helen Te
- **HRSA Representatives**
 - Marilyn Levi
- **FDA Staff**
 - Scott Brubaker
 - Brandy Clark
- **CDC Staff**
 - Sridhar Basavaraju
 - Isabel Griffin
 - Pallavi Annambhotla
- **UNOS Staff**
 - Taylor Livelli
 - Susan Tlusty
 - Tamika Watkins
 - Sandy Bartal
 - Logan Saxer
 - Joel Newman
 - Sara Langham