

## **OPTN Ad Hoc Disease Transmission Committee**

### **Meeting Summary**

**September 21, 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 in Richmond, VA, on 09/21/2023 to discuss the following agenda items:

1. Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV-Positive Tests Public Comment Feedback
2. Public Comment Changes and Vote: Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation Public Comment Feedback
3. Abstract Updates
4. Standardize the Patient Safety Contact and Duplicate Reporting Workgroup Discussions
5. Attaining Efficiency in Organ Allocation
6. Remaining MPSC Referral Prioritization
7. Case Review Efficiency
8. Closed Session

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

### **1. Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV-Positive Tests Public Comment Feedback**

The Committee reviewed public comment feedback on the [Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV-positive Test Results](#). 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 important to consider whether discrepant test results for HIV will impact non-use of organs.

The Committee was asked how they want to move forward based on the feedback gathered from the concept paper.

Summary of discussion:

There were no decisions were made by the Committee.

The Chair commented that the algorithm will be discussed with relevant partners, such as the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administrators (HRSA), and the OPTN HIV-positive vs. HIV-infected Workgroup.

A member stated that if the Committee moves forward with an HIV algorithm, it may be necessary to consider an algorithm for the Hepatitis B Virus (HBV) and Hepatitis C virus (HCV) to rule out false negatives. He asked why there should be an algorithm for HIV when the donor pool is small and no other viruses. Another member asked if there was value in understanding the scope of the false-positive HIV population. He noted that it would be helpful to have data on this population. Staff replied that there is no specific data on false positive HIV results. However, there are incidences where OPOs have not allocated organs from donors with a positive HIV test through the HOPE Act because of suspected false positive results. These cases are referred to the Membership and Professional Standards Committee (MPSC). While this incident has occurred less than ten times, this project was a referral from the MPSC and, therefore, was identified as an issue. Another member commented that it would be beneficial to review data on the percentage of organs not utilized for donors who test positive for HIV.

**2. Public Comment Changes and Vote: Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation Public Comment Feedback**

The Committee reviewed public comment feedback on [Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation](#). This policy aims to help clarify endemic diseases and provide guidance for deceased and living donors. This document condenses four existing guidance documents into one. There was overall support from the OPTN Transplant Coordinator, Living Donor, and OPO Committees.

Public comment themes included:

- Support for the updated guidance document
- Cost and availability of recommended testing
- Concerns about lack of social and medical history to inform screening
- System enhancements are needed for endemic disease screening
- Concerns about turnaround time of testing and organ utilization

Additionally, the Committee reviewed post-public changes to the guidance document based on public comment feedback. The Committee was asked the following:

*Does the Disease Transmission Advisory Committee support sending this guidance document to the OPTN Board of Directors in December 2023?*

Support: 16 Oppose: 0 Abstain: 0

Summary of discussion:

**Decision #1:** The Committee supported sending Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation to the OPTN Board of Directors in December 2023.

CDC staff asked why hunting/taxidermy was excluded from the introduction section. Staff replied that there was sentiment that hunting/taxidermy was not a risk factor for the endemic diseases discussed in the guidance document.

Next steps:

The guidance document will go to the OPTN Board of Directors in December 2024 for approval.

**3. Abstract Updates**

The Committee heard updates on HBV Reactivation in Recipients of HCV positive organs and Coccidioidomycosis Transmission Through Organ Transplantation abstracts that will be submitted to the American Transplant Congress (ATC) in 2024. The purpose of the HBV Reactivation in Recipients of HCV Organs abstract is to determine the risk of HBV reactivation or transmission in recipients of HCV-positive organs. The purpose of the Coccidioidomycosis Transmission Through Organ Transplantation abstract is to describe the donor-related risk factors, transmission penetration rate, clinical manifestations, and outcomes associated with the transmission of Coccidioidomycosis through solid organ transplantation from 2013 to 2022.

Summary of discussion:

There were no decisions made by the Committee.

*HBV Reactivation in Recipients of HCV*

There were no further discussions.

*Coccidioidomycosis Transmission Through Organ Transplantation*

The Chair noted it's important to consider what else can be done to support appropriate screening, especially as the prevalence of coccidioidomycosis (cocci) is expanding throughout OPTN regions.. The Vice Chair noted that it can cause confusion if a donor is from an endemic area and happens to travel and die in an area where cocci is not seen, which can easily be overlooked. Another member expressed concerns about the communication between the donor hospital and OPO when reporting disease transmission and suggested a communication enhancement between the two entities.

A member inquired about how many centers are performing endemic testing in the endemic regions shown in the data. A member responded that most centers may not be testing; however, the centers accepting the organs within that same geographic area are more likely to use prophylaxis. Another member noted that there should be testing if a donor is from an area endemic for cocci..

**4. Standardize the Patient Safety Contact and Duplicate Reporting Workgroup Discussions**

The Committee heard an update on the project, *Standardize the Patient Safety Contact and Duplicate Reporting*. [OPTN Policy 15.1](#) Patient Safety Contact (PSC) requires each OPO and transplant program to identify a patient safety contact and develop and comply with a written protocol for the patient safety contact to fulfill all the following responsibilities. However, protocols are inconsistent across OPOs and transplant programs, which can lead to difficulty and increased time spent contacting the PSC or

receiving confirmation of successful notification. Additionally, [OPTN Policies 15.4.B and 15.5.B](#) require both OPOs and transplant programs to report recipient diseases or malignancies to the OPTN; this results in duplicate reporting and causes an increased burden on the system.

This project is a referral from the MPSC and highlights the need for consistency in the type of contact provided. Several PSCs currently listed are incorrect and out of date. The MPSC also expressed the necessity of establishing a consistent policy for reporting disease transmissions, including notification, follow-up, and receiving and disseminating information needed to effectively ensure timely communication of potential disease transmission. The goal of the Workgroup is to ensure that the PSC is regularly updated and audited, and to reduce OPO and transplant program duplicate reporting of potential donor-derived transmission events to the OPTN Improving Patient Safety Portal.

The Committee reviewed potential policy revisions for the PSC, which include:

- Requiring a transplant program’s or OPO’s patient safety contact work at the institution.
- Requiring a backup contact for the PSC.
- Requiring acknowledgment and confirmation of recipient through an OPTN Computer System enhancement for deceased donor and recipient patient safety events.
- Living donor requirements will stay the same as what is in current policy.

The Committee also reviewed potential policy revisions for the duplicate reporting of infectious disease results to the OPTN, which include:

- Eliminate the need for OPOs to report recipient illness to the OPTN.
- OPOs will still be required to report recipient illness to other transplant programs.
- OPOs will still be required to fill out the potential disease transmission report.

*Does the Committee support the policy changes proposed by the Standardize the Patient Safety Contact and Duplicate Reporting Workgroup?*

Summary of discussion:

**Decision #2:** The Committee supports the policy changes proposed by the *Standardize the Patient Safety Contact and Duplicate Reporting Workgroup*

Regarding the policy revision for duplicate reporting, a member asked if the OPO will not be required to report a recipient’s illness to the OPTN. The Chair replied yes, the goal is to eliminate duplicate reporting from the transplant program and OPO. Another member inquired if there is a standardized process in which the OPO retrospectively reviews donor data. The Chair replied that this is the intent of the OPTN Computer System enhancement. She explained that when there is a positive test that results after cross-clamp, the transplant program will automatically receive a notification about the test results. Staff further explained that with this enhancement, a report can be generated to see what was reported by the OPO and when the transplant program acknowledged that they saw the test results.

Next steps:

The Committee will seek feedback from the OPTN Living Donor Committee on addressing the PSC reporting requirements for living donor hospitals.

## **5. Attaining Efficiency in Organ Allocation**

The Committee heard a presentation on attaining efficiency in organ allocation through the development of an OPTN Task Force (“the Task Force”). The rationale for the Task Force is that there is a need for urgent action to increase efficiency in organ allocation and improve organ utilization. The Task

Force will evaluate existing data and recommendations regarding system challenges and improvement. Additionally, the Task Force will prioritize issues to address and recommend short and long-term strategies to address larger challenges related to organ non-use and out-of-sequence organ allocation.

Summary of Discussion:

There were no decisions were made by the Committee.

A member asked how to volunteer for the Task Force. Staff replied that if people are interested in being part of the Task Force, they should send their names to the Committee Liaison and update their OPTN Volunteer Interest Form.

Next steps:

The Committee will review current projects and evaluate projects aligning with the efforts to improve organ allocation and usage efficiency.

**6. Remaining MPSC Referral Prioritization**

The Committee reviewed the remaining two referrals from the OPTN Membership Professional Standards Committee (MPSC).

The MPSC also asked the Committee to reevaluate the policy prohibition on storage of HCV positive vessels, which leads to a lack of available deceased donor vessels for use in transplant recipients who received an HCV-positive organ and need post-transplant vessel reconstruction.

Additionally, The MPSC asked the Committee to clarify OPTN Policies [15.5.A: Transplant Program Requirements for Post-Transplant Discovery of Donor Disease or Malignancy](#) and [15.5.B: Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient or Malignancy](#). Programs are unclear about the organisms that should be reported and the timeframe after transplantation at which these diseases should be reported. The MPSC emphasized that this is specifically needed in the context of lung transplantation.

*What should the committee pursue as a future policy change?*

**Decision #3:** The Committee agreed that more data needs to be reviewed on storage of HCV positive vessels before this referral is addressed. The Committee agreed standardizing reporting of infectious diseases or malignancies should be the work they prioritize next.

Summary of Discussion:

*Storage of HCV Positive Vessels*

A member inquired if there is any data on the harm done to patients because of a lack of stored vessels. Staff replied that there is no exact data on that; these are cases that were referred to the MPSC. Another member shared that in his experience, the amount of times that HCV-positive vessels are needed is low, but the consequences of not having them when needed is high.

A member commented that this project may have a smaller scope and expressed concerns about limited data and lack of expert opinion. The Chair agreed and commented that if the Committee pursues this project next, it will involve significant discussion with CDC and Food and Drug Administration (FDA) representatives. Another member asked how big of a problem this is and inquired if there was data supporting that there is patient harm. A member commented there are instances where vessels are

used for non-transplant related purposes. FDA staff agreed. Staff acknowledged that these instances may occur, however it was emphasized that these are a violation of OPTN Policy. The MPSC is made aware of any potential cases and the OPTN Operations and Safety Committee has attempted to educate the community on this issue. The Chair explained that there is no repository where people report surgical difficulties related to vessel availability and donor status. CDC staff stated the scope of the problem may not be significant, and the harm being done may not be substantial. He further commented that quantifiable evidence that supports there is harm would need to be reviewed before moving forward with this referral.

The Chair suggested that the Committee could look at recipients from HCV-positive donors, specifically in the liver, and review their outcomes based on graft loss and other specific complications that may be related to vessels. Members agreed that more information is needed to determine the scope of this issue.

### *Communicating Post-Transplant Disease*

A member asked who is responsible for reporting if recipient cultures are positive. The Chair replied that the OPO should be notified by the transplant program of positive cultures. However, in current OPTN Policy, there is a lack of specificity about what programs should be doing and what programs are responsible for reporting. A Member agreed that it is unclear what is required for reporting; he noted that it would be helpful to clarify reporting requirements. A member asked if the Pathogens of Special Interest document is accessible. The presenter replied yes.

#### Next steps:

The Committee will review data relevant to the storage of HCV-positive vessels to help determine the scope of the issue.

### **7. Case Review Efficiency**

The Committee heard a presentation on case review efficiency. The presentation included an overview of the potential disease transmission event reporting process. The process map identifies the steps taken when a potential disease transmission event is reported to the OPTN. Additionally, the Committee reviewed sick recipient follow-up questions that are sent to transplant programs..

#### Summary of Discussion:

There were no decisions were made by the Committee.
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A member asked how it is determined what cases are reviewed by the CDC, CDC staff responded they review cases that are related to a pathogen of public health importance, if there are severe illnesses of recipients, or if there is a death in a recipient.

A member noted that an autopsy report should be required through sick recipient follow-up. Another member asked how initial contact established. Staff replied that they follow up with the transplant program via email. Another member noted that a question that should be included in the sick recipient follow-up questions is whether the patient was on prophylaxis for the pathogen of interest before the notification of this event.

A member noted that any time a gender-discordant recipient donor pair, chromosome analysis should be completed. Another member asked if HBV testing results are needed pre- or post-transplant. A member answered both. Another member inquired if it was worth asking for a pretransplant HBV core; she explained that it would be helpful for case adjudications. Regarding the general questions, the Chair

commented that knowing if the recipient had any known risk factors should be included. She further noted that it was suggested to incorporate the follow-up questions based on disease type into the OPTN Transplant Information Electronic Data Interchange (TIEDI) forms so that the transplant program is required to answer the questions. Another member agreed and stated that any opportunity to mandate reporting would make the process more robust. She explained that there have been times when programs are contacted regarding follow-up questions but may not respond, which makes it challenging to adjudicate cases.

Next steps:

The Committee will continue to discuss follow-up questions based on disease types.

**8. Closed Session**

The Committee had a closed-session review of potential donor-derived transmission events.

**Upcoming Meeting**

- October 23, 2023

## Attendance

- **Committee Members**
  - Lara Danziger-Isakov
  - Stephanie Pouch
  - Anil Trindade
  - Michelle Kittleson
  - Gerald Berry
  - Maheen Abidi
  - Riki Graves
  - Tanvi Sharma
  - Anna Hughart
  - Helen Te
  - Cynthia Fisher
  - Rachell Miller
  - Sarah Taimur
  - R. Patrick Wood
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **FDA Representatives**
  - Scott Brubaker
  - Brandy Clark
- **CDC Representative**
  - Sridhar Basavaraju
  - Isabel Griffin
- **UNOS Staff**
  - Taylor Livelli
  - Tamika Watkins
  - Susan Tlusty
  - Joel Newman
  - Sara Langham