OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Meeting Summary

OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
May 9, 2023
Conference Call

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

Introduction

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

1. Candida Cases Update
2. Algorithm Clean-up
3. Feedback on Guidance Document Revisions and Concept Paper
4. Patient Safety Contact Workgroup

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

1. Candida Cases Update

The Committee heard an update on the Candida abstract that was submitted for IDWeek.

Data summary:

Candida Case Summary

- 124 solid organ transplant (SOT) recipients received organs from these donors:
  - 60 kidney
  - 27 liver
  - 15 heart
  - 14 lung
  - 8 multi-visceral or other

- The Committee adjudicated these potential donor derived transmission events as eight as proven, 16 as probable, 23 ad possible, one as unlikely, 51 as excluded, and 24 intervention without disease transmission. The Candida case findings included: Mycotic aneurysm, bleed, or hematoma occurred in 22 SOT recipients
  - 10 of which were adjudicated as proven or probable
- Allograft explant was performed in 14 recipients (13 kidneys and 1 other), 7 of which were adj
- Death occurred in 17 SOT recipients (one proven, seven possible, seven excluded, one unlikely, one unknown)
- Only six of the 17 recipients who died received antifungal therapy
- Seven deaths occurred
  - Lack of culture results did not support escalating adjudications beyond possible

Summary of discussion:

A member commented that there were discussions about the attributable mortality from the derived candidacies. He explained that it was a challenging question to answer with the given data because there were no definitive attributions of donor-derived candidacies. The high morbidity and mortality in patients where reviewers could not confirm the cause was suggested to be categorized as an unrecognized transmission. The Chair noted attributable graft loss is of concern because while some patients died, others lost grafts which is a significant issue.

2. Algorithm Clean-up

The Committee reviewed the algorithm to adjudicate confidential medical peer review cases in closed-session meetings. In previous meetings, the Committee discussed certain situations where the case would escalate adjudication when an affected organ has increased risk related to a specific pathogen. For example, a liver recipient with a late transmission of Hepatitis B Virus (HBV) from a donor with high-risk behavior. This algorithm aims to ensure consistency amongst reviewers when adjudicating cases. The Committee was asked to determine the following:

- What other situations should be added to the following scenarios:
    - Liver recipients with a late transmission of HBV from a donor with high-risk behavior.
    - Lung recipients who have hyperammonemia from mollicute infections.
- Is 'donor-origin' the best way to refer to the adjudication for malignancy cases?

Summary of discussion:

A member stated that it would be helpful to highlight some of these scenarios when reviewing cases. Another member mentioned that there had been times when the case could not be escalated from possible to probable yet fit the exact scenarios listed. She explained that having scenarios where cases can be adjudicated from possible to probable will be helpful. Members agreed that the recommended scenarios should be added to the algorithm. Another member agreed and added that when reviewing HBV cases, it is often asked how much weight should be put on the lack of risk behavior. Additionally, the member inquired if there should be language on contextualizing community exposure risk in the algorithm. A member agreed with this idea and shared that when reviewing HBV cases, it's unclear how recipient risk is being assessed. Another member suggested adding drowned donors when the lung is infected.

A member asked how the changes would be made to the algorithm. The Chair replied that there would be a footnote page that could be intermittently modified based on experience and understanding to develop consistency as the Committee continues to review cases. Another member asked if there is no instance where initial event donor diseases end in possible to unlikely and noted that sometimes that will be the outcome of a case. The Chair pointed out that this should be monitored when using the algorithm. Another member suggested adding an area about when and how to identify the severity. Members agreed with this idea. Regarding the addition of 'donor origin, a member commented that the proper terminology is unclear and stated it would be helpful to have an addendum that includes information about donor origin.

Next steps:

Staff will incorporate the suggestions into the algorithm and discuss the best way to reference the term donor origin.

3. Feedback on Guidance Document Revisions and Concept Paper

The Committee reviewed feedback from the Organ Procurement Organization (OPO) and Operational and Safety (OSC) Committees on the guidance document revisions, *Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation* and the concept paper, *Clarification of OPO Requirements for Organ Donors with HIV positive Test Results*, going to July 2023 public comment. The OPO and OSC Committees supported updating the guidance document.

Regarding the concept paper, both Committees strongly supported an algorithm that would deem a donor as Human Immunodeficiency Virus (HIV) positive but not infected. The Committees shared situations at their OPOs where organs were not utilized due to a suspected HIV-positive donor who was not HIV-infected. Additionally, the OPO Committee explained that they often receive a western blot confirmatory test for positive HIV donors.

Summary of discussion:

There were no further discussions.

Next steps:

The Committee will vote on sending the guidance document and concept paper to July 2023 public comment cycle.

4. Patient Safety Contact Workgroup

The Committee heard an overview of the patient safety contact workgroup. This work group aims to clarify the patient safety contact (PSC) requirements in *OPTN Policy 15.1* and ensure the PSC is regularly and accurately updated in the OPTN computer system. This will help ensure patient safety through accurate reporting of test results from OPOs and transplant programs.

Summary of discussion:

There were no further discussions.

Next steps:

The PSC project will be presented to the Policy Oversight Committee in June 2023.

Upcoming Meeting(s)

- May 22, 2023
- June 13, 2023

Attendance

- **Committee Members**
  - Lara Danziger-Isakov
  - Anil Trindade
  - Charles Marboe
  - Cindy Fisher
  - Helen Te
  - Jason Goldman
  - Kelly Dunn
  - Sam Ho
  - Sarah Taimur
  - Ann Woolley
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **CDC Staff**
  - Sridhar Basavaraju
  - Isabel Griffin
  - Pallavi Annambhotla
  - Rebecca Free
- **FDA Staff**
  - Brychan Clark
- **SRTR Staff**
  - First Name Last Name
- **UNOS Staff**
  - Taylor Livelli
  - Tamika Watkins
  - Susan Tlusty
  - Emily Womble
  - Laura Schmitt
  - Lee Ann Kontos
  - Logan Saxer
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- **Other Attendees**
  - Anna Hughart-Smith
  - Riki Graves
  - Tanvi Sharma