OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
March 26, 2024
Houston, TX

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

Introduction

The Ad Hoc Disease Transmission Advisory Committee (Committee) met in Houston, TX on 03/26/2024 to discuss the following agenda items:

1. Public Comment Feedback Review: *Standardize the Patient Safety Contact and Reduce Duplicate Reporting*
2. Post-Public Comment Changes
3. New Project Update: *Requirements for Communicating Post-Transplant Disease*
4. Abstract updates: Drowning Donors
5. West Nile Virus Presentation
6. *Align OPTN Policy with U.S Public Health Guideline* 2–Year Monitoring Report
7. Patient Safety Site update
8. Closed Session Review

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

1. Public Comment Feedback Review: Standardize the Patient Safety Contact and Reduce Duplicate Reporting

The *Standardize the Patient Safety Contact (PSC) & Reduce Duplicate Reporting* proposal was available for public comment from January 23, 2024 to March 19, 2024. The Committee reviewed community feedback from this public comment period.

Summary of discussion:

> Decision #1: The Committee decided to strike the proposed policy language that would have required the PSC be an employee of the OPTN member institution.
>
> Decision #2: The Committee decided to proceed with the proposed timeframe of 24 hours for acknowledgement of receipt of positive donor or recipient results, despite some feedback requesting a longer timeframe.

The Committee decided to strike the proposed policy language that would have required the PSC be an employee of the OPTN member institution. There was mixed community feedback on this aspect of the proposal. During the public comment cycle, some respondents supported the proposed PSC requirement, while many expressed that it would pose a significant burden to transplant programs. Community feedback indicated that many transplant programs rely on third party contractors to fulfill the PSC role. It was also discussed that there is no data available to help the Committee understand whether third party contractors' response times are delayed compared to those employed by the institution. A HRSA representative stated that this proposal originated from community feedback about

delays with communicating patient safety information to third party contractors listed as the PSC for an institution. Although prior issues with third party contractors were the driver behind this proposed requirement, members of the committee agreed that ultimately the institution is responsible for ensuring their PSCs can execute the role according to OPTN policy.

The Committee decided to proceed with the proposed time frame of 24 hours for acknowledgement of receipt of positive donor. Some community feedback recommended allowing additional time for acknowledgement of receipt, with a suggestion of 72 hours. However, 24 hours is stated several times in OPTN Policy 15 and there are potential donor-derived disease transmission events (PDDTE) that require immediate action by the Organ Procurement Organizations (OPO) or transplant program.

The Committee decided to proceed with the proposed requirement for OPOs and transplant programs to complete a self-audit of their PSCs every 6 months. There was a suggestion to require the institution to update PSCs every time there is a change. OPTN contractor staff commented that currently, there are some institutions that promptly update the PSC each time the designated contact is unavailable, while others have not updated it for several years. Members felt the requirement to self-audit PSC information every 6 months would mitigate the issue of outdated PSC information without being too prescriptive in policy.

In response to community feedback, the Committee clarified that neither current nor proposed policy precludes the use of a group-accessible e-mail for the PSC information.

Post-Public Comment Changes

The Committee reviewed the proposed policy language for the *Standardize the Patient Safety Contact & Reduce Duplicate Reporting* proposal.

Summary of discussion:

Decision #3: In addition to the proposed changes in agenda item one, the Committee decided to leave the phrase “as soon as possible” in policy language tied to required notifications between OPTN members.

The Committee began to consider changes to the proposed policy language as discussed in agenda item 1 of this document. Members also discussed ways to clarify proposed language to reflect the intended meaning of the role and responsibilities of the patient safety contact in OPTN Policy 15.1. There was a concern about the use of “as soon as possible” in the proposed language. The Chair said this is difficult to measure in policy, but ideally, any required notifications of patient safety information should be communicated immediately. Members agreed that the PSC may not have the clinical knowledge to determine whether it’s appropriate to delay action on certain information.

Next steps:

The Committee will review updated policy language for this proposal at their upcoming meeting and vote to submit the proposal for Board approval in June 2024.

New Project Update: *Requirements for Communicating Post-Transplant Disease*

The Committee heard the background, purpose and project plan for the *Requirements for Communicating Post-Transplant Disease* (Workgroup), also discussed at the Workgroup meeting on

March 5, 2024. The OPTN Policy Oversight Committee approved the project on 3/18/2024 and the Executive Committee approved it on March 25, 2024.

Summary of discussion:

No decisions were made on this item.

There was no discussion.

Next steps:

The Committee will continue to receive updates on the Workgroup's progress.

Abstract update: Drowning Donors

The Committee received an update on a review of PDDTEs from drowned donors from 2017-2022. The optimal drowned donor and organ recipient management is not yet established.

Data Summary:

Donor Epidemiology:

- Total number of PDDTEs reviewed - 23
- Age: median was 16 years of age; 8 donors were age 3 and under
- Seasonality: 13 in Summer, 4 in Spring, 5 in Fall and 1 in Winter
- Water type: 11 chlorinated water, 6 fresh water lake/pond, 2 sea water, 2 bath water, 1 unknown
- Number of PDDTEs that could plausibly be related to the donor drowning/water transmission - 7

Results:

- 21 recipients associated with the 7 possible PDDTEs
- Results by organ: 11 kidney, 5 liver, 3 heart, 2 lung
- Pathogens: Zygomyces/Mucorales - 3; Pseudomonas – 2; Legionella – 1; Scedosporium – 1

Summary of discussion:

No decisions were made on this item.

A member asked whether there was information on wet versus dry drowning in the donors. The member leading this work stated that this could not be determined with the available donor information. The discussion highlighted the rarity of these events but emphasized their severe consequences; the Chair noted that severe recipient illness is typically associated with fungal infections in these cases. Members discussed that there was not enough information to make treatment recommendations to the transplant community. The need for further investigation to determine the need for medical interventions was strongly emphasized.

Next steps:

Members working on this project will continue reviewing these cases and prepare an abstract for Infectious Disease (ID) Week 2024.

West Nile Virus Presentation

Partners from the Centers for Disease Control and Prevention (CDC) presented data showing West Nile virus (WNV) transmitted to organ transplant recipients from 2002-2023.

Data summary:

There were 11 clusters reviewed that were associated with 30 recipients. 26 of 30 recipients became ill. Of the 26 ill recipients, 20 recipients had encephalitis and 8 with encephalitis died. The data presented shows that most transmission events occurred between July and October, which corresponds to the peak of West Nile virus infection in the general population. The CDC estimates that screening could have prevented 7 PDDTE (ie. 12 cases of encephalitis and 3 deaths).

Summary of discussion:

No decisions were made.

Members from the CDC discussed potential WNV testing methods and suggested seasonal WNV screening for donors. There was some concern about whether adding WNV testing would cause delays in organ allocation. A member commented that their OPO has been doing year-round testing for WNV and has not experienced issues with delays. The CDC stated that 95% of positive results are true positives, therefore, the number of organs unused due to being falsely identified as WNV positive would be minimal.

Next steps:

The Committee will consider whether to propose a policy project involving donor screening for WNV.

***Align OPTN Policy with U.S Public Health Service Guideline* 2–Year Monitoring Report**

The Committee reviewed the *Align OPTN Policy with U.S. Public Health Service Guideline* 2-year Monitoring Report. Data were presented from the pre-implementation era (3/1/2019-2/28/2021) and the post-implementation era (3/1/2021-3/1/2023).

Data summary:

There was a decrease in the proportion of donors considered to have risk factors for Human Immunodeficiency Virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) post-policy implementation. For living donors, there was an increase in negative HIV, HBV and HCV test results reported post-policy. For transplant recipients, there was an increase in negative test results reported for all tests, post-policy. Notably, for living liver donors, there was an increase in HCV tests not done and a decrease in negative results reported. Utilization rates decreased and non-use rates increased for most organ types, but patient survival remained similar pre- and post-policy. There was a statistically significant decrease in one-year post-transplant survival for lung recipients who received an organ from a donor with PHS risk factors reported.

Summary of discussion:

No decisions were made.

Regarding the percentage of tests reported as “not done”, the Chair requested information be shared from site survey findings. It was confirmed that “not done” and “unknown” are separate responses in the OPTN Computer System, thus, are distinguishable in data review. Site survey findings showed that more than 21% of tests reported as “not done” were reported inaccurately on transplant recipient 6-month follow-up forms. It was found that 52% of HIV nucleic acid testing (NAT), HBV NAT, and HCV NAT were reported as “not done” but were completed within the correct timeframe and were negative. 28.5% of HIV, HBC, HCV NAT were reported as negative but the test was not done in the appropriate timeframe. 15% of HIV, HBC, HCV NAT were reported as negative but the program could not provide

documentation of the testing. OPTN contractor staff conducting site surveys were interested in collaborating on educational materials with the Committee.

Next steps:

OPTN contractor will continue to monitor compliance issues related to this policy.

Patient Safety Site update

There is a plan to separate the patient safety and disease transmission pages to improve navigation and provide more specific information. The Committee was asked to provide feedback on ways to improve the OPTN patient safety site.

Summary of discussion:

No decisions were made.

Feedback from the community suggests adding links to abstracts, updating outdated documents, and tracking website metrics for improvement. The Committee discussed the need to include updates on ongoing projects and pending implementation dates on a resource page. There was a suggestion to provide more information on the adjudication process and what happens to safety reports after they are submitted.

Closed Session Review

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

Upcoming Meeting

- April 22, 2024, 12PM ET

Attendance

- **Committee Members**
  - Lara Danziger-Isakov
  - Stephanie Pouch
  - Rachel Miller
  - R. Patrick Wood
  - Dong Lee
  - Helen Te
  - Charles Marboe
  - Marty Sellers
  - Anil Trindade
  - Riki Graves
  - Anna Hughart-Smith
  - Tanvi Sharma
  - Sarah Taimur (virtual)
  - Cindy Fisher (virtual)
- **HRSA Representatives**
  - Marilyn Levi (virtual)
  - James Bowman (virtual)
  - Kala Rochelle (virtual)
- **CDC staff**
  - Ian Kracalik
  - Sridhar Basavaraju (virtual)
  - Pallavi Annambhotla (virtual)
  - Carolyn Gould (virtual)
- **FDA representatives**
  - Scott Brubaker (virtual)
- **UNOS Staff**
  - Tamika Watkins
  - Leah Nunez
  - Susan Tlusty
  - Dave Roberts
  - Logan Saxer
  - Cole Fox (virtual)
  - Dzhuliyana Handarova (virtual)
  - Rebecca Murdock (virtual)
  - Sara Langham (virtual)
  - Sandy Bartal (virtual)
  - Houlder Hudgins (virtual)
  - Laura Schmitt (virtual)