OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
January 3, 2022
Conference Call

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

Introduction

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 1/03/2022 to discuss the following agenda items:

1. Welcome and agenda
2. HIV Positive vs. HIV Infected Workgroup Recap
3. Request for Information Strategy
4. Summary of Evidence Quarterly Review
5. Closing Remarks and Reminders

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

1. Welcome and agenda

The Chair welcomed Committee members. Staff presented an overview of the meeting agenda.

Summary of discussion:

There was no further discussion by the Committee.

2. HIV Positive vs. HIV Infected Workgroup Recap

The Vice Chair gave an overview of the primary goals of the Workgroup. She emphasized the intention of this Workgroup is to ensure patient safety by clarifying OPTN policy, so no Human Immunodeficiency Virus (HIV) infected organs are transplanted into HIV uninfected recipients. She explained that current policy uses the term "positive" not "infected" for HIV.

Multiple situations have arisen in which OPOs have had at least one positive HIV result, however based on clinical judgment and additional negative tests, it is believed that the positive test result is inaccurate, and that donor is not infected with HIV. These situations are sometimes referred to as false positives. Policy states that HIV positive organs must be allocated within the HOPE act framework and the OPTN Computer system is set up that any HIV positive result for a deceased donor entered in the system will then automatically shift the donor to only show up for HOPE Act eligible candidates. Policy does not have any allowances or variances for donors that may have had a positive result but are not believed to be HIV infected.[1]

The goals for the Workgroup are to either:

[1] OPTN Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors (Accessed December 15, 2022) https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

1. Clarify policy that any deceased donor HIV positive result requires allocation only to HIV infected candidates

   This would mean that the use of an algorithm, further testing, or clinical judgment to classify a donor with an HIV positive test that may not reflect HIV infection would be prohibited specifically in OPTN policy.

2. Determine circumstances in which a deceased donor with an HIV positive result can be allocated as HIV uninfected to an HIV negative candidate (circumstances in which a testing algorithm with potential clinical judgment can be used to determine that a positive result is likely not indicative of HIV infection)

   This would mean that an algorithm could be utilized (with potential clinical judgment) in situations where the Workgroup could define a test result not to be a true positive HIV result indicating HIV infection.

The Vice Chair explained the Workgroup is in support of attempting to develop an algorithm to determine a donor as HIV positive, but not HIV infected. The Vice Chair noted that there was an overall sentiment that there is a lack of data that allows members to identify the scope of the problem. The OPTN does not collect data on HIV positive candidates on the OPTN Waiting List. Therefore, it is difficult to properly identify the number of donors with positive HIV test results who are later determined not to be HIV infected.

Summary of discussion:

There was no further discussion by the Committee.

3. Request for Information Strategy

Staff explained the Committee can put out a concept paper to receive feedback from the community to gather better data. Members suggested the concept paper could ask how many times organ procurement organizations (OPOs) encounter a donor with a positive HIV test who is later found to be HIV uninfected.

Summary of discussion:

The Vice Chair noted the same question could be asked for transplant centers. A member vocalized support for this approach to define the scope of the problem. The Past Chair stated the HOPE Act has provided adequate information on the rate of test positivity for HIV uninfected scenarios. He stated the concept paper will not be as sufficient for data collection and for assessing the magnitude of the problem. A member noted there are several HIV donors that are not utilized, which would cause HOPE Act data to not be precise. He encouraged the Committee to explore every method of data collection.

A Workgroup member asked what information can be provided about discards. She stated that she hopes to determine how many times this results in organ discard and she wonders if OPOs have this information. A member stated OPOs rarely come across HIV donors and often do not engage with these donors. He stated the OPOs he works with rarely do confirmatory testing as well. A member agreed and stated the HOPE Act data show this is an issue and a sizeable portion of HIV positive donors, so there are enough data to move forward without a concept paper.

The Past Chair stated the HOPE Act data underestimate the problem. The Chair stated it is important to determine the potential scope and impact of an algorithm. She agreed the HOPE Act data are important and informative, and that many of those determinations occur after organs are allocated or transplanted. More information is needed. The Past Chair asked if the community responds that this is

not a problem if that will take precedent over the HOPE Act data. A member stated HIV positive organs are not always discarded because of HIV positivity.

A member noted the false positivity rate of HIV assays are very low. He agreed defining the scope through a concept paper and other methods is the best path forward. A Workgroup member stated whatever is decided must be able to be understood and accepted by the entire community. Members agreed. A member stated bringing false positives to the forefront and highlighting what that means for decision-making processes will be helpful for information sharing.

Another member noted that sample quality of donors for testing is an issue that will never be able to be addressed. A member stated that HIV is already stigmatized and treating these organs differently when dealing with false positivity will stigmatize this disease further. The Past Chair agreed.

Next Steps:

Members agreed to discuss specifics of the questions asked for feedback from the community in their in-person meeting in March.

4. Summary of Evidence Quarterly Review

The Chair presented potential edits to the Summary of Current Evidence and Information– Donor SARS-CoV-2 Testing & Organ Recovery from Donors with a History of COVID-19 and the Summary of Current Evidence and Information–Monkeypox in Donor Screening and Transplantation.

Summary of discussion:

Summary of Current Evidence and Information– Donor SARS-CoV-2 Testing & Organ Recovery from Donors with a History of COVID-19

Members agreed to remove the timeline for post-positive testing for SARS-CoV-2 to determine acute infection. Members noted this should be framed as an area of uncertainty.

Members agreed to remove several case series referenced in the document that are not as robust and focus on a small cohort. Members agreed to review and revise the section discussing living donors.

The Past Chair stated commenting on lung donation in this Summary of Evidence should be included with new updated data.

Summary of Current Evidence and Information–Monkeypox in Donor Screening and Transplantation

Members agreed to change monkeypox to Mpox in the document due to the name change of the virus. Members noted the background of the document needs to show the decline in cases and the impact of vaccination in the general population.

Members noted the quarterly review of these documents should be reduced to biannually or as needed. Staff responded this can be taken to the OPTN Executive Committee.

5. Closing Remarks and Reminders

Staff reminded members that the Committee will participate in closed-session case review in their next meeting. She also noted that edits to the Summary of Evidence documents will be due at the end of the month. The Chair thanked members for their participation.

Summary of discussion:

There was no further discussion by the Committee.

Upcoming Meeting

- January 23, 2022, 12PM EST, teleconference

Attendance

- **Committee Members**
  - Ann E. Woodley
  - Anil Trindade
  - Cindy Fisher
  - Dong Lee
  - Gerald Berry
  - Helen Te
  - Jason D. Goldman
  - Judith Anesi
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Michelle Kittleson
  - Marty Sellers
  - Ricardo La Hoz
  - Sarah Taimur
  - Sam Ho
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **FDA Staff**
  - Scott Brubaker
  - Brychan Clark
- **CDC Staff**
  - Sridhar Basavaraju
  - Rebecca Free
  - Sherry (Michele) Owen
- **Other Members**
  - Emily Blumberg
  - Jonah Odim
- **UNOS Staff**
  - Lee Ann Kantos
  - Emily Womble
  - Cole Fox
  - Sandy Bartal
  - Susan Tlusty
  - Taylor Livelli