OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
May 4, 2021
Conference Call

Ricardo La Hoz, MD, FACP, FAST, FIDSA, Chair
Lara Danziger-Isakov, MD, MPH, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee (DTAC) met via Citrix GoToMeeting teleconference on 05/04/2021 to discuss the following agenda items:

1. Open Session: PHS Specimen Storage Requirement Data Request
2. Closed Session: Confidential Medical Peer Review

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

1. Open Session: PHS Specimen Storage Requirement Data Request

The Committee reviewed a potential data request related to the specimen storage requirement that was implemented as part of the proposal to align OPTN policy with the 2020 PHS Guideline.

Data summary:

On April 26, the OPTN Executive Committee requested an analysis of the PHS specimen storage requirement when reviewing the new DTAC project on PHS data collection in DonorNet. The goal of the data request would be to help answer the question of how long should specimens for living and deceased donors be required to be stored, from a recipient safety perspective?

The following parameters were presented for a data analysis based on all DTAC-reviewed cases and their time from recovery date to case reporting:

- Stratify by CDC-led vs. not
- Stratify reporting time by year
- Stratify all time by HIV/HBV/HCV, all other pathogens, and malignancies
- Stratify all time by deceased vs. living donor

Summary of discussion:

The CDC representative on the committee inquired as to where this data request came from, and why there is pushback for this requirement. UNOS staff explained that concerns have been raised during and after public comment at regional meetings, as well as by the OPTN Executive Committee. The CDC brought up the concern that there can be isolated rare events that occur further out than most potential transmission events investigated, and they may not be able to investigate those without a specimen. While some members expressed concern about cost of specimen collection during public comment, but the lack of data in development of the approach was also concern expressed by the community and one that a data request may be helpful to address. The CDC mentioned that they are also interested in these specimens for emerging diseases, which may not be recognized and diagnosed in the recipient for many years, which was the case for hepatitis.

One DTAC member brought up concerns about potential underreporting in the community, especially when disease is recognized later in the recipient, and that the reporting process is passive. He was concerned that reducing the timeframe for storage could weaken the potential to investigate these cases and provide patient safety gaps. One member posed that an even longer time than 10 years may be warranted based on the data, and concerns for emerging disease, and that it may be warranted to store specimens through the duration of the recipients' lifetimes. Multiple committee members expressed concerns about community response to potentially extending the timeframe beyond ten years.

The HRSA representative asked if the American Red Cross has specimen storage requirements, and a CDC representative explained that they do not. Previously there a federally funded biorepository for blood donors, but not currently. The HRSA representative noted that England contextualized their storage requirements by length of time for prior disease transmissions in the 80s and 90s.

One member noted that, given previous feedback in public comment and from the OPTN Executive Committee, reviewing data on specimen storage may be helpful or at least support a due-diligence approach. The CDC representative posed that they may not be comfortable shortening the timeframe. The Chair posed that there was consensus to make the data request, review the information, and make sure to contextualize it in the potential implications of the data and potential for underreporting.

Next steps:

UNOS Research staff will draft a data request and provide for leadership to review prior to HRSA submission.

2. Closed Session: Confidential Medical Peer Review

Summary of discussion:

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

Upcoming Meetings

- May 24, 2021, 12 PM EDT, Conference Call
- June 1, 2021, 2 PM EDT, Conference Call
- June 22, 2021, 3 PM EDT, Conference Call

Open Session Attendance

- **Committee Members**
  - Ricardo La Hoz
  - Kelly Dunn
  - Debbie Levine
  - Gary Marklin
  - Meena Rana
  - Marian Michaels
  - Raymund Razonable
  - Saima Aslam
  - Lara Danziger-Isakov
  - Helen Te
  - Charles Marboe
  - Avi Agarwal
  - Ann Woolley
  - Heather Stevenson
  - Jason Goldman
- **HRSA Representatives**
  - Jim Bowman
- **CDC Staff**
  - Sridhar Basavaraju
  - Pallavi Annambhotla
  - Ian Kracalik
  - Rebecca Free
- **FDA Staff**
  - Brychan Clark
- **UNOS Staff**
  - Abigail Fox
  - Courtney Jett
  - Leah Slife
  - Sandy Bartal
  - Nicole Benjamin
  - Laura Cartwright
  - Cassandra Meekins
  - Kristine Althaus
  - Darby Harris
  - Susan Tlusty

Closed Session Attendance

- **Committee Members**
  - Ann Woolley
  - Avi Agarwal
  - Charles Marboe
  - Debbie Levine
  - Gary Marklin
  - Heather Stevenson-Lerner
  - Helen Te

    - Jason Goldman
    - Kelly Dunn
    - Lara Danziger-Isakov
    - Marian Michaels
    - Meenakshi Rana
    - Raymund Razonable
    - Ricardo La Hoz
    - Saima Aslam
- **HRSA Representatives**
    - Jim Bowman
- **CDC Staff**
    - Ian Kracalik
    - Pallavi Annambhotla
    - Rebecca Free
    - Sridhar Basavaraju
- **FDA Staff**
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- **UNOS Staff**
    - Abby Fox
    - Cassandra Meekins
    - Courtney Jett
    - Kristine Althaus
    - Sandy Bartal