OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
May 24, 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 or the Committee) met via Citrix GoToMeeting teleconference on 05/24/2021 to discuss the following agenda items:

1. Open Session: Pediatric Blood Testing – OPTN policy & PHS Guideline
2. Open Session: PHS Risk Criteria Data Collection
3. Open Session: Lower Respiratory Testing Update
4. Closed Session: Confidential Medical Peer Review

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

1. Open Session: Pediatric Blood Testing – OPTN policy & PHS Guideline

The Committee reviewed a potential new project regarding a concern that the current OPTN policy aligning with the PHS Guideline may be inappropriate for certain small pediatric candidates receiving pre-transplant testing directly prior to transplant.

Data summary:

The DTAC and Pediatric Committee leadership received a letter from a member organization expressing concern over small infants that are required as part of the new OPTN policies aligning with 2020 PHS Guideline to receive pre-transplant testing for HIV, HBV and HCV upon hospital admission but prior to transplant. The concern relates to infants being less likely to be at high risk for HIV, HBV and HCV but more vulnerable to a harmful blood volume ratio. The Pediatric Committee reviewed this issue on their call on 5/19/21, and agreed this issue warranted action by addressing policy and/or educational guidance to the community.

This requirement was included as part of the OPTN Policies to Align with 2020 PHS Guideline proposal that was approved by the Board of Directors in December 2020 and implemented March 2021. The requirement to have pre-transplant testing for HIV, HBV and HCV for all transplant candidates is not new; rather, the change relates to the timing of the tests, which is upon hospital admission but prior to transplant. This requirement generally is to align with the PHS Guideline in an effort to improve patient safety by identifying potential donor derived transmissions and necessary treatment for candidates as quickly as possible.

Summary of discussion:

The DTAC agreed that the issue was important and should be addressed. DTAC leadership with pediatric expertise provided their feedback from attending the Pediatric Committee call, highlighting that this is potentially unnecessary for certain pediatric candidates and may make a blood transfusion necessary because of the high blood volume ratio in certain pediatric candidates. The DTAC also discussed that the rate of false positives with this population is higher because they are less likely to be positive for HIV,

HBV and HCV. The Committee also discussed how the volume of blood drawn can vary by institution. The issue with a high blood draw ratio does not apply to adults the same way it applies to children. The Committee agreed that the timing of the blood draw for infants and underweight pediatric candidates could be harmful and needed to be addressed from a patient safety perspective. The DTAC perspective, in accordance with the Pediatric Committee's views, will be shared with the member that reached out to both committees.

Next steps:

The DTAC and Pediatric Committee leadership teams will co-sign a letter to the member that expressed concern indicating their consensus and potential next steps. Staff will set up a Workgroup with members of the two committees to move this project forward.

2. Open Session: PHS Risk Criteria Data Collection

The Committee reviewed background, policy development process, and the Data Advisory Committee (DAC) checklist before voting to send this proposal out for public comment.

Summary of discussion:

The Committee had no comments on the background, proposed solution, and policy development process slides of the presentation. The Committee discussed how this project aligned with the DAC data collection principles by reviewing the DAC checklist. The Committee agreed that collecting this data would help in the precision and clarity of gathering data, since these data are hard to pull from existing UNet^{SM} systems without significant manual effort. OPO representatives identified that the data is available now, so adding these fields wouldn't be a significant burden to members – the data will just be easier to find if this proposed change were to be implemented. Regarding alternative data sources, the Committee agreed that the data are not easily available internally or externally, which is why the project is being pursued. Overall, the Committee agreed that the proposed data collection was in line with the DAC data collection principles and that the questions had been positively answered on the checklist. The Committee voted unanimously to submit this proposal for public comment.

Next steps:

This proposal will go out for public comment in August 2021.

3. Open Session: Lower Respiratory Testing Update

The Committee reviewed an updated figure showing the proportion of lung donors receiving lower and upper respiratory testing for SARS-CoV2 by week through the week of May 3, 2021.

Data summary:

The table showed that testing of lung donors increased in percentage from around 30% in January to around 75% by early May.

Summary of discussion:

The Committee discussed whether lower respiratory testing could be further stratified by type of specimen testing – such as sputum or bronchoalveolar lavage (BAL). The associate policy analyst clarified that data on the specific type of tests performed are not available. The research analyst clarified that a total of donors recovered with at least one lung was 2298. Data are not on whether the results are available prior to transplant because those data are not collected. The emergency policy requiring lower respiratory testing for all lung donors is implemented May 27, 2021: one month after Executive Committee approval. Staff has done outreach to OPOs and those that were not testing as high a

proportion of lung donors by lower respiratory specimen; no concerns have been raised about the implementation date so far.

A Committee member suggested identifying whether other organs are used when there is a lower respiratory test even if the lungs are not used, and stratifying by DCD versus brain death for lung donors. A member pointed out that sometimes lower respiratory specimens are collected and tested prior to donor evaluation, which could be a confounding factor in comparing lung with other donors. But the Committee could still look at lower respiratory test by organ type and whether utilization for non-lung organs was impacted by this change.

Next Steps:

The research analyst will incorporate this feedback into the monitoring plan for this proposal; the Committee will hear more updates once the data post-implementation has been accumulated.

4. Closed Session: Confidential Medical Peer Review

Summary of discussion:

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

Upcoming Meetings

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

Open Session Attendance

- **Committee Members**
  - Avi Agarwal
  - Debbie Levine
  - Gary Marklin
  - Helen Te
  - Jason Goldman
  - Kelly Dunn
  - Marian Michaels
  - Meena Rana
  - Raymund Razonable
  - Ricardo La Hoz
  - Saima Aslam
  - Lara Danziger-Isakov
  - Stephanie Pouch
  - Ann Woolley
  - Heather Stevenson
- **HRSA Representatives**
  - Marilyn Levi
- **CDC Staff**
  - Pallavi Annambhotla
  - Rebecca Free
- **FDA Staff**
  - Brychan Clark
  - Scott Brubaker
- **UNOS Staff**
  - Abigail Fox
  - Courtney Jett
  - Darby Harris
  - Jennifer Musick
  - Kristine Althaus
  - Lindsay Larkin
  - Leah Slife
  - Meghan McDermott
  - Rebecca Brookman
  - Sandy Bartal
  - Sarah Booker
  - Nicole Benjamin
  - Susan Tlusty
- **Other Attendees**
  - DongHeun Lee

Closed Session Attendance

- **Committee Members**
  - Ann Woolley
  - Avi Agarwal

    - Debbie Levine
    - Gary Marklin
    - Helen Te
    - Jason Goldman
    - Kelly Dunn
    - Lara Danziger-Isakov
    - Marian Michaels
    - Meenakshi Rana
    - Raymund Razonable
    - Ricardo La Hoz
    - Saima Aslam
    - Stephanie Pouch
    - Heather Stevenson
- **HRSA Representatives**
    - Marilyn Levi
- **CDC Staff**
    - Pallavi Annambhotla
    - Rebecca Free
- **FDA Staff**
    - Brychan Clark
    - Scott Brubaker
- **UNOS Staff**
    - Abby Fox
    - Courtney Jett
    - Jennifer Musick
    - Kristine Althaus
    - Sandy Bartal
    - Sarah Booker