

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

April 26, 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 met via Citrix GoToMeeting teleconference on 04/26/2021 to discuss the following agenda items:

1. Add Specific PHS Risk Criteria to DonorNet Project
2. POC Update
3. Closed Session: Confidential Medical Peer Review

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

1. Add Specific PHS Risk Criteria to DonorNet Project

UNOS IT staff discussed questions for Committee clarification on the proposed project, and then presented an IT mockup of how this would function within DonorNet.

Data summary:

- DonorNet, DDR, KPD: "According to the OPTN policy in effect on the day of referral, does the donor have risk factors for blood-borne diseases transmission?" –does this require updating?
- Add these criteria solely for donor evaluation (nowhere else)?
 - DonorNet data cascades to DDR - Need individual criteria in TIEDI as well (or just "overall risk" question)?
- Provide all criteria regardless of donor age? Or hide pediatric criteria if adult donor? If so what age cutoff?

Summary of discussion:

Committee members agreed that the current overall risk question is appropriate and does not need changing. They felt that the community is already comfortable with it, and there is no reason to change it.

Committee members agreed that the individual risk criteria need to be displayed in DonorNet, not just the DDR, so that it's able to be accessed by transplant programs for real-time donor evaluation. Committee members would like the individual risk criteria from DonorNet to also cascade into the DDR. Committee members wanted to ensure that the individual risk criteria would only need to be filled out if the overall risk question was answered "yes".

Committee members discussed the potential for displaying the pediatric risk criteria, breastfed by a mother with HIV infection and born to a mother with HIV, HBV, or HCV infection, for only pediatric donors. The pediatric specialists on the committee agreed that while extremely rare, an older child may be breastfed by a mother with HIV, and recommended a cutoff of <13 for pediatric donors for consistency with other pediatric definitions. The OPO representatives on the committee felt that it

would be more consistent to include all 10 risk criteria in DonorNet, and that the two additional boxes to check are not a significant difference in level of effort. Other committee members also pointed out that with the changes in donor risk categorization, there should be a significantly lower number of donors with risk factors. Committee members agreed that “not applicable” should be an option for the two pediatric-specific risk criteria, instead of “unknown”. Committee members also agreed that “unknown” should continue to be an option for all other risk criteria. UNOS staff asked that for validation of the risk criteria question, should “unknown” be counted the same as a “yes”, or should the question not validate? Members agreed that only “yes” answers should validate and confirm that the donor has risk factors. The FDA representative pointed out that the universal Donor Risk Assessment Interview (uDRAI) does not include “unknown” as an option, and that the guidance alongside it says to seek another historian if the coordinator feels like the historian being interviewed doesn’t know the donor’s history.

Committee members also wanted to confirm that the 10 risk criteria would be available on the main page of DonorNet for when a transplant program is assessing an organ offer. UNOS IT staff confirmed that is the current plan, and the committee’s coordinator representative affirmed that this would be the ideal option.

Next steps:

The Committee will vote to send the proposal to public comment in May, with public comment starting in August.

2. POC Update

The Vice Chair presented the Policy Oversight Committee’s spring report out.

Summary of discussion:

Members had no questions or concerns.

3. 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 4, 2021, 3 PM EST, Teleconference
- May 24, 2021, 12 PM EST, Teleconference
- June 1, 2021, 3 PM EST, Teleconference

Open Session Attendance

- **Committee Members**
 - Ann Woolley
 - Avinash Agarwal
 - Charles Marboe
 - Debbie Levine
 - Gary Marklin
 - Heather Stevenson-Lerner
 - Jason Goldman
 - Kelly Dunn
 - Lara Danziger-Isakov
 - Marian Michaels
 - Meenakshi Rana
 - Raymund Razonable
 - Ricardo La Hoz
 - Saima Aslam
 - Stephanie Pouch
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **CDC Staff**
 - Ian Kracalik
 - Pallavi Annambhotla
 - Rebecca Free
 - Sridhar Basavaraju
- **FDA Staff**
 - Scott Brubaker
- **UNOS Staff**
 - Abigail Fox
 - Cassandra Meekins
 - Courtney Jett
 - Darby Harris
 - Kristine Althaus
 - Laura Cartwright
 - Leah Slife
 - Nicole Benjamin
 - Sandy Bartal

Closed Session Attendance

- **Committee Members**
 - Ann Woolley
 - Avi Agarwal
 - Gary Marklin
 - Heather Stevenson-Lerner
 - Jason Goldman
 - Kelly Dunn
 - Lara Danziger-Isakov

- Marian Michaels
- Meenakshi Rana
- Raymund Razonable
- Ricardo La Hoz
- Saima Aslam
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