

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

January 29, 2021

Conference Call

Ricardo La Hoz, MD, FAST, FACP, FIDSA, Chair

Lara Danziger-Isakov, MD, MPH, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 01/29/2021 to discuss the following agenda items:

1. Public Comment Proposal: Modify the Deceased Donor Registration (DDR) Form
2. SARS-CoV-2 Summary of Evidence: Review and Vote

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

1. Public Comment Proposal: Modify the Deceased Donor Registration (DDR) Form

The Organ Procurement Organization (OPO) Committee Chair presented on their public comment proposal for DTAC's feedback.

Summary of discussion:

DTAC leadership requested that the OPO committee include data collection for PHS risk factor criteria in the DDR in their summer public comment proposal, as lack of information on what risks specific donors have was a limitation in the past policy evaluation. The OPO chair brought up that while that would be outside of the scope of this proposal, she can bring it back to the committee to discuss for their August public comment proposal. While all OPOs already collect this information on the Donor Risk Assessment Interview (DRAI), adding additional elements to the DDR is outside of the scope of this proposal.

Committee members agreed that renaming the "serologies" section to "infectious disease testing" and moving nucleic acid testing (NAT) into that section as well would be beneficial and in line with current practice.

Committee members brought up that the question "clinical infection confirmed by culture" is not currently a useful data field without more information on the cultures. There is a difference between positive cultures and infection, and cultures can be positive without symptoms. In addition, collecting more granular information on this would likely get complicated, especially if trying to determine specific symptoms with the next of kin.

Committee members discussed the data field for "history of tuberculosis (TB)". They discussed that it needs to be better defined, if it's symptomatic history, risk factors for infection, or previous positive test results. It's helpful to know that information when assessing for the risk of latent disease and potential for disease transmission, but they would like more granular information on where the donor was born, traveled, lived, and other risk factors. In addition, they would like to know if the donor had previously had a positive skin test. The main concern with that suggestion was that family members may not understand the difference between latent/active TB and the significance of a positive skin test. However, they felt that the potential consequences of donor-derived TB warranted any additional information possible, even if it will not necessarily be consistently reported.

Committee members agreed that while Chagas is not being evaluated by most OPOs at this point, it is a useful question to leave in the DDR.

Next steps:

UNOS policy and community relations liaison will draft a committee response to the proposal for leadership to review.

2. SARS-CoV-2 Summary of Evidence: Review and Vote

The DTAC Chair presented on the summary of evidence document and requested committee feedback.

Summary of discussion:

CDC was concerned about the strength of the wording. They felt that testing all potential lung donors by lower respiratory sample *will* decrease the likelihood for unanticipated SARS-CoV-2 transmission, instead of *could* decrease the likelihood. The main concern from committee members was that there has only been one donor-derived infection so far, so there may not be adequate evidence of that at this point. One CDC member recommended the term “likely” decreases risk, and the committee came to consensus on that wording.

The CDC also felt that there should always be a nasopharyngeal (NP) swab performed, as the infection begins in the nose, and a lower respiratory tract specimen only might miss an earlier, milder case. However, they found in their data review that NP swabs are less sensitive than lower respiratory specimens in the setting of acute COVID-19. The committee chair brought up that the committee felt that it would be beneficial to always test a respiratory sample for SARS-CoV-2 regardless of the organs being donated, and then further specified that a lower respiratory sample performed in the setting of lung donation would further reduce the risk of unanticipated transmission. The CDC felt there is an additive benefit for both an NP swab and lower respiratory test being performed. Committee members mentioned that there needs to be balance between what is the safest option for recipients versus potentially losing organs for recipients. If testing becomes too onerous without sufficient data to support it, there may be potential for organ discard, and sequential testing would make it far more difficult for OPOs and transplant programs in a short period of time. One OPO representative mentioned that his OPO always obtains an NP swab, but that they aren’t routinely obtaining lower respiratory samples. Currently transplant programs are not requesting it, and instead requesting current NP swabs and the full clinical picture/CAT scan. He also mentioned that not every OPO may have the ability to obtain a lower respiratory sample.

The committee Vice Chair mentioned that there isn’t sufficient information on the sensitivity or specificity of various testing modalities in deceased donors, and that this document will be needed to be updated as more information becomes available. Committee members agreed that this document needs to be updated regularly, and that the committee needs to be nimble and responsive to the community.

The committee voted unanimously to send the summary of evidence to the OPTN Executive Committee for release to the community. 13 yes, 0 no, 0 abstain.

Next steps:

UNOS policy and community relations liaison will send the summary of evidence to the OPTN Executive Committee for review.

Upcoming Meetings

- February 22, 2021, 12 PM EST, Teleconference

- March 19, 2021, 11 AM EST, Teleconference
- March 22, 2021, 12 PM EST, Teleconference

Attendance

- **Committee Members**
 - Ann Woolley
 - Charles Marboe
 - Gary Marklin
 - Helen Te
 - Jason Goldman
 - Kelly Dunn
 - Lara Danziger-Isakov
 - Marian Michaels
 - Meena Rana
 - Raymund Razonable
 - Ricardo La Hoz
 - Saima Aslam
 - Stephanie Pouch
- **HRSA Representatives**
 - Chris McLaughlin
 - Jim Bowman
 - Marilyn Levi
- **CDC Staff**
 - Ian Kracalik
 - Jefferson Jones
 - Pallavi Annambhotla
 - Rebecca Free
 - Sridhar Basavaraju
- **UNOS Staff**
 - Abby Fox
 - Courtney Jett
 - Craig Connors
 - Darby Harris
 - Kristine Althaus
 - Laura Cartwright
 - Leah Slife
 - Liz Robbins Callahan
 - Nicole Benjamin
 - Peter Sokol
 - Robert Hunter
 - Roger Brown
- **FDA Staff**
 - Brychan Clark
 - Scott Brubaker
- **Other Attendees**
 - Diane Brockmeier