

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

October 26, 2020

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 10/26/2020 to discuss the following agenda items:

1. Align OPTN Policies with 2020 US PHS Guideline

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

1. Align OPTN Policies with 2020 US PHS Guideline

Committee Past Chair discussed the feedback received during public comment as well as the proposal being submitted to the OPTN Board of Directors for review.

Summary of discussion:

One committee member raised the concern of 96-hour time limit for serologies to be drawn prior to OR date. HRSA specifically said in their letter to the OPTN that this would be required to remain identical to the PHS Guideline for the OPTN to remain compliant with the final rule. One member brought up that the way the policy is written, the serologies would need to be redrawn but not necessarily resulted prior to OR. There was some division on this issue among the committee, as they wanted donors to continue to be utilized, but didn't like the idea of results still pending at time of transplant. In addition, programs may choose to delay the OR until those results are back.

One committee member brought up that the policy evaluation plan doesn't currently capture all of the relevant issues, such as if samples are being re-drawn for infectious disease testing. The data fields do not currently allow for serial reporting. Multiple members expressed that they would like to better evaluate potential delays this proposal could create for OPOs, especially as positive serologies could trigger a match run re-execution. UNOS IT and Research looking into potential solutions and/or methods for evaluation.

Multiple members discussed the language of "OR time" and how the interpretation could vary for OR entry, incision, cross-clamp, removal of the first organ, or removal of the last organ. UNOS staff explained that the current standard is OR entry time. In addition, UNOS staff clarified that the compliance plan for the policy includes a draw time within 4 days of the OR date, as the dates are what is collected within UNet.

Vote to send the proposal for OPTN Board of Directors consideration: 15 yes, 0 abstain, 0 no.

Upcoming Meetings

- November 18, 2020, CLOSED SESSION Teleconference
- November 23, 2020, CLOSED SESSION Teleconference

- December 1, 2020, CLOSED SESSION Teleconference

Attendance

- **Committee Members**
 - Ann Woolley
 - Avi Agarwal
 - Charles Marboe
 - Deb Levine
 - Gary Marklin
 - Heather Stevenson-Lerner
 - Helen Te
 - 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
 - Jefferson Jones
 - Pallavi Annambhotla
 - Sridhar Basavaraju
- **FDA Staff**
 - Scott Brubaker
- **UNOS Staff**
 - Brian Plucinski
 - Caitlin Bergendhal
 - Cassandra Meekins
 - Courtney Jett
 - Darby Harris
 - David Klassen
 - Emily Ward
 - Kristine Althaus
 - Leah Slife
 - Peter Sokol
 - Sandy Bartal
 - Shannon Edwards
 - Susan Tlusty