

**OPTN Disease Transmission Advisory Committee
Meeting Minutes
April 22, 2019
Conference Call**

**Marian Micheals, MD, MPH, Chair
Ricardo La Hoz, MD, Vice Chair**

Introduction

The Disease Transmission Advisory Committee met via Citrix GoToTraining teleconference 04/22/2019 to discuss the following agenda items:

1. Update on Increased Risk Recommendations to the Health and Human Services (HHS) Advisory Committee of Blood and Tissue Safety and Availability (ACTBSA)
2. Committee Vote: Modify HOPE Act to Include Other Organs

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

1. Update on Increased Risk Recommendations to the Health and Human Services (HHS) Advisory Committee of Blood and Tissue Safety and Availability (ACTBSA)

DTAC members presented recommendations on behalf of the OPTN on 4/15-16. In this part of the meeting, the committee was updated on recent input on increased risk recommendations by ACTBSA.

Summary of discussion:

ACTBSA recommended maintained designation for Increased Risk Designation (IRD) for HIV, HBV, and HCV. They also supported the Nucleic Acid Test (NAT) and serology as a requirement for all donors in addition to universal testing for all recipients 2-4 weeks post-transplant. They agreed that the term IRD should be altered in order to be less bias for donor and candidate families. ACTBSA supported a shortened timeframe from 12 months to 3 months. This committee added that they recommended the use of a universal Uniform Donor Risk Assessment Interview (DRAI) and that this data collection should be funded by the Organ Procurement and Transplantation Network (OPTN).

ACTBSA recommended the removal of STI, hemodialysis, women having sex with men with MSM, Hemodilution (when only criterion), 18 month olds with mothers with a risk for HIV, HCV, and HBV, and 12 month olds breastfeeding with mothers with risks from the IRD criteria. This committee also supported funding for counseling and consent improvement processes. They asked for the creation of tools for the education of transplant providers. The committee voiced their support for the payment of treatment for unanticipated HCV donor-derived infection.

Next steps:

ACTBSA's recommendations are discussed in inter-agency meetings and then presented to the Blood, Organ, and Tissue Senior Executive Council (BOTEC) who will make recommendations to HHS. The goal is to have the draft recommendations posted to the Federal Registrar for public comment by the end of the calendar year, but this timeline will depend upon how many of the recommendations are accepted or changed. A member commented that once these recommendations are finalized and put into practice, the OPTN will need to ensure policies are aligned with the newly published guidelines. Another member reminded DTAC that anyone can make a public comment, including individual DTAC members.

2. Committee Vote: Modify HOPE Act to Include Other Organs

Members reviewed HOPE Act support and public comment themes. DTAC took a vote to move to send the proposal to the Board of Directors (BOD).

Summary of discussion:

The Modify HOPE Act to Include Other Organs proposal received general support from 5 individuals and all 11 regions. It also received support from the Thoracic, Transplant Coordinators, Patient Advisory, and Pediatrics committees in addition to the following societies; American Society for Histocompatibility and Immunogenetics (ASHI), American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), Society of Thoracic Surgeons (STS), International Society for Heart and Lung Transplantation (ISHLT), American Nephrology Nurses Association (ANNA), and HOPE in Action Multi Consort.

A common theme from these groups was support for the continued review of HOPE Act processes to ensure the safe utilization of HIV- positive organs in addition to ongoing data collection. Those in support also asked for the inclusion of patient advocacy and any updates on provided guidance. Also, in general Organ Procurement Organizations (OPO) were supportive of the HOPE Act.

DTAC took a Committee Vote on- Does DTAC recommend the proposal, “Modify HOPE Act to Include Other Organs” to go to the OPTN BOD in June for consideration? The committee was asked if they had any edits to the proposal and all members agreed they did not. A member made a motion to have the proposal move forward to the BOD and this motion received a second.

Vote: 18-Y, 0- No

Next steps:

Modify HOPE Act to Include Other Organs will move forward and begin its process to go before the BOD in June.

Upcoming Meeting

- May, 20 (Teleconference- Closed Session)