

OPTN/UNOS Ad-Hoc Disease Transmission Advisory Committee
Meeting Minutes
January 23, 2017
Conference Call

Cameron R. Wolfe, M.D., Chair
Marian G. Michaels, M.D., M.P.H., Vice-Chair

Introduction

The Ad-Hoc Disease Transmission Advisory Committee (DTAC) met via teleconference on January 23, 2017 to discuss the following agenda item:

- 1. Guidance on Explaining Risk Related to Use of Increased Risk Donor Organs When Considering Organ Offers** The following is a summary of the Committee's discussions.

The Committee heard an update from the Chair of the Joint Society Working Group regarding Guidance on Explaining Risk Related to Use of Increased Risk Donor Organs When Considering Organ Offers.

Summary of discussion:

DTAC, in collaboration with the Joint Society Steering Committee (JSSC)¹, developed a guidance document during the third and fourth quarters of 2016 to inform and facilitate conversations between transplant team members and their patients on organs from increased risk donors. At the conclusion of their conference call on November 4, 2016, the Joint Society Working Group (JSWG) voted to hand to the leadership of the societies for their consideration. The Chair of the JSWG presented an update on this document to DTAC for their consideration.

The working group Chair summarized that this document was developed collaboratively. The structure of the working group was that DTAC participants functioned as primary authors and representatives from the JSWG served as editors. In addition, subject matter experts were consulted during the creation of the document. After the document was developed by the working group, the societies that comprise the JSSC reviewed the document. Each body endorsed the guidance without edits.

After the societies endorsed the document, minor edits were made:

- for grammar, clarity, and style by UNOS staff,
- display relative risk both as a percentage and as a ratio (per 10,000 donors), and
- to add clarity regarding the risk of undetected disease transmission in the setting of death secondary to drug overdose within the window period for nucleic acid testing.

The working group Chair reviewed the proposed timeline with the Committee, as well as the next steps to navigate public comment, post public comment consideration, and Board consideration.

¹ Joint Society Steering Committee – representatives from the American Society of Transplantation, the American Society for Transplant Surgeons, and the North American Transplant Coordinators Organization.

The Committee Chair thanked the working group Chair for successfully leading this project through the JSWG pathway and opened the floor for questions. Members of the Committee held a discussion on the potential that Figure One and Table Three of the paper appear to present conflicting data. Members clarified that Table 3 reflects the risk if *outside* the nucleic acid testing (NAT) window period, and Figure One reflected being *within* the NAT window period. At the conclusion of the discussion, the Committee acknowledged that concrete data would be ideal, however this data are small and based on literature that is a few years old. Mathematical modeling is used to demonstrate to providers the risk of disease transmission associated with NAT within a window period of exposure. Members of the Committee shared that the concern is centered on donors with *recent* increased risk behaviors, rather than donors with distant behaviors. Further, all donors come with some risk, and it's likely this risk cannot be reduced to zero. At the conclusion of the discussion, members felt it was important to keep both renderings as they currently appear in the draft. Additionally, some members felt that a few clarifying sentences could enhance the understanding of the document.

Members also discussed the use of a recent graphic in a pending publication from colleagues at the Centers for Disease Control and Prevention (CDC). In the current draft, this graphic appears in black and white. CDC colleagues have approved the use of this to appear in color (red and blue lines) and with representative lines for HIV and HCV. These changes will make the graphic easier for the reader to understand.

At the conclusion of the discussion, the Chair asked UNOS staff how to best proceed with late edits suggested by the Committee and to move forward on the project. UNOS staff advised that it was appropriate for the Committee to allow the Chair edit privileges after the vote. In light of this advice, the Committee voted to solicit public comment on the guidance document, with edit privileges to the Chair to amend the document consistent with the current discussions (Yes - 13, No - 0, Abstain - 0).

Next steps:

- The Chair will update the document consistent with the discussions and share with UNOS staff.
- The POC will consider this document for public comment in March 2017.

With no further business to discuss, the call was adjourned.