OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee (DTAC)
Meeting Minutes
April 11, 2017
Conference Call

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

Introduction

The OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee (hereafter, the Committee) met via Citrix GoToTraining teleconference on 04/11/2017 to discuss the following agenda items:

1. Case Review
2. Guidance on Explaining Risk Related to Use of U.S. PHS Increased Risk Donor Organs When Considering Organ Offers
3. Toxoplasmosis Project Post Production

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

1. Case Review

The DTAC reviewed 2016 case reports of potential donor derived disease transmission.

2. Guidance on Explaining Risk Related to Use of U.S. PHS Increased Risk Donor Organs When Considering Organ Offers

The Committee reviewed comments posted to the OPTN web site on the Committee's proposed guidance document currently out for public comment from 03/27/2017 – 04/25/2017.

The Chair and Vice Chair have been discussing the guidance document with a variety of individuals and transplant related groups. There was also a national webinar that discussed the document. Generally the perception has been positive, most people feel this will be very helpful.

Due to the short time line from the end of the public comment period and when the document will go to the Board of Directors for approval, the committee wanted to begin review of the comments currently posted so that they can start discussions about modifications if necessary.

The Committee liaison referred to the link to the public comment document which also contained a link to the webinar, which was well attended. There are three public comments to date. It's the committee's responsibility to consider all public comments.

The first comment is from Allen S. Anderson, MD:

- Generally clear and well-conceived/executed document and I support the concept. How many cases of HIV/HEPC/HEPA have been transmitted in the last 5 years via organ donation? The percentages are useful but absolute numbers are quite low as well and might be another means of communicating this information to patients.

  Also, it might be reasonable to suggest that the risk of donor transmitted viral disease be characterized within the context of overall risk of organ failure/complications of transplantation, as well as the risk of deferring transplant (which is well-mentioned in the paper).

The committee chair expressed these are two common themes. First theme is, can you actually tell us the number of cases. A committee member will be presenting HCV data at ATC. There

have not been HIV transmissions and very few HBV transmissions. Once that has been presented DTAC will be able to incorporate a sentence to say here is our absolute number so far. This has previously been avoided so that it would not be the only consideration but will be added to meet public comment request.

The Committee discussed that second half of the comment is also reasonable. The risk of dying by staying on dialysis will be added with available data to address the question.

A committee member added that there are papers out there that look at those very questions, and calculators. The document can cite them as references because they are very dense.

A committee member agreed but felt the comments were coming up enough on the conference calls that the DTAC should have a little paragraph reiterating zero HIV transmissions and the number of the hepatits C (HCV) transmissions. In one of the comments it was noted that the commenter probably meant hepatitis B (HBV) instead of hepatitis A (HAV). It was noted that the risk of dying while waiting for an organ, as well as survival rates, differ significantly among organ types. The Committee though will add some information to address these public comments.

Another member suggested adding comparative risk as shown in the presentation slides.The committee discussed that the motor vehicle analogy was confusing to some and caused people to go off topic.

The second comment was from John Renz:

- The data are clear with the transmission risk so low, diagnostic modalities so sensitive, and excellent treatment available, any program that enhances education and utilization should be prioritized.

The concenus from the committee was that this was a good comment and they hope that transplant programs will use these resources although specific programs themselves cannot receive priority.

The third comment was from Michael D. Voigt:

- The information provided by the guidance document is excellent. However I think that the information, as presented, will be counterproductive, because it focuses patients' attention on the very small risk of getting an infection from a PHS high risk donor, rather than the risk of dying if the patient does not take the organ. This document will nudge people to NOT take PHS high risk organs, because of the well-known immediacy bias. I think the guidance document would be improved by changing figure 2 to compare the risk of acquiring HIV infection to the risk of person dying if they wait for another organ. This would have to be somewhat organ-specific. This is more relevant than comparing the risk of HIV acquisition to the risk of having a traffic accident. (Strictly speaking the correct comparison should be to compare the risk of dying from HIV versus the risk of dying on the waiting list, if they do not take the organ).

A committee member felt the commenter didn't understand that this document was not for the patient, but that the document is geared to helping OPOs and transplant hopsitals better understand and communicate increased risk with their patients.Some members indicated that the document should emphasize all the rest of the reasons donors are classified as increased risk, yet functionally they have close to zero risk of transmitting. It was thought to emphasize the positive of the relatively low risks.

DTAC will be meeting again a couple of weeks to make any changes that may come out of additional comments and discussions.

A committee member suggested considering including more on HBV since there is not much information in the public about HBV transmission and DTAC would have relevant data.

It was confirmed that the idea was to present absolute transmission numbers. The chair thought this document could include this but that it would be important in how this was presented since there are more nuances regarding true positive antigens verses core antibody transmissions that then become viremic.

3. Toxoplasmosis Project Post Production

The deceased donor toxoplasmosis screening went live as scheduled on April 6th. Currently,116 donors had the toxoplasmosis screening as indicated on the DonorNet® infectious disease page. The results breakdown are as follows:

- Hemodilution status: 4 yes/107 no
- 10 positive results
- 89 negative results
- 0 unknown results
- 5 not done results
- 2 indeterminate results

The positive rate is roughly 10% and the DTAC felt that was in line with what they would expect to see. Some talking points are also being developed for toxoplasmosis results in addition to the current LMS module available. One member asked if the five donors that did not have the test were around the first of the month where they may have started the donor work up prior to the switch over or right around the switch. The liaison felt that could be plausible and will research the question. DTAC members were pleased with the data to date showing that the testing is underway.

Upcoming Meeting

- May 9, 2017

Attendance

- **Committee Members**
  - Cameron Wolfe, Chair
  - Marian Michaels, Vice Chair
  - Remzi Bag
  - Dan Kaul
  - Ricardo La Hoz
  - Ajit Limaye
  - Aneesh Mehta
  - Tammie Peterson
  - Robert Sawyer
  - Joanna Schaenman
  - Patrick Wood
  - Helen Irving
  - Kathleen Lilly
  - Nicole Theodoropoulos
- **HRSA Representatives**
  - Jim Bowman
- **CDC Staff**
  - Sridhar Basavaraju
- **OPTN/UNOS Staff**
  - Tory Boffo
  - Marissa Clark
  - Cassandra Meekins
  - Susan Tlusty
  - Chris Wholley