

**OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee**  
**Meeting Summary**  
**October 21, 2015**  
**In-Person Meeting, Chicago, IL**

**Daniel Kaul, MD, Chair**  
**Cameron Wolfe, MD, Vice-Chair**

*Discussions of the full committee on October 21, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <https://optn.transplant.hrsa.gov>*

**Committee Projects**

**1. Modifications to How New Donor Information Received Post-Transplant is Reported to Recipient Centers**

The Committee reviewed progress to date on this project. The project is seeking to address the problem where instances where communication delays or failures of new donor information learned post-transplant led to potential transplant recipient morbidity or mortality. The Committee seeks to improve communication regarding new information that is critical to recipient care, enhance recipient safety, and help to prevent or quickly react to potential donor-derived disease transmission.

A Failure Mode and Effects Analysis (FMEA) was conducted in 2014 to analyze the process used to communicate this information and all of the potential failure points that could lead to potential recipient harm. The FMEA included representation from the OPO, Transplant Coordinators, and Transplant Administrators Committees.

At their in-person meeting, the DTAC discussed several items that are being prepared to address this issue. The Committee reviewed the policy proposal being developed for January 2016 public comment that would clarify post-recovery and post-transplant reporting requirements. A major focus is specifying what types of results must be reported to whom by OPOs. Current data show that some results are unnecessarily reported and may be contributing to system failures due to reporting fatigue.

The DTAC and CDC edited a list of special pathogens that will be maintained by the OPTN Contractor. This list will clarify reporting while maintaining the benefit that CDC plays in disease transmission investigations. In addition, the policy proposal will be more specific to the types of results to be reported to filter out those which do not require DTAC review and reduce the burden on the existing patient safety contacts without compromising safety and patient care.

The DTAC discussed a memo received from the Membership and Professional Standards Committee (MPSC) requesting that the DTAC review recommendations for reporting of toxoplasmosis and other respiratory testing results when these tests are done by the transplant hospital. The Committee decided to include proposing a requirement that toxoplasmosis results be reported back to the host OPO so that in turn these can be shared with all transplant hospitals. Edits from suggestions at the in-person

meeting will be incorporated into the policy draft. The Committee will vote on proposed policy to send out for public comment in January 2016.

Members received an update on efforts to work with representatives from AOPO and the OPO Committee to identify and disseminate effective practices in communication of results for OPOs. A similar effort is planned for transplant hospitals and will involve representatives from the Transplant Administrators and Coordinators Committees as well as possible external groups such as NATCO.

The DTAC originally considered developing programming modification to the patient safety contact list. This effort is not currently being pursued. The UNOS IT Customer Council is considering developing a pilot to enhance how results received post recovery or transplant could be communicated through DonorNet® using a notification system similar to what is currently used for organ notifications.

Staff from UNOS IT presented a mock up of how DonorNet might be modified to facilitate reporting and be tied to electronic notifications. DTAC supports this concept. Feedback from the DTAC included that the electronic notification would be excellent but only for positive results. They agreed with the suggestion to include those on call for organ offers for the notifications. They provided feedback on issues with distinguishing pre versus post test results.

## **2. Developing Education and Guidance on Explaining Risk Related to Use of Increased Risk Donor Organs When Considering Organ Offers**

In response to brainstorming on ideas of how to increase the number of transplants in support of OPTN Strategic Goal #1, the DTAC developed and submitted a project to develop education and guidance on communicating PHS increased risk status. The transplant community has repeatedly requested assistance on how best to explain relative risk of transplant related to PHS increased risk donors to potential organ recipients. Helping candidates understand the potential risks related to receipt of these organs versus refusing an organ for transplant is an important, but challenging topic. The Committee believes that clearer understanding of risk in using these organs may lead to a greater number of transplants using increased risk organs that may otherwise take longer to allocate or ultimately be discarded.

During the in-person meeting the concept of this project was reviewed. There have been questions related to whether this type of guidance should come from the OPTN or the professional societies. The DTAC wishes to compile a list of existing resources in this area of research and work with the professional societies to develop education or guidance that will benefit both transplant professionals in effective communication and candidates in better understanding risk/benefit ratio. The CDC also indicated that they are working on some materials that would fit in with the project.

It was pointed out that this project will involve external subject matter experts in education as well as researchers from Northwestern University who have developed an application related to this idea. The end products of the project have yet to be determined and will be developed to meet the needs for both patients and the transplant community. This project was approved by the Policy Oversight Committee in September 2015. The project will be considered as a potential Joint Societies Work Group project in November 2015. This project is anticipated to reduce unnecessary discard of increased risk organs.

## Other Significant Items

### 3. Committee Brainstorming to Increase the Number of Transplants

The DTAC conducted further brainstorming to increase the number of transplants at its October 21, 2015 in-person meeting. The following are all ideas the Committee considered:

- 1) Use data from DTAC reviews to provide guidance on use of contralateral kidneys in cases where there are small nodules/renal cell carcinomas or cases where there are small liver nodules that may not pose significant risk.
- 2) Increase donors used that may be otherwise medically ruled-out or consented but not recovered (e.g. non-HIV sepsis).

Care teams may not be considering or referring patients with infections. Education must be developed and provided so that infection in potential donors does not automatically rule out calling OPOs to evaluate. Another issue contributing to this problem is lack of transplant infectious disease expertise being called upon to help evaluate. We need to collect data on Intervention without Documented Transmission (IWDT) cases and help provide infectious disease expertise resources to OPOs.

- 3) Study and publish outcomes of transplantation from high-risk donors to reduce unnecessary non-use. Identify the timing and best methods to educate candidates, transplant teams, and potential donor care teams. There is misunderstanding surrounding positive infectious disease test results as well as issues in understanding true risk for transmission in donors (e.g. HCV Ab (w/neg NAT; Hep B core; Syphilis). There is also misunderstanding and overestimation of risk related to malignancy transmission. There may be language changes needed to help educate on the spectrum of risk for PHS increased risk donors. (Note this is an existing project under development).
- 4) Educate the critical care community on topics such as
  - a. Donor management goals pre-consent
  - b. Infectious Diseases Society of America (IDSA) guidelines to include donor management
- 5) Import organs from non-US sites
- 6) Educate public/families about donation/ethnic/religious differences.
- 7) Education about newer organ preservation techniques.

### 4. Case Review

The Committee reviewed potential donor-derived disease transmission events reported to the OPTN. It was decided to conduct a separate summary review of non-thoracic Toxoplasmosis cases to look at the need to educate the transplant community on the impact that the disease can have on recipients receiving organs other than hearts. These data may possibly be summarized for an American Transplant Congress (ATC) abstract.

### 5. Data Request Reviews

- 1.) DTAC support staff reviewed results from an ongoing data request for reporting by region and Donation Service Area (DSA) prepared in response to an ongoing data request at the previous meeting. Key findings included:
  - The total cases reported and reviewed by DTAC increased steadily from 157 in 2010 to 284 cases in 2013. The number of cases reviewed dropped very slightly in 2014 to 279. As of November 11, 2015, the DTAC has received 244 cases that

have been reviewed or are in the process of review. It is anticipated that the total 2015 caseload will be similar to 2013 and 2014.

- The percentage of 2013-2014 deceased donors with a reported case through 8/21/2015 varies by region (1.9 to 10.8%) and all but one region is under 5%.
  - Across DSAs, the percentage of deceased donors recovered 2013-2014 with a reported case through 8/21/2015 ranges from 0 to 66%. All but three DSAs had 6.3% or less; these others were at 66.1%, 18.9%, and 9.3%.
  - Regionally, the percentage of 2013-2014 recovered deceased donors with a proven/ probable case through August 21, 2015 ranged from 0.0% to 0.5%.
  - The percentage of cases reported 2013-2014 resulting in a proven/probable classification ranged from 0% to 30% across regions.
  - In 2011 there was a large increase in living donor cases reported (n=9) and this trend has continued in 2012 (n=8), 2013 (n=12), and 2014 (n=19).
- 2.) Following a data request at the prior DTAC in-person meeting, results to assess whether pediatric donors might be resulting in unused organs due to HCV NAT positive results (suspected to be false positives) were reviewed at the meeting. The key findings are listed below:
- As of September 11, 2015, there were 2,300 deceased donors recovered in the United States between April 1, 2015 and June 30, 2015:
  - Overall, 21% of donors recovered during this period were PHS increased risk donors.
  - There were no HCV NAT positive pediatric deceased donors (n=238) in the cohort.
  - All pediatric deceased donors who had a negative HCV NAT result also had a negative HCV serology result.
  - Approximately 93% of adult deceased donors (n=2,062) that had a positive HCV NAT result had a positive HCV serology result.
  - For those seven adult HCV NAT positive deceased donors with a negative HCV serology, more than 70% were PHS increased risk donors, and more than 70% were transplanted.

The Committee requested that exploration be done regarding results of donors evaluated but not recovered to ensure that the data are answering the question originally asked. The Committee requested that the next analysis and presentation be conducted once a full year's worth of data are available. The full report is available upon request.

Committee members also were made aware of the availability of data related to post-transplant malignancies from an ongoing data request in the meeting packets. The data will be prepared and presented at the next in-person meeting in April 2016. At that point the Committee will decide whether to continue monitoring this data.

### **Upcoming Meetings**

- October 27, 2015 (Monthly teleconference)
- November 24, 2015 (Monthly teleconference)