

**OPTN/UNOS Ad Hoc Disease Advisory Transmission Committee**  
**Meeting Summary**  
**November 24, 2015**  
**Conference Call**

**Dan Kaul, MD, Chair**  
**Cameron Wolfe, MD, Vice Chair**

*Discussions of the full committee on November 24, 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 <http://optn.transplant.hrsa.gov>.*

**Committee Projects**

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

Members reviewed the latest draft of pathogens of special interest list. The representative from the Centers for Disease Control and Prevention (CDC) had requested that Enterovirus D68 be added to the list. It was noted that this would be done. It was also clarified that both Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) were on the list.

The group debated whether to exclude serology testing indicating Lyme disease due to issues in interpreting the disease status from this testing. An example of how Lyme disease might be discovered through carditis and subsequent serology testing. The group decided to leave all results indicating Lyme disease (including serology) for the current time. They will reassess this decision as needed based on report volume and significance.

It was noted that the list will not be part of policy and can be amended by the Committee at any time. This will allow for responsiveness to emerging conditions or other needed changes.

The need to have a clause that rules out previous history of infection that is not current or dormant but could be reactivated was discussed. Draft language clarifying this for the list will be circulated once developed for DTAC members to consider.

Members reviewed the latest proposed policy draft for modifications to how new donor information received post-transplant is reported to recipient centers.

The clean copy of the policy was reviewed first. It was noted that DTAC will seek specific feedback regarding vascularized composite allografts (VCA). How VCA will fit in and what the needs will be are still to be figured out. VCA will not be excluded.

This proposal specifies certain donor results, but puts the emphasis back on tracking and investigating sick recipient disease versus unnecessary follow up of donor test results that do not have clinical relevance.

The DTAC discussed the table developed for reporting positive donor results received post-transplant by OPOs. The last row was modified to address risk of infection only.

The malignancy requirement was modified to include findings highly suggestive of malignancy to include results that may be suspicious but not able to be confirmed (e.g. suspicious kidney pathology) yet not include all malignancy risks (e.g. smoking).

It was noted that it is rare but there are times when the DRAI (donor risk assessment) will be completed with a parent and then another person will come forward post-transplant with additional information not known by the official historian. This information (e.g. IV drug use) may then place the donor in the official PHS increased risk category. This is one scenario the last row is attempting to capture. It was questioned whether in the age of NAT this was relevant. It was noted that the transplant hospital will then need to put the recipient on surveillance and that is the worthy benefit.

DTAC members commented on the intro language clause for discovery of recipient disease or malignancy. The language had been edited to remove subjectivity clause. It was decided to put the wording "and there is substantial concern" back in. This will allow cases where routine follow up calls are made not to be pulled unintentionally into the disease investigation policy and compliance monitoring. It was noted that medical judgment cannot be avoided. It was noted that this issue can also be addressed later in this process (e.g. after public comment) if needed.

It was debated whether the language should require OPOs to conduct additional testing but ultimately that was not left in the proposed language. The addition of the requirement for transplant hospitals to communicate back all toxoplasmosis results (including negatives) was highlighted as a new requirement.

The desire to have UNOS close the feedback loop with the final determination on reports was discussed. It was noted that if feedback were provided it would increase reporting. The concerns over breaking confidential peer medical review were brought up as the reason this is not done currently. The Committee requested that this question and desire to provide more feedback be revisited with policy and legal OPTN leadership.

The issue of placing reporting burden squarely on one party (OPO) and one place (OPTN) was suggested to maximize compliance and minimize complexity. After further discussion, it was noted that the OPTN cannot be the intermediary and that living donor (transplant) hospitals will always have to report because of living donors. It was ultimately decided to leave the proposed language as is. This is important because of the needs to get information out to other recipient centers in a quick manner. One transplant hospital representative stated that the living donor section was clear. It was clarified that existing living donor policy addresses the fact that public health authorities may need to be notified of certain living donor infectious testing disease results.

DTAC members did have concerns about the language in the OPO policy that states that OPOs must have a protocol to obtain all results post-transplant and report them to the OPTN Contractor. The intent of this proposed language is to have all results uploaded to DonorNet®. Standard OPTN policy practice is to use the term "report to the OPTN Contractor" versus naming specific applications and these may change. The Committee is worried that this will be misinterpreted to mean report all results through the Improving Patient Safety (IPS) portal. One of the primary goals of the proposal is to reduce unnecessary reporting so that reporting fatigue will be reduced and proper focus placed on situations that are more relevant and their follow up. The Committee suggested changing the verb to "provide". They did not feel comfortable with this solution

and requested that policy leadership work with the Committee to develop a better alternative.

The Committee did consider the needs to have all reports and it was decided that this is important. The IT Customer Council is also developing a pilot tool for communicating results. This tool will not be as relevant or work without negative results. It is important for a transplant hospital to be able to review all test results such as prior to discharge. It was noted that transplant hospitals would not lose positive results with a deluge of negatives because negatives and other non-relevant results are not included in the policy requirements for reporting to the patient safety contact.

The need to have a protocol for reporting to tissue banks was kept because it was noted that not OPOs have all good relationships with tissue banks.

Then the strikethrough and underline version was shown with the few changes made during this meeting.

The Committee unanimously (11-Yes, 0-No, 0-Abstain) voted to send the proposal out for January 2016 public comment. The next step will be for the Policy Oversight and Executive Committees to review the proposal prior to its release.

### **Implemented Committee Projects**

2. **Reporting Whether Donor Screening Tests are Completed using Qualified Specimens** (Board approved in November 2010)
3. **Review of Minimum Screening Requirements for Deceased Donor Evaluation** (Board approved in June 2014)
4. **Aligning OPTN Policy with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation** (Board approved in November 2014)

These three projects were bundled together because they all touch specific areas of common code, and include some of the infrastructure for the HOPE Act. The programming and last phase of the PHS policy requiring NAT testing was implemented on August 10, 2015.

OPO representatives of the DTAC commented having to answer “yes” or “no” for each test in DonorNet about hemodilution status was redundant. This feedback has been shared with the UNOS IT Customer Council representative as well. It was requested to have more customer involvement in programming development processes. It was noted that many use the term “plasma diluted” versus “hemodiluted”.

The research support analyst for DTAC reviewed the plans to evaluate how these policies are working post-implementation. The post implementation evaluation will include looking at data for the following indicators:

- How many OPOs are using hemodiluted samples for donor screening? (#2)
- How many of these donors result in reports of potential disease transmission to the Patient Safety System? (#2)
- How many OPOs are using HIV antigen/antibody combination diagnostic testing versus HIV antibody screening? (everyone must select one) (#3)

- How many OPOs are using HIV antigen/antibody combination diagnostic testing instead of NAT? (Applies only for PHS “Increased Risk” donors) (#3)
- The number of HIV, HCV, and HBV cases reported and reviewed by the DTAC (#4)
- The number of cases classified as a proven or probable transmission(#4)
- The number and outcome of affected recipients (#4)

Due to the very small number of cases expected, the analysis will be initiated one year post-implementation, and will be updated every six months for three years. The policy evaluation will be created as one report, but split into three sections. After receiving one or two data report presentations, then the DTAC may revisit the frequency of presenting the data versus providing it for review.

The DTAC approved these plans and made a formal data request to conduct the post-implementation evaluation as presented.

### **Upcoming Meeting**

- December 9, 2015 (Monthly case review teleconference)