

**OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee
Report to the Board of Directors
December 1-2, 2015
Richmond, Virginia**

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

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This report reflects the work of the OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee from May 2015 through November 2015.

Action Items

1. None

Committee Projects

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

Public Comment: January 2016 (estimated)

Board Consideration: June 2016 (estimated)

Committee and Member Quality reviews have highlighted a number of 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.

Following this effort, the DTAC is preparing several steps for recommended action. A policy proposal is being developed for January 2016 public comment that would clarify post-recovery and post-transplant reporting requirements. A major focus will be on 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 CDC and DTAC have developed a list of special pathogens that will be maintained by the OPTN Contractor. This will clarify reporting while maintaining the benefit that CDC plays in disease transmission investigations. The CDC can provide special technical assistance that cannot otherwise be provided by the DTAC. 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 is also working 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. The DTAC has provided feedback for this effort based on findings from this project.

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

Public Comment: August 2016 (estimated)

Board Consideration: December 2016 (estimated)

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.

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.

Data presented at the 2015 American Transplant Congress (ATC) illustrate the need for this project. Depending on organ type, between 7.4 to 16.4% of transplant programs did not use any increased risk donors (2005-2014). Conversely, between 16.4 to 42.3% of transplant programs used 10% or more of increased risk donors showing the variation in practice. Other data demonstrated that all increased risk donors do not present the same level of risk. For example, the residual risk identified through HCV ELISA screening for IV drug users was 350 per 10,000 donors compared to only 0.46 per 10,000 donors for hemophiliacs. With the percentage of donors identified as high risk doubling from 10.3% in 2011 to 20.6% in 2014, the need for this project is greater than ever to help put risk in perspective and facilitate decisions with greater understanding.

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 CDC will also collaborate in the development. 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.

Implemented Committee Projects

4. Improvements to Potential Donor-Derived Disease Event Reporting in the Improving Patient Safety Portal

Public Comment: n/a

Board Approval: [June 2013](#)

Implementation Date: June 11, 2015

Programming enhancements to the Improving Patient Safety Portal section used to report potential donor-derived disease transmission events (PDDTE) were released on June 11, 2015. These enhancements include the addition of drop down fields for basic information received or requested during the reporting of every PDDTE. The modifications now standardize information received through the system; streamline the reporting process for members; and provide clear information for case processing and management by UNOS staff.

Projects 4-6 have been addressed for programming as an “infectious disease bundle” because they all touch specific areas of common code. They have been implemented as a group, and include some of the infrastructure for implementation of programming related to the HIV Organ Policy Equity (HOPE) Act.

5. Reporting Whether Donor Screening Tests are Completed using Qualified Specimens

Public Comment: [March 19 – July 16, 2010](#)

Board Approval: [November 2010](#)

Implementation Date: August 10, 2015

This programming was released on August 10, 2015 as one part of three bundled DTAC projects. Each individual deceased donor infectious disease test result reported in DonorNet must also now include data entry in a separate field that indicates whether the specific individual test was completed using a hemodiluted specimen. This programming supports the policy passed in November 2010 that requires OPOs to report this information.

The post implementation evaluation will review how many OPOs are using hemodiluted samples for donor screening and how many of these donors result in reports of potential disease transmission to the Patient Safety System.

The DTAC will continue its yearly review of numbers and trends in cases of potential disease transmission reported to the Patient Safety System to determine if other actions need to be considered.

6. Review of Minimum Screening Requirements for Deceased Donor Evaluation

Public Comment: [September 6 – December 6, 2013](#)

Board Approval: [June 2014](#)

Implementation Date: August 10, 2015

This programming was released on August 10, 2015 as one part of three bundled DTAC projects. The Board approved modifications to minimum screening requirements for deceased donor evaluation at its June 2014 meeting. Policy language was implemented prior to programming. The programming in DonorNet supports patient safety and reduces the free-text data entry burden for OPOs and review for transplant hospitals. The programming added a field to capture HIV antigen/antibody combination test results and updated labeling of fields for syphilis testing results.

As part of evaluating this policy change, the DTAC will review:

- How many OPOs are using HIV antigen/antibody combination diagnostic testing versus HIV antibody screening?
- How many OPOs are using HIV antigen/antibody combination diagnostic testing instead of NAT?

The DTAC also reviews the number of overall potential disease transmission events versus the total number of donors per year; the number of potential disease transmission events involving diseases for which potential donors are screened; and the number of confirmed donor derived disease transmissions versus the total number of potential cases reported and the total number of transplants per year.

DTAC will continue its yearly review of numbers and trends in cases of potential disease transmission reported to the Patient Safety System and determine if additional policy modifications regarding donor screening requirements and/or reporting should be considered.

7. Aligning OPTN Policy with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation

Public Comment: [March 14 – June 12, 2014](#)

Board Approval: [November 2014](#)

Implementation Date: August 10, 2015

This programming was released on August 10, 2015 as one part of three bundled DTAC projects. The Board approved modifications to policy that added requirements for HIV and HCV nucleic acid testing (NAT) for both deceased and living donors. With the programming release, fields were created to capture results for these tests. In addition, Waitlist screening candidate acceptance criteria were modified to indicate willingness to accept organs from donors with positive HBV NAT and HCV NAT results.

The evaluation of this proposal will monitor the number of HIV, HCV, HBV potential disease transmissions reported to the DTAC that are classified as a proven or probable transmission event. The analysis will be initiated one year after policy implementation and will include providing the number of HIV, HCV, and HBV cases reviewed by the DTAC, the number of cases classified as a proven or probable transmission, and the number and outcome of affected recipients. Due to the very small number of cases expected, the analysis will be updated every six months for three years after implementation.

8. What to do when Infectious Disease Screening Results affecting Match Runs are Updated

Public Comment: [January 27-March 27, 2015](#)

Board Approval: [June 2015](#)

Implementation Date: November 19, 2015

This proposal was designed to reduce opportunities for unintended donor-derived disease transmissions. Policy was approved that outlines when OPOs must re-execute a match run due to a change in certain infectious disease testing results to positive. A three-pronged approach guides the logic creating (1) a pathway for re-executing the match run when an organ had not yet been accepted, (2) a pathway for addressing a pending acceptance for an organ, and (3) a pathway for receiving a new positive HIV result to enhance safety upon approved allocation of these organs as part of the HOPE Act.

Programming was released on November 19th to implement this policy. Matches run prior to a change in positive infectious disease results as outlined in policy will be locked and electronic organ offer notification ability will be disabled. OPOs will have one hour to notify transplant hospitals of new positive results for HBV, HCV, and CMV (intestine matches only) for consideration only for the primary potential transplant recipient. The transplant hospital has one hour to respond following receipt of the new positive results. If the organ is declined for the first primary potential recipient, then the match must be re-executed in order to

allocate the organ. If no one had accepted the organ, then the match must be re-executed in order to proceed with allocation. HIV positive organs will follow different rules. When any HIV test result is changed to positive, then allocation must stop on the existing match runs. Liver and kidney matches may be re-executed and allocation can occur as allowed by the federal HOPE Act (effective November 21, 2015) and other relevant OPTN policies.

The evaluation of this proposal will assess whether the number of instances where a donor is positive for HCV, HBV, or CMV (intestine only) and was not indicated to be positive on the match run with documented acceptance has decreased between the pre-policy and post-policy periods. Due to the small number of such instances, this analysis will be first initiated one year after implementation, and will be monitored by the committee annually for three years.

Other Committee Work

9. Case Review

The Committee continues to review potential donor-derived disease transmission events reported to the OPTN. There have been a total of 1,510 cases reported and reviewed from 2006 to 2014. Members reviewed data on 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).

The full data report can be accessed upon request.

10. 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 are language changes needed to help educate on the spectrum of risk for PHS increased risk donors.
 - 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.
11. Data Analysis of HCV NAT results and impact on pediatric donation

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. 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.

12. Review of Current Committee Abstracts and Manuscripts in Development

Currently, the Committee is working on several abstracts for ATC 2016 submission. These include:

- 10-year review of cases reported to DTAC through the PSS
- Utilization of PHS Increased Risk Organs, which is evidence for a recently POC-approved project for guidance on explaining risk related to use of increased risk donor organs when considering organ offers
- Review of non-thoracic Toxoplasmosis cases.

Additionally, an abstract was submitted to the International Society of Heart and Lung Transplantation (ISHLT) reviewing donor-derived disease transmission events in thoracic organ transplantation. Lastly, the committee is wrapping up a manuscript examining Coccidioidomycosis transmission in organ transplantation.

13. Reporting of Donor-Related Post-Transplant Malignancies

The Committee continues to request updates on post-transplant malignancies reported on Tiedi forms as donor-related and not reported in the Improving Patient Safety system as PDDTE Data indicate that there continue to be malignancies reported only through one or the other mechanism. Many of these are appropriately reported- including post-transplant malignancies more than five years after donation or living donor with malignancy noted post-donation. One exception, however, are several cases identified where post-transplant malignancy has been reported years after the initial donor-related report was reviewed by the Committee. 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.

The latest data report is available upon request.

Meeting Summaries

The committee held meetings on the following dates:

- October 21, 2015 (In-person meeting in Chicago, Illinois)
- Case review calls on the second Tuesday of each month

Meetings summaries for this Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=95>.