

**OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee  
Report to the Board of Directors  
June 1-2, 2015  
Atlanta, GA**

**Daniel R. Kaul, MD, Chair  
Cameron R. Wolfe, MD Vice Chair**

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*This report reflects the work of the OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee from November 2014 through April, 2015.*

**Action Items**

1. What to do when Infectious Disease Screening Results Affecting Match Runs are Updated

*Public Comment: [January 2015](#)*

There is currently no requirement in policy to re-execute a match run if there is a change in the deceased donor's infectious disease testing results that would impact a candidate's appearance on a match run. Currently, four serology results are used to screen potential transplant recipients on or off an organ match run:

<b>If the deceased donor tests positive for:</b>	<b>Then candidates may choose not to receive organs on the following match runs:</b>
Cytomegalovirus (CMV)	Intestine only
Hepatitis B Core Antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Human T-Lymphotropic Virus (HTLV)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas

When considering this list, it is important to note that the requirement to screen deceased donors for HTLV was eliminated from policy in 2009. Only a small number of OPOs are still completing this test, so maintaining screening for candidates is no longer practical or appropriate. Additionally, the Board approved the addition of candidate screening based upon hepatitis B and hepatitis C nucleic acid test (NAT) results in November 2014. These additions have not been implemented yet, but are anticipated in August 2015.

A joint subcommittee, including representation from the OPO and Operations & Safety Committees, considered the potential safety concerns related to the lack of requirements for re-executing the match run if any of these tests were originally reported as negative or pending and positive results were then received during allocation. This updated information could screen some potential transplant recipients from appearing on the match run. Failure to re-execute the match increases opportunity for human error for both the OPO and transplant hospital, in communicating and receiving the updated information. If an error occurs, an organ could unintentionally be allocated to a candidate who is not willing to receive offers from organs who are positive for a specific infectious disease. This could result in an unintended donor-derived disease transmission. After reviewing data and numerous discussions regarding OPO and transplant hospital practices, the Joint

Subcommittee recommended a three-pronged approach for addressing this issue: (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 HIV Organ Policy Equity (HOPE) Act.

During its March 31, 2015 in-person meeting, the Committee considered and addressed public comment feedback on its proposed language. After careful consideration, the Committee reviewed final proposed language during an April 14, 2015 teleconference (**Exhibit A**). This language included:

- The creation of a new definition for “primary potential transplant recipient”
- Removal of more specific proposed language related to informing the potential recipient of new positive test results in addition to requirements already in place in *Policy 15.3.A: Deceased Donors with Additional Risk Identified Pre-Transplant*
- Minor clarifications based upon public comment feedback received
- Stylistic edits suggested by UNOS staff for clarity

After completing this line-by-line review of all of the proposed final language, the Committee voted unanimously to recommend the proposal for consideration by the Board of Directors (12 support, 0 oppose, 0 abstentions).

**RESOLVED, that additions and modifications to *Policies 1.2: Definitions, 2.9: Required Deceased Donor Infectious Disease Testing, 5.3.B Infectious Disease Screening Criteria, 5.4.C Liver Offers, 5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results, and 5.5.C OPO Requirements for Positive HIV Results, as set forth in Exhibit A, are hereby approved, effective pending programming and notice to the OPTN membership.***

## Committee Projects

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

Public Comment: August 2015 (estimated)

Board Consideration: December 2015 (estimated)

Committee and member quality reviews have highlighted a number of instances where communication delays or failures for new donor information learned post-transplant led to 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. As part of this effort, the Committee also looked closely at the current patient safety contract requirement, as it is not functioning as efficiently in some institutions as others, and has presented challenges in communicating important information in some cases.

This project utilized a failure mode and effects analysis (FMEA) approach. The use of FMEAs was an initiative identified in the 2012 OPTN Strategic Plan. A joint subcommittee, including representatives from the OPO Transplant Coordinators, and Transplant Administrators Committees, worked together to complete an FMEA on this communication process. The final report of this effort will be used as part of the evidence base for proposed policy modifications and automation of communication meant to enhance patient safety.

This project was temporarily put on hold to address the completion of the PHS-related policy modifications and further slowed by the appearance of Ebola in the U.S. and many committee members' involvement in preparing their own institutions for recognizing and addressing this disease. Committee leadership continued to discuss the need to address this effort from both a policy and a programming approach to aid the transplant community. Due to the desired programming for automation of some of these efforts, the leadership favored a two-pronged approach to addressing the problem.

The Committee formed a subcommittee to review the FMEA report and related policy. The first stage of this effort will be proposed policy related to developing a triage system for OPOs reporting new information to transplant hospitals. Additionally, policy related to reporting requirements for what should be entered into the Improving Patient Safety portal will be addressed. These aspects are anticipated for public comment in August 2015. The subcommittee has also requested an estimate for programming to automate the patient safety contact list. This automation would allow OPOs and transplant hospitals to update their own primary and back up contact information in real time. The subcommittee anticipates that members will want to review and update their patient safety contact list based upon proposed policy modifications, and treat this in much the same way they update their on-call coordinator listings.

The subcommittee will reconvene on May 8, 2015 by teleconference to begin review of draft policy language.

### **Committee Projects Pending Implementation**

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

Public Comment: n/a

Board Approval: [June 2013](#)

Projected Implementation: Second quarter, 2015 (estimated)

The Board approved enhancements to the portal used to report potential donor-derived disease transmission events (PDDTE) in June 2013. The current system for reporting PDDTE relies heavily on an open text field where the submitter provides a narrative. In an effort to standardize the information received through the system, staff recommended the addition of drop down fields for basic information received or requested during the reporting of every PDDTE. These enhancements will streamline the reporting process for members and provide clear information for case processing and management by UNOS staff. The Executive Committee prioritized and scheduled the implementation of this project during its April 9, 2014 teleconference.

The following projects are being addressed for programming as an "infectious disease bundle" because they all touch specific areas of common code. They will be implemented as a group, and include some of the infrastructure for implementation of programming related to the HOPE Act.

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

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

Board Approval: [November 2010](#)

Projected Implementation: Third quarter, 2015 (estimated)

The Board approved a proposal to modify requirements for screening potential donors, to including reporting of whether individual deceased donor tests were completed using a hemodiluted specimen (not a qualified specimen as defined by the FDA). Policy was implemented without fields to collect this information in DonorNet<sup>SM</sup>. The Executive Committee prioritized and scheduled the implementation of this project during its April 9, 2014 teleconference.

5. Review of Minimum Screening Requirements for Deceased Donor Evaluation

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

*Board Approval:* [June 2014](#)

*Projected Implementation:* [Third quarter, 2015 \(estimated\)](#)

The Board approved modifications to minimum screening requirements for deceased donor evaluation at its June 2014 meeting. Policy language was implemented prior to programming, but programming will enhance patient safety and reduce the free-text data entry burden for OPOs and review for transplant hospitals. Programming will include the addition of a field to capture HIV antigen/antibody combination test results and update labeling of fields meant to capture syphilis testing results.

6. 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](#)

*Projected Implementation:* [Third quarter, 2015 \(estimated\)](#)

The Board approved modifications to policy that will add requirements for HIV and HCV nucleic acid testing (NAT) for both deceased and living donors. This effort will involve programming new data fields to collect this information.

**Implemented Committee Projects**

7. Donor Screening Guidance for Seasonal and Geographically Endemic Infectious Diseases

*Board Approval:* [November 2014](#)

The Committee's guidance to aid living donor recovery hospitals in recognizing risks and screening for seasonal and geographically endemic infectious diseases during the evaluation process is available on the OPTN website. It has been highlighted as an additional resource in other educational efforts developed by Instructional Innovations and will be reviewed yearly to determine if updates are needed to content or links to additional web resources included in its text.

**Review of Public Comment Proposals**

The Committee reviewed one of the eighteen proposals released for public comment from September 29 through December 5, 2014.

8. Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act (Organ Procurement Organization Committee)

The Committee is excited about the removal of this prohibition, allowing for the exploration of this new opportunity to expand the donor pool. It appreciates that this is a multi-step policy development process due to the need for more information from the National

Institutes of Health (NIH) regarding the research protocol and its implications on OPTN functions.

The Committee supports the language as written with one comment. It was noted that an organ or vessel itself is not HIV positive, but rather it is recovered from an HIV positive donor. The Committee requests that the OPO Committee consider revisions to clarify this point in Policy 16.7.B. The Committee's own proposal to align OPTN Policy with the new 2014 PHS Guideline also touched upon this section of policy, so this issue may already be resolved.

The Committee reviewed two of the ten proposals released for public comment from January 27 to March 27, 2015.

9. Address Requirements Outlined in the HIV Organ Policy Equity Act (Organ Procurement Organization Committee)

The Committee considered this second update to the OPO Committee's work on incorporating HOPE act requirements into policy. A member asked if HIV positive donors with co-infection of HCV were prohibited from the study. Committee members who have also participated in the HOPE Act work group noted that there is no specific prohibition of donors that has been made available to the public at this time. Unless this is included in the NIH research protocol, this is anticipated to be left to medical judgment. Changes to HCV treatment may also change the overall opinion and acceptance of using organs from donors who are positive for this disease.

After review of the proposal, Committee members noted no concern related to the progress of this project or the plan outlined within it. Members eagerly await the release of the NIH research protocol that will outline specific requirements for both donor and recipient selection.

10. Modify Sterile Internal Vessels Label (Operations & Safety Committee)

Committee members spent considerable time reviewing the current internal label versus the proposed simplified version of this label. It was suggested that the new proposed label would raise caution that would then send the transplant professional back to the more detailed poly-plastic hang tag label that is attached to the outermost bag of the triple barrier in which the vessel container is stored while refrigerated. This larger, more detailed label is not sterile, and therefore, not in the operating room. It includes a breakdown of individual tests rather than the larger HBV, HCV, and HIV categories on the proposed label.

Committee members are concerned that results such as a positive HBV surface antibody result could be misconstrued using this new, simplified label. This could also be the case for a label marked positive due to a donor's HBV core antibody result, as current policy does not prohibit storage and use of the vessel. The Committee suggests that the Operations & Safety Committee consider leaving more detailed check boxes specifically for HBV on the internal label. The Committee believes that specifically listing options for surface antigen, core antibody, and surface antibody may be of more clinical value in this setting.

**Other Committee Work**

11. Alignment of OPTN Policies with the 2013 PHS Guideline Webinar

The Committee continued to develop educational materials to help the transplant community better understand the application of the 2013 [PHS Guideline for Reducing Human Immunodeficiency Virus \(HIV\), Hepatitis B Virus \(HBV\), and Hepatitis C Virus \(HCV\) Through Organ Transplantation](#). A live webinar was conducted to review additional, related policy changes approved by the Board in November 2014 that were implemented in February

2015, and respond to questions from participants during the course of the call. Over 400 individuals registered to participate in the call. All questions received during the course of the event were addressed, with responses to those that could not be addressed due to time on the call posted on the OPTN website. Additionally, this event was recorded for later viewing. Feedback from participants was favorable, with members noting that they found this to be a helpful tool in implementing these changes in their own institutions. All recordings and posted materials related to the PHS educational effort may be reviewed on the [TransplantPro website](#).

#### 12. Project Brainstorming Related to Updated Focus on Strategic Plan Goals

The Committee received an overview of proposed updates to the OPTN's Strategic Plan Goals. As part of this work, it is anticipated that the living donor and patient safety goals will be combined, and benchmarks will be put in place to guide the number of projects/level of effort that should be addressed within each goal. Primary focus will be put on increasing the number of organ transplants, with 40% of projects targeted to impact this goal. The emphasis on patient safety efforts has been recommended as 10% by the Executive Committee. Currently, the project portfolio is far out of line with the recommended benchmarks. While a number of projects will be going to the Board for consideration in June, the remaining volume of projects will still not fall within the Executive Committee's recommendations. The proposed recommendations were released for public comment in April 2015. Assuming no change post-public comment and Board approval, a number of projects will have to be cut or put on hold to meet this new framework. Additionally, Committees will need to think of ways to address the primary goal of increasing the number of transplants - which is a departure from the work of some Committees, including this one. Based upon these discussions, the Committee opted to cancel one of its recent POC-approved projects, "Consider Time Requirements for Deceased Donor Testing," as this was seen as having a potentially negative impact on the primary goal.

Committee members raised concerns related to the impact of the new benchmarks on its ability to react to concerns that might arise in the community related to infectious disease. A member noted that patient safety committees are often reacting to real time events occurring in the transplant community (e.g. H1N1, Ebola, HIV transmission). Education through guidance documents or other modalities are often created to address these concerns with the goal of raising awareness and preventing recurrence. Staff recognized the need for these unexpected but critical activities, noting that creation of guidance documents that have no programming implications would certainly be an option as needed, but that larger educational efforts requiring Instructional Innovations or IT support carry a higher level of effort that would need to be considered by the Executive Committee or Board if not already approved by the Policy Oversight Committee.

The Committee respects the need for increased focus, and appreciates efforts to move projects from idea to Board consideration more efficiently, but is concerned regarding the 10% benchmark for patient safety and the appearance of this number in comparison to the other categories. Committee members were committed to brainstorming new ideas that will promote other goals in the strategic plan that will benefit the transplant community. Two new ideas were discussed:

- Guidance on Explaining Risk and Obtaining Informed Consent A number of public comment responses submitted regarding policy modifications related to the PHS Guideline (both the increased risk donor definition and other recommendations related to testing donors, screening, candidates) requested guidance on how to best approach informed consent for increased risk donors. Studies have demonstrated

that organs from increased risk donors are more likely to be discarded even though these organs are typically otherwise of high quality. Particularly with the addition of NAT testing, the risk of donor-derived infection from these organs is typically very low compared to other risks associated with transplantation. Improving the informed consent process to allow recipients to more accurately balance the risk of donor derived infection versus the benefit gained from accepting the organ, may increase the appropriate utilization of these organs. Historically, the Committee has suggested that this topic may be better suited for the professional societies to address. In light of the new strategic plan goals and ongoing requests from members for guidance and tools, the Committee sees value in pursuing this effort and seeking input from the professional societies in its development. Committee members believe that there is great value in reaching out to the professional societies to request representation for a working group that will address this issue.

- Additional Education Related to Discard of Kidneys with Renal Cell Carcinoma (RCC) The Committee is addressing the issue of potentially unnecessary discard of the contralateral kidney when RCC is found through a manuscript already in development as well as an earlier manuscript on malignancy. Additionally, the Committee drafted a TransplantPro article on this topic. The Committee's case review experience still shows extremely limited transmission involving RCC and a high number of discards of one or both kidneys (and even other organs) when it is found or even suspected based upon frozen section results of a small tumor. The Committee believes that continuing targeted education will be beneficial on this topic and that it may lead to an increase in transplant due to a reduction in unnecessary discard of organs.

### 13. Case Review

The Committee completed its review of PDDTE reported in 2014 during its in person meeting on March 31, 2015. A total of 524 events were reported, with the Committee reviewing and classifying 278 events. The explosion of reporting in 2013 and 2014 indicates a proactive awareness of the reporting system in the transplant community. The 246 cases not reviewed by the Committee included:

- Duplicate reports (a PDDTE reported by an OPO and one or more transplant hospitals)
- Potentially unnecessary reporting (donor positive culture, but no ill recipients)
- Updates to current cases mistakenly reported as new events
- Other types of events mistakenly reported as a PDDTE (patient safety situation or living donor adverse event)

The high number of cases reported but not reviewed by the Committee coupled with the ongoing high number of cases reviewed and classified as excluded indicate potential noise in the system that may desensitize OPOs and transplant hospitals from acknowledging more critical events as they arise. The Committee is optimistic that policy changes recommended as part of the post-transplant communication of new donor information project, described above, will help rectify this situation and enhance the patient safety system with a reduction of potentially unnecessary reporting for members.

### 14. 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 a PDDTE (**Exhibit B**). 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 Malignancy Subcommittee will be reconstituted to consider this issue and review these cases for a better understanding of this concern. The end result of this effort may be education or modification to policy based upon the group's discussion.

15. Review of Current Committee Abstracts and Manuscripts in Development

Part of the Committee's charge is to provide education and guidance to the transplant community toward prevent future disease transmission. As a result, the Committee develops various presentations and papers through the year to provide transplant professionals with new information, education, and guidance towards this goal. The Committee heard updates from authors of three abstracts to be presented at the 2015 American Transplant Congress and received status updates on several manuscripts currently under development.

16. Project NOTIFY Update

The Committee received an update from a former member on ongoing work conducted through the [World Health Organization](#) to improve awareness and communication regarding donor-derived disease transmission and other patient safety situations.

**Meeting Summaries**

The committee held meetings on the following dates:

- November 25, 2014
- December 9, 2014
- January 13, 2015
- March 10, 2015
- March 31, 2015
- April 14, 2015
- Case review calls on the second and fourth 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>