

OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee (DTAC)
Meeting Summary
August 14, 2014
Chicago, Illinois

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Discussions of the full committee on August 14, 2014, 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. Aligning OPTN Policy with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation

The Committee's recommended policy additions and modifications related to the 2013 *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation* were released for public comment from March 14 to June 12, 2014. The Committee reviewed feedback on its proposal, which was mostly favorable overall. Most concerns related to perceived high false positive rates for nucleic acid testing (NAT), including: (1) effect on subpopulations (e.g. pediatric and living donors); (2) how to rule out potential false positive test results (is repeat testing appropriate?); (3) access to NAT in all donor service areas that may result in delayed donation or even lost donors; (4) time before implementation to allow OPOs and transplant programs to educate staff and change internal protocols.

Additionally, the Living Donor Committee raised concerns regarding proposed informed consent changes related to the PHS Guideline and their potential impacts for living donors. The Living Donor Committee noted that privacy may be compromised and/or offers to donate may be revoked or declined based upon sharing this type of sensitive information. While the DTAC appreciated the sensitivity of sharing this type of information, it could not support potential withholding of sensitive by relevant information to be shared and considered with a potential living donor for the sake of protecting potential relationships between living donor and recipient. The living donor will always maintain the option of withdrawing an offer to donate, and this can be done at any time with assistance from the living donor advocate in a way that can protect or shield the donor from offering the specific reason for withdrawal from donation.

After careful review and discussion, the Committee noted that the Final Rule and the key focus of enhancing patient safety do not lend themselves to modifying policy prior to Board consideration. The Final Rule requires OPTN policy to be consistent with CDC recommendations in the area of donor testing. Without changes to the PHS Guideline, the Committee does not believe it can offer alternatives to HCV NAT for all organ donors. The briefing paper will be finalized to respond to these themes, and the Committee will reconvene to approve policy language, as originally proposed, on a conference call in September. The Committee plans to take this proposal to the Board for consideration during its November 13-14, 2014, meeting.

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

The Committee received an update on this effort and the failure mode and effects analysis (FMEA) to analyze the process used to communicate this information and all of the potential failure points that could lead to potential recipient harm.

This Joint Subcommittee, including representatives from the OPO, Transplant Coordinators, and Transplant Administrators Committees, began the FMEA process in May 2014 using a series of monthly teleconferences. Representatives actively participated in outlining a process map describing the current practices for sharing this information with transplant hospitals. From there, potential failure points were identified and ranked based upon severity, likelihood, and detectability.

This group then met in Chicago on August 13, 2014, to begin finalizing its work. After reviewing the list of failure points and the final rankings assigned based upon discussions from the various conference calls, the joint subcommittee began to brainstorm on action plans to address each. These actions might include, policy modification, education and sharing of best practices, and automation of process to reduce human error. The Joint Subcommittee voiced strong support for updates to the patient safety contact list within DonorNetSM through the development of a platform similar to the OPO console, where transplant hospitals can note on call coordinators in real time. This, in conjunction with allowing the posting of post-transplant test results as attachments in DonorNetSM, were noted as high impact changes that would benefit both the OPO and transplant hospitals. Staff will take these recommendations back to OPTN IT staff for consideration.

This careful analysis will provide evidence base for policy modification. A contractor used on the previous efforts facilitated the FMEA process, and a public comment proposal is anticipated in 2015, though the Joint Subcommittee recognized that the evidence generated as part of this group will lead to a number of related committee projects.

3. What to do when Serologies Affecting Match Runs are Updated

The Committee received an update from its Joint Subcommittee, including representatives from the OPO and Operations & Safety Committees, regarding this effort. Currently, there is no policy in place to require that a match run be re-executed if new donor screening results are learned that impact whether a donor is willing to receive an offer for a positive organ. The tests currently used for screening potential candidates from a match run include:

If the donor tests positive for...	Then, candidates may choose not to receive offers for the following organs:
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas
Hepatitis C (HCV)	Heart, Intestine, Kidney, Liver, Lung, Pancreas
Human T-Lymphotropic virus (HTLV)	Heart, Intestine, Kidney, Liver, Lung, Pancreas
Cytomegalovirus (CMV)	Intestine

Representatives from the Joint Subcommittee discussed practical concerns regarding potentially rescinding an organ offer for a potential recipient who had provisionally accepted an organ and concerns related to how to address potential recipients appearing on a newly executed match run that had been added to the wait list since the re-execution of this updated match run. Joint Subcommittee members reviewed draft policy language based upon previous discussion of this topic, but recognized that no surgeons were on this most recent call. Because surgeons are often considering and provisionally accepting these offers, the group agreed that their input was critical before considering whether to move forward with this proposed language. The Joint Subcommittee will reconvene in September to finalize these discussions.

A Spring 2014 public comment proposal is anticipated.

4. Living Donor Screening Guidance for Seasonal and Geographically Endemic Infectious Disease Screening

The Committee reviewed a near final draft of a guidance document developed to complement proposed changes to living donor infectious disease testing requirements that the Board of Directors will consider in November 2014. The Living Donor Committee and DTAC favored a requirement on living donor recovery centers to develop a written protocol for identifying and testing potential donors at risk for transmissible seasonal or geographically defined endemic disease as part of their medical evaluation process rather than specifying a handful of specific diseases as required in current policy. Committee members recognized that these and other diseases must be considered as a potential risk factor in some living donors. Developing internal policy on how to address these concerns will give living donor centers more flexibility in how they want to incorporate this important process into evaluation and make compliance monitoring more straightforward for OPTN staff.

The guidance document was developed to provide living donor recovery programs direction on what might be helpful to include in the written protocol for evaluation for these types of diseases. Additional information regarding the Committee's case review experience is meant to enhance, but not be the focal point of the document. The document was crafted to provide an easy to understand, practical resource that will be helpful at the physician and living donor coordinator level. Raising awareness is critical. The policy, if passed, will not require everyone to be tested, but rather will require transplant centers to have a protocol in place to recognize when testing is appropriate and important to enhance patient safety.

The guidance document is awaiting plain language review by OPTN staff and will then go back to the Committee for final review during its September 9, 2014, teleconference. At that time, the Committee will vote on whether to take it to the Board for consideration during its November 13-14, 2014, meeting.

Committee Projects Pending Implementation

5. Improvements to Potential Donor-Derived Disease Transmission Reporting in the Improving Patient Safety Portal

This longstanding effort to update the Improving Patient Safety Portal is slated for programming beginning in December 2014, and is expected to be implemented in March 2015. Updates to the portal are anticipated to streamline the reporting process for members and provide more uniform detail for the Committee as they begin to review potential transmission events. It will rely more heavily on pick lists and pull down menus and reduce the free text entry burden on members filing reports.

6. Reporting Whether Donor Screening Tests are Completed Using Qualified Specimens

This longstanding effort, which will provide a radio button to note whether a required test was completed using a qualified specimen, is expected for implementation in March 2015.

7. Review of Minimum Screening Requirements for Deceased Donor Evaluation

This proposal, which was approved by the Board of Directors during its June 2014 meeting, will update the label for syphilis data collection and also add a new field to collection results for HIV combined antigen/antibody testing results. It is awaiting prioritization by the Executive Committee and has not yet been added to the IT schedule of work.

Review of Public Comment Proposals

The Committee did not review any public comment proposals during this meeting.

Other Significant Items

8. Update on Joint Subcommittee Projects with DTAC Representation

The Committee received updates on three projects that members are participating on alongside other committees:

- HOPE Act (with OPO and Operations & Safety Committees)
- Infectious Disease Verification Process (with Operations & Safety Committee)
- Review Deceased Donor Import Policy (with Ad Hoc International Relations Committee)

Please see the Host Committee reports (listed first in the parentheses) for details regarding these ongoing efforts.

9. Ongoing Review and Classification of Potential Donor-derived Disease Transmission Events Reported in 2014

The Committee reviewed and classified two cases investigated by the CDC.

The Committee also reviewed and classified sixteen additional staff-led cases. The remaining two potential transmission events remaining on the agenda will be classified pending receipt of additional laboratory details on the recipients.

Upcoming Meetings

- The Committee meets on the second Tuesday of each month to review and classify potential donor derived disease transmission events and conduct other committee business as needed. The group will reconvene next on September 9, 2014.
- Chicago meeting dates for 2015 are currently under consideration.