

OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee
Meeting Minutes
December 9, 2014
Conference Call

Daniel Kaul, MD, Chair
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Discussions of the full committee on December 9, 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. What to do when Infectious Disease Screening Results Affecting Match Runs are Updated

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

- HBV
- HCV
- Human T-Lymphotropic Virus (HTLV) (if donor screening was completed)
- Cytomegalovirus (CMV) (pertinent only for the intestine match run, though several joint subcommittee members agreed that this is no longer clinically relevant)

A Joint Subcommittee, including representatives from the OPO and Operations & Safety Committees, ultimately determined that, in these instances, the match run must be re-executed *unless* an organ has already been accepted for a potential transplant recipient when new positive infectious disease results (as listed above) are discovered that will impact appearance on the match run. They proposed that:

- The host OPO must:
 - Report this new infectious disease information to the first transplant hospital that accepted an organ offer as soon as possible, but within an hour of receipt of the new test result.
 - Re-execute the match run if the intended recipient declines the offer after receiving this updated information. Allocation must then be completed using the new match run.
- The intended recipient's transplant hospital must:
 - Inform the potential recipient of the donor's new positive infectious disease test result
 - Meet the requirements of *Policies 15.3.A: Deceased Donors with Additional Risk Identified Pre-Transplant* and *5.4.F Allocation to Candidates Not on the Match Run* for communication and documentation of this new information if the potential recipients proceeds with transplant after receipt of this new donor information.

Draft policy to incorporate these proposed ideas was shared with the Committee for consideration on this call. Additionally, the Committee was asked by staff to also

consider including a time requirement for the completion of required deceased donor testing. Current policy is silent on this. From a patient safety perspective, it is clear that this information would be a critical component in the evaluation of a donor, the recent addition of NAT requirements to policy have complicated this. While having all test results back prior to organ transplant is optimal, the Public Health Service specifically notes in its 2013 *PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation*¹ that when it is not feasible to have NAT results prior to transplant, the results are still useful in guiding recipient treatment.

The intent of such a requirement would not be to impede OPOs, but to clarify expectations and enhance patient safety. OPTN staff from the Organ Center and the Member Quality Department worked with the liaison to craft draft policy language to address this potential loophole, which would allow an OPO to complete retrospective donor testing (though it is unlikely that transplant hospitals would consider offers without this important information). Due to the operational nature of such a policy requirement, the DTAC voted against including this language in its proposal (0 yes, 12 no, 0 abstained), but will seek feedback from the UNOS Organ Center as well as the OPO and Operations & Safety Committees. This may be a future policy consideration for these groups, and specific feedback on this topic is requested from the transplant community on the At-A-Glance page that proceeds this proposal. The Committee plans to take this new project idea to the Policy Oversight Committee for consideration during its January 8, 2015 teleconference.

After completing a comprehensive review of the draft policy language, the Committee voted unanimously in favor of sending the proposal out for public comment in early 2015 (14 yes, 0 no, 0 abstained). It will be submitted to the Policy Oversight and Executive Committees for review and approval prior to its release.

Other Significant Items

The Committee did not review or classify any of the scheduled donor-derived disease transmission cases for this call. The full call was spent reviewing and voting upon the proposed public comment document, as described above

Upcoming Meetings

- The Committee has a standing call on the second Tuesday of every month at 4:00pm ET
- A tentative second standing call for the fourth Tuesday of the month is scheduled to allow for other committee business or case overflow as needed.

¹ The full 2013 PHS Guideline may be reviewed at:
<http://www.publichealthreports.org/issueopen.cfm?articleID=2975>.