

OPTN/UNOS Operations and Safety Committee
Meeting Summary
November 24, 2015
Conference Call

Theresa Daly, Chair
David Marshman, 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. Standardize coding system for organ tracking (AKA Electronic Tracking and Transport Project or TransNet)

Members were briefed on the status of the TransNetsm programming-only request that was to be considered by the OPTN/UNOS Board of Directors in December 2015. The proposal was put on hold by OPTN Executive leadership.

After discussion during Board of Directors (BOD) meeting preparation, questions remained about whether adequate information existed for an informed decision. It was also noted that the prioritization of TransNet versus DonorNet® mobile might not be a BOD, but an Executive Committee decision. The TransNet proposal had noted the limited resources for mobile programming and the need to keep TransNet a priority despite loss of HRSA dedicated funding. In addition, a new pathway for IT programming has been created through the IT Customer Council to respond to member requests. The debate brought up other issues about specifying the decision(s) being made, by whom, and the need for more guidance about process and roles for the two IT pathways that now exist. In addition, questions need to be answered about the proper process to handle potential resource conflicts.

TransNet will have sufficient funding until spring 2016. There are also upcoming roundtable sessions for DonorNet at the OPTN/UNOS Board of Directors meeting due to its significant number of enhancement requests. The need for transparency was noted particularly with an enterprise level project yet the impact of making TransNet an OPTN IT Road Map versus Community Road Map project merits further discussions in a different setting. It was decided that more information and time was needed to work through the process questions. The proposal could be brought in June to the OPTN/UNOS BOD if it was determined that is the most appropriate path. The Operations and Safety Committee (OSC) was asked to work with the Information Technology Advisory Committee (ITAC) to discuss programming needs, resources, and prioritization.

2. Infectious disease verification

Committee members discussed options for releasing proposed policy for the spring 2016 public comment period which begins January 25, 2016. Two options were sent to the group via email for consideration. The first proposed policy language is built upon the ABO verification language approved by the OPTN Board of Directors that will go into

effect in June 2016. The second version is an alternative if consensus cannot be reached on the first version. The second version would require OPOs and transplant hospitals to develop their own protocols for infectious disease verification with certain elements to be included.

The group starting discussing edits to the first version which adds infectious disease verification steps to pre-recovery and pre-transplant verifications going into effect next year.

It was noted that the deadline for public comment is nearing in December. The committee had hoped to have proposed language out to address additional concerns raised by the federal HIV Organ Policy Equity (HOPE) Act that went into effect on November 21, 2015. This will allow transplantation of organs from HIV-positive donors to HIV-positive recipients participating in Institutional Research Board (IRB) approved studies following guidelines published by the US Secretary of Health and Human Services. The research criteria were just published on November 23, 2015. It was noted that the criteria contains some safety measures to help prevent inadvertent transmission of HIV. The research criteria does mention that both donor and recipient HIV status must be verified. While the language is not specific and only addresses HIV, it could provide some protections while the Operations and Safety Committee is preparing its proposal. Timelines for spring 2016 public comment were reviewed with the committee.

It was also noted that the committee might want to delay public comment until the ABO policy is fully implemented. It may be confusing to the community to have proposed modifications to policy about to go into effect as well as a public comment proposal amending the same language. It was noted the upcoming ABO webinar has registrants highlighting the fact that many have an interest but may also still have questions. One member spoke in favor of delaying the infectious for this reason.

The Committee decided to go ahead and work through some of the proposal questions during this call.

The group discussed the option of adding “pre-operating room holding area” to the place where the pre-transplant verification can take place when surgery starts prior to organ arrival. It was suggested and agreed upon to change this language to “pre-operative holding area”. It was discussed whether it would have to be the same team that verifies information once the organ arrives. It was clarified that is not part of the approved or currently proposed requirements. One member indicated that if the option to add the pre-operative holding area is made then the community would train in the OR as the currently approved policy requires and then staff may want to revisit a process they have just developed. It was also noted though that this would provide greater flexibility for staff. It was suggested that this be one of the points or questions for which the committee seeks specific feedback during public comment.

Another point was clarified on acceptable sources. When the recipient will be receiving a positive organ, the acceptability can be noted (e.g. from the surgeon) in the recipient medical record or it could be the actual informed consent document. An attestation is also acceptable following verification of the donor results. Screening criteria (e.g. willingness to accept a positive organ) in the OPTN computer system would not be considered an acceptable source.

The group discussed the option to avoid repeating the infectious disease results verification if it was completed prior to organ arrival. The question came up if the wording should be “expected” versus “required” results. Expected results could be difficult for the transplant hospital to know. Required results would be much more specific and consistent. The original verification table was for HIV, HBV, and HCV tests that screen off the match as recommended by the Ad Hoc Disease Transmission Advisory Committee. It was noted that HBV NAT can screen a candidate off the match run but it is not a required test by policy. Often it is done because some OPOs do a triplex NAT test. After discussion and debate, it was decided to change the proposed policy to tests required by policy.

It was also noted that OPOs are required by newly implemented policy to provide new/updated positive results to transplant hospitals within one hour of learning of these new results. It was also discussed that most OPOs in practice do enter test results as “pending” when tests have been sent but results have not yet come back.

It was noted that NAT results do not have to be back to start transplant surgery. There is no policy requirement for this. It was discussed if there should be any minimum tests required before transplant surgery starts. There is no current policy requirement for this. It was noted that a positive (e.g. HCV) recipient in some centers might take an organ with unknown infectious disease testing result status. Overall OPOs agreed that serologies are completed prior to organ release except for rare instances. One OPO noted that even in the expedited cases they do have serology (screening) results back prior to organ release.

The group felt that they discussed important points, suggested two changes and reached some other conclusions. They did agree, however, that voting within the meeting time left following the discussion would not be prudent. Members expressed the desire to have more time to discuss the proposal.

It was decided to have one more meeting before the public comment deadline to discuss additional questions and decide on whether to send the proposal out for public comment in January 2016. The meeting will be scheduled following an availability query of members.

Committee Projects Pending Implementation

3. Clarify requirements for blood type verification

Members were given an update on the status of implementing modifications to ABO policies. A tool kit to help members prepare has been published on both the OPTN and Transplant Pro website. The tool kit contains the following materials:

- Checklist for OPOs
- Checklist for Transplant Hospitals
- Clean copy of ABO policies that will be implemented
- Draft monitoring compliance plan
- Frequently asked questions

Theresa Daly, the Committee chair will be presenting the staff at UNOS Member Quality the day of the OPTN/UNOS Board of Directors meeting. The first of two webinars to help

members prepare will be held on Tuesday, December 8th. To date, there are 606 persons registered.

Upcoming Meeting

- December 2015 (Monthly teleconference date to be determined)