

OPTN/UNOS Operations and Safety Committee
Meeting Summary
September 23, 2014
Chicago, IL

Theresa Daly, Chair
David Marshman, Vice Chair

Discussions of the full committee on September 23, 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. ABO Determination, Reporting and Verification

Committee members reviewed public comments and a comparison of public comment and post public comment language for the ABO Determination, Reporting, and Verification proposal that was out for public comment in Spring 2014. The Committee reviewed final proposed policy language with modifications based on public comments. This final language included:

- Two substantive changes: Eliminating the option for OPOs to conduct one blood collection and send samples to two different laboratories and limiting the verification done at deceased donor organ recovery to cases when “the intended recipient is known.” These substantive changes will mirror CMS requirements. These substantive changes were developed with input from the OPO Committee.
- Separate sections for deceased donor, living donor, and pre-transplant verifications. These requirements had been in one table, but were separated based on public comment feedback.
- Other minor modifications based upon public comment feedback received
- Stylistic edits suggested by Committee members and UNOS staff for clarity

During the meeting, Committee members identified two additional areas needing modifications:

- Addition of requirement for protocol to include how an organization handles discrepant blood types
- Addition of language requiring living donor vascularized composite allograft (VCA) blood type reporting and verification in the medical record since OPTN computer system is not equipped to handle VCA blood type reporting currently

After a line-by-line review of each of the proposed modifications, the Committee voted unanimously to recommend the proposal for consideration by the Board of Directors (17 support, 0 oppose, 0 abstentions) at their November 2014 meeting.

2. Modify ABO Subtyping Terminology References for Consistency

The Committee reviewed final proposed policy language. No changes were made post public comment. After a line-by-line review of each of the proposed modifications, the Committee voted unanimously to recommend the proposal for consideration by the

Board of Directors (17 support, 0 oppose, 0 abstentions) at their November 2014 meeting.

3. Infectious Disease Verification

The Committee received an update on the infectious disease verification project. A work group with members of the HOPE Act safety sub group and additional representatives from the OPO, Transplant Administrators, and Transplant Coordinators Committees has been formed and is currently meeting monthly. Available data have been reviewed. There were five proven/probable viral disease transmission advisory cases between 2009 to the present related to this issue. Among these cases, 60% were from deceased donor organs and 40% were from living donor organs. In addition, three cases were related to donor HCV infection and two cases were related to donor CMV infection. Twelve recipients received infected organs and five recipients became infected following the transplantation. In addition, there have been two living donor and one deceased donor cases with similar process issues reported that were not classified as proven/probable transmission.

A document comparing current and proposed verification requirements has been prepared for living and deceased donors. The work group is in the process of overlaying possible infectious disease verification requirements at points where ABO checks are required to see where these could be done together. Infectious disease verification poses several unique challenges such as the number of infectious disease tests, the timing of when results are received, differences between deceased and living donor testing requirements, and possibilities of discordant results between serology and nucleic acid testing (NAT). The DTAC is preparing recommendations for which infectious disease tests should be included in a verification process.

Candidates must be tested for HIV, HBV, and HCV, however these results are not required to be reported. HOPE Act candidates will have results reported- a change being initiated by the HOPE Act work group. All transplant programs must report acceptance criteria for certain positive results from donors (e.g. HCV). The work group has had preliminary discussions that this might be a point to require second user verification of acceptance of infected organs. The Committee agreed that this would be a point to add for infectious disease verification.

The Committee will continue to receive updates. A winter 2015 public comment proposal is targeted. The Committee will consider a proposal following recommendations from the work group at one of it's late 2014 teleconference meetings.

4. Electronic Tracking and Transport (ETT) Application (TransNet-A Service of the OPTN)

The Committee received an update on the status of this project. During the summer of 2014, a beta test version (5.0) was developed using feedback to date. On September 10-11, 2014, eight OPOs each sent two representatives for training at UNOS to learn how to use the system as well as go through competency training to be certified to use the system. The train-the-trainer session also included sessions on how to go back and train OPO staff at home to use the system. Participants included the five original field test OPOs and three new OPOs (New England Organ Bank, LifeCenter Northwest, and Mid-America Transplant Services).

UNOS is providing up to eight Android tablets and portable printers to use during the beta testing from September 18, 2014 through January 15, 2015. If additional devices are desired, participating OPOs will purchase these on their own. Each set (tablet and printer) costs approximately \$800. At completion of each case, participants will be required to submit a survey answering how beta testing went, ease of use, and suggested enhancements or improvements. TransNet project staff will travel to the three new OPO sites to assist with deployment. Results from beta testing will be used to determine future enhancements.

Enhancements between the field and beta versions include the ability to pull case data directly into the system from DonorNet. The following fields can be imported: donor hospital, donor identification data, ABO (if double verified), date of birth, donor initials, and infectious disease results. The beta version can print labels for blood tubes with and without ABO. Case transfers can be completed via Wi-Fi or Bluetooth. Authentication is done with the user name and password that associate the user with their DonorNet permissions. Anyone using the application must be certified in proficiency by their OPO. The beta version requires validation of infectious disease results for the vessels label. Second user verification can be done locally or remotely.

The beta version allows the coordinator to choose organs planned for recovery and print associated documentation and specimen labels. The application produces all shipping labels that are both bar coded and human readable. Each organ package contents are scanned as they are placed in external shipping container and ice time is entered.

TransNet staff are working with seven transplant hospitals to recruit for testing. These transplant hospitals are located in the same areas where these five original OPOs are located. Transplant hospitals planning to participate in the HOPE Act may also be recruited for pilot participation. Transplant hospital discovery trips will be conducted to further understand process and use cases. UNOS will supply pilot sites with a portable printer to be able to print a recipient ID band. Staff are investigating the possible use of existing hospital handheld scanners. If these are not compatible, UNOS will provide them with a scanner.

Transplant hospital training will be held in October with testing beginning after training through January 2015. Testing will start with one hospital at a time and be organ specific. Monthly progress calls will be made to provide support and receive feedback. The goals for transplant hospitals will be to print the recipient ID band from match run; scan external organ label upon arrival, and scan recipient ID band and internal organ labels in the recipient OR. Instructional innovations is hosting five monthly train the trainer sessions.

User data will be gathered through January 2015. The current application works only on an Android device. Feedback from multiple sources has been the desire to have the application available for other platforms (e.g. iPads and Surface tablets). Multi-platform application development will start in November 2014. Beta testing for transplant hospitals and on multi-platforms is planned for summer 2015.

A progress update will be presented to the OPTN/UNOS Board of Directors (BOD) at the upcoming November 2014 meeting. Based on preliminary findings up to this point, plans are to start a voluntary national OPO deployment starting March 2015.

The OSC ETT subcommittee has been meeting since August 2013. This subcommittee has provided feedback and been informed of progress to date at multiple steps. The Committee expressed support and praise for the progress to date. The Committee discussed potential mandatory usage. The Committee agreed that use should be mandated when the product is completely ready. The sentiment was expressed that if use were voluntary then not everyone would adopt its usage and the full benefits of the system would not be realized.

The Committee did not recommend a limited mandatory deployment for HOPE Act participants. The Committee's opinion is that deployment should not be mandated partially or before the system is ready for full deployment. The Committee also wanted to give sufficient time for members to budget for purchasing and spoke of the need for multi-platform ability before full acceptance and mandatory deployment.

An update will be provided at every committee meeting and to the OPTN/UNOS Board of Directors at their November 12-13, 2014 meeting.

5. Modify or Eliminate the Internal Vessels Label

A sub group of the ETT work group has been meeting since December 2013. The group has reviewed the following data elements: vessels labeling and packaging safety situations, disposition of extra vessels, and site survey compliance. Less than 2% of extra vessels are transplanted into secondary recipients (i.e., recipients who received a solid organ from a different donor), which averages about 120 vessels annually. These vessels are of most concern since they would have been stored and certain, such as infectious disease testing results, must be verified prior to use. In addition, usage in secondary recipients is limited to less than 30% of all transplant hospitals. The majority of hospitals (83%) have used only 1-10 extra vessels in secondary recipients over a four-year period. The sub group discussed that the sporadic and often infrequent use indicates repackaging of extra vessels is not a skill set readily developed and presents a challenge facing transplant hospitals.

Repackaging vessels may be required prior to storage. Transplant hospitals have raised concerns about what to do if the orange and white polyplastic label gets lost during the original unpacking and transplant. Several representatives shared that most OR staff do not have access to DonorNetSM due to the large numbers of OR staff. When infectious disease results do need to be confirmed, it is often the surgeon or the fellows that access DonorNetSM to verify results on stored vessels. Transplant hospital members expressed concerns in emergencies where accessing DonorNetSM for infectious disease verification becomes challenging due to time sensitivity and lack of OR staff access. Although transplant hospitals have concerns, the entire group acknowledged the many challenges with the internal sterile label such as possible outdated results and the inability to read results without disrupting the sterile field.

The work group has come to consensus on eliminating the infectious disease results on the internal sterile label. They are debating whether to retain the question on whether the vessels are from a PHS increased risk donor. Most current data on extra vessel usage, vessel risk status, and transmission of disease through extra vessels have been requested. These data will be used to develop final recommendations for full Committee consideration regarding possible proposed policy changes. The Committee agreed with work group's direction and progress to date and will await final recommendations.

A proposal will be prepared for Committee consideration in late 2014 with a target of winter 2015 public comment.

6. Developing a System to Review and Share Safety Event Data

The Committee reviewed the latest safety situation data. Reporting has continued to increase since 2006 with an exception in 2009. During the first half of 2014, 81 events were reported through the electronic Improving Patient Safety Portal (IPS) and 50 events were reported through “other pathways” (e.g. emails, calls or letters to UNOS). There were 213 events reported through both the IPS and other pathways in 2012 and again in 2013. Based on the current reporting rate, reporting in 2014 is projected to exceed the previous levels. These data are “front end” reports and do not contain investigative follow up or findings.

The most frequently reported events were related to communication issues (23%), transplant process/procedure issues (23%), packaging/shipping issues (18%), labeling issues (15%), testing issues (14%), recovery process/procedure issues (12%), and organ allocation/placement issues (11%). Nearly 80% of issues reported by labs between 2012 and the first half of 2014 were either testing issues (50%) or data entry issues (29%). Transplant hospitals most often reported communication issues (32%), while OPOs most frequently reported testing issues (25%).

The data review included additional information on high occurrence subcategories with unusually high frequencies relative to other subcategories. There were 14 subcategories between 2012-June 2014 that fell in the top 5% in terms of high frequency. The review included four subcategories that showed a statistically significant increase between 2012-2013 and the first half of 2014. Situations where organs were not transplanted (either not recovered or recovered and discarded) were reviewed. A total of 51 subcategories had an associated organ not transplanted and the Committee reviewed any subcategory that had at least two events resulting in organs not transplanted.

The Committee chose to focus on the most frequently occurring events where an organ was not transplanted. They chose the top priority situations which were communication issues (delayed communication and inaccurate/insufficient donor/organ/vessel information) and living donor issues (organs recovered but not transplanted). The Committee also prioritized switched laterality which the Kidney Committee is actively addressing with representatives from the OSC.

The Committee strongly felt that a work group needed to be reconvened to address these issues. The OSC Patient Safety Advisory Group will be reformed and nine members volunteered to participate. The Committee requested that support staff seek additional information such as root cause to properly guide the efforts. A formal data request for additional information will be made.

This group will conduct additional work such as failure, modes, and effects analysis to identify areas for possible action. The Committee will seek additional root cause information and subject matter experts to assist these efforts. Recommendations will be brought back to the full Committee.

Other Significant Items

7. Imminent Death Donation

OSC representatives are participating in an Ethics Committee led work group regarding imminent death donation. The Committee received some articles in advance as well as a slide review from the most recent meeting. Due to the controversial nature of the topic, all Committee representatives (OPO and Living Donor as well) were asked to seek an opinion from their full Committees as to whether the topic should continue to be discussed.

The Committee debated this issue. OPO representatives stated that nearly everyone has been asked once to do this practice. One OPO representative relayed one positive experience. Several members were greatly concerned that even having the discussion about this topic could significantly erode trust in the system. Some wanted to have the conversation so that the Committee could take a formal position against the practice. Others were not certain and thought it might be acceptable within a very narrow and limited set of circumstances. Members asked about current policy which does not speak to this practice either way. For some members, not discussing the topic would appear as a tacit approval. There may be more unintended consequences, if an event happens and it is revealed that the transplant community knew this was happening but chose to stay silent. Following significant debate, the Committee took a vote.

The Committee voted to recommend continued discussions on this topic (10 in favor, 4 oppose, and 0 abstain). This decision will be relayed back to the Ethics Committee.

Upcoming Meeting

- October 28, 2014 (teleconference meeting)