

**OPTN/UNOS Operations and Safety Committee  
Meeting Summary  
January 27, 2015  
Conference Call**

**Theresa Daly, Chair  
David Marshman, Vice Chair**

*Discussions of the full committee on January 27, 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. TransNet<sup>sm</sup> /Electronic Tracking and Transport Project**

The TransNet<sup>sm</sup> project manager updated the Committee on project progress. The three OPOs who completed training in October 2014 have continued to use the application along with the five beta sites. Communications were sent to all OPOs in January 2015 announcing upcoming monthly train-the-trainer sessions to be held at UNOS. The notice contained the equipment that OPOs will need to purchase to participate. It also outlined the expectations. Participating OPOs will need to send three staff members, including one management and one front line staff members, to training. It is expected that the OPOs will go back and train the rest of their staff following the UNOS training. All users will need to pass a proficiency test prior to using. OPOs will be expected to use the application on at least half of their donor cases. The voluntary national OPO deployment will begin in March. The March, April, and May sessions are full. Sessions for June and July will be opened soon. A total of 22 OPOs will be trained and/or using the application following those three sessions.

OPOs will provide the first level of support and then issues will be escalated to UNOS IT staff if the OPO cannot resolve them. TransNet<sup>sm</sup> programming has been brought in house with the UNOS IT department. UNOS staff have programmed the version that will be rolled out with the March deployment. UNOS IT will be exploring development for platforms other than Android. The goal is to have a version for use on other platforms (e.g. iOS) ready for July testing and possible September release. The in-house team is staffed to handle the rapid cycle development required to keep the project on its aggressive timeline.

TransNet<sup>sm</sup> project staff have started transplant hospital discovery. Transplant hospitals in New York and California have hosted visits and Chicago area hospitals are on the schedule as well. About 10 sites have been part of the discovery thus far. One hospital, Piedmont Hospital in Atlanta, Georgia is actually testing the current version. The model they are using will probably be replicated in other transplant hospitals. One issue will be how transplant hospitals integrate the system and process with their own electronic medical records (EMRs). During this discovery, transplant hospitals have welcomed being part of the development process. They have requested that the application include programming for assistance with vessels labeling and management as well as ABO verification in the OR. Project staff are getting a sense of what existing equipment (e.g. scanners and printers) that transplant hospitals currently have available for use with the

system. A version for transplant hospital testing is expected to be ready in the next three to six months.

## **2. Proposal to Modify ABO Determination, Reporting, and Verification Requirements**

The Committee has reworked the Spring 2014 proposal based on public comment and comments made at the November 2014 OPTN/UNOS Board of Directors meeting. Public comment on this proposal starts today and will run through March 27, 2015. Regional representatives will receive training on February 3<sup>rd</sup> and present this proposal during this cycle. The revised OPTN public comment website was demonstrated to show how it has been modified to be a blog style, real-time forum. Comments will be posted within 24 hours after screening for inappropriate, vulgar, or other content that does not meet the posted guidelines (e.g., comment contains solicitation for organs). Commenters' names and organizations will be posted along with their comments. Comments can also be endorsed. It is hoped that this style will encourage useful and substantive conversations about proposals. Committee chairs will be the ones formally responding on behalf of the Committee on posted comments if necessary.

The Committee will consider public comments at its April 14, 2014 in-person meeting and vote on a proposal for the OPTN/UNOS Board of Directors to consider at their June 1-2 meeting.

## **3. Proposal to Modify the Sterile Internal Vessels Label**

This proposal has been posted for public comment starting today (January 27, 2015) through March 27, 2015. Regional representatives will present this proposal at the upcoming regional meetings following the training scheduled for February 3, 2015.

The Committee will consider public comments at its April 14, 2014 in-person meeting and vote on a proposal for the OPTN/UNOS Board of Directors to consider at their June 1-2 meeting.

## **4. Proposal to Allow Collective Patient and Wait Time Transfers**

Committee members received an overview of public comments made on this proposal during the session running from September through December 2014. The proposal overall was well received. All regions voted in favor of the proposal. In addition, NATCO, AST, ASTS, and the American Association of Nephrology Nurses submitted comments supporting the proposal.

The Committee sought feedback on some specific areas such as the requirements for accepting hospitals to provide updates post transfer. While the proposal contained a requirement for one update at 90 days post transfer, the general sentiment was to continue the reports as needed until all transferred patients had been fully evaluated. The Committee also received some comments on possible requirements for patients to be informed of changing status and the need for the closing center to forewarn patients that status may change upon transfer. The Member Quality department at UNOS also has developed some questions regarding the proposal's implementation.

A subgroup of five OSC members will review all comments and bring back recommendations to the full OSC for possible post public comment changes. The Committee will vote on a proposal to send to the OPTN/UNOS Board of Directors for consideration at their June 1-2 meeting. OSC will vote at either their March 24, 2015 teleconference or at their April 14, 2015 in-person meeting.

## **Collaborative Committee Projects**

### **5. Imminent Death Donation**

The Ethics Committee is leading a multi-committee work group including the Living Donor, OPO and Operations and Safety Committees to discuss concepts of possible imminent death donations. One of the OSC representatives gave an update on the progress of this project. The Ethics Committee has reviewed this concept and determined that it is an emerging practice and may be ethical under some circumstances. At the last work group meeting in January, positions from other Committees were shared as there is not consensus on this concept. The OSC had differing opinions when this was discussed in September 2014 but overall supported a continued discussion. The Living Donor Committee expressed serious reservations as it is unclear but could be considered a living donation. The OPO Committee supports the concept as there are overall benefits to donor families.

The work group is identifying and discussing all possible ethical concerns. Possible surgeon liability was mentioned as well as public perception as concerns to be addressed. One OSC member questioned if the group had discussed the OPO role particularly since current OPO medical malpractice coverage would not cover this practice. It was acknowledged that the OPO role is not clear and questions about roles, legal implications, and concerns will continue to be discussed by the work group.

### **6. Simultaneous Liver-Kidney Allocation**

The Kidney and Liver Committees are leading a project on simultaneous liver-kidney (SLK) allocation. The OSC representative gave an update on progress to date. A proposal had been developed in 2009 but was tabled due to the potential complexity in programming with numerous kidney variances. With the release of the new Kidney Allocation System (KAS) in December 2014, all variances went away. This work group has had vigorous discussion on the underlying principles but has reached consensus that too many SLKs are being done. Questions about the benefit of performing a SLK as well as concerns about taking away kidneys needed for the kidney waiting list have been discussed.

The group has tried to develop guidelines for when SLK is appropriate. Who should qualify, what time, duration, and what level of renal insufficiency should make someone qualify in the first place are some of the questions being considered. The term "safety net" is used to describe what would make a candidate qualify for the getting access to that kidney. Other questions debated include where these would fall on the list and what happens if a candidate receives a liver only and then subsequently needs a kidney. The work group is examining data such as liver transplant survival rates. The group has settled on that there will be some type of safety net. Details are being developed and a basis will be dialysis time. One concern that renal insufficiency and kidney failure may not occur within one year but may take three or four years to appear was expressed. One OSC member mentioned that the AST will be holding an educational webinar on this topic. The Kidney Committee liaison will present recommendations to the OSC on the February monthly conference call.

### **7. Transport of Living Donor Organs**

The Living Donor Committee originally started this project in 2011. The Operations and Safety Committee was recently placed as a co-sponsor of this project. The project had been placed on hold while the Electronic Tracking and Transport (ETT) project was

conducting its work. The Living Donor Committee resurrected the project since the ETT project and TransNet<sup>sm</sup> application will first focus on deceased donation.

This work group includes TAC, TCC, and OPO Committee representatives. The group has just started meeting to conduct a Healthcare Failure Modes Effects and Analysis to identify possible failure modes and recommendations to mitigate risk in the transport of living donor organs.

## **8. HOPE Act**

The OPO Committee is leading a multi-disciplinary work group to develop policies and programming needed to implement the HOPE Act. The first public comment released in Fall 2014 dealt with authorizing transplantation of HIV positive donors into HIV positive candidates at transplant programs participating in Institutional Review Board approved studies that meet criteria developed by the U.S. Department of Health and Human Services.

The work group also developed a subsequent public comment proposal now out for consideration. The work group is awaiting criteria that have yet to be published from the National Institute of Allergy and Infectious Diseases (NIAID) although this is expected possibly in February 2015. Policy and practice will need to align with these criteria. The work group is also focusing on the operationalization of this initiative including needed programming. Infectious disease verification requirements are being developed under OSC leadership as a separate project. Required data collection and respective organization responsibilities are being discussed and will be finalized after the NIAID research criteria are published.

## **1. Marking Kidney Laterality**

The Kidney Committee is leading a work group on this topic, which includes OSC and OPO representatives. This work group is developing guidance on suggested marking practices. This document will be targeted for June 2015 OPTN Board of Directors consideration. A draft will be shared with OSC members for comment prior to submission.

## **Upcoming Meeting**

- February 24, 2015 (teleconference meeting)