

**OPTN/UNOS Operations and Safety Committee
Meeting Summary
October 13, 2015
In-Person Meeting, Chicago, IL**

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

Discussions of the full committee on October 13, 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)

Programming Request:

Public Comment: January 2016 (Estimated)

Board Consideration: June 2016 (Estimated)

The Health Resources and Services Administration (HRSA) contract modification to the OPTN providing special dedicated funding to support TransNet ended on September 30, 2015. A list of functionality that is planned and can likely be completed with unspent remaining funds has been reviewed with the Committee and the TransNet work group. The OSC agreed that this list as presented will provide functionality for OPO usage as well as basic transplant program usage. The Committee noted that the functionality will be sufficient to support basic mandatory OPO usage.

The Committee discussed additional functionalities that have been identified as desired. Programming on this list will need to be approved and prioritized according to the standard OPTN information technology programming process. The OSC decided that the highest priority should be given to functionality that will eliminate having to have two different processes. This includes three areas: ABO verification prior to organ arrival, living donation, and directed donation. The fourth priority would be to have functionality to track vessels and use the system to perform required reporting. Other items exist on this list but have been given a lower priority. These include mobile device usage and other enhancements to promote usage in the donor management (ICU) phase for OPOs. Other items were prioritized as well.

The Operations and Safety Committee will request that this programming be approved for incorporation in the OPTN IT road map at the December 2015 OPTN/UNOS Board of Directors meeting. The Committee voted unanimously (17-Yes, 0-No, 0-Abstain) to make this request.

Table 1: Requested Functionality

Functionality	Short Requirements Description	Operations and Safety Priority	Rationale	IT Estimated Effort	Hours (Upper Limit of Range)
Living donors	This would provide OPO and transplant hospital functionality to label and package living donor organs. It would also provide transplant hospital organ receipt and pre-transplant verification functionality.	High	Do not want two different processes (Manual process for living donors and TransNet functionality for deceased donors)	Very Large	3995
Directed Donation	This would provide transplant hospital functionality allowing printing of recipient ID bands for organs allocated Not on A Match Run (NOMR) as well as receipt and verification of these organs	High	Do not want two different processes (Manual process for NOMR and TransNet process for organs on a match run)	Large	745
Pre-transplant verification when surgery begins before organ arrival	This would provide transplant hospital functionality for completion of the new policy requirement (5.7.A) to be implemented in June 2016 that will require a verification when candidate surgery begins prior to organ arrival. The functionality would include reports that could be generated for documentation of verification	High	Do not want two different processes (Manual process for this verification and TransNet functionality for verification completed upon organ arrival)	Very Small (DR)	56
GPS Tracking	This would provide tracking functionality either through use of a device or through further development of tracking latitude and longitudes that is posted on the TransNet website	Medium	The work group recommends that this functionality using a device be delayed until transplant hospital development and acceptance is further along.		Outside vendor

Functionality	Short Requirements Description	Operations and Safety Priority	Rationale	IT Estimated Effort	Hours (Upper Limit of Range)
iPhone/Android phones	This would provide OPO functionality to use the TransNet application on these devices	Medium	Concerns exist whether the phone screens would be large enough and whether it is wise to use phones for TransNet since they are needed for texting and calling as part of organ offer and information sharing processes.	Large	1645
ICU Enhancements	This would provide OPO enhancements to enable use of application/printing on alternative devices TBD. This will reduce the burden of equipping all staff that conduct donor management prior to recovery with tablets and zebra printers.	Medium	This has been request from multiple OPOs who desire to use TransNet in the ICU/donor management phase but are not able to due to equipment logistics and cost	Large	1645
Vessel disposition functionality including reports, catalog, and feedback to UNet	This would provide transplant hospital functionality to scan vessels upon receipt and record vessels dispositions. This functionality would provide verification functionality for vessels used in secondary recipients. It would generate transplant hospital reports for verifications and disposition. It would upload these data into UNet and satisfy required vessels disposition reporting (policy in effect 10/22/15)	Medium	Transplant hospitals have asked for this functionality. It is not in the high category because it will not solve having two different processes	Small	220
VCA	This would provide OPO functionality to label and package VCA organs.	Low	Currently VCA transplantations are low volume events. The donors and match are not programmed in UNet at this time.	Medium	745
Total Hours					9051

2. Proposal for Mandatory OPO Usage:

Public Comment: January 2016 (Estimated)

Board Consideration: June 2016 (Estimated)

The Committee discussed the current status of nationwide voluntary OPO use of TransNet that started in March 2015. As of October 2015, 31 OPOs have completed the three-day required training at UNOS headquarters including passing proficiency testing. An additional six OPOs have signed up for future training dates. The Committee developed a survey that was conducted by the Association of Organ Procurement Organizations (AOPO) in September 2015. This survey found that an additional eight OPOs plan to sign up for training. Ten OPOs were uncertain of their future plans. Two OPOs indicated that they did not plan to sign up or use TransNet. The survey also measured reasons for uncertainty of usage to help staff develop targeted strategies to reach all OPOs. The two primary reasons for non-commitment were waiting for product availability in iOS (n = 5) and waiting to hear more feedback from OPO community (n=3). The iOS version of TransNet will be released in December 2015.

A study of individual OPO usage showed that a TransNet case was created for 57.3% of all deceased donors recovered by the 31 trained OPOs during September 2015. Fourteen OPOs (46.7%) from this cohort created TransNet cases for every donor recovered. Two OPOs had not used TransNet for any cases and these sites have received individual follow up and technical assistance. Details of this data analysis are available upon request.

TransNet has continued to receive exceptional reviews for training, technical support, and overall process improvement. Community feedback at conferences such as the AOPO Tri-Council has been very positive.

The Committee reviewed proposed policy to mandate OPO usage. The Operations and Safety Committee voted unanimously (17-Yes, 0-No, 0-Abstain) to send proposed policy out for the January 2016 public comment cycle. The proposal will mandate TransNet use to label deceased donor organs and vessels for those that must be labeled already in current policy (those traveling outside the recovery facility). The proposal will also require transmittal of cases to the OPTN Contractor in real time to enable web-based tracking. The Committee plans proposing an implementation date in 2017 to allow ample time for OPOs to budget, prepare, and train for TransNet.

TransNet project staff are working concurrently on transplant hospital functionality. Fifteen sites were visited during the discovery phase. Five transplant hospitals have started beta testing. A total of 27 transplant hospitals have indicated an interest in beta testing. These sites are in various planning stages with TransNet staff. Getting transplant hospitals live into beta testing has proven to be more timely and involved due to multiple levels of needed approvals at hospitals and equipment issues (e.g. scanners and printers). Another issue facing transplant hospitals is how to integrate the system and process with their own electronic medical records (EMRs). TransNet staff has recognized this issue and has set up preliminary talks with one EMR vendor to assess how these needs might be addressed.

The beta test version for transplant functionality includes an organ check in and pre-transplant verification. The functionality highlights new or positive donor infectious disease testing results. Transplant hospitals use the system to print a recipient ID band that is attached to the candidate prior to surgery. Upon organ arrival, the organ is

checked in. In the operating room, the recipient ID band and the organ label(s) are scanned to ensure right organ/right recipient and ABO compatibility.

The TransNet team met with Centers for Medicaid and Medicare Services (CMS) and other Health Resources and Services Administration (HRSA) staff on July 30, 2015 to provide a demonstration of functionality and discuss future plans. One major goal is to develop a product that will meet both OPTN and CMS requirements in certain policy areas such as ABO verification. Staff will continue to work through HRSA Division of Transplantation staff to collaborate with CMS in reaching this goal where possible to improve safety and OPTN member ability to comply with safety policies.

3. Infectious Disease Verification

Public Comment: January 2016 (Estimated)

Board Consideration: June 2016 (Estimated)

While there is a process for ABO verification to prevent accidental transplant of incompatible blood types, there is no similar process of verification related to infectious disease. Current policy requires verification of all infectious disease results prior to use of deceased donor extra vessels in secondary recipients or living donor recipients as well as for deceased donor organ transplants not on a match run. Policy for these organs specifies that the transplant hospital verify the medical suitability between the deceased donor organ and recipient prior to transplant. Current policy does not require this type of verification in all organ transplants.

There have been cases where positive serology results have been available but inadvertently missed resulting in preventable disease transmission or near misses of preventable disease transmission. In March 2014, the MPSC referred this issue to the Committee and requested development of a policy proposal requiring infectious disease verification at two points during living donor procedures. This safety check will become increasingly important as the HIV Organ Policy Equity (HOPE) Act will allow use of organs from HIV positive donors in HIV positive candidates starting in November 2015 under approved Institutional Research Board (IRB) research protocols with standards set by the Secretary of Health and Human Services. The HOPE Act safety sub group discussed this issue and recommended a process be developed. In June 2014, the full HOPE Act work group also recommended this issue be referred to OSC to develop a proposed process and policy.

A work group with members of the HOPE Act safety sub group and additional representatives from the OPO, Transplant Administrators, and Transplant Coordinators Committees was formed and continues to meet monthly.

Data tabulated in 2014 show 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. Three cases were related to donor hepatitis C (HCV) infection and two cases were related to donor cytomegalovirus (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.

The work group has developed proposed language that would apply to all infectious diseases that would potentially screen a candidate off a match run (hepatitis B (HBV),

HCV, HIV, and CMV-intestine candidates only). These were selected following a DTAC recommendation.

The proposal has infectious disease verification checks that would coincide with pre-surgical ABO verifications will go into effect in June 2016. These would occur at deceased donor recovery, living donor recovery, pre-transplant prior to organ arrival, and pre-transplant upon organ receipt.

The OSC discussed possible proposal language for the January 2016 public comment cycle. The Committee identified issues that need further discussion including what will be acceptable sources for verification including when results change post recovery; the ability to conduct the verification in the OR; the concept that if all results are available, negative, and verified prior to organ arrival that this step will not be repeated upon organ receipt; and possible requirements for when infectious disease testing must be completed. The Committee deferred voting at their in-person meeting. They will hold further discussions at their scheduled October 22, 2015 monthly conference call and November 2, 2015 infectious disease verification work group call. The Committee plans to vote on proposed policy language at their November 24, 2015 monthly conference call. A proposal may be sent out for the January 2016 public comment cycle.

Committee Projects Pending Implementation

4. Clarify requirements for blood type verification

Members were informed of the Executive Committee approval to change the policy implementation date from February 1, 2016 to effective pending programming and notification to the membership. This request was made because it became the UNOS Information Technology department estimated that they could complete programming associated with the proposal by early 2nd quarter 2016. While the programming is not necessary to implement the policy, the programming enhancements will assist members with compliance. There are four regional meetings left and the Committee update has been modified to reflect the change in the implementation date.

Additional volunteers were requested to serve on the ABO implementation subcommittee. It was announced that the first webinar will be held on December 8th to help members prepare for the upcoming policy changes. Volunteers are needed to prepare and review educational materials.

5. Improvements to Vessel Disposition Reporting

Members were informed that programming for electronic reporting of vessels disposition in UNet will be released on October 22, 2015. Policy approved in November 2012 by the OPTN/UNOS Board of Directors will go into effect that date to require transplant hospitals to report extra vessels use disposition within seven days of use or destruction. UNOS Instructional Innovations released a training video on October 8, 2015.

Other Significant Items

6. Trends and Patterns in Patient Safety Situations Reported to the OPTN

The Committee reviewed the last six months of patient safety situation data. There were 129 patient safety situation reports (79 submitted online through the Improving Patient Safety Portal (IPS)) between January 1 and June 30, 2015. Reporting from transplant hospitals made up 61% of reports during the same time frame which represents an increase of the total proportion of reports originating from this source. Nearly one-quarter (23%) of all reports since 2012 involved a communication issue. Seventy of the 230

(30%) of the communication unique safety situation reports involved delayed communications.

Of 811 events reported through both the IPS and other pathways since 2012, organ(s) were not transplanted as a result of the event in at least 91 (11%) cases. Organs were considered not transplanted if either an organ was recovered but discarded due to the event, or an organ was not recovered due to the event. These cases most frequently involved packaging issues, recovery procedure/process issues, and communication issues.

The Committee also reviewed transportation data from the UNOS Organ Center. Between July 2014 and June 2015, the Organ Center facilitated 2,445 shipments. There were a total of 28 shipment failures with 30 of the 36 organs involved being discarded. The primary reasons noted were weather, mechanical failure, or transport cancellation. In addition, there were 109 near misses with delays ranging from 2 to 12 hours. The full report is available upon request.

The Committee and Member Quality are working on ways to improve reporting and use of patient safety data. The Member Quality Director attended and presented at the most recent OSC in-person meeting. Current patient safety data reviewed are considered “front-end” data and are based on the initial report but do not include information resulting from subsequent investigation conducted by the UNOS Patient Safety Incident Handling Team (PSIHT) within Member Quality. Member Quality plans to add a validation step where PSIHT members categorize reports post-investigation. This will account for other factors arising during the discovery process.

In addition, MQ is developing a process where PSIHT will review these data and bring data highlights, trends, and recommendations, including aggregate root cause information, for Patient Safety Advisory Group (PSAG) and OSC consideration as they work on system improvements. The proposed steps would be:

- **Post case categorical analysis/validation**

PSIHT staff will validate data using a standardized classification schema. Part of this effort would include moving towards an existing Healthcare Performance Improvement model, perhaps modified for transplant, to collect more extensive information surrounding individual and system level failure modes. This will allow MQ to both capture factors contributing to error or failure type, but also assess the level of impact or harm.

- **Data mining and trend analysis**

Every 6 months, PSIHT staff will mine the data attempting to identify themes and repeating patterns. They will conduct some casual analysis to identify commonalities across like cases.

- **Data prioritization**

Of potential case types of interest identified, PSIHT will prioritize findings and make recommendations to the OSC based on what would likely have the largest impact and most benefit to the transplant community.

- **Data extraction and dissemination**

PSIHT staff would then manually extract pertinent information from the subset of cases decided upon and disseminate for committee deliberation.

- **Comprehensive analysis by Ops & Safety PSAG**

The OSC could then perform a comprehensive analysis on the data, detect areas of highest concern, as well as elicit learnings regarding failure points and gaps that could jeopardize patient safety or lead to preventable organ discard.

MQ and OSC communications regarding safety data would be based on urgency needs. Pathways already developed would be refined for several types of channels such as the patient safety alert, patient safety trends, and patient safety prevention. Alerts and trends communications will follow an immediate and intermediate time frame and process to communicate urgent matters to the transplant community. Routine events would be presented to Operations and Safety on a quarterly basis. The goal would be to turn lessons learned into actionable knowledge through various patient safety initiatives and educational opportunities. This will help better link findings to improve safety through a systematic approach.

Instructional Innovations has worked with the PSAG and an internal patient safety group to develop two patient safety vignettes that are fictional cases based on trends observed in patient safety reports and referrals for educational topics from the Membership and Professional Standards Committee (MPSC). The first video was released on June 5, 2015. The first video featured two scenarios. One scenario featured a delayed communication of post-transplant results led to recipient death. The other case featured a switched kidney laterality situation where the kidney had to be discarded. As of August 28, 2015, there were 580 views. Video evaluations as well as informal community feedback has been extremely positive. Of the 45 persons completing an evaluation survey, 44 either agreed or strongly agreed that the program addressed timely information needed to perform their job.

A second patient safety video will be released on October 29, 2015. This video focuses on how delayed communication and process decisions ultimately led to a liver organ discard. Instructional innovations, PSAG, and internal patient safety experts will continue collaborating on this quarterly series.

7. Brainstorming OPTN/UNOS Strategic Plan Goal 1: Increase the Number of Transplants

The Operations and Safety Committee completed their brainstorming exercise to increase the number of transplants to support the OPTN/UNOS Strategic Plan Goal #1. The following list includes all of the ideas presented. The first three listed are the top priorities for OSC to pursue.

- Adjust push/pull outcomes metrics.
 - Outcomes requirements lead to risk aversion plus decreases transplants
 - Fix transplant center metrics and allow flexibility to increase acceptance of marginal organs
 - Increase allowable risk taking
 - Increase use of non-HIV sepsis donors
 - Remove OPO and disincentives to chasing single organ donors and transplant program metrics for using high risk donors based on outcomes
- Reduce non recoveries and discards of transplantable organs
 - Streamline placement of non-perfect or marginal organs through UNet/DonorNet enhancements and provisional testing

- Put final processes and improvements in place to prevent discard of transplantable organs
- Develop a better placement process for marginal organs
- Make DonorNet active, not passive, to allow for increases in donors (dynamic)
- Back-up offers/provisional yes
- Increase critical care provider education
- Improve transplant center/OPO communications through means such as the previous collaborative
- For intra operative turn downs, mandate a delayed cross clamp unless there is donor instability to increase likelihood of organ placement
- Decrease non-standard donor management that leads to “lost” organs
- Current allocation policy decreases use of hard to place organs. Make appropriate changes. Provisional “yes” leads to delays and later lost organ
- Remove disincentives for living donors
- Improve transplant center list management
- Have more proactive preparation for provisional yes, back-ups
- Develop agreements/extension to cooperate with other countries/territories to increase organ placement from isolated US areas
- Increase the wait time for DCD death
- Reduce knowledge deficit of intensivist/donor hospital staff. Increase education of critical care providers through societies
- Balance out DCD vs. brain death
- Increase DCD awareness. Reduce public awareness deficit by enlisting high profile spokespersons people to push donation message

Upcoming Meetings

- October 27, 2015 (Monthly teleconference)
- November 24, 2015 (Monthly teleconference)