OPTN/UNOS Operations and Safety Committee
Meeting Summary
April 19, 2016
Richmond, VA

Theresa Daly, Chair
David Marshman, Vice Chair

Discussions of the full committee on April 19, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov/.

Committee Projects

1. **Standardize coding system for organ tracking (TransNet)**

   The Committee conducted a final review of public comment on the proposed mandatory use of TransNet for OPOs packaging and labeling deceased donor organs.

   The proposal was well received in public comment. All regions unanimously supported the proposal except Region 5. Region 5 passed the proposal but had two "no" votes.

   American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), American Society for Histocompatibility and Immunogenetics (ASHI), and NATCO all support the proposal. AOPO sent in a letter of support after the end of public comment. The OPO Committee also supports the proposal.

   The proposed policy language was reviewed with the Committee. Two clarifications were made after public comment in response to comments made. Policy language was clarified that first, transplant hospitals are not required to use TransNet when repackaging organs and second, OPOs are not required to use TransNet when packaging living donor organs. Functionality does not exist for either of these uses at the current time.

   A recurring theme heard during public comment was that mandatory transplant hospital use needs to be planned and be enacted as well. Eight comments were made urging the development and use of TransNet by transplant hospitals in order to gain the full benefits of the system. Region 6, AST and ASTS requested that this development include performing required verifications (e.g. ABO) using TransNet. The Committee plans to move forward with proposing mandatory transplant hospital use. Committee members continue to reiterate that on the transplant hospital side the preparation time will be significantly longer than OPOs and may take several years. It has been noted that the OPTN policy requirement will be needed before many hospitals will commit time and resources to this process.

   The Living Donor Committee requested during public comment that functionality be developed for use with living donor organs. The Committee wholeheartedly agrees with TransNet development and expansion of use for transplant hospitals on the recipient side as well as living donor recovery hospitals for living donor organ labeling and packaging. Discovery and preliminary requirements gathering has started for living donor organs.

   The Committee reviewed the proposed policy language. One change for language consistency was made to labeling of mechanical preservation machines. The Committee discussed that as these machines become more commonly used (e.g. Perfusix ex-vivo

lung and TransMedics organ care system) that further questions may need to be addressed but that the scope is bigger than the OSC alone. The Committee voted unanimously (16-0) to send the proposed language for mandatory OPO TransNet use on packaging and labeling deceased donor organs for consideration by the OPTN/UNOS Board of Directors at their June 2016 meeting.

The latest OPO training update was reviewed and 46 OPOs to date either have attended or have signed up for training. A draft TransNet data dashboard using Tableau was presented. The first tab showed OPO usage. The second and third tabs showed possible data presentations incorporating elements such as organ type and ice time. The Committee was asked to think about what types of data would be useful and how they would like it presented. The Committee requested a list of available data fields as well as factors to consider with each to assist in the development of future dashboards.

2. **Infectious Disease Verification**

The Committee reviewed the latest draft of the infectious disease verification policy language that would be sent out for public comment in August 14-October 14, 2016.

The Committee reviewed various suggested style edits. They debated placement of the language of the actor that can perform the verification and whether it belonged in the preceding paragraph or in the table. The OSC prefers in the table because users may just cut out and post the table. Another member added that tables should be able to stand alone. The OSC would prefer merging cells; however, this will not meet Section 508 compliance.

The OSC requested that HBV and HCV be added to common acronyms that can be used throughout policy. This will be evaluated by the policy director to assess the impact across the entire body of policy.

The OSC debated about whether to add that the verification prior to organ arrival can occur in the pre-operative area. New Centers for Medicaid and Medicare Services (CMS) interpretive guidelines released several weeks ago require that living donor pre-recovery verification must take place in the operating room and specifically prohibits use of the pre-operative area for this process. While these two verifications are not the same, the OSC does not want to confuse the community. One member noted that we should not be consistent with CMS if it does not make sense. It was shared that the AST the CMS director, Thomas Hamilton a letter that protest the IGs as making rules that are inconsistent with the final rule and outside of the scope of the proper process (public comment).

Ultimately, the OSC decided to make this a specific public comment question for feedback and not include the option of the pre-operative area in the language going out for public comment since it could be added post-public comment. They will make sure that the public comment document contains detailed background information to assist with the discussion during public comment.

The Committee discussed the need to use TransNet to the fullest capability to help conduct this verification. The organ tracking system (TransNet) was added as an acceptable source where possible. The Committee decided ultimately that it could not be a source for recipient information for the OPO verification because the donor ID band may be printed before an intended recipient is identified. It was noted that the match run is being modified and will reflect the recipient ABO as well as compatibility status so that acceptable source will become more user-friendly for this purpose.

It was noted that knowing the intended recipient is important for extra-renal recipients because of cold ischemic time considerations. Data show that organs are more likely to go unused when the recipient is not known (except for kidneys).

The Committee voted (15-1) to send the proposal out for public comment.

Committee Projects Pending Implementation

3. **Clarify requirements for blood type verification**

The Committee received an update on ABO implementation efforts. The contents of the ABO toolbox were reviewed. The ABO transplant hospital recipient OR verification video developed by Instructional Innovations in consultation with the ABO Implementation Work Group and Patient Safety Advisory Group was viewed. The video will be released on May 4, 2016. The following day a Town Hall webinar will be held to answer remaining questions from previous webinars.

Committee members received a demonstration of the IT programming being performed for the project. They were able to see a demonstration of the second user verification for subtype. Committee members discussed struggles with trying to find all required data elements for ABO verification particularly when surgery will start prior to organ arrival. Through the discussion it was noted that most exist in the system but may not be easily accessible or in one view. Differences between OPO and transplant views from the match were discussed. The IT team will explore options to assist with bringing all data elements into a more user-friendly view that will assist with performing verifications.

4. **Definition of a Transplant Hospital**

Jeff Orlowski, the Membership and Professional Standards Committee (MPSC) Vice-Chair presented the most recent working definition of a transplant hospital. A previous version had gone out for public comment in August 2014.

One member asked about the rationale behind the geographic criteria and commented that with redistricting it may be advantageous to have two programs combined even though they may be further apart than the proposed criteria. It was shared that the MPSC discussed this at length. It was noted that the rationale behind this was to have a tight geographic limitation for the primary physician to cover so that adequate time can be spent at the program. It was noted that most programs will not be changed if the proposed definition passes and there will be an option to apply to the MPSC with special circumstances. It was reiterated that the definition allows exceptions for pediatric and adult programs on the same campus as well as VA and other adult and/or pediatric programs on the same campus. The OPTN definition and the CMS definition may or may not be the same depending on how the program applies to the OPTN.

5. **Patient Safety Situation Data and Future Data Validation and Analysis Plan**

Committee members reviewed the most recent patient safety situation data through December 2015. During 2015, the OPTN received 237 voluntary patient safety situation reports. About 60% (n =147) are reported electronically through the Improving Patient Safety Portal and the remainder come through other channels such as calls or emails. Since enhancements to the reporting system were made in 2014 where members self categorize events, the percent classified as other has risen to the most frequent high-level category. In 2015, "other" types of events represented 14% of all reports. The next most common types of events reported involved communication (13%) and/or data entry (13%). The most frequent subtype of communication events reported are delayed

communications. Waitlist data entry issues are the most frequently reported in that category.

The Member Quality (MQ) Director and Patient Safety Incident Handling Team (PSIHT) representatives discussed how they are moving forward to help OSC reach data that are more actionable. It was acknowledged that the OSC does need deeper and validated data to gain insight to understand root causes and underlying contributory factors for safety situations. It was also shared that they are hampered in the ability to identify safety gaps. It was shared how they are working on definitions and a future common taxonomy and common cause analysis. MQ reiterated that they are committed to developing a system to share more actionable data with the OSC to help do work that is more meaningful.

They discussed efforts to implement validation of existing patient safety data reports. Research support has developed a new database using Research Electronic Data Capture (REDCap). The PSIHT will be performing a post-investigation validation on categorization of all reports received from both the safety portal and those that come in via other channels. This will help ensure that categorization accurately and fully represents the situation reported. These will be recorded within the new transitional database. The validated data will be analyzed for trends and PSIHT will provide recommendations for prioritization based on their reviews and validation of the data at the next in-person meeting in the fall of 2016.

In addition, discussions are underway to work possibly with Healthcare Performance Improvement (HPI), a company that has worked with hundreds of health systems and hospitals across the nation to develop a common taxonomy for categorization of safety events as well as causal analysis and level of harm. The goals would be to train staff in causal analysis as well as assess how the OPTN data could fit within and start using the HPI taxonomy to allow for more robust and comparable data analysis.

The goal of high reliability was shared. Two members discussed their experiences and talked about how it involves a corporate culture change. One question was also asked about the possibilities of ever sharing high harm event lessons. It was acknowledged that there are legal issues, which make it difficult to share the events that are significant but would jeopardize confidentiality. Staff will continue the discussions about sensitivity in areas of potential imminent threats and how to handle any potential sharing of actionable information.

6. **Patient Safety Advisory Group**

The work of this group was discussed as two patient safety videos have been developed and released. A third one is scheduled for release on May 4th. It is designed to be used as a teaching tool for ABO verification in the recipient OR. The group is starting to work on ideas for the 4th video. The MPSC has shared referrals with OSC based on topics they have observed that need addressing. All members were encouraged to participate.

7. **Transportation Issue**

Prior to arrival of the scheduled speaker, one OSC member provided his perspective of being involved with transportation issues after the fatal Michigan air crash. This work was done 10 years ago. A group led by Jim Cutler looked at whole transport issue. Experts from aviation and Emergency Management Services (EMS) were involved. This group asked if air travel was needed as often as it is used. Questions arose about what are the safety parameters that vendors have or should have as well as insurance

considerations. It was noted that in many instances it was found that third party brokers were often performing these functions and without any safety standards.

This led to changes within the member's OPO to start reviewing ARGUS ratings. The risks versus benefits of using helicopters was reviewed and the need to keep missions separate between those in the cockpit versus those of the transplant team were noted. The previous work has found that ground transportation has been identified as the weak link.

Dr. Marlon Levy from the Virginia Commonwealth University (VCU) transplant program arrived and presented his recent transportation experience and concerns to the Operations and Safety Committee for consideration.

During a recovery trip on New Year's Eve 2015, the transplant team from VCU was involved in a significant automobile accident post-recovery on the way back to the airport. The accident did cause physical injuries to the attending surgeon, Dr. Levy. The host OPO had arranged the transportation. The accident highlighted the issue that OPOs may not have safety protocols when selecting and using ground transportation services.

Through this experience the lack of policies and regulations addressing these issues were discovered. CMS has no policies on this matter and the OPTN policy requirement is that the host OPO is responsible for determining that non-local procurement teams have transportation to and from the local airport.

There are numerous modes and set ups among various transplant organizations these include private vehicles driven by team member, ambulance/EMS, donor-hospital van/vehicle, contracted transportation company, OPO-operated vehicle, transplant-center operated vehicle, police/law enforcement, and taxi. There is no ongoing comprehensive data or publications on ground team fatalities/serious injuries.

In 2009, the National Transportation Safety Board released 21 recommendations for HEMS. Some of the data shared by Dr. Levy noted that EMTs working in ambulances have a four times higher work place mortality than the average worker. Most serious and fatal injuries occur in the rear of EMS vehicles to non or improperly restrained passengers. Various studies have shown that over 80% of fatalities are to rear unrestrained passengers. AOPO and transplant administrator surveys have reported significantly more accidents involving ground versus air transportation.

There are though no federal regulations that would cover all types of transportation modes used to transport organs. There are many questions to consider that OSC members noted many organizations might not be considering. These include questions such as if there is a contractual arrangement with transportation companies, is it written into the contract that drivers must be trained and vehicles properly equipped or what are the legal and moral obligations of deferring to the operators instead of ensuring it contractually?

There are many other considerations including accreditation, organization policy standards, licensing, maintenance, after manufacture safety, insurance, driver impairment, background checks, mechanic certifications, fatigue policies, and incident management to name some of the considerations. It was noted that the OPO should not be considered the Operator of the Ambulance for any purpose.

One of the challenges noted was variation in state laws and regulations. Another member stated that this was needed as no one advocates for fellows and trainees. The

speaker noted that because many events occur outside the office and it is a daunting and complex task that the issue has not gotten the attention needed.

The OSC was asked to take a closer look at this issue. Members discussed the possibility of bringing survey data up to date. They discussed some type of education to get the message out for organizations to consider what are their transport policies and how is risk management involved. It is suspected that often it is not discussed or covered. It was noted that while policy development may be challenging it could be required that organizations have an internal policy and disclose it to teams. The OSC does want to help address this issue and will discuss next steps at its next meeting.

8. **Brainstorming on OPTN Strategic Plan Goal 1**

Due to time constraints, this agenda item was delayed until the monthly teleconference call.

Upcoming Meeting

- April 26, 2016 (Monthly teleconference call)