OPTN/UNOS Operations and Safety Committee Meeting Summary February 23, 2016 Conference Call

Theresa Daly, Chair David Marshman, Vice Chair

Discussions of the full committee on [Month, Day, Year] are summarized below. All committee meeting summaries are available at http://optn.transplant.hrsa.gov/.

Committee Projects

1. Standardize coding system for organ tracking (AKA Electronic Tracking and Transport Project orTtransNet)

Public comment for the Operations and Safety Committee (OSC) proposal for mandatory use of TransNet on deceased donor labeling was released on January 25, 2016. The comment period runs through March 25, 2016.

Results and comments to date were reviewed with members. Six regions have met to date. All have voted unanimously to support the proposal. Only one person abstained in region 10. There have also been comments and growing interest in seeing TransNet be implemented on the transplant hospital side. Some have commented that making TransNet mandatory for transplant hospitals is needed and will help centers get it established in their institutions. Region 6 members asked about OPOs that help with KPD packaging and if they would be required to use TransNet. It was noted that living donor functionality will be developed hopefully in the future but would not be required in this proposal. The region also commented that the cost is insignificant for devices and training compared to loss of organ for transplantation.

The future desired state would be to have all organs (deceased and living) be packaged by TransNet. OSC members asked that the Committee start laying out timelines for transplant hospitals. It was noted that requirements gathering has been started for transplant hospitals. Vessels and ABO verification were functionalities requested during the initial discovery.

The Committee and several regions have commented that OPOs will benefit tremendously from the current system but to get all the benefits it must be a comprehensive system used by both OPOs and transplant hospitals. Some OSC members suggested developing a TransNet transplant hospital mandatory public comment soon with an extended implementation period. It was noted that a long lead time was needed due to hospital IT infrastructure. Several transplant hospitals representatives suggested a three-year implementation and commented that one year would not be enough time.

It was shared that there are currently 5-10 transplant hospitals that are piloting or close to becoming pilot sites. It was noted that organizationally, more efforts are required due to various types of staff involved (e.g., OR staff) and the additional levels of approval needed that all leads to more time overall required to get transplant hospitals on board.

Getting OPOs mandatory will allow more focus to be placed on transplant hospitals. The Committee wants to see the momentum continue to deepen transplant hospital

participation. It was suggested to reach out to transplant hospitals to get them to put in actual public comments regarding this importance.

2. Infectious Disease Verification

The Committee reviewed proposed changes to living donor requirements that have been developed to verify infectious disease testing results. The Committee had previously discussed deceased donor and transplant recipient verification language.

Transplant representatives on the call noted they agreed with proposed language. It was noted that the recovery surgeon must participate in the attestation. A question was asked about opposition to surgeon participation from the first ABO proposal. It was explained that surgeons will verify donor information in OPO deceased door recoveries. The situation of a KPD chain was brought up. It was noted that all of the ABO living donor pre-recovery policy language was already passed without opposition including surgeon participation. The differences between deceased and living donor intended recipients were noted in that living donor surgeries are more planned and that intended recipients do not change as often as they do in deceased donors. It was noted that it might be difficult to obtain documentation of recipient willingness to accept positive results. One transplant representative noted that they do receive recipient information ahead of time and that transplanting positive results would be rare in KPD chains. It was also noted that the transplant hospitals would not have the entire record required for audit but some documentation. The language will be shared with Kidney Committee members to gather their feedback. It was also noted that members do have to document that acceptable sources were used but are not expected to document which specific sources were used from the auditing perspective. The word "intended" was agreed upon to add before recipient, as there are times that recipients change in living donation as well.

A formal vote on proposed language to be sent out for fall 2016 public comment will be conducted at the in-person meeting on April 19, 2016. The Committee will have a chance to make further refinements if needed after the public comment process.

Committee Projects Pending Implementation

3. Clarify requirements for blood type verification

The Committee received an update on progress of implementing ABO policy modifications approved in June 2015. The ABO implementation work group continues to meet at least monthly to develop tools, such as the updated templates, to help the community prepare. In February, the work group actually met three times and has completed FAQs. They are also working on other resources such as compatibility table, flow charts, Transplant pro articles, and needed electronic medical record data fields.

The compliance webinar is scheduled for March 23, 2016. Instructional Innovations at UNOS is working on an e-learning path to be released in late spring. The Patient Safety Advisory Group and the ABO implementation work group are collaborating to develop a safety video on ABO verification processes in the OR. This will be the fourth video in the series and will be released in late spring. TransNet and Member Quality staff are working together to make sure that TransNet functionality will also have the ability to help members with certain aspects (e.g. ABO verification form) for those that may be piloting the system. The other IT programming efforts are continuing and an implementation date is being narrowed down to late June or early July but excluding the week of July 4th.

Review of Public Comment Proposals

4. Improving Post Transplant Communication of New Donor Information (Ad Hoc Disease Transmission Advisory Committee)

The Committee strongly supports this proposal.

The Committee had one request that DTAC further define requirements and provide more clarity on what is intended to be captured for reporting all histopathology results. A level of clarification is needed so that the system does not end up with extraneous reporting in this area (e.g. kidney biopsy results with sclerosed glomeruli being reported to lung centers).

The Committee supports OPOs conducting routine toxoplasmosis screening on all donors. It was noted that previous DTAC efforts to mandate toxoplasmosis testing by OPOs were not successful due to cost consideration and lack of perception of risk. It was noted that regional feedback has been favorable this time thus far. The mortality and morbidity data on non-heart recipients was noted to be convincing evidence to make this change. It was also discussed that having OPOs conduct testing and disseminate results was the safer, more reliable practice that is in line with how OPOs currently operate. Depending on transplant hospitals to conduct testing and share back results post-transplant to the OPO to then share back to other centers is not the most efficient or reliable way to handle the need. Chances of failure or adverse outcomes are greater with the current system.

Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors (Ad Hoc Disease Transmission Advisory Committee)

The Committee supports this proposal.

The Committee had no specific questions or comments about this proposal.

Upcoming Meeting

March 22, 2016, (monthly teleconference call)