

**OPTN/UNOS Operations and Safety Committee**  
**Meeting Summary**  
**December 15, 2015**  
**Conference Call**

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

*Discussions of the full committee on December 15, 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. Infectious disease verification**

Committee members continued their discussion of options for releasing proposed policy for the spring public comment period that begins January 25, 2016. The Committee debated several points of the proposal on their November 24, 2015 call but decided they were not ready to vote on that call.

Committee members were briefed on the upcoming deadlines and that this would be the last opportunity to send this proposal out for spring 2016 public comment. The Committee was informed that postponing until fall 2016 public comment was another option that would allow for ABO policy implementation in June 2016 to occur first. This is a consideration because the infectious disease verification will touch the same language. Concerns have been raised about causing confusion over amending significantly debated and complex policy that has not yet been implemented. The con of not going out for public comment is that this language will not be in tandem or ready to provide additional protections with the HOPE Act implementation.

It was noted that if we move forward in the next cycle, the Committee could ask all of the outstanding or unresolved questions as part of public comment. The Committee was asked to provide feedback on whether they want to try to move forward for this cycle.

The chair indicated that she does want to see something in tandem with the HOPE Act but also wants a good product so there is flexibility either way. Several members concurred. One person mentioned that HOPE Act would be governed by required IRB protocols so these will provide some coverage until the HOPE Act moves out of its research phase. One member noted that progress has been made and they felt the Committee was relatively close to consensus on this language.

The Committee discussed some of the specifics of the language following feedback from the last calls.

Several proposed modifications were reviewed. The order of the clause in the OPO pre-recovery verification was switched to clarify that OPOs are not verifying that infectious disease results are available but that they are verifying the results.

The group debated the proposed line that the host OPO must document any test results pending at the verification. It was asked where would this be located and how would it be communicated to the transplant hospital. The question was considered would it be a

separate communication or just an indication in DonorNet. It was also noted that as is the line could be interpreted to mean all pending results versus the four viruses (HIV, HBV, HCV, and CMV-intestine only) that are the focus of this proposed policy change.

It was noted that DonorNet would be the logical place for documentation and would help avoid duplicate documentation. It was stated that to document that you documented pending results would not be well received.

Member Quality discussed their concerns about how the timing of the verification would be audited in relation to pending results. When it is retrospective look there must be documentation around the verification point of time. The added language can help but it was noted that having DonorNet as the sole source of documentation is problematic because it does not capture time of verification.

OPOs will capture the time of verification. It was explained that many OPOs already have a verification process where the time of verification is documented and that currently recovering surgeons sign off on infectious disease results. In this type of process, pending results would be added to this form. This type of documentation is maintained by the OPO and not sent to the transplant hospital.

It was also asked how critical results are communicated and how this policy would address this issue. Another member noted that the re-execute the match run policy that recently went into effect requires notification within one hour of receiving results that affect the match (positive results).

Ultimately, it was suggested that the pending language be deleted but then to seek feedback on this issue through public comment. The questions would solicit feedback on how does OPO record so that this can be auditable and how the information is consistently transmitted to the transplant hospital.

The upcoming DTAC proposal on how infectious disease results will be communicated post-transplant (or post-recovery) was discussed. The Committee was interested to review this proposal to see what issues this proposal would address. They also want to assure consistency and congruency between these two proposals.

The group discussed verification of the donor ID. It was asked should the donor ID band from TransNet be required for use. It was also noted that the timing of these two proposals was important. It was also asked if the organ tracking system should be an acceptable source.

The group discussed how donors are identified. It was noted that hospital ID bands would not have the UNOS donor ID. It was explained that several items must be used to ascertain that the correct donor is being identified. Members noted the importance when two recoveries are taking place at one time. It was stated by some that they do not access DonorNet in the recovery operating room. It was noted that currently authorization or other forms brought by the OPO often serve as the source for the donor ID. Some felt the term donor ID in policy was confusing and requested clarification that this was UNOS donor ID.

It was clarified that language being discussed was currently approved but not yet implemented policy. It was noted it would impact ABO implementation. It was stated that TransNet is not universal yet and that most hospitals do not have secondary identification band with the UNOS donor ID unless they have TransNet.

The group identified briefly the remaining questions such as use of the organ tracking system as a source; personnel who could verify positive versus negative results,

language around not having to repeat the verification twice, living donor language that will require all results to be available since this is required by policy currently, and possibly adding the pre-op area as a place for verification.

Due to time and the number of outstanding questions, the group decided that this policy should be held back until after ABO implementation and released for fall public comment. It was noted that it is prudent to implement ABO before possibly adding to confusion in the community with additional changes.

The infectious disease work group and full Committee will continue their discussions on this proposal. It will be planned to send out for the fall 2016 public comment session.

The group will also consider the DTAC proposal and currently required infectious disease policy testing sections as they work to resolve the remaining questions.

The Committee was thanked for their engagement and continued improvements to the proposed language under discussion.

### **Upcoming Meeting**

- January 26, 2016 (monthly teleconference call)