OPTN/UNOS Operations and Safety Committee
Meeting Summary
October 6, 2016
Conference Call

David Marshman, Chair
Dr. Michael Marvin, Vice Chair

Discussions of the full committee on October 6, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov.

Committee Projects

1. Infectious Disease Verification

The Committee's proposal for infectious disease verification (IDV) is active in the current public comment cycle (August 15, 2016 – October 15, 2016). The IDV work group will continue to meet and discuss public comments received. Two regions (Regions 1 and 2) have passed the proposal. There has been significant public comment and concerns with the proposal. The Committee has also presented the proposal to numerous Committees where there has been more support but also suggestions and concerns made. The Committee will discuss comments and next steps at the October 25, 2016 in-person meeting.

Review of Public Comment Proposals

2. Transplant program outcomes review system changes (Membership and Professional Standards Committee)

Dr. Matt Cooper, Membership and Professional Standards Committee (MPSC) vice chair, presented this proposal to the Operations and Safety Committee. Committee members commented that while data from the use of the higher risk kidneys would be excluded from certain MPSC actions, that the data could still impact Scientific Registry of Transplant Recipients (SRTR) Program Specific Reports (PSR), Centers for Medicare and Medicaid Services (CMS) outcomes, and insurance payer contracts used in consideration for designation as a Center of Excellence. The MPSC responded that they only have purview over OPTN flagging criteria and that they hope that they can get CMS and others on board with the concept in this proposal. If this proposal passes, it could help push CMS in this direction. The MPSC vice-chair stated that it is important for the MPSC and OPTN/UNOS to make this statement that this is important for our patients and to start moving the needle. A Committee member asked how much of the clinical factors are captured already in the SRTR scores. It was noted that the Kidney Donor Profile Index (KDPI) has 10 characteristics that are captured in SRTR for expected survival. Some members have stated they may not change behavior to use high KDPI organs because these data are included in the risk-adjusted model and that the KDPI designation alone is preventing them from using the kidneys. One member commented that the risk models for donors fairly captures risk but there is no similar adjustment for candidates such as those who may have cardiac disease. The proposal will not really address that problem. It was requested by the Committee that once high risk if high-risk is taken out of MPSC flagging, that the data be shared with all transplant centers along with the full data. Having these two data sets may assist transplant centers is deciding to use high KDPI organs. It was noted that this could be requested from SRTR.

It would also be helpful to have both high risk and total pool data together to use when dealing with CMS and insurance payers to more accurately portray outcomes and lessen the risks of using high KDPI organs. It was stressed that all transplant programs, not just those that are flagged, could benefit from this data.

3. Transplant program performance outcome measures (Membership and Professional Standards Committee)

Dr. Matt Cooper, MPSC vice chair, presented this proposal to the Operations and Safety Committee. Committee members confirmed that those that would be flagged in tiers 2 and 3 would be done in a completely random fashion. They noted that would pull in some programs that would not otherwise be flagged in the current practice. The Committee requested that when the MPSC requests information as a result of these flags that it be as close as possible to what is already being requested by CMS as part of Focused Quality Assurance Process Improvement (F-QAPI) or Systems Improvement Agreement (SIA). The Committee noted that small volume programs would not be treated differently under this model. It was also noted that the process for tier 2 and 3 programs would be conducted electronically. The Committee requested that the programs who are selected be provided meaningful feedback.

The MPSC acknowledged that they do want to provide an equal return on investment to the program that is providing requested information and give meaningful feedback to promote performance improvement. It was stated that information requested under these reviews would be close to what is already being produced for other efforts. The MPSC noted the goal was to help with process improvement so that catastrophic issues can be prevented.

One member noted that the proposal is well intended but also offered several concerns. The proposal process is complex and will be difficult to explain to all levels of transplant hospital staff including senior leadership. It was also noted that the resources required to respond to MPSC inquiries may be significant and take away from other quality improvement activities. Concerns over inappropriate use for tier 2 and tier 3 programs by insurance payers were reiterated.

The MPSC vice chair acknowledged these concerns and noted that unfortunately they do not have control over insurance payer actions. Again, it was stressed that this is a quality improvement initiative versus a punitive action. The MPSC will strive to work with existing quality improvement data and processes as much as possible versus creating extra requests and provide feedback.

4. Split versus whole liver transplantation white paper (Ethics Committee)

A Committee member asked if the suggestion to update recipient consent at various intervals in the white paper should also include suggested time intervals. The Ethics Committee chair responded that they felt that if there were going to be actual time frames they would need to be developed through another Committee such as Liver and Intestines. The rationale behind considering updated consents is that liver candidates often change status more quickly and can become sick to the point where they are not able to consent themselves. The intent would be that the consent discussion for various types of possible offers, such as increased risk or split liver, are done before the candidate may become too sick to actively participate in consenting for the various offer types that may be made including split liver.

5. **Ethical considerations of imminent death donation (Ethics Committee)**

   The Committee had no questions or comments. They support the white paper as written.

Upcoming Meetings

- October 25, 2016 (In-person meeting, Chicago, IL)