OPTN/UNOS Operations and Safety Committee Meeting Summary April 26, 2016 Teleconference Call

Theresa Daly, Chair David Marshman, Vice Chair

Discussions of the full committee on April 26, 2016 are summarized below. All committee meeting summaries are available at <u>https://optn.transplant.hrsa.gov/</u>.

Committee Projects Pending Implementation

1. Modifications to ABO determination, reporting, and verification

Members discussed the question of source documentation in relation to the new ABO policies. Confusion over the difference between use of the term source document that has a specific definition in policy versus acceptable sources that can be used for OR verifications was noted. The importance of moving towards electronic sources versus paper sources was suggested as an important goal. It was clarified that source documents are original records or copies of original records (e.g. actual lab ABO results). The definition of source document is needed in policy because only source documents can be used when entering blood types into UNetsm.

The terms source document and acceptable sources are not synonymous. Acceptable sources in some cases are data from the OPTN computer system that are not always source documents (according to the OPTN policy definition) because they are transcribed into the system. Sources that can be used during OR verifications include both source documents and other acceptable sources such as the OPTN computer system. Members again noted the need to clear up confusion for both the OSC and greater transplant community. The importance was highlighted as the infectious disease verification proposal will also be moving to public comment. The upcoming town hall on May 5th will be an opportunity to help distinguish the definition of source document from a broader category of acceptable sources.

Other Significant Items

2. Policy Oversight Committee Update

The Committee received an update from the Policy Oversight Committee (POC) inperson meeting that was deferred from the in-person meeting due to time constraints. At their in-person meeting, the POC recommended that multiple ongoing projects continue work. The POC thanked the OSC for waiting to send the infectious disease verification project to public comment until after the implementation of the ABO policies.

Other POC recommendations were reviewed with OSC members including setting time limits on several other projects. The POC also recommended four other new projects. The OSC did not have any new projects up for review. The Executive Committee, however, did not agree with the POC recommendations for the new projects and, at this time, these projects will not move forward. OSC members also reviewed a new dashboard showing the overall status of the entire OPTN project portfolio.

It was noted that TransNet does have a large impact on the OPTN Strategic Goal #4 safety allocation. If the TransNet project is approved the Board of Directors in June, it

will have the effect of reducing hours in the safety goal. All hours are allocated into one particular goal, which underscores the importance of assigning the most relevant primary OPTN strategic plan goal. It was noted that the OSC is both operations and safety. It does not mean that safety projects will not be identified or potentially approved but that all projects will be considered in relation to the portfolio as a whole. OSC members were encouraged to keep focus on projects that are already approved such as the infectious disease verification (IDV) project.

3. Brainstorming OPTN Strategic Plan Goal 1 Follow Up

Brainstorming on Goal 1 was started at the OSC fall in-person meeting. Top ideas from this October meeting were reviewed. Some of these included streamlining placement of marginal organs, preventing organ discards, making Donor Net active versus passive to dynamically adjust to changes; handling back-ups and provisional acceptances more efficiently; adjusting push-pull metrics; increasing allowable risk; increasing use of non-HIV septic donors; adjusting transplant program metrics; and increasing wait time for donation after circulatory death (DCD).

It was noted that many committees had similar ideas and several of the OSC ideas are actually in flight in other projects. These projects were reviewed. Task 17 addresses the eligible donor definition and includes OSC representation. Task 18 also known as COINN is examining alternate ways of transplant program evaluations to promote the goal of expanded use of organs. This group also has OSC representation. Another project to examine transplant program metrics is also continuing under the Membership and Professional Standards Committee (MPSC). The overall principal is to address risk avoidance that may be leading to unnecessary discard or non-use of transplantable organs.

A DonorNet optimization project is underway led by the OPO Committee. This effort is taking multiple brainstorming ideas from nearly all committees that identified how the system could be improved to facilitate better organ placement. The group has met once and is working to define and identify reasons for inefficient placement. Some of the reasons include OSC and other committee identified problems such problems with provisional acceptances, time limits, and other issues. The OSC has been asked to provide two volunteers. Five members volunteered to assist with this project. The importance of the project was noted by OSC members.

Upcoming Meeting

• May 24, 2016 (monthly teleconference)