OPTN/UNOS Operations and Safety Committee Meeting Minutes February 22, 2018 Conference Call

David Marshman, CPTC, BS, Chair Michael Marvin, MD, FACS, Vice Chair

Introduction

The Operations and Safety Committee (Committee) met via Citrix GoToTraining teleconference on 2/22/2018 to discuss the following agenda items:

- 1. Public Comment Proposal: White paper on manipulating waitlist priority (Ethics Committee)
- 2. Public Comment Proposal: Concept paper on expedited placement (Organ Procurement Organization Committee)
- 3. Public Comment Proposal: Clarify informed consent policies for transmittable disease risk (Ad Hoc Disease Transmission Advisory Committee)
- 4. Other Business

The following is a summary of the Committee's discussions.

1. Public Comment Proposal: White paper on manipulating waitlist priority (Ethics Committee)

The Committee heard a presentation on the white paper "Manipulation of the Waitlist Priority of the Organ Allocation System through the Escalation of Medical Therapies" out for public comment presented by the Ethics Committee Chair. The Operations and Safety Committee members provided very positive feedback on this paper. They noted the importantance of discussing this topic particularly as allocation changes and discussions are taking place. The Committee will submit the following formal public comment:

The Operations and Safety Committee (OSC) strongly supports the development and publication of the Ethics Committee's white paper "Manipulation of the Waitlist Priority of the Organ Allocation System through the Escalation of Medical Therapies". OSC commends the Ethics Committee for a well written and thorough analysis of an issue that many transplant professionals suspect exists but one that is challenging and difficult to discuss.

The Committee feels strongly that addressing this topic is a particularly significant and timely need as the OPTN is revisiting certain principles of allocation (e.g. geography) and organ specific allocation policies. Committee members acknowledged that transplant professionals might feel that they might be acting in the best interest of their patients but that behaviors identified in the white paper then can become normalized. The Committee feels that it is necessary to have a public document that addresses the ethical expectations in transplant. These tenets help maintain public trust and the generosity of donor families which are critical foundations of our transplant system.

2. Public Comment Proposal: Concept paper on expedited placement (Organ Procurement Organization Committee)

The Committee received a presentation from the Organ Procurement Organization (OPO) chair on the concept paper "Expedited Organ Placement" out for public comment. OSC members have a few questions. The OPO chair clarified that expedited placement would not likely impact accepted offers and back up offers unless a defined OR trigger for expedited placement

occurred. In addition, OSC members were also directed to provide feedback on the proposal through an on-line survey available on the OPTN website.

The Committee plans to submit the following formal public comment that reflects their discussions at the meeting and survey responses:

The Operations and Safety Committee supports the overall idea of developing expedited organ placement. The OPO Committee has initiated the discussion of this notion with their Concept Paper on Expedited Organ Placement.

The Committee believes that this paper is very timely and is important to discuss in the context of issues outlined in the Ethics Committee paper, "Manipulation of the Waitlist Priority of the Organ Allocation System through the Escalation of Medical Therapies". Several members requested that the OPO Committee take into account effective practices that might differ between local and national allocations. The Committee asks that the Committee also consider distance to delivery as they develop the concept.

Committee members agree that the allocation system should include an expedited placement trigger that would allow OPO to expedite organ placement. They also agree that the allocation system should include an expedited placement trigger based on an event like an organ declined in the OR or after a well-defined point in the process. The Committee believes that the allocation system should give higher priority to candidates more likely to accept an organ that has a higher likelihood of discard based on models.

They believe that hospitals should be allowed to choose whether or not they want to have their candidates on an expedited list.

Committee members have varying opinions on whether once an expedited trigger has been met, the OPO should use their own discretion to get the organ placed for transplantation. They do not have a consensus opinion on whether once an expedited trigger has been met, the list of potential candidates should be limited to those at hospitals with a recent past history of transplanting similar donors.

The Committee has mixed opinions on whether DonorNet should set a transplant hospital's acceptance criteria based on the hospital's past acceptance practices. The Committee would not support this principle unless there was a well-defined way to change when there was a change the logic for individual patient circumstances or when there was a staff or philosophy change at a transplant program.

3. Public Comment Proposal: Clarify informed consent policies for transmittable disease risk (Ad Hoc Disease Transmission Advisory Committee)

The Committee received a presentation from the Ad Hoc Disease Transmission Advisory Committee's chair on their proposal to "Clarify Informed Consent Policies for Transmittable Disease Risk" out for public comment. Following their discussions, the Committee plans to submit the following formal public comment:

The Operations and Safety Committee supports the Ad Hoc Disease Transmission Advisory Committee's public comment proposal to "Clarify Informed Consent Policies for Transmittable Disease Risk". The Committee provides two suggestions for consideration:

1.) Remove the proposed informed consent for Cytomegalovirus (CMV) for intestine patients in response to the specific request for feedback. One Committee member whose program conducts intestine transplants explained that extensive education regarding CMV is performed at listing and throughout the evaluation process.

2.) Be more specific about the timing of the required informed consent. Although the current language states that consent must be obtained before transplant, there has been confusion in the community about intent and interpretation of that clause.

Next steps:

The Committee will submit formal public comments on the OPTN website.

4. Other Business

No other business was discussed.

Upcoming Meetings

- March 22, 2018 Teleconference
- April 11, 2018 In-Person Meeting (Richmond, VA)