

OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Summary
January 14, 2016
Conference Call

Joseph Rogers, MD, Chair
Kevin Chan, MD, Vice Chair

Discussions of the full committee on January 14, 2016 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. Modification of the Adult Heart Allocation System

Section §121.8 of the Final Rule states that when an allocation change is proposed, a transition plan must be developed to transition candidates from the old allocation system to the new. UNOS staff presented a transition plan for the Modification of the Adult Heart Allocation System to the Thoracic Organ Transplantation Committee (Committee) addressing three issues:

- Transferring statuses from old system to new
- Transferring waiting time from old system to new
- Handling approved and “in flight” exception requests

The Committee questioned whether the transition plan included new guidelines for the Heart Regional Review Board (RRB). UNOS staff indicated that the Heart Subcommittee would need to look at current (2010) RRB guidelines but that in practice, there are no changes. Evaluating current RRB guidelines should be an effort that coincides with implementation of this policy.

The Committee discussed transitioning candidates whose information was not updated during the window of opportunity granted to centers prior to policy implementation to Status 6. The Committee was confident centers would not disadvantage their candidates by failing to update their information in a timely manner and agreed with this plan.

The Committee supported the transition plan as proposed. The plan is outlined in the proposal currently out for public comment.

Other Significant Items

2. Toxoplasmosis surveillance and reporting

The Ad Hoc Disease Transmission Advisory Committee (DTAC) Chair presented a portion of the DTAC proposal currently out for public comment pertaining to the surveillance and reporting of toxoplasmosis.

The DTAC proposal would require transplant hospitals that perform toxoplasmosis testing to report all results (including negative results) back to the host OPO for rapid and complete dissemination to all recipient programs. DTAC requested specific feedback regarding transplant community experiences with toxoplasma testing and whether the Thoracic Committee supported requiring OPOs to conduct toxoplasmosis testing for all deceased donors, as this would be more consistent with other testing and

promote safe practice for all recipients, particularly for non-heart recipients that can be negatively impacted and die from donor-derived toxoplasmosis infection.

The Thoracic Committee supported the OPO conducting universal toxoplasmosis testing. However, they recommended the OPO, not the transplant center as is proposed, report the results as they do for any other infectious disease on donors.

3. Status 1A Exceptions and the Use of CardioMEMS

The Committee discussed several status 1A exception requests recently submitted in which the Committee's interpretation of policy was used to justify registering the center's candidates as Status 1A by exception.

"A member...emailed the Committee to inquire whether an individual being monitored with the CardioMEMS device should be considered to require "continuous hemodynamic monitoring of the left ventricular filling pressures" for the purposes of meeting Status 1A. The Subcommittee reviewed current policy, which requires candidates to be admitted to the transplant hospital that registered the candidate on the waiting list, and the candidate "requires continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, and requires continuous hemodynamic monitoring of the left ventricular filling pressures.

The Subcommittee agreed that using the CardioMEMS device to monitor the candidate's pressures does not meet the spirit of the status 1A policy, which is to prioritize those candidates that are most unstable and at imminent risk of death. However, the policy is not written in a way that would preclude those monitored with CardioMEMS from registering as status 1A. Nevertheless, to meet this status 1A criterion these candidates must also be admitted to the hospital that registered them on the waiting list, and it is likely that those candidates that are monitored with CardioMEMS will be in an ambulatory setting and not admitted to the hospital, and therefore would not qualify for status 1A."

After these exception requests were denied by the RRB, the requesting transplant program appealed to the Committee's Review Board Appeal Subcommittee. The Committee reconvened to discuss the equivalency of CardioMEMS with the pulmonary artery catheter in the interpretation of current Status 1A policy. It was the unanimous consensus of the Committee that CardioMEMS does not adequately fulfill the criteria to provide "continuous hemodynamic monitoring of left ventricular filling pressures" as stated in Policy 6.1.A: Adult Heart Status 1A Requirements. In addition, to qualify for an exception under Policy 6.3: Status Exceptions, the center must demonstrate that "a heart candidate has an urgency and potential for benefit comparable to that of other candidates listed at that status." A letter was issued to the center indicating that interpretation of current policy stated above is insufficient justification to list a candidate for a status 1A exception.

Upcoming Meeting

- March, 2016