

Meeting Summary

OPTN Heart Transplantation Committee Meeting Summary January 19, 2021 Conference Call

Shelley Hall, MD, Chair Richard Daly, MD, Vice Chair

Introduction

The Committee met via Citrix GoToMeeting teleconference on 01/19/2021 to discuss the following agenda items:

- 1. Final Rule Presentation
- 2. Updates
- 3. 2021 Roster
- 4. Removal of DSA 6 Month Monitoring Report

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

1. Final Rule Presentation

UNOS staff provided a presentation about the four governing structures of the Organ Procurement and Transplantation Network (OPTN) and how they are integrated into both Committee work and policy development.

Summary of discussion:

Proposed policies must demonstrate that all proposed changes are authorized and comply with the OPTN's governance requirements. These requirements come from four sources: National Organ Transplant Act (NOTA), OPTN Final Rule, OPTN Contract, and OPTN Policies and Bylaws.

NOTA

Passed in 1984, this federal law established the OPTN to operate and monitor an equitable system for allocating organs, maintain the waiting list, and work to increase the supply of donated organs.

OPTN Final Rule

Issued by Health and Human Services in 2000, this rule specifies the work the OPTN must perform, what work the OPTN may perform, and how certain work must be performed. This work typically falls into the categories of allocation, testing, data collection, and membership.

OPTN Contract

UNOS' contractual obligations as the OPTN require that proposals are developed with consideration of both NOTA and OPTN Final Rule requirements. Committee members are asked to continue to engage in detailed and robust deliberations so that compliance with NOTA and the Final Rule are documented throughout the development of a project.

OPTN Policies & Bylaws

OPTN policies are rules that govern operation of all member transplant hospitals, organ procurement organizations, and histocompatibility labs in the United States. OPTN bylaws outline membership requirements to participate in the United States' transplant network.

All committee project work needs to be authorized by NOTA, OPTN Final Rule, or the OPTN Contract but must comply with NOTA, OPTN Final Rule, the OPTN Contract, and OPTN policies and bylaws.

The members were walked through an example proposal in which the authority and compliance for the project were evaluated.

2. Updates

Summary of discussion:

Develop Measures for Primary Graft Dysfunction (PGD) in Hearts

The PGD request for feedback document will go through public comment January 21st- March 23rd. A summary for responses received will be shared with the Committee in at the February meeting. The next Subcommittee meeting is scheduled for January 28, 2021.

Heart Status Extension Review

The Heart Status Extension Review project received endorsement by the Policy Oversight Committee and approval by the Executive Committee. The next Subcommittee meeting is scheduled for January 20, 2021.

Proposals Approved at the December Board of Directors Meeting

The Pediatric and Adult heart guidance approved by the Board of Directors in December are scheduled to go into effect early February. The December approved adult heart policy modifications are scheduled to go into effect late March. The National Heart Review Board for pediatric candidates is on schedule to be implemented in or by June.

The Chair asked about developing educational outreach to assist in the implementation of the policy modifications and guidance documents. The Chair raised a concern that the emails from UNOS have too much information and suggested creating a concise email that would only be sent to heart programs. UNOS staff will follow up with the UNOS Communications team. The Chair suggested creating draft content that the Committee could provide feedback on via email between meetings.

Regional Meetings and Public Comment

Public comment is open between January 21st and March 23rd. The transplant community is encouraged to visit the OPTN website to review the proposals and submit feedback. The Chair encouraged the members to reach out to colleagues in their regions to engage them in Heart Transplantation Committee proposals.

UNOS staff will help regional representatives prepare for their regional meeting presentations over the next few weeks.

3. 2021 Roster

UNOS staff provided an update on the selection process for new Heart Transplantation Committee members.

Summary of discussion:

A call for nominations goes out in July to invite transplant community members to apply to open committee positions. Members were encouraged to suggest skills and expertise that should be considered when reviewing at-large committee position applicants to UNOS staff via email. Leadership will review the at-large applicants in the next couple of weeks.

The Chair invited members to encourage colleagues from their region to apply for open committee positions and to send any recommendations to Heart leadership.

4. Removal of DSA- 6 Month Monitoring Report

UNOS Research staff presented a summary of the six-month monitoring report following the removal of donor service areas (DSAs) previously used in heart allocation. The members received the full report in their meeting materials.

Summary of discussion:

DSAs were replaced with increments of 250 nautical miles (NM) distance from the donor hospital on January 9, 2020. The goal of this policy modification is to increase equity in access to transplant and take a step closer to the continuous distribution of hearts.

Waitlist

Although there was no anticipated impact of this policy on the waitlist, it is included in the monitoring report in order to identify any unintended consequences. The monitoring report found that waitlist additions remained similar across the pre and post-implementation eras. A similar proportion of candidates were removed from the waitlist due to death or for being too sick to transplant pre and post-implementation.

Transplant

When reviewing transplants by distance traveled, pediatric status 1A and adult statuses 3,4,5, and 6 had an increase in the median distance traveled post-implementation. Median distance traveled for pediatric statuses 1B and 2 as well as adult statuses 1 and 2 decreased post-implementation.

Post-implementation, more hearts are being shared outside of the DSA but less than 250 NM from the donor hospital and there is also an increase in transplants traveling less than 250 NM. This indicates broader sharing.

A member asked if the increased discard rates during the post-implementation, pre-COVID and postimplementation, COVID-shutdown eras were significant. The Chair commented that this could be due to a transplant program's comfort level with accepting offers from hospitals further away that were not being offered pre-implementation. It was noted that the discard rate did decrease during the postimplementation, COVID-stabilization period.

A member asked about the use of local recovery teams for heart procurement during COVID and if this practice has continued. The member noted that thoracic teams are less likely than abdominal teams to use local recovery and suggested comparing the discard results to that of abdominal organs to see if the use of local recovery results in less discards. The Chair asked if data about the use of local recovery teams is collected in a way that can be analyzed without manual effort. UNOS Research staff commented that finding this information would require data mining and shared that there is a good amount of community interest on this topic. A member commented that the American Society for Transplant Surgeons (ASTS) is developing a repository of surgeons that could be contacted to perform and be reimbursed for procurement.

A member raised a general concern relating to the low utilization rates included in the monitoring report.

A member asked if there were any post-implementation findings relating to increases or decreased in transplant and waitlist volume that could be attributed to transplant program size (i.e. larger programs increased transplant volume and smaller programs decreased in transplant volume). The Chair suggested stratifying the monitoring report by program size. UNOS staff will include this information in the next report.

A member asked if there were any changes in retransplants and dual transplants. UNOS staff commented that this was not looked at specifically. The member commented that kidney transplants have increased during COVID despite the decrease in living donation. The member continued that this indicates that deceased donor transplants have increased for kidney and is curious if this phenomenon is also occurring for heart.

A member asked if data is collected relating to the amount of time between a donor being identified and procurement. A member commented that she published an article relating to donor length of stay in the Journal of Cardiac Surgery this year.

A member asked about the change in acceptance rates for statuses 5 and 6. The Chair commented that the graph displayed indicates an increase in both status 5 and 6 post-implementation.

Upcoming Meeting

• February 16, 2021

Attendance

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- **Committee Members**
 - o Adam Schneider
 - Arun Krishnamoorthy
 - Cindy Martin
 - o David Baran
 - o Donna Mancini
 - o Hannah Copeland
 - o J.D. Menteer
 - o John Hammond
 - o Jonah Odim
 - o Jose Garcia
 - o Michael Kwan
 - Kelly Newlin
 - o Rachel White
 - o Rocky Daly
 - Ryan Davies
 - Shelley Hall
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- SRTR Staff

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- Katie Audette
- o Melissa Skeans
- Monica Colvin
- Yoon Son Ahn
- UNOS Staff
 - o Eric Messick
 - Janis Rosenberg
 - Keighly Bradbrook
 - Leah Slife
 - o Rebecca Murdock
 - o Sara Rose Wells
 - Sarah Konigsburg
 - o Susan Tlusty

• Other Attendees

- o Evan Kransdorf
- o Samantha Taylor