

OPTN Heart Transplantation Committee

Meeting Summary

May 17, 2022

Conference Call

Shelley Hall, MD, Chair

Rocky Daly, MD, Vice Chair

Introduction

The Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 05/17/2022 to discuss the following agenda items:

1. Review of proposed modifications to eligibility criteria regarding intended ABO-incompatible deceased donors
2. Discussion of new Committee project activity

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

1. Review of proposed modifications to eligibility criteria regarding intended ABO-incompatible deceased donors

UNOS staff provided an update on the proposed revisions to OPTN *Policy 6.6.B Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts*. The policy changes will also impact the allocation tables in OPTN *Policy 6.6.D Allocation of Hearts from Donors at Least 18 Years Old* and OPTN *Policy 6.6.E Allocation of Hearts from Donors Less Than 18 Years Old*. UNOS staff are making final updates to the proposed policy language and will schedule a Committee vote for early-mid June 2022. If approved by the Committee, the proposed policy will be reviewed by the Policy Oversight Committee and the Executive Committee for submission to public comment from August 3rd to September 28th, 2022.

Summary of discussion:

The proposed changes to heart policy governing ABOi eligibility criteria and the allocation of donor hearts will allow for older, pediatric heart candidates to be listed for an ABOi donor heart than current policy permits. The proposed changes could be very helpful for older pediatric candidates who still do not produce anti-A or anti-B antibodies. Additionally, the proposed increase in the registration age criteria from less than two years old to less than 18 years old is expected to benefit heart transplant recipients who received an ABOi heart previously by increasing their access to donor hearts.

The policy also gives pediatric candidates with 'high' titers access to donor hearts, within important guardrails. For example, the proposal will create a new "tertiary blood type match," and candidates who meet the criteria will have better access to transplantation, but the proposed policy does not necessarily encourage such transplants, which are still deemed experimental, because access for such candidates is well down the classification rows in the allocation tables. A member of the Pediatric-Heart Workgroup stated that the proposal represents a fair and balanced approach to improving access for such candidates. The Vice-Chair encouraged members to send any questions or concerns they had about the proposal to Committee leadership ahead of the final vote to allow for sufficient discussion and consideration ahead of time.

Next steps:

UNOS staff will circulate the Pediatric-Heart Workgroup's Excel spreadsheet reflecting the classification rows in allocation tables 6-7 and 6-8, which indicates the number and percentage of transplants that occurred within each classification row. The final version of the policy language with sufficient time ahead of the Committee's vote. If members have any questions, they are encouraged to reach out to Committee leadership or UNOS staff ahead of the Committee's vote. All materials are posted on the Committee's Sharepoint site.

2. Discussion of new Committee project activity

The Heart Committee will begin a policy project to address previously identified issues associated with adult status 2. As the Committee has previously discussed, the increased assignment of candidates to adult heart status 2, particularly by exception rather than by the established criteria, suggests that transplant programs are concerned that their candidates may not get transplanted at statuses 3 and lower. The project is an opportunity to develop policy solutions as "pre-work" for the Committee's upcoming continuous distribution project. Addressing known issues now will help prevent those issues from being replicated in the new continuous distribution allocation framework.

Summary of discussion:

The Vice-Chair added that this is a great opportunity for the Committee members to think through ways to better stratify existing policy criteria without completely taking apart the current allocation system. The Committee may want to consider whether ranking the devices within a status by medical urgency could improve the allocation system's overall performance. For example, current policy groups multiple mechanical circulatory support devices (MCSDs) into the same statuses, and gives them equal priority. One member suggested that not all support devices should be treated equally and considered providing more priority for patients with a left ventricular assist device (LVAD) and less priority to patients with an intra-aortic balloon pump (IABP). A member added that stratifying these devices is the challenge of having an allocation system with statuses guided by medical therapies as opposed to statuses guided by illnesses. A member noted that medical therapies can vary by gender due to different body sizes which could have implications for which status a patient is eligible for.

The Vice-Chair reminded the Committee that there will be multiple iterations of continuous distribution and the first step is to transition the existing heart policy into the new allocation framework without substantial changes. This project is proposed to resolve some of the existing challenges with status 2 to avoid delaying the revision until after continuous distribution is implemented. The Vice-Chair noted that the Committee will likely have to make some compromises in the initial development of continuous distribution but reminded the Committee that the ultimate goal is to develop a Heart Allocation Score. A member added that the policy development and implementation is a very intricate and complex process, noting that it can be a long timeline from idea to implementation.

The Committee members will likely want to review the reasons transplant programs provide when submitting exception requests. UNOS staff indicated that they would email the members the Briefing Paper, *Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy*. A small-scale review of exception requests for status 2 assignments was performed as part of the project and is described in the Briefing Paper.

Next steps:

The Committee will continue to discuss this project and determine next steps forward in subsequent meetings.

Upcoming Meeting

- June 21, 2022

Attendance

- **Committee Members**
 - Adam Schneider
 - Amrut Ambardekar
 - Cindy Martin
 - Cristy Smith
 - Hannah Copeland
 - Jennifer Carapellucci
 - JD Menteer
 - Jonah Odum
 - Michael Kwan
 - Nader Moazami
 - Rocky Daly
 - Tariq Ahmad
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Grace Lyden
 - Katie Audette
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Janis Rosenberg
 - Keighly Bradbrook
 - Kristin Cuff
 - Laura Schmitt
 - Sara Rose Wells
 - Susan Tlusty
- **Other Attendees**
 - Earl Lovell
 - Jen Cowger
 - Martha Tankersley
 - Timothy Gong