

**OPTN Thoracic Organ Transplantation
Heart Subcommittee
Meeting Summary
June 25, 2020
Conference Call**

Shelley Hall, MD, Subcommittee Chair

Introduction

The Heart Subcommittee met via Citrix GoToMeeting teleconference on 06/25/2020 to discuss the following agenda items:

1. Monitoring Report: Eliminate the Use of DSAs in Thoracic Distribution
2. Review potential projects

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

1. Monitoring Report: Eliminate the Use of DSAs in Thoracic Distribution

UNOS staff gave an overview of a three-month monitoring report following the elimination of Donation Service Areas (DSAs) in thoracic distribution.

Summary of discussion:

The Chair thanked the incoming committee members for joining the meeting.

UNOS Research staff reviewed the three-month heart monitoring report following the elimination of DSAs in thoracic distribution. DSAs were previously used in the allocation of hearts and heart-lungs but were removed from allocation policy along with OPTN regions in the summer of 2018. Starting January 9, 2020, heart allocation policy replaced DSAs with the measure of 250 nautical miles (NM) distance from the donor hospital.

As part of the monitoring plan, the committee will be presented data on the following metrics at 3 months, 6 months, 1 year, and 2 years post-implementation.

- The number/% of transplants stratified by distance (NM) between donor hospital and transplant center
- Volume of transplants by de-identified heart transplant centers
- Distribution of the distance (NM) between donor hospital and transplant center, including range, IQR, mean, and median
- Number and percent of transplants by geographic classification (local, regional, national) and distance (NM) between donor hospital and transplant center
- Distribution of ischemic time (hours) for heart transplants, including range, IQR, mean, and median
- Unadjusted post-transplant patient survival stratified by distance (NM) between donor hospital and transplant center
 - This metric will be presented in future reports when a sufficient amount of data is collected is draw conclusions

This report compares a pre-implementation cohort of 732 adult heart transplants performed from January 9, 2019- April 9, 2019 to a post-implementation cohort of 757 adult heart transplants performed from January 9, 2020- April 9, 2020. Between these two eras, the number of transplants increased by 25 post-implementation. The percentage of recipients transplanted at Statuses 1 and 3 decreased while the recipients transplanted at Statuses 2 and 4 increased post-implementation.

More heart transplants are being performed within 250 nautical miles (NM) and between 250-500 NM post-implementation. There are less heart transplants being performed between 500-1000 NM post-implementation.

Of 112 transplant centers that performed at least one adult heart transplant during one of the two eras, 59 performed more adult heart transplants post-implementation than they did pre-implementation. There were 42 centers that performed fewer adult heart transplants after implementation than pre-implementation.

The median distance traveled between donor hospital and transplant hospital decreased slightly post-implementation. Hearts traveling less than 250 NM are being allocated more to regional and national shares rather than local. The share type for hearts traveling greater than 250 NM did not change significantly post-implementation. Total ischemic time has not been affected. The committee will continue to monitor these metrics in addition to other metrics as more data are made available.

The Subcommittee Chair commented that these initial findings are aligned to what the Subcommittee expected. A member asked if the transplant hospitals were setting limitations on the distance they were willing to accept a heart transplant. UNOS staff commented that most transplant hospitals set a limit of 1500 NM for thoracic organs but this information is not included in the current report.

A member commented there was little change since the removal of DSAs. The Subcommittee Chair considers the removal of DSAs a success since it has brought in the distance of sharing slightly. A member agreed that this looks good at a national level but raised a concern about the impact at a regional level, specifically in areas that have a higher population density. The member suggested adding this as a component of the monitoring report. UNOS staff agreed that this would be an interesting analysis to review.

A member asked if there could be other confounders between the two eras being compared such as offer acceptance rates or number of discards. UNOS staff commented that these specific variables were not included in the three month monitoring report. Another UNOS staff asked the member why acceptance practices might have changed post implementation from a clinical standpoint and commented that discard rates for heart are very low. Discard is defined as an organ that is recovered for transplant and then not transplanted. Heart discard rates are less than 1%. Denials are defined as an organ that is not accepted. A member commented that discard and denial data would be interesting to review in light of COVID-19. The Subcommittee Chair agreed that looking at denials would have value especially due to any changes that may have occurred due to COVID-19. It was suggested to review how denial codes are being used. A member commented that comparing the denial codes between the two eras could provide more granularity for further research.

UNOS staff said they will think of the best way to approach these questions from a research perspective and will present some suggestions for further clarification with leadership. A member commented that the variation in Organ Procurement Organizations (OPO) practices should also be considered.

The Subcommittee Chair noted that in March, some OPOs may not have had the ability to test for COVID-19 so these organs may not have been offered. This and other effects of COVID-19 may make

comparison pre and post-implementation difficult. UNOS staff asked the members to avoid blurring the impact of COVID-19 and the removal of DSAs.

The Subcommittee agreed that reviewing discard rates would not be helpful. UNOS staff asked if they should begin looking at matches to prepare additional analyses. The Subcommittee Chair suggested comparing the offers versus acceptances for the two eras to assess if there is any difference. A member suggested reviewing the utilization, acceptance, and refusal rates.

The Subcommittee Chair mentioned that this report only shows 3 months of data and that having a year worth of data will allow for more conclusions to be drawn but will be complicated due to the effects of COVID-19 including related transportation issues which may increase national denials. A member commented that their donor teams were prevented from flying in April and May. The Subcommittee Chair requested utilization rates for the 3 month era from the report. Following the meeting, Heart Committee Leadership, in consultation with OPTN staff, decided to delay submitting data requests until a larger cohort may be analyzed.

Next steps:

Research staff will provide suggestions for further analysis and determine additional metrics to include in the monitoring reports with leadership.

2. Review potential projects

UNOS Staff and the Subcommittee Chair reviewed potential project ideas.

Summary of discussion:

The Subcommittee Chair shared that work is being done to clear up a backlog of project forms. These forms have been reviewed by staff and leadership and have been closed and/or combined in order to more accurately reflect the initiatives of the committee going forward.

When evaluating which project ideas the Heart Committee should focus on during the next year, UNOS staff asked members to consider:

- How does the idea address National Organ Transplantation Act and Final Rule?
- What evidence exists to suggest a policy action or other solution is required to address the idea?
- Would a solution be evidence-based?
- What data collection, analyses, and/or modeling would be needed to address the idea?
- Priority-level of idea?
- What kind of timeframe would be needed to address the idea?
- How does the idea impact transplant programs, OPOs, histocompatibility labs, and the OPTN?
- How does the idea impact the OPTN? (Information Technology, Professional Education, Member Quality, etc.)

The Subcommittee Chair said the meeting would be used to introduce project ideas and that slides will be sent out to allow a deeper dive in a future discussion. Active projects include monitoring current adult heart allocation policy and ongoing modifications of current adult allocation policy. The Subcommittee Chair noted that the new incoming members will be involved in the discussion for ongoing modification to policy.

Projects that are considered highest priority include modifying policy to accommodate new technologies, utilization and alternative approach to higher risk donors and recipients, and the establishing of a National Heart Review Board. The National Heart Review Board for Pediatrics is undergoing implementation.

Projects that are important to consider and will be discussed further include defining and collecting data on primary graft dysfunction, developing guidance on hemodynamic monitoring, and work to improve access for sensitized patients.

Developing a Heart Allocation Score (HAS) is considered a low priority because it requires a minimum of five years of data collection. UNOS staff shared that Continuous Distribution for heart will begin in late 2022 which will also impact the timeline for HAS. A project around Donation after Cardiac Death (DCD) Donors is also a low priority since DCD donation is still being researched.

All other project ideas have been closed because they are obsolete or have already been addressed.

The Subcommittee Chair invited the Subcommittee to share their ideas. The Subcommittee will continue to propose new project ideas as new issues arise in the heart transplantation community.

UNOS staff said that the project ideas spreadsheet will be available on the Thoracic Organ Transplantation Committee's SharePoint site as well as the Heart Transplantation Committee's SharePoint site as soon as it is finished being developed. This spreadsheet includes more details on each project idea. UNOS staff invited the members to reach out with any questions.

The Subcommittee Chair addressed the new members, saying that the policy process is slower than one would anticipate due to the amount of data collection and analysis required as well as the process of going through public comment and board approval.

A member suggested collecting more data on lower statuses and exception forms to inform continuous distribution and HAS.

UNOS Staff reminded the members of the upcoming committee and regional meeting dates and told them that prep work will soon begin for the public comment presentations.

Next steps:

UNOS Staff will send out the slides and spreadsheet for members to consider prior to future discussions on projects to undertake as the Heart Transplantation Committee.

Upcoming OPTN Heart Transplantation Meetings

- July 21, 2020
- August 18, 2020
- September 15, 2020
- October 20, 2020
- October 29, 2020: Committee In-person meeting, Chicago, IL
- November 17, 2020
- January 19, 2021
- February 16, 2021
- March 16, 2021
- April 20, 2021
- April 2021: Committee In-person meeting, Chicago, IL – TBD

- May 18, 2021
- June 15, 2021