OPTN Heart Transplantation Committee
Meeting Summary
September 4, 2024
Conference Call

J.D. Menteer, MD, Chair
Hannah Copeland, MD, Vice Chair

Introduction

The Heart Transplantation Committee met via WebEx teleconference on 09/04/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Six-month monitoring results associated with *Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates* policy changes
3. Overview of incorporating exceptions in CD of Hearts
4. CD of Hearts Update, Summer 2024: Public comment and regional meeting feedback
5. Open forum
6. Closing remarks

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

1. Welcome and agenda review

The Chair welcomed the members and provided an overview of the agenda. Members calling in by phone only were reminded to tell OPTN contractor staff their names for attendance purposes. Non-committee members and those without business before the Committee were reminded that they should follow the proceedings using vimeo.com/optn. OPTN contractor staff reminded the members about the continuous distribution and other heart-related resources that are available on the OPTN website and on the Committee's SharePoint site.

2. Six-month monitoring results associated with *Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates* policy changes

OPTN contractor staff presented the six-month monitoring results associated with the Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates policy changes. The results were presented as comparisons across three timeframes. The results of the analysis indicate that the willingness to accept ABOi hearts at listing remained consistent. The results suggest that utilization of ABOi hearts from donors less than one-year old decreased slightly, but it is uncertain if the result is related to the policy change.

Summary of discussion:

No decisions were made as part of this agenda item.

The Chair wanted to make sure the Committee members understood that with six-month monitoring reports, generally there is limited data available for analysis. As a result, members should consider the results as informational.

OPTN Contractor staff said the project was implemented in two stages. The first set of changes were implemented on 03/16/2023. The changes included: eliminating the requirement that a pediatric candidate be registered on the waiting list before age 2 to qualify for ABOi heart transplant, and expanding eligibility to all heart, heart-lung, and lung candidates listed before age 18 with appropriate anti-A/anti-B titers. The second set of changes were implemented on 11/30/2023 and expanded ABOi eligibility to include pediatric status 2 heart and heart-lung candidates. Because of the split implementations, the monitoring reports makes comparisons across three time periods:

- Pre-implementation: 09/14/2022 – 03/15/2023
- Transition: 03/16/2023 – 11/29/2023
- Post-implementation: 11/30/2023 – 05/29/2024

The six-month monitoring report and presentation include information about the willingness to accept ABOi heart offers, ABOi heart transplants, heart utilization, and pediatric waiting list mortality. The 12-month monitoring report will provide similar information and will also include additional stratifications and titer information at listing and at transplant. Future monitoring will include information about median time to transplant and post-transplant outcomes. The major takeaways from the monitoring results are:

- Little change in candidates willing to accept an ABOi heart at listing, ABOi heart transplants, or pediatric waiting list mortality;
- Deceased donor heart utilization has decreased, especially for donors <1 year of age, but this is unlikely to be a result of this policy change;
- Small increase in candidates age >2 willing to accept ABOi heart at listing and transplants to candidates age >2; and
- No increase in Status 2 candidates willing to accept ABOi heart at listing.

Contractor staff said status 1A candidates were most likely to be willing to accept an ABOi organ offer followed by status 1B. Furthermore, there seems to be no impact associated with allowing pediatric status 2 patients to indicate they are willing to accept an ABOi heart. If anything, there may have been a slight decrease. The analysis found no statistically significant difference in waiting list mortality across the three eras, but the sample sizes available for analysis were quite small.

In terms of transplants, the results of the analysis suggest some positive impact associated with the increased candidate age for eligibility. Previously, only candidates listed before turning two years of age would have been receiving these transplants. However, starting at the transition period, the results reflect a small number of ABOi transplants going to older pediatric candidates. According to the results, there have been two transplants that went to pediatric candidates who were between 11 and 17 years old. One transplant occurred during the transition era and the other occurred in the post-implementation era. This indicates that heart candidates across the pediatric spectrum are able to receive these organs as intended by the policy.

OPTN contractor staff pointed out that one of the key metrics identified for determining success was utilization of donor hearts associated with the policy changes. Utilization refers to the number of donor hearts received relative to the number of donor hearts available. Non-use refers to the number of hearts transplanted out of the total hearts recovered. According to the monitoring results, utilization decreased some, from about 28% to about 26% from the pre- to post-implementation eras. The rate of non-use increased from about 1% to 1.75%. However, these are small numbers. This is especially true for the non-use number. Moreover, since the results are based on only six months of data, it is difficult to say if the data reflect actual trends. It is also unlikely that any decrease in utilization would be related to this policy change. As a result, the finding may reflect something that is going on in the broader

system. Contractor staff said that a piece of information to keep an eye on in future monitoring reports is that there was a fairly large decrease in the utilization of hearts from donors who were less than one year of age. It may just be a function of the small numbers involved but something to be aware of.

A member noted the Heart Committee and a workgroup of Heart Committee and Pediatric Committee members put a lot of work into developing the initial policy with the goal of balancing increased access to transplant and avoiding high-risk transplants. One reason for increasing the age limit was to benefit older pediatric candidates who had ABOi transplants as neonates. The member noted that the results are reassuring because they indicate that ABOi transplants are being used appropriately. A member of the Workgroup asked if the 12-month monitoring report could include an analysis of pediatric status 2 patients who are admitted to the hospital and those who are not. The individual said the Workgroup had considered whether it is appropriate to require pediatric status 2 candidates who are not admitted to the hospital to travel for blood work to meet the reporting requirements for maintaining their eligibility. OPTN contractor staff said the analysis would be included in the future monitoring reports. The analysis identified two individuals in the 11-17 year old category who received ABOi heart transplants. The Committee members were interested in details about the recipients and were told that as of the time of the analysis both individuals were still alive.

Meeting attendees were excited that the community was able to safely expand the allowable boundaries for ABOi heart transplant.

Next steps:

OPTN contractor staff will produce 12-month and 24-month monitoring reports in the future.

3. Overview of incorporating exceptions in CD of Hearts

The Committee members began their initial discussion about how to incorporate exceptions requests within the CD allocation framework. The current exception process was summarized, including the responsibilities and activities of the regional review boards. An overview of ways exceptions and review boards could be incorporated in the CD framework was provided along with a demonstration of how the OPTN Computer System assists in the creation of exception requests in lung CD.

Summary of discussion:

No decisions were made as part of this agenda item.

The Chair presented an overview of the questions the Committee will consider as it works to incorporate exception requests in CD of hearts. This included descriptions of how the adult and pediatric review boards currently operate. The adult heart regional review boards (RRB) follow the RRB Operational Guidelines available on the OPTN website. Transplant programs submit exception requests to have candidates assigned to heart status for which the candidates do not qualify by policy criteria. Such requests are reviewed by a panel of reviewers in one of the 11 RRBs. RRBs do not review requests from transplant programs within that region. Reviewers are drawn from a regional pool of representatives. The number of RRB representatives assigned to review a request varies by region, as the number of potential representatives depends on the number of programs in region. Each RRB is led by a chair, who only votes to break ties among the other representatives.

The National Heart Review Board (NHRB) for Pediatrics follows the NHRB for Pediatrics Operational Guidelines. The NHRB for Pediatrics was implemented in June 2021, in part, to ensure pediatric exception cases were reviewed by clinicians and surgeons with experience in pediatric heart matters. Reviewers of pediatric exception requests are drawn from a national pool of representatives, as

opposed to the regional review board process used with adult exception requests. From the national pool of representatives, each exception request is assigned to nine randomly selected representatives for review. Transplant program size is accounted as part of the random selection process so that each case is reviewed by those with the perspectives of small, medium, and large-sized programs.

The OPTN Heart Committee is identified as the final reviewer of exception appeal requestions as established in *Policy 6.4.A: Review Board and Committee Review of Status Exceptions*. The Committee has established a subcommittee to perform such reviews and is the final step in the exception process.

As the Committee considers how best to incorporate exceptions in the heart CD framework, the Chair reminded the members about the importance of maintaining consistency across organ-specific CD policies. Members were reminded that CD was OPTN Board approved in 2018 as the new system for allocating organs. CD aligns with the Board's request for creation of a consistent, cross-organ framework which implements operational consistency managing exceptions and review boards. As a result, the Committee should work towards making Heart exception request policy reflect those of other organ CD frameworks. The Chair reviewed steps for achieving cross-organ operational consistency as part of implementing CD, including creating national review boards for each organ allocation framework and similar processes for submitting exception requests, reviewing, voting, and decisioning exception requests, and appeals.

In relation to heart implementing such consistency, the first step involves creating a national heart review board for adults. Similarly to the current operational guidelines for both adults and pediatrics, each adult heart transplant program can submit up to two representatives to serve on a national pool of reviewers. It was also mentioned that specialty boards can accommodate cases that need specific reviewers, like pediatrics.

The second step is developing processes for submission of exception requests. Under CD, transplant programs submit an attribute-based exception request for their candidate, including the justification narrative supporting the request. It is likely that medical urgency will be the most commonly used attribute for heart exception requests. An important Committee consideration will be determining whether to keep retrospective reviews of exception requests or adopt a prospective review process. The Lung Committee uses prospective reviews. For Heart exception requests, prospective review could help prevent the overuse of exception requests. However, challenges to implementing a prospective approach include the risks to patient safety and the high volume of heart exception requests.

The third step is to develop procedures for reviewing exception requests and voting. The fourth step is to determine how cases will be decided. An exception case will close when either a majority approval or denial is met, or, the case reaches the end of the timeline for voting, whichever is first. The fifth step is to determine the appeals process. If the exception request was denied, the transplant program has the option to submit an appeal within a certain number of days after the denial notification. Currently, heart transplant programs have one day to submit an appeal.

The Chair reviewed the operational aspects of how exception requests are expected to function in CD, and how the operational aspects are intended to ensure consistency across different organ allocation systems. For example, exceptions will be attribute specific. (In the current heart allocation system, exceptions are used to obtain a specific heart status.) In the CD framework, exceptions will apply to only those attributes where information is known prior to match run. As a result, transplant programs cannot request exceptions associated with the proximity efficiency attribute since the distance between the donor and candidate hospitals is unknown until the match run is performed. Exceptions will ask for a percentage of an attribute's total points; so, the awarded amount equals the points of the criteria being

requested; this avoids issues associated with attribute weights changing in the future. The Chair reviewed an example exception request where the following information is assumed:

- Medical urgency accounts for 50 points of Heart's Composite Allocation Score
- Criteria *MCSD with Malfunction* is assigned 35 medical urgency points
- Candidate A's medical urgency score is 20

Also assume that the hypothetical transplant program staff agree that Candidate A's medical urgency is equivalent to that of the *MCSD with Malfunction* criteria which is equal to 35 points on the medical urgency rating scale. The transplant program wants Candidate A's medical urgency score to be 35. As a result, they request 70% of the 50 total medical urgency points (70% of 50 total medical urgency points = 35). If approved, Candidate A's new medical urgency score is 35 by exception, replacing the previous score of 20.

OPTN contractor staff provided a demonstration of how lung exception requests are created in the OPTN Computer System. Contractor staff used the test environment to create a hypothetical lung exception request for medical urgency. A transplant user can enter a percentage of the goal requested for candidate. (Lung exception requests are goal-specific, but going forward, committees developing CD frameworks will use attribute-specific requests.) The OPTN Computer System calculates the number of exception points requested based on the percentage entered and the total number of points available. The user also enters the justification narrative and authorization, and then submits the exception request.

The Committee then discussed the expectations associated with creating consistency across the frameworks and also how the Committee envisions incorporating exceptions in heart CD. The Chair noted the on-going concern that it is relatively easy to have hearts exception requests approved in the current allocation system. The Chair asked whether the use of a prospective approval process yields less approvals. OPTN contractor staff commented that this problem could exist in both prospective and retrospective systems, but a prospective system may be more effective in that respect. Contractor staff also noted that the Lung Committee uses lung review board meetings to review exceptions received to promote consistency in review board and provide guidance to review board members and the broader community.

A Committee member expressed concern about the number of inappropriate exception appeals and requested data on how many patients are transplanted at denied statuses. The member questioned whether there should be penalties for inappropriate use of exception requests.

Another member asked why lung exception requests focus on the percentage rather than the number of points? OPTN contractor staff explained that this allows for scaling to account for future changes to the weighting of the goals and/or attributes. (It is expected that OPTN committees will change attribute weights as performance information becomes available and/or attributes are added or removed. Members asked if the new system permits review boards to award a different number of points than requested. Several members expressed a preference for a prospective appeal process. A Committee member asked if OPTN contractor staff could review requests and provide context for how the review boards have awarded points for similar points in the past, and to request additional detail in the narrative, if needed. Another member noted that the Committee previously provided a template for proper exception requests for assignment at status 2, but the community has not used it as much as was hoped for. A member recommended that the Committee needs to consider how to help patients, patient families, and donor families understand how these policy changes will impact them.

Next steps:

Due to time constraints, the Chair did not review future items or next steps for consideration at this time.

4. CD of Hearts Update, Summer 2024: Public comment and regional meeting feedback

Members were reminded that meetings remain in OPTN regions 3, 5, 7, and 11. OPTN contractor staff provide a short overview of how the CD update presentation is organized as well as the role of the Heart Committee's presenter. A Committee member who attended the Region 10 meeting said that there had not been a lot of specific discussion about continuous distribution of hearts. Another member stated they had a similar experience at the regional meeting where they presented.

Next steps:

OPTN contractor staff will continue working with members presenting the CD of Hearts Update at the regional meetings. Contractor staff will also continue updating the Committee about the feedback received.

5. Open forum

There were no requests to speak during this part of the meeting.

6. Closing remarks

The Chair thanked the members for attending.

Upcoming Meetings

- ~~July 2, 2024 from 4:00 to 5:30 pm~~
- ~~July 16, 2024 from 5:00 to 6:00 pm~~
- ~~August 7, 2024 from 4:00 to 5:00 pm~~
- ~~August 20, 2024 from 5:00 to 6:00 pm~~
- ~~September 4, 2024 from 4:00 to 5:00 pm~~
- September 17, 2024 from 5:00 to 6:00 pm
- October 2, 2024 from 4:00 to 5:00 pm
- October 9, 2024 from 9:00 am to 4:00 pm (In-person meeting, Detroit, MI)
- October 15, 2024 from 5:00 to 6:00 pm
- November 6, 2024 from 4:00 to 5:00 pm
- November 19, 2024 from 5:00 to 6:00 pm
- December 4, 2024 from 4:00 to 5:00 pm
- December 17, 2024 from 5:00 to 6:00 pm
- January 1, 2025 from 4:00 to 5:00 pm
- January 21, 2025 from 5:00 to 6:00 pm
- February 5, 2025 from 4:00 to 5:00 pm
- February 18, 2025 from 5:00 to 6:00 pm
- March 5, 2025 from 4:00 to 5:00 pm
- March 18, 2025 from 5:00 to 6:00 pm
- April 2, 2025 from 4:00 to 5:00 pm
- April 15, 2025 from 5:00 to 6:00 pm
- May 7, 2025 from 4:00 to 5:00 pm
- May 20, 2025 from 5:00 to 6:00 pm
- June 4, 2025 from 4:00 to 5:00 pm

- June 17, 2025 from 5:00 to 6:00 pm

Attendance

- **Committee Members**
    - J.D. Menteer
    - Hannah Copeland
    - Denise Abbey
    - Tamas Alexy
    - Jennifer Cower
    - Kevin Daly
    - Rocky Daly
    - Jill Gelow
    - Eman Hamad
    - Mandy Nathan
    - David Sutcliffe
    - Martha Tankersley
- **HRSA Representatives**
    - Jim Bowman
- **SRTR Staff**
    - Yoon Son Ahn
    - Katie Audette
    - Grace Lyden
- **UNOS Staff**
    - James Alcorn
    - Darby Harris
    - Kelsi Lindblad
    - Alina Martinez
    - Eric Messick
    - Leah Nunez
    - Sarah Roache
    - Laura Schmitt
    - Sara Rose Wells
- **Other Attendees**
    - Neha Bansal
    - Brian Feingold
    - Shelley Hall
    - Glen Kelley