OPTN Heart Transplantation Committee
Meeting Summary
July 16, 2024
Conference Call

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

Introduction

The Heart Committee met via WebEx teleconference on 07/16/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Update and discussion: Overview of continuous distribution of hearts
3. Presentation and discussion: Continuous distribution of lungs – One-year monitoring report and lessons learned
4. Open forum
5. Closing remarks

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

1. Welcome and agenda review

The Chair welcomed the members to the meeting and provided an overview of the agenda topics.

Summary of discussion:

No decisions were made as part of this agenda item.

The Chair welcomed the Committee members. The Chair described the meeting's agenda items and who would be presenting.

Next steps:

Not applicable.

2. Update and discussion: Overview of continuous distribution of hearts

The immediate past Committee Chair presented background information about the reasons why and the timeline associated with moving to continuous distribution (CD), an overview of CD as an allocation framework, and the Committee's efforts developing a heart CD allocation framework.

Summary of discussion:

No decisions were made as part of this agenda item.

The meeting discussed the progress and implementation of continuous distribution for hearts and lungs, emphasizing the need to prioritize medical urgency and efficient organ use through a borderless allocation system that assigns a candidate-specific score based on the most important factors associated with transplantation. The discussion also addressed some of the challenges associated with developing

and implementing CD as an allocation framework that may include increased organ procurement with the CD system, and concerns about potential disadvantages for certain patient populations.

In terms of background, the Secretary of the U.S. Department of Health and Human Services (HHS) directed the OPTN in late 2017 to remove the use of distance and geographic boundaries as a primary factor in allocating donor lungs, and this was then applied to all donor organs. At that time, the policy of allocating lungs based on geographical boundaries was deemed inconsistent with the final rule, which emphasizes medical urgency and efficient organ use. An OPTN ad hoc committee was created. They proposed developing a borderless distribution system based on proximity to donors and recipients, utilizing the framework of continuous distribution. The ad hoc committee also emphasized the importance of developing a system that could be utilized across all organs. Continuous distribution for lungs was implemented on 03/09/2023, after two and a half years of work. The other organ-specific committees are currently developing CD allocation frameworks.

The immediate past Chair described how the Committee has been working on continuous distribution for 18 to 24 months and is making good progress. Continuous distribution assigns a patient a composite allocation score (CAS) based on attributes such as medical urgency, blood group, distance, and waiting time, eliminating classification boundaries. The CAS system includes goals such as medical urgency, post-transplant survival, candidate biology, and candidate access. The Committee has relied on data analysis and member expertise in developing framework and attributes, such as adjusting points for blood type candidates and deciding to assign priority within sensitization based on the number of HLA antibodies a program is willing to list for the candidate. Current heart allocation policy stratifies medical urgency using six adult heart statuses and three pediatric heart statuses. For CD, the Committee has worked on transitioning the adult and pediatric statuses to a single continuum based on the criteria in place now. Additionally, the criteria can be moved along the continuum to better reflect the associated medical urgency. For example, intra-aortic balloon pumps are currently a criterion in status 2; however, in CD, the medical urgency associated with balloon pumps could be reduced so it no longer aligned with other status 2 criteria. A criterion could also be given greater medical urgency along the continuum, such as what is being proposed for the status 4 LVAD criteria. In this case, a candidate could get additional medical urgency points in a graduated manner based on the amount of waiting time they accrue. The examples demonstrate the flexibility available in CD. It was discussed how the implementation of the lung CD system has experienced an increased aggressiveness in organ procurement and more DCD (donation after circulatory death) offers. While the lung CD framework includes a post-transplant survival attribute, the Heart Committee has concerns about trying to include it is an attribute in the first version of heart continuous distribution. For instance, there are concerns about potentially disadvantaging certain patient populations. In a CD system, a patient gets points based on the rating scale in pace for each of the attributes. The points are summed to create the Composite Allocation Score.

There's one more aspect to developing the CD framework and that involves assigning different weights to the attributes. For example, the Committee might decide that the medical urgency attribute should account for up to 25 of the composite allocation score points. Similarly, pediatrics and distance could be allowed more, whereas sensitization might only be allowed a total of ten points. As a result, a candidate might be eligible for 50% of the total points for a single attribute but based on the overall weightings assigned to the attributes, the 50% might only be worth five points in the final composite allocation score. The next important question for the Committee is how to weight the attributes and decide which ones are more important than the others? Based on those decisions, the Committee will build a framework and submit it for modeling. This will occur over the next few months and then eventually

move to developing the policy language, submitting it for public comment, and then to the OPTN Board for approval.

Two additional topics were discussed. First, the Committee's decision not to include a post-transplant survival attribute in the first iteration of heart CD. It was stated that post-transplant survival is the most important thing transplant programs consider. As a result, programs are held to a very high standard for outcomes. Furthermore, there is not a great system or model already in place for predicting survival after heart transplant. The second topic discussed was why hasn't the Committee chosen to replace the medical urgency statuses with a candidate risk score? It was acknowledged that other groups are developing such a score. However, developing and implementing such a score as part of the first iteration of heart CD might be making too many changes very quickly to heart allocation. If the Committee were to make too many changes as part of the first iteration, then it would be difficult to determine which of the changes produced any different outcomes. It was suggested that it might be appropriate to implement the first version of CD and then re-visit opportunities to add a candidate risk score or a post-transplant survival attribute in the future.

Next steps:

The Committee will continue developing the heart CD allocation framework.

3. Presentation and discussion: Continuous distribution of lungs – One-year monitoring report and lessons learned

The immediate past chair of the OPTN Lung Transplantation Committee presented the one-year monitoring results associated with the implementation of the lung CD allocation framework. The presentation addressed how the Lung Committee developed the framework and shared lessons learned.

Summary of discussion:

No decisions were made as part of this agenda item.

The presenter described the attributes included in the lung CD allocation framework and how the Lung Committee determined the rating scales and other components of CD. The presenter then summarized what has been learned since implementation. Removing geographic boundaries has helped increase the number of transplants and decrease the number of waitlist removals. Addressing biological disadvantages has helped increase opportunities for sensitized candidates, at least anecdotally, and transplants have increased for all height groupings; however, blood type O candidates need more attention. The use of five-year transplant survival instead of one-year survival has been supported by the community, but it may have disadvantaged certain older candidates. The Committee is working with SRTR to address these topics. Additionally, the Committee is aware that changing the geographical boundaries has led to organs traveling a great deal farther. The increased distances have impacted their match run efficiency and placement of organs. Perhaps with more modeling the Lung Committee might have foreseen that broader sharing would result in very broad distances for organs to travel. That increase is impacting lung programs' costs and resources. It has also added to the donor coordinator burden. It will also be important to build up knowledge among the heart transplant programs, getting them ready, looking for alternatives, ways to be smart in taking on more offers. This will be important to talk about and talk with your community now. Finally, the expeditious task force is looking at variances in different projects. These will come up and go to thoracic organs over time. The Committee was encouraged to keep an eye on the task force's web page and see what's going on.

The presenter's advice to the Heart Committee was to keep a broad perspective and move topics that cannot be resolved to a parking lot so the Committee can continue moving towards implementation. The presenter also said that the Committee cannot perform enough modeling. Use SRTR and OPTN data analytics. There is a lot of data available to help with modeling.

The Chair asked if the Lung Committee has witnessed changes after implementation in physician behavior or medical practice around the use of ex vivo perfusion? The presenter stated that it appears that transplant programs have become very aggressive. Transplants have increased since implementation, so programs are going after organs, and that has led to the use of perfusion devices a little bit more. The presenter added that with the use of NRP and other technologies, it is taking a little more time to go through each offer and to talk with the OPOs about making sure these are safely done so transplant programs can procure both organs if NRP is being used. It appears that local procurement is being used more. Additionally, the use of DCD organs has increased so that has been positive. It is difficult to be sure that is the result of CD implementation though. There are more DCD organs. The programs are trying to perform more transplants. Certainly, trying to perform more transplants if a great thing, especially for candidates, but it also puts more stress on the system.

A Committee member asked how Lung CD addresses modeling for small sub-populations, such as pediatrics or patients with rare causes of end stage lung disease? The presenter responded that the Lung Committee did not handle those subpopulations since they were such small numbers of candidates. For pediatrics, a lot of the decision-making was made by the community, and they relied on the Values Prioritization Exercise as well. In terms of modeling, the Committee did have the basic modeling needed for pediatrics, but it always came out. There wasn't really anything that the Committee was sub-analyzing.

Another Committee member asked how a candidate's post-transplant survival score is impacted if they have co-morbidities? Does having co-morbidities leave a candidate out of consideration? The presenter said such a candidate is still included in the process. Post-transplant survival is only one part of the composite allocation score. The presenter provided an example of someone who is 80 years old, and a program is trying to consider that person for a transplant. The individual's post-transplant survival score would be lower than that of a 25-year-old because the 25-year-old would have a longer survival. Now the different components of that post-transplant survival attribute besides age include creatinine and a few other variables. So, not having a component of the score does not someone unable to get transplant. However, such a candidate may not get the points that you deserve. Now, let's say a candidate is on Lasix, with a high creatinine value. A transplant program could ask for an exception. The program could argue that the candidate's creatinine is high because the individual is on Lasix, and ask for an exception for a higher number of points for the post-transplant score, or other attribute. And the lung review board would review that and say yes, we can understand this or NO. And that's one way a transplant program can break down each component of the CAS and they should look at if it's maximized and it represents the appropriate characteristics of the patient.

The Committee member also asked if the Lung Committee had performed any analyses of how CD accounts for the presence of co-morbidities among different racial groups? For example, African Americans have higher disease co-morbidities. The presenter said there were some analyses of the impact by racial group, but there weren't any results that were impactful enough to indicate any of the CD components would disadvantage racial groups. A Committee member pointed out that one of the reasons not to address post-transplant survival with this version of CD is to avoid disadvantaging patients and there is not a way to ensure that it would not happen as part of the first implementation.

Next steps:

OPTN contractor staff will document the conversation and share the summary with the Committee members. The members can use today's discussion as a reference for addressing similar issues as they continue developing the heart CD framework.

4. Open Forum

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

5. Closing remarks

The Chair thanked the members for their participation. Members were told about the Heart CD update as part of the upcoming regional meetings. For this cycle, the organ-specific committees developing CD frameworks are giving a single presentation and covering their progress in one or two slides. There will be a breakout session for meeting attendees to answer questions posed by the committees, as well as discuss any individual questions they may have. OPTN contractor staff will be contacting the regional meeting presenters to schedule prep calls.

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
  - Denise Abbey, Visiting Board Member
  - Maria Avila
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Eman Hamad
  - Earl Lovell
  - Mandy Nathan
  - John Nigro
  - David Sutcliffe
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Monica Colvin
  - Grace Lyden
- **UNOS Staff**
  - Cole Fox
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Kelley Poff
  - Sarah Roache
  - Laura Schmitt
  - Holly Sobczak
  - Sara Rose Wells
- **Other Attendees**
  - Marie Budev
  - Shelley Hall
  - Glen Kelley