OPTN Heart Committee
Meeting Summary
February 7, 2024
Conference Call

Richard Daly, MD, Chair
J.D. Menteer, MD, Vice Chair

Introduction

The Heart Committee (Committee) met via WebEx teleconference on 02/07/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Public comment proposal: Executive Committee: OPTN Strategic Plan 2024 – 2027
3. Request for feedback: Promote Efficiency of Lung Allocation
4. Public comment and regional meetings
5. Open Forum

1. Welcome and agenda review

The Chair welcomed the members and briefly described the agenda items being discussed as part of the meeting. He mentioned that the public comment proposal and the request for feedback presentations address subjects that have an impact on heart allocation and are important for the Committee to be aware of. He also said that the presenters are interested in obtaining the Committee members' feedback about the topics and so members should feel free to discuss each item. The Chair also let the members know that both of the Committee's patient representatives are being considered for election to the OPTN Board of Directors. Finally, the Chair reminded everyone to participate in the Values Prioritization Exercise on the OPTN website. Members were reminded that the in-person Committee meeting will be held in Houston on March 29, 2024.

Next steps:

Not applicable.

2. Public comment proposal: Executive Committee: OPTN Strategic Plan 2024 – 2027

For the OPTN Strategic Plan, increasing the number of transplants is a top priority. However, some committee members felt that continuous distribution should remain a priority as well, as it offers flexibility and could increase equity. There was discussion around using marginal donors for high-risk recipients to increase transplants.

Summary of discussion:

The Chair introduced the topic. He let the Committee members know that the Strategic Plan proposal makes increasing transplants the number one OPTN priority. As a Committee, we should be thinking about whether that means that continuous distribution has less priority after all of the Committee's work. The Chair encouraged the members to share with the Executive Committee presenter that continuing their efforts around continuous distribution offers an opportunity for new attributes that will

increase the number of transplants because of the flexibilities that come with the allocation system, as well as increasing equity in the system. The Chair also mentioned the potential for increasing heart transplants if they could use marginal donors in high-risk recipients without the use negatively impacting transplant program outcomes as is currently the case.

The Executive Committee member presented the proposal to the Committee. He described the process the Executive Committee used to gather community ideas and feedback about the plan over more than a year's worth of time. The Executive Committee intentionally selected goals with greater specificity to allow for focusing resources on key opportunities, driving action to ultimately benefit patients. The proposed goals are to: improve the offer acceptance rate, optimize organ use, and enhance OPTN efficiency. The Executive Committee recognized that all goals focus on benefiting patients. The presenter said that there is a definite desire at the OPTN Board level to raise the visibility of patients in the process and acknowledge that patients need to participate in the decision-making process as well as the physicians and other experts. The presenter said that 95 percent success is too much success, and that patients agree with the statement. The presenter's point being that the OPTN needs to consider whether we are turning down collectively in the organization too many organs in the pursuit of perfection. The presentation showed that an objective associated with the goal of optimizing organ use, is to explore and evaluate alternative allocation strategies for organs at high risk for non-use. Among the metrics associated with the goal to help determine success is the decreased percentage of organs not recovered for transplant from deceased organ donors, including heart and lung donor organs.

The presenter also discussed how in the past the OPTN Policy Oversight Committee and the Executive Committee have approved most committee project ideas. However, as the OPTN looks at its resources and the great length of time needed to implement many of those projects, the Executive Committee has begun to realize not all projects can be approved. As a result, the Executive Committee will be looking more closely at projects that have the lowest cost and highest benefits.

Following the presentation, the Committee was shown an additional slide which identified two projects that are considered to clearly align with the goals of the proposed strategic plan. Neither of the proposals are sponsored by the Heart Committee. The Committee's Continuous Distribution of Hearts project and the proposed idea of escalating status for time on ventricular assist device were also displayed as projects 'possibly not in alignment' with the intent of the draft strategic plan. It was mentioned that following implementation of continuous distribution of lungs the non-use of organs has increased, in part due to the broader sharing of organs that was built into the new allocation framework. So, while continuous distribution has a great deal going for it as an improved allocation framework, it can still result in issues that need addressing. Committees working on broader sharing considerations have to recognize the impact of prior decisions and make choices about how to get the best sharing organs more broadly with reducing the non-use of organs.

A Committee member pointed out that the strategic plan is really trying to incentivize greater organ utilization, and pointed out that physicians and patients agree on that as a goal. The member continued that transplant program performance is still measured by its waiting list mortality rates. And, because the number of transplants a program performed annually is generally small, the mortality rates are substantially impacted by one or two deaths over the course of that year. These factors play a large role in whether any program is going to be comfortable using higher risk donor hearts, thus making it even more challenging to increase the number of transplants performed. The member added that this also impacts contracting with insurance. The Executive Committee presenter pointed out in recent years the MPSC has implemented metrics that are intended to ease some of the concerns about mortality rates that are being described.

The Vice Chair added that if the OPTN wants to increase the number of heart transplants being performed, then we have to make use of marginal donor hearts. Furthermore, to make use of marginal donor hearts, there has to be agreement about which marginal donor hearts to use and who, or what are the patient characteristics, we're going to transplant with those hearts. The Vice Chair mentioned that others have talked about having a separate allocation system or separate waiting list for marginal donor hearts. It was also stated that non-use is much more of an issue with kidney transplantation than hearts; and that is seems like heart is being measured against kidney non-use. The Vice Chair said that allowing this to prevent or slow the development and implementation of continuous distribution of hearts is not appropriate because it results in hearts continuing to be allocated based on an antiquated system. The Vice Chair also stressed the importance of finishing the continuous distribution of hearts project.

A Committee member echoed the comments about the circumstances of non-use are different for heart and kidney transplantation. The member recommended that the OPTN Board should consider approaching the matter of increasing the number of transplants from the perspective of thoracic transplant versus abdominal transplant. The idea of mortality needs to be differentiated so that it more directly captures what the programs are responsible for in terms of patient management and care versus what is outside the programs' control.

Another Committee member agreed with the Vice Chair that pausing the Committee's work addressing continuous distribution of hearts does not make sense. The member said that it could also result in a loss of trust among patients and providers. The member suggested that if the data being collected and analyzed could focus on observed versus expected outcomes, then it might lead to greater flexibility around the outcome measures. Transplanting marginal donor hearts in 'marginal' candidates is going to result in an expected survival that is lower. Two points were made by another Committee member. First, that more donor hearts could be transplanted if there was greater acceptance of Donation after Cardiac Death (DCD) hearts. The member stated that the way DCD donor hearts are defined results in potential donor hearts going unused; however, those definitions should not be considered immutable, and re-visiting them could lead to more transplants. Second, the member said that the community needs to define mortality in better terms. Transplant programs ought to be measured against mortality related to the management of the patient, or selection of the patient. Those activities ought to be scrutinized. But it seems unfair to count a death against a program if the transplant went successfully, but the recipient suffered a stroke afterwards and passed away.

Th Executive Committee presenter acknowledged that some of the issue revolves around who wants a perfect kidney, but that there are also aspects of continuous distribution that need examining. For example, broader sharing of donor lungs and other donor organs has resulted in OPOs dealing with tremendously more transplant programs and transplant programs dealing with more OPOs resulting in congestion in the system and time delays. The presenter also mentioned the opportunity to educate the public about the nuances of a "95 percent success rate" and how that also means some groups of candidates may not get transplanted because of program concern about mortality rates. The presenter also encouraged Committee members to look into the changes MPSC has made in recent years related to risk-adjusted outcome metrics.

Next steps:

OPTN Contractor staff said they would use the Committee members' comments to draft a formal response that will eventually be posted on the OPTN public comment website. A draft of the response will be shared with Committee leadership for review and approval before being submitted to the OPTN website.

3. Public comment request for feedback: Promote Efficiency of Lung Allocation

The OPTN Lung Committee wanted to provide an overview of the additional data collection and results associated with the implementation of continuous distribution of lungs. In particular, the Lung Committee and the OPTN Organ Procurement Committee (OPO) created a workgroup to identify opportunities to make the allocation process more efficient.

For the lung allocation efficiency proposal, the Lung Committee is seeking feedback on adding new donor data fields, a feature to bypass bilateral lung candidates if only a single lung is available, and an option to opt into receiving offers from isolated geographic areas beyond the maximum recovery distance specified. Committee members felt the isolated areas opt-in feature could be helpful for heart allocation as well. There was discussion around how this might impact programs in isolated regions.

Summary of discussion:

Since implementation, there have been several positive outcomes associated with the continuous distribution of lungs. For example, there have been fewer removals from the waitlist due to death or too sick to transplant, in addition to reduced waiting list mortality. In addition, lung transplants have been trending upward. However, there have also been increases in organ travel distance. While the increases in travel distance were identified in the simulation modeling, it has changed how programs are operating and causing some challenges.

As a result, the Lung Committee and OPO Committee created a workgroup to identify opportunities to make the lung allocation process more efficient for both lung transplant programs and OPOs. The proposal identified two new data elements in order to help aid in the evaluation of lung offers. The proposed elements are 'history of anaphylaxis to tree nut and/or peanuts and previous sternotomies. Lung transplant programs may rule out potential donors based on these criteria, and so the Committee wants to collect data to determine whether to include them in some future iteration of offer filters. Lung offer filters were implemented in the week prior to this meeting.

In addition to those items, the Lung Committee is also requesting feedback on other potential system enhancements. These include: (a) 'bypass bilateral and other lung' button if only a single lung is available, and (b) opt in to offers from isolated areas beyond specified maximum recovery distance. With regard to the 'bypass bilateral and other lung' button, the OPO would be able to use the button when the circumstances exist for them to consider bypassing the remaining bilateral lung candidates on the match run so that the only candidates remaining on the match run would be those who could accept the lungs with the laterality that remains. This change is proposed to help improve efficiency because currently OPOs have to manually bypass those programs or they are continuing to make those offers and it also requires the transplant programs to deny them. So, this is really for the Heart Committee's consideration as it moves forward with offer filters and efficiency opportunities.

The Lung Committee was interested in knowing if the Heart Committee believes the isolated areas opt-in functionality proposed for lung offer filters would be helpful for heart programs? If so, then there may be efficiencies in implementing the change across multiple organs rather than doing it individually. Currently, lung transplant programs set the 'maximum recovery distance' for each candidate. If a program wants offers from remote or isolated areas, like Alaska, Hawaii, or Puerto Rico, then the program may set the distance very broadly resulting in the program receiving excessive offers.

The opt in approach would allow lung transplant programs to receive offers from remote or isolated areas while setting a shorter 'maximum recovery distance' and thus not receiving as many excessive offers. A policy option for the Heart Committee's consideration would also be to use Sea-Tac Airport in Seattle, Washington as the location of the donor hospital for organs procured in Alaska. Current heart,

lung, and VCA policies do not include this consideration but abdominal policies do. The Committee members were asked if it would help prevent unwanted organ offers and promote the use of donor organs from geographically isolated areas?

The Committee's region 6 representative stated that it would be very helpful to have the opt in option because the Alaska and Hawaii donors the program would be very helpful because lungs can travel a little farther than hearts, plus the TransMedics option is a huge boon for the member's program which is located in Seattle. The member said that it expands the program's donor pool without getting overrun by offers from other areas that they may not take donor organs from or be so far down on the match run that they would likely never get the offer. So, adding the option would be a powerful bonus for programs in the Pacific Northwest that need to go farther out in some of their offerings.

The Vice Chair asked if there has been any opposition from programs in the remote areas because they fear having donors take away from them, while on the other hand, it is challenging for them to receive donors for their candidates because of the distances involved? The presenter indicated that OPOs would be contacted and welcomed ideas for other groups who should be contacted. A member asked whether including the option would result in some programs becoming more competitive in taking organ offers because they are willing to use TransMedics or another preservation tool to keep a heart viable longer? It could lead to programs following this path because it provides access to high quality donor organs that other programs are not competing for.

Next steps:

OPTN Contractor staff said they would use the Committee members' comments to draft a formal response that will eventually be posted on the OPTN public comment website. A draft of the response will be shared with Committee leadership for review and approval before being submitted to the OPTN website. The response will focus on the potential system enhancements that the members discussed.

4. CD of Hearts Request for Feedback and Values Prioritization Exercise public comment update

The meeting began with a discussion of feedback received so far on the committee's request for feedback document addressing the continuous distribution of hearts allocation framework. Key themes included concerns about impacts on pediatric candidates and the lack of inclusion of post-transplant survival attributes.

There were 230 responses so far to the Values Prioritization Exercise. Committee members were encouraged to complete the exercise and ask OPTN staff to do so as well.

Summary of discussion:

Members were again encouraged to reach out to other patients and patient families, their patients, colleagues, and any other individuals or organizations from whom they think it will be helpful to obtain feedback on the attributes. Committee members were reminded that a .pdf file had been uploaded to their SharePoint site with all the comments received on the OPTN website as of February 20, 2024. It was also stated that the OPTN Contractor staff would continue sharing the new comments with the Committee as such comments are received.

Next steps:

The members were also reminded that at a Committee meeting following the end of public comment on March 19, 2024, summaries of the comments received about the RFF and the results of the Values Prioritization Exercise will be provided to them.

5. Open Forum

There were no speakers for the open forum discussion period.

Upcoming Meetings

- February 20, 2024
- March 6, 2024
- March 19, 2024
- March 29, 2024 – In-Person Meeting, Houston, TX
- April 3, 2024
- April 16, 2024
- May 1, 2024
- May 21, 2024
- June 5, 2024
- June 18, 2024

Attendance

- **Committee Members**
  - Rocky Daly
  - JD Menteer
  - Tamas Alexy
  - Amrut Ambardekar
  - Kim Baltierra
  - Jennifer Carapellucci
  - Jennifer Cowger
  - Tim Gong
  - Eman Hamad
  - Glen Kelley
  - Earl Lovell
  - Cindy Martin
  - Nader Moazami
  - John Nigro
  - Fawwaz Shaw
  - Christy Smith
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
  - Kala Rochelle
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Grace Lyden
- **UNOS Staff**
  - Cole Fox
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Holly Sobczak
  - Kaitlin Swanner
  - Sara Rose Wells
- **Other Attendees**
  - Shelley Hall
  - Jim Sharrock