OPTN Heart Transplantation Committee
Meeting Summary
August 7, 2024
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 08/07/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Public comment presentation: Lung Committee, Promote Efficiency of Lung Donor Testing
3. Heart offer filters: Initial usage and Committee feedback
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 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. The Chair introduced the Visiting Board Member who will serve as a Committee member. The Visiting Board Member's term on the Committee is 07/01/2024 through 06/30/2025.

The Visiting Board Member shared the story of their transplant journey as a heart recipient. The member previously served on the OPTN Patient Affairs Committee.

Next steps:

Not applicable.

2. Public comment presentation: Lung Committee, Promote Efficiency of Lung Donor Testing

The OPTN Lung Transplantation Committee submitted a public comment proposal focused on promoting the efficiency of lung donor testing. The Committee is proposing changes to *OPTN Policy 2.11.D: Required Information Deceased Lung Donors*. The Lung Committee is also providing information to organ procurement organizations regarding the lung donor information that lung transplant programs need.

Summary of discussion:

Decision #1: The Committee members agreed that the changes addressed in the Lung Committee proposal are appropriate. The members expressed support for the proposal.

The Vice Chair of the OPTN Lung Transplantation Committee presented an overview of the Lugn Committee's public comment proposal. The Committee is proposing changes to *OPTN Policy 2.11.D: Required Information Deceased Lung Donors* that offer guidance to organ procurement organizations (OPO) when OPOs are putting together loan offers. The Vice Chair said that proposed changes address standardizing how arterial blood gases are measured. The Committee is modifying the policy language related to computed tomography (CT) scans, by adding "if performed" to acknowledge that in some rare instances, a donor hospital may not have the technology to perform a CT scan. The proposed changes also establish that interpretation of chest x-ray images should occur within three hours prior to the initial offer being made, and that either an echocardiogram or right heart catheterization should be performed to determine if pulmonary hypertension is present. The proposed changes would use additional guidance to provide this information to OPOs.

The Lung Committee is proposing these changes partly in reaction to the high volume of donor offers all transplant programs began experiencing following the implementation of lung CD. The Committee and the community recognized that the process for offering donor lungs needed to become more efficient. The Lung Committee determined that efficiency could be improved by standardizing the information lung transplant programs need to make decisions on whether to accept or reject an offer. By standardizing the information provided, transplant programs should have what they need to answer yes or no and move through the offers more quickly and more efficiently. It is hoped that improving efficiency will result in more lungs being transplanted.

To comply with the changes, the Vice Chair said that OPOs will be responsible for providing more information about lung donor testing and may need to modify their internal processes. Transplant programs will need to be aware of the changes requiring lung organ donor testing.

The Vice Chair asked the Committee members if they think the proposed lung testing requirements strike a proper balance between requiring information that transplant programs need to decide on an offer and what the OPOs are reasonably able to provide? The Vice Chair said that OPOs were well represented on the workgroup that developed the policy proposals and it was a very collaborative effort.

The Heart Committee Chair said that their initial reaction is that the Lung Committee has struck a conservative balance regarding the number of required blood gases. Additionally, the proposal sets out the testing expectations and that is really helpful and reduces confusion. The Chair added that this seems like a good idea. The immediate past Chair said that the proposed changes are appropriate and did not see any issues with it. The past Chair added that the proposal is really just standard of care and that the Lung Committee did a good job. The Lung Committee Vice Chair thanked the members and added that the changes are intended to make offer evaluation easier for everyone involved. Moreover, these were things that are being done and have been done, but now they are in writing so it is up front for everyone. A patient representative on the Committee strongly agreed that this represents standard of care.

A Committee member said that the defined pulmonary hypertension by echocardiogram leading to a right heart catheterization might be one of the more variable elements of decision making between OPOs and different centers, but defining that more specifically is going to be really challenging. The Lung Committee Vice Chair acknowledged that interpreting RVSP results can be operator and/or reader

dependent and that pulmonologists are not necessarily looking at the images, but all of this is considered in context with other information about the donor to help guide decision-making. The OPO representatives on the workgroup agreed that it should be done and that way the information is available if requested.

Another Committee member who has OPO experience was very supportive of the changes. The member said that having more structured or frequent testing allows the OPOs to get ahead of the problems when they are having them. Oftentimes, if the testing is spread out over many hours, by the time the OPO realizes it, they are delaying everything, including getting the case to the OR. Documenting the steps creates the structure and allows for consistency in practice for all involved. The Lung Vice Chair added that the OPO representatives on the workgroup wanted these practices in writing because they can use the information to train their coordinators.

Another Committee member echoed the previous sentiments that what is proposed does not seem overly burdensome and may actually improve the efficiency of the process. The member also said that there are going to be fewer centers with the capability to perform some of the right heart catheterization, and as a result, providing the options of echocardiogram or right heart catheterization is very important. The member continued that it might also be helpful to let a transplant program notify an OPO about the information the program is specifically interested in obtaining. That way the program gets the information it needs. The Lung Committee Vice Chair said the idea would be shared with the Lung Committee.

Next steps:

OPTN contractor staff will prepare a draft response about the proposal based on the Committee's questions and comments. The draft will be shared with leadership and based on their comments, a formal Committee response will be submitted to the OPTN website.

3. Heart offer filters: Initial usage and Committee feedback

OPTN contractor staff presented initial findings about the use of Heart offer filters.

Summary of discussion:

No decisions were made as part of this agenda item.

Contractor staff presented a quick update about the use of heart offer filters and also asked the Committee members several questions for discussion. Heart offer filters were released on June 13, 2024, so what was shared was preliminary results based on about 49 days, or a month-and-a-half of use. Contractor staff said they would be looking at providing more updates when there are about six-months and 12-months of data available for analyses. Since implementation, 19 heart transplant programs are using filters. This represents about 13% of the 149 programs. Whether a program is using filters is measured by having at least one filter actively enabled. By comparison, 13% is less usage than other organ filters, but it was also acknowledged that kidney and lung offer filters have been in place longer than heart filters so that has some impact on usage. Contractor staff expressed their interest in learning more about the Heart Committee members' experience with offer filters and what steps, if any, might help increase adoption if that is something the Committee and community want to accomplish.

Contractor staff reminded the members that offer filters does filter offers at the transplant program level. In addition, programs can set candidate inclusion / exclusion criteria. So, it is possible that a filter will filter offers to some of a program's candidates, but not all candidates. Information was presented identifying the percent of donor offers filtered where the donor is considered only if all offers from that

donor to the candidates at a program were filtered off. Contractor staff said that essentially the information shows the percent of phone calls that a program could have saved if one considers filtering out all of the offers as equal to saving a program an unnecessary phone call. The information presented showed the percentage of donor offers filtered since a transplant program enabled filters. The percentages range between 3% up to almost 50%. On average, the programs are filtering about 15% of donors.

Information about the components that are enabled was presented. There are only a small set of criteria available for heart programs to filter using. The criteria consist of: DCD status, distance between the donor and transplant hospitals, and donor age. Donor age includes thresholds for greater than and less than. Any one filter can be comprised of multiple criteria/components. More than half of the filters in place are comprised of at least two components. For example, a program may filter on DCD status and donor age, or DCD status and distance between the donor and recipient hospitals. As of now, it appears that DCD status represents the largest single component, followed by donor age.

OPTN contractor staff said that when approximately six months of data is available for analysis, then they will be able to report on the system impact of filters, such as how does it affect the length of match runs? And/or, how does it affect how many notifications are being sent to allocation organs? There will also be additional information available about the filtering criteria that have been enabled. For example, distance is a filtering component that uses thresholds. With additional detail, contractor staff will be able to perform additional analysis of something like what kinds of distances are being used? It was also stated that there are candidate exclusion criteria that allow programs to control which candidates or populations of candidates get filters applied to them or not. Those will also be analyzed in the future.

Contractor staff also said that there is an Operations and Safety Committee project that will be focusing on how to improve some of the kidney offer filter functionality, along with other considerations. That is expected to be released later this year. Following that implementation, there will be an opportunity to revisit the non-kidney filters, and that is another reason that contractor staff are requesting feedback concerning how the initial phase has been working.

Members were asked for feedback regarding the following questions:

- What have been the members' experiences with filters?
- What are other factors that would encourage your transplant programs or other programs to use filters?
- Are there any specific criteria that the members would be interested in adding as a filter?

Three Committee members are associated with programs that are using offer filters. A Committee member asked if with the implementation of kidney offer filters, was there a rush by programs to implement them at the program level, or has it been more of a gradual adoption? Contractor staff said that with kidney there was an initial uptick in early adopters, but that leveled out after a few months. What really proved helpful and spurred more adoption by programs was additional educational efforts. The educational effort took different approaches, for instance there was some one-on-one coaching early on. Additionally, some webinars were created where medical directors, physicians, coordinators all had an opportunity to share their experiences using the kidney offer filters. It was after the educational efforts when they saw increased use of the filters.

The Chair said that their program has not had the time to fully discuss how they will employ the filters. It is taking a little bit of time for everyone to reach consensus on the best approach.

A member asked about the expectation around the use of filters? Are transplant programs expected to use them? Is there going to be a threshold for adoption? The member added that 13% adoption seems

very small, even with the understanding that they just became available in June. Contractor staff said that the goal is increased adoption of the filters but for now there is no specific percentage of adoption among transplant programs. Analysis of kidney filter usage indicates that organs get allocated after fewer notifications, so an OPO does not have to contract as many programs. Furthermore, transplant programs have shared the inclusion of offer filters has reduced the number of phone calls staff receive about offers which has helped improve their quality of life.

OPTN contractor staff explained that the OPTN data used to establish the filters has to be uploaded to the OPTN electronic matching system as a discrete field in order for it to be compared with a donor record. The data used in the filters needs to be explicitly structured when entered into the OPTN donor system. It was pointed out that, in addition to the project that was just presented, the Lung Committee is working on a separate data collection project after they realized that more explicit and granular data were needed in the OPTN Data System in order to create the filter criteria they desired. As such, contractor staff asked if there is OPTN data collected in discrete data fields that could help identify opportunities to expand donor offer filters? This could also apply to specific, and/or frequently used terms of phrases used in open text data fields.

A Committee member said that there is variation in the data fields that OPOs use to report certain historical data information. Some of it is reported through donor highlights, some through the Donor Risk Assessment Intake form, and some information is captured based on the historical record versus the DRAI that the donor family provides. The location of the reported data or how it is captured sometimes is not consistent. Another member asked if the opportunity exists to combine some of the continuously distributed values, and was told yes they can be combined. OPTN contractor staff said that being able to combine offer filters is one of the important differences between it and candidate inclusion/exclusion criteria.

Next steps:

More information about the use of heart offer filters will be provided to the Committee around the beginning of 2025, after approximately six-months' worth of data is available for analysis. During the interval, the Committee should feel free to share ideas for future filters in order to determine whether OPTN data is already available or whether a data collection project would be required.

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

OPTN contractor staff provided an overview of the Committee's public comment proposal, Continuous Distribution of Hearts Update, Summer 2024, and described how information about the Update is being shared at the regional meetings.

Summary of discussion:

No decisions were made as part of this agenda item.

OPTN contractor staff reminded members that the current OPTN public comment cycle started on 07/31/2024. Members were told that they can go to the OPTN website to review the public comment document or watch the educational video recorded by the Committee Chair. Contractor staff explained that because the Committee did not have an opportunity to share the VPE results with the heart community after the January-March, 2024 public comment cycle, it seemed that this was a good opportunity to do that. Probably half or more of the Update document addresses the VPE results and goes into some detail. There were also public comments submitted during the last public comment cycle regarding some of the attributes the Committee has worked on or decisions made around those

attributes and rating scales. The Update document also addresses some of the comments, such as improving medical urgency determination, the potential for the unintended consequences associated with the proximity efficiency attribute, and the Committee's agreement not to include a post-transplant survival attribute in the first iteration of continuous distribution and the supporting information the Committee used to come to that agreement. Contractor staff also stressed, especially for the members who will be presenting at the regional meetings, that this is an update of the Committee's work to date. It is not a policy proposal.

Contractor staff told the Committee that four comments about the Update document have already been submitted on the OPTN's website and briefly summarized the comments. One of the comments addresses the proximity efficiency attribute, and the commenter suggested higher weighting for the attribute than the VPE results suggest because of the increasing costs associated with traveling greater distances or using the perfusion devices to prolong the organ. Another commenter suggested that pediatric candidates may be disadvantaged by inclusion of a prior living donor attribute. Another commenter suggested that the Committee and OTPN might need to start thinking about how the continuous distribution of hearts will impact multi organ candidates. The fourth comment focused on limiting the broader sharing of organs.

Contractor staff also provided an overview of how the continuous distribution presentations are organized for this cycle of regional meetings. There is a single CD update presentation involving all the organs currently developing CD allocation frameworks with each committee responsible for summarizing their current work and asking for feedback. There is also a breakout session for those attending the regional meetings to provide greater feedback about the questions asked by each CD project. The one Committee member who already presented at their regional meeting said the presentation of all the organ updates together and the inclusion of the breakout session was very helpful because it put all the organs in one concise framework and the breakout session let attendees with an interest in heart allocation ask more specific questions. The member said that the heart breakout session discussed the potential impact on pediatric candidates, and those at the table were comfortable knowing the Committee has put a great deal of thought into pediatric candidates under the new allocation framework.

Next steps:

OPTN contractor staff will continue updating the Committee about feedback obtained through public comment and the regional meetings. Staff will provide the members with a public comment analysis document as part of the 10/09/2024 in-person meeting. The analysis document will summarize the main themes identified in the comments, as well as provide each individual comment received on the OPTN website.

5. Public forum

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

6. Closing remarks

The Chair thanked the members for attending the meeting and participating in the discussion. Members were also told that they should feel free to share by email or phone any comments related to today’s discussions or any upcoming meetings with leadership or contractor staff.

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
  - Maria Avila
  - Kim Baltierra
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Timothy Gong
  - Eman Hamad
  - Jennifer Hartman
  - Earl Lovell
  - Mandy Nathan
  - Jason Smith
  - David Sutcliffe
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Cole Fox
  - Kelsi Lindblad
  - Alina Martinez
  - Carlos Martinez
  - Eric Messick
  - Kelley Poff
  - Sarah Roache
  - Laura Schmitt
  - Holly Sobczak
  - Sara Rose Wells
- **Other Attendees**
  - Shelley Hall
  - Glen Kelley
  - Dennis Lyu