OPTN Heart Transplantation Committee
Meeting Summary
September 17, 2024
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 09/17/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Public comment presentation: Liver and Intestine Transplantation Committee, Continuous Distribution of Livers & Intestines Update, Summer 2024
3. Incorporating exceptions in CD of Hearts
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 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. The Chair mentioned that the Committee's in-person meeting is scheduled for 10/09/2024 in Detroit, Michigan and reminded the members to book their travel plans. The Chair added that the 10/02/2024 Committee meeting will be cancelled.

2. Public comment presentation: Liver and Intestine Transplantation Committee, Continuous Distribution of Livers & Intestines Update, Summer 2024

The Chair of the OPTN Liver and Intestinal Organ Transplantation Committee provided a presentation regarding the Committee's project "Continuous Distribution of Livers and Intestines Update, Summer 2024." The presentation focused on how the Liver Committee handles exception requests within their continuous distribution framework. The presentation emphasized the importance of collaboration between OPTN committees developing CD frameworks and sharing best practices.

Summary of discussion:

No decisions were made as part of this agenda item.

The Liver Committee Chair gave a presentation about Continuous distribution of livers and intestines, with a particular emphasis on handling exception requests. Key points of the presentation addressed:

- The use of Model End-Stage Liver Disease (MELD) scores and exceptions.
- The transition from standard and non-standard exceptions to a more integrated system.
- The introduction of condition-associated priority to replace the term "exceptions."

- The use of median MELD at transplant to standardize exception scores across different regions.

The Liver Committee Chair stated that they are working on integrating exception requests into the continuous distribution system. The Liver Committee is replacing the term "exception" with the term "condition-associated priority" to better reflect the integration into the system. The Liver Committee Chair provided an overview of the MELD score and the use of exceptions in liver allocation. The MELD score is central to the liver allocation system. The MELD score has been updated to MELD 3.0. Exceptions, now termed "condition-associated priorities," are being incorporated into the continuous distribution framework to eliminate the need for separate exception handling. The Liver Committee has identified several key attributes for continuous distribution. There is the medical urgency attribute, which has typically been determined by a candidate's MELD score. There is also the patient access attribute. Patient access in the liver CD allocation framework includes factors like geographical location and access to transplantation centers.

The Liver Committee Chair described how standard and non-standard exceptions function within the liver allocation system. Standard exceptions are well-defined and written into policy. They are automatically granted when certain criteria are met. Non-standard exceptions are more flexible and are detailed in guidance documents, allowing for easier updates based on new data and clinical changes. A critical component of the Liver exception process involves the concept of median MELD at transplant. Median MELD at transplant is used to standardize exception scores across different regions. This approach helps to address geographical disparities in transplant access. The median MELD score is calculated around the donor hospital rather than the transplant center to ensure fairness. According to the Liver Committee Chair, the use of median MELD scores helps maintain anonymity in the review process, reducing bias.

The Liver Committee has encountered challenges in their efforts to incorporate exceptions into the CD of livers allocation framework, and they have identifies some solutions. The Liver Committee has worked to address discrepancies in MELD scores required for transplants in different regions in an attempt to address geographical discrepancies. Additionally, the committee is developing processes to operationalize both standard and non-standard exceptions within the continuous distribution framework. The Liver Committee is working on stratifying exception points for liver cancer patients based on tumor size and other factors. The Liver Committee is also considering the use of donor modifiers to adjust priority points based on the quality of the donor organ.

The presentation provided a comprehensive overview of the Liver Committee's efforts to integrate exception requests into the continuous distribution framework and emphasized the importance of collaboration and shared best practices between committees. The Liver Committee is focused on ensuring fairness, reducing geographical disparities, and maintaining transparency in the CD allocation process. The Liver Committee Chair said they are seeking feedback from the Heart Committee on various aspects of their continuous distribution framework, including the proposed travel efficiency attribute.

Some Heart Committee members expressed support for the way the Liver Committee is addressing the patient access category, especially geographic proximity and prior transplantation. A Committee member noted the complexity associated with the Liver Committee's transition of exceptions into CD and how it might be very hard for patients and families to understand the nuances.

The Liver Committee Chair provided more context on exception points. Currently, a patient gets the more beneficial of either the higher of laboratory MELD or exception MELD. Liver transplant programs must apply for exceptions for their candidates, but standard exceptions are essentially rubber stamped. However, National Liver Review Board approval is required for some non-standard exceptions.

The Heart Committee Chair asked if the liver allocation system is experiencing any problems with too many transplant programs asking for exceptions when medical urgency is not accurately documented? The Liver Committee Chair noted that this was a problem previously. However, the exception review system was revamped about six years ago. As part of those changes, the National Liver Review Board was created which has helped reduce the problem. The Liver Committee Chair said that geographic anonymity of where the exceptions are coming from has also helped with this issue. Moreover, the Liver Committee included detailed information on exceptions in the guidance documents they produced. According to the Liver Committee Chair, the community saw a dramatic drop in the amount of MELD exceptions being approved and found a tremendous improvement in the efficiency once the guidance documents were in place. The Liver Committee Chair added that it took some time, but eventually the number of exception requests dropped by approximately 30 percent after the Liver Committee implemented the very standardized process. As a result of the increased standardization, the acceptance rates may have increased because transplant centers are only applying when appropriate.

The Heart Committee Chair circled back to the travel efficiency attributes that the two committees are developing. The Chair discussed how the Committee decided that the driving versus flying comparison is a challenge because heart transplant programs rely heavily on flying. This is true in urban areas where programs will use helicopters to avoid road congestion and it applies to other areas where programs are traveling greater distances. The Chair said that the Committee agreed that the number of miles was deemed to be a very good measure for heart CD. The Chair said the Committee is developing its proximity efficiency attribute in a way that tries to avoid very long distance transplants, as opposed to overly encouraging nearby transplants.

Next steps:

Feedback on the Liver Committee's travel efficiency attribute was requested.

3. Incorporating exceptions in CD of Hearts

The Heart Committee discussed how to incorporate exception requests into their continuous distribution framework. The goal heading into the discussion was to have a clear understanding of how exception requests will be managed in heart CD ahead of the Committee's 10/09/2024 in-person meeting. During the 10/04 meeting, the hope is for the Committee to make some decisions about operationalizing exceptions.

Summary of discussion:

No decisions were made as part of this agenda item.

The Chair started the discussion by reminding members of the importance of developing a consistent, cross-organ continuous distribution framework. Such a framework will have components similar to those developed by the other organ CD frameworks. There also needs to be consistency within the heart CD framework. In CD, exception requests will be attribute-specific and based on known information prior to a match run. As of now, proximity efficiency is the only heart-specific attribute for which exceptions will not be allowed. CD will also rely on the use of a percentage-based system for exception points, similar to the Lung Committee's approach.

OPTN contactor staff demonstrated an example of how exception requests are managed in lung CD. Contractor staff explained that the information used in the example was made up and did not represent an actual patient on the waiting list. Contractor staff also stated that exceptions in lung CD are based on the goals, rather than the attributes. Exceptions in heart CD will be based on attributes, and eventually lung may transition to attributes as well. Lung transplant programs still must submit the descriptive

narrative as part of the exception request. In the example, OPTN contractor staff explained that transplant programs ultimately want to obtain a specific number of points within a goal. Contractor staff demonstrated that in order to obtain the desired number of points, a transplant program enters a percentage of the goal's total points. The percentage entered is then calculated into the number of points a candidate would receive through the exception. The candidate's current calculated score is also displayed so the program easily can compare the current score against the exception score. If the exception request is approved, the exception points replace the calculated points. On the other hand, the calculated points can still be used when the exception points are less. Transplant programs can use the tool to determine what percentage to request.

The Chair pointed out that in order to know how many exception points are needed, a transplant program needs to know the amount of points assigned to various life support levels. The Chair suggested that to assist transplant programs, the calculator tool should include information indicating the points (or percentage) for heart therapies such as Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) and inotrope dependent in-patient supports, for example. In addition, such information would need to be updated as policy changes occur. OPTN contractor staff showed that the lung CD tool has a hyperlink to lung Composite Allocation Score (CAS) summary data that provides the kinds of information the Chair identified. The CAS summary data is an aid to help lung programs determine the percentage of points to request. In addition, the data are updated monthly. Contractor staff said the heart CD calculator could link to a similar resource.

Some Committee members noted that the Liver Committee may have an advantage transitioning their exception process to CD because they have experience developing and working with a standardized risk score. They also said that the Liver Committee's transition to CD appears very complicated and questioned the relevance of the information to heart CD. Members cautioned that developing and/or implementing a complex process makes it harder to understand and predict outcomes. A member noted that patients and families need to be able to understand the exception system as well. Therefore, the Committee will need to consider the messaging of any new exception process so it is explainable by physicians, nurses, and families. The Chair agreed and suggested focusing messaging on medical urgency as it is more difficult to explain exception points.

Another member added that points are abstract, so the Committee should strive to introduce as much transparency in the exception process as possible, especially around the impact on the likelihood of offers. For example, the Committee might want to explore ways to provide some practical examples reflecting when candidates are likely to get an offer, sharing waitlist mortality rates associated with the points being requested, and other information. There was also a suggestion about examining the potential of tying exception points to estimated waitlist outcomes.

The Chair suggested that guidance documents and more stringent exception criteria may be worth further consideration by the Committee. Other members echoed the importance of having clear criteria for exception requests.

Next steps:

During the upcoming in-person meeting, the Committee aims to further develop their continuous distribution exception process, balancing complexity, transparency, and usability. Members were also encouraged to think about the ideal structure for the Heart Committee's exception request process and come prepared to discuss it at the next meeting.

4. Open Forum

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

5. Closing remarks

In closing, members were told about an upcoming webinar related to the OPTN Membership and Professional Standards Committee's (MPSC) public comment document titled "Update Criteria for Post-Transplant Graft Survival Metrics." The proposal aims to reduce transplant program concerns about performance reviews in the hopes of encouraging the use of more complex donor organs to increase the number of transplants. The Committee members were encouraged to attend the town hall scheduled for 09/27/2024 and provide comments about the proposal on the OPTN website.

The Chair thanked the members for attending and reminder them that the next Committee meeting is the in-person meeting on 10/09/2024 in Detroit, Michigan.

Upcoming Meetings (ET)

- ~~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~~ – Cancelled
- October 9, 2024 from 8:00 am to 3:00 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
  - Tamas Alexy
  - Maria Avila
  - Kim Baltierra
  - Jennifer Cowger
  - Kevin Daly
  - Rocky Daly
  - Jill Gelow
  - Tim Gong
  - Eman Hamad
  - Earl Lovell
  - Cindy Martin
  - Mandy Nathan
  - JJ Nigro
  - Jason Smith
  - Dmitry Yaranov
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Monica Colvin
  - Grace Lyden
- **UNOS Staff**
  - Cole Fox
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Sarah Roache
  - Laura Schmitt
  - Holly Sobczak
  - Emily Ward
  - Sara Rose Wells
- **Other Attendees**
  - Scott Biggins
  - Shelley Hall
  - Glen Kelley