OPTN Heart Transplantation Committee
Meeting Summary
February 18, 2025
Conference Call

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

Introduction

The Heart Transplantation Committee met via WebEx teleconference on 02/18/2025 to discuss the following agenda items:

1. Welcome, introductions, and agenda review
2. Public comment presentation: Kidney Transplantation Committee: Update on the Continuous Distribution of Kidneys, Winter 2025
3. Update regarding Heart Committee's public comment proposal: Escalation of Status for Time on Left Ventricular Assist Device and regional meeting feedback
4. Other Committee business
5. Open Forum
6. Closing remarks

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

1. Welcome, introductions, and agenda review

The OPTN Heart Transplantation Committee Chair welcomed the members and reviewed the agenda items for the meeting. The Chair also reminded the members about the dates and times of several upcoming Committee meetings. The Chair then introduced the Chair of the OPTN Kidney Transplantation Committee for the first presentation.

2. Public comment presentation: Kidney Transplantation Committee: Update on the Continuous Distribution of Kidneys, Winter 2025

The Chair of the OPTN Kidney Transplantation Committee presented an update of the committee's continuous distribution (CD) activities as of the current public comment cycle. The Heart Committee had requested the presentation as an opportunity to learn about the experiences of other committees developing CD allocation systems. The Heart Committee will consider such experiences as they continue developing a heart CD allocation framework.

Summary of discussion:

No decisions were made as part of this discussion.

The Kidney Committee provided a comprehensive update on the continuous distribution project for kidneys, detailing several critical aspects of their ongoing efforts. The presentation aimed to inform the community about the progress made and the next steps in the project. Key areas covered included efficiency goals, the development of a data-driven definition for hard-to-place kidneys, and the creation of an expedited placement pathway for hard-to-place kidneys. The Kidney Committee Chair reminded the Committee members that on 09/05/2023, the OPTN Board of Directors (Board) passed a resolution

directing the OPTN Kidney and OPTN Pancreas Transplantation committees to ensure that their continuous distribution efforts address non-use, allocation out-of-sequence (AOOS), and expedited placement. The Chair said that today's update expands on the Kidney Committee's ongoing efforts to incorporate the Board's goals into their CD project.

The Kidney Committee has been working to incorporate efficiency goals into the continuous distribution framework. This includes efforts to expand non-use modeling capabilities and policy development. In February 2024, the Kidney Committee submitted a request to the Scientific Registry of Transplant Recipients (SRTR) to assess the feasibility of incorporating non-use and efficiency metrics into the Organ Allocation Simulation (OASim) model. These metrics include utilization and non-use of deceased donor kidneys, timing and sequence number at acceptance, cold ischemia time, and equity and access metrics specifically for recipients of high Kidney Donor Profile Index (KDPI) and hard-to-place kidneys.

In November, SRTR reported their success in modeling non-use alongside the committee's previously required equity in access and outcomes metrics. The committee will utilize these capabilities to understand the impact of continuous distribution on non-use and further optimize potential policies to meet equity and efficiency goals. Currently, the Kidney Committee's partners at the Massachusetts Institute of Technology (MIT) are working to incorporate the non-use sub-models into the optimization process. The committee is also considering several potential efficiency-specific modifications to the match run to support decreased non-use and continuous distribution.

The Kidney Committee has made significant progress in developing a data-driven definition of "hard-to-place" kidneys. This definition aims to establish an evidence-based standard to describe which kidneys are at increased risk of non-use and thus may require an alternate allocation pathway. The committee has been utilizing a multi-pronged approach to consider and incorporate clinical criteria, allocation thresholds, and cold ischemia time. The definition will incorporate both pre-recovery (predictive) and post-recovery (identified) characteristics. Allocation and cold ischemic time criteria can identify hard-to-place kidneys in real-time, while clinical criteria can help predict increased risk of non-use.

The committee is considering several potential criteria in combination for kidneys with a KDPI of at least 50. (Higher KDPI values suggest shorter graft survival.) The donor criteria include:

- Six hours of cold ischemic time
- Allocation sequence number 100 or higher
- Hypertension history greater than five years
- Donor age over 60
- Diabetes duration of five years or more
- Donation after Cardiac Death (DCD)
- Glomerulosclerosis greater than 10% on at least one biopsied kidney
- Donor use of continuous renal replacement therapy (CRRT)

The Kidney Committee aims to set a definition of hard-to-place based on a combination of these criteria. The committee will continue to review data to determine the appropriate number of criteria needed. This data review may lead to modifications, removals, or additions to the criteria based on public comment feedback.

The Kidney Committee also provided updates on the efforts of the kidney expedited placement workgroup. Previously, this workgroup had been collaborating with the OPTN Expeditious Task Force to support the development and testing of potential expedited placement protocols under the expedited placement variance policy. In August 2024, HRSA provided a critical comment directing work on the expedited placement variance to be paused. However, the OPTN maintains an interest in kidney

expedited placement, and previous public comment feedback has shown support for a standard, transparent, and effective expedited placement pathway for kidneys at increased risk of non-use.

In October 2024, the Kidney Committee opted to pursue a national kidney expedited placement policy. This policy will be developed to operate within the current allocation system and can be modified later to accommodate continuous distribution-based allocation. The expedited placement workgroup will leverage previous discussions regarding potential expedited placement frameworks. Key components of this framework are detailed in the update for community consideration. Expedited placement will be based on separate public comments, considerations, and implementation from the greater continuous distribution effort.

As part of the presentation, the Kidney Committee Chair posed several questions to the Heart Committee members for consideration. For example, the Heart Committee was asked whether they support the factors identified by the Kidney Committee to develop a preliminary definition of "hard-to-place" kidneys? The Heart Committee members expressed general support for the factors identified, recognizing the importance of a data-driven approach to defining hard-to-place kidneys. Members highlighted the need for flexibility in the criteria to accommodate evolving technologies and clinical practices. Members were also asked whether historical organ offer acceptance patterns should be used to qualify transplant programs to participate in expedited placement? The Heart Committee agreed that historical organ offer acceptance patterns could be a valuable metric for qualifying transplant programs. However, members emphasized the need for transparency and fairness in the qualification process to ensure all programs have an equal opportunity to participate.

The Heart Committee Chair asked how the Kidney Committee addressed kidneys that can be put on pumps and how that impacted their CD efficiency goals? The Kidney Committee Chair responded that the pump question has come up on multiple occasions. The problem with addressing pumps is that their use is not uniform across all the OPOs. The Chair also said that the kidney pumps commonly being used now cannot be loaded on planes, but such pumps can be driven. The Kidney Committee Chair added that because pump use is not uniform, the Kidney Committee is not comfortable trying to mandate use at this point; however, the topic is still under consideration. The Chair said putting kidneys on the pump would help with utilization and it potentially could help with efficiency because more kidneys would be used but it's a more complicated discussion to have.

The Heart Committee Chair also asked for an overview of how the Kidney Committee is addressing efficiency as part of their CD effort? The Kidney Committee Chair said that during their work developing a CD allocation framework, efficiency was primarily addressed as proximity efficiency. As a result, it involved matching and trying to keep marginal donors or kidneys with higher KDPI for use closer to the donor hospitals in order to be able to maximize utilization. Since the Board’s directive on 09/05/2023, the Kidney Committee totally shifted their efficiency focus to developing a hard-to-place definition and expedited placement.

A Heart Committee member asked about the Kidney Committee’s thought process around incorporating DCD donors and NRP in CD given the fluid nature of how a hard-to-place kidney might be defined now and how that might change in the future? The Kidney Committee Chair said that has been a complicated topic and something they will keep considering. Another member thanked the Kidney Committee for their work trying to define hard-to-place kidneys and for addressing allocation out-of-sequence issues. The Kidney Committee Chair was asked how they are addressing waiting time in Kidney CD and what lessons learned can be shared with the Heart Committee? The Kidney Committee Chair said what was extremely helpful was when they worked with the MIT optimization tool and they could visually see how the allocation process changed when attribute weights were modified. The Chair pointed out that waiting time is the most important factor in current kidney allocation, but waiting times are variable

across the country, meaning that waiting time in one region of the country may mean something different in another region. The MIT optimization tool helped put weighting time in the greater context of CD. The Heart Committee Chair asked if there were any particular variables that jumped out when the weighting of the waiting time attribute was wrong? The Kidney Committee Chair did not have many specifics about waiting time, but did say that they saw longevity matching (as measured by KDPI) and proximity efficiency moved in opposite directions when more weight was given to one or the other of the attributes.

Next steps:

The Heart Committee will continue following the Kidney Committee's efforts developing a continuous distribution allocation framework and look for opportunities to learn from such efforts.

3. Update regarding Heart Committee's public comment proposal: Escalation of Status for Time on Left Ventricular Assist Device and regional meeting feedback

OPTN contractor staff provided another update about the feedback received to date regarding the *Escalation of Status* public comment document.

Summary of discussion:

No decisions were made as part of this discussion.

The chair invited OPTN contractor staff to present the latest feedback and themes from the public comments and regional meetings. OPTN contractor staff shared the public comment feedback with the Committee members. The feedback includes information submitted on the OPTN website about the proposal and comments made during the OPTN regional meetings. The comments are grouped into general themes and those were shared with the Committee.

Contractor staff reported that as of the previous afternoon, 50 comments had been submitted on the proposal. The majority of these comments were supportive, with 43 out of 50 indicating support for the proposed changes. Of the seven comments that did not explicitly support the proposal, it was unclear whether they were opposed or simply did not address the proposal directly.

General themes from the public comments included support for the proposal and suggestions for shortening of the eligibility timeframes. In terms of support for the proposal, 22 commenters supported the proposal as is. Another 21 commenters supported the proposal but suggested changes, primarily focusing on reducing the eligibility timeframes for status escalation. Specific suggestions included reducing the eligibility timeframe to five years for status 2 and three years for status 3. A Committee member inquired about the sources of the comments suggesting reduced eligibility timeframes. OPTN contractor staff responded that the feedback came from a diverse group, including candidates, family members, and transplant hospital staff.

Some concerns were also identified. For example, some comments expressed concern about providing status 2 eligibility to candidates who are not experiencing complications with their device. There was also feedback about the potential confusion in the community regarding the proposal and its relation to other ongoing changes, such as the Committee's development of a continuous distribution allocation framework. The need to clearly articulate what the proposed policy changes will do and what they will not do was emphasized.

The Chair acknowledged the general support in public comment for the proposal and emphasized the importance of balancing the need for timely transplants with the potential impact on waitlist mortality

for higher urgency patients. The Chair noted that the feedback suggesting shorter eligibility timeframes indicates that the committee is moving in the right direction with the proposal.

A Committee member expressed concerns about the eligibility for status 2 for candidates without complications, suggesting that further information and discussion would be beneficial. They highlighted the importance of understanding the clinical implications of moving patients without complications to a higher status.

Another member discussed the initial bolus of patients moving to status 2 and the ongoing need for a mechanism to prioritize patients who have been on LVAD support for extended periods. They emphasized that the proposal aims to differentiate between patients who have been on LVAD support for varying lengths of time, ensuring that those who have been waiting longer receive higher priority.

The Chair reiterated the goal of the proposal to improve access to transplants for patients who have been on LVAD support for extended periods, while minimizing the impact on waitlist mortality for higher urgency patients. The Chair acknowledged the feedback suggesting adjustments to the proposal and encouraged committee members to voice any important adjustments before the proposal goes to the OPTN Board of Directors.

The discussion concluded with a consensus that the proposal is generally well-received, with some suggestions for adjustments. The Committee will continue to refine the proposal based on ongoing feedback and prepare for the next steps in the approval process.

Next steps:

The Committee plans to hold an in-person meeting after the public comment period ends to discuss any final adjustments to the proposal before it goes to the OPTN Board of Directors later in 2025. OPTN contractor staff will continue to monitor and compile public comments and regional meeting feedback to inform the Committee's discussions.

4. Other Committee business

OPTN contractor staff said that the regional meetings have been rescheduled as virtual meetings. The early meetings that were paused have been rescheduled. OPTN contractor staff also said that a draft public comment response to the Kidney Committee's presentation would be created and shared with Committee leadership for review and approval. The Committee members were told that a similar draft public comment for the OPTN Multi-Organ Committee's presentation was also being prepared.

5. Open Forum

No requests from the public were received prior to the meeting to address the Committee during open

6. Closing remarks

The Chair thanked the members for their participation during the meeting and added that the discussion helps evolve the proposed policy language in a positive direction for the whole heart transplantation community. A member said that they had received an email suggesting that the upcoming in-person meeting would be converted to a virtual "in-person" meeting and asked if there was any additional information. The Chair said that there are different messages out there and the Committee members should remain flexible at this point.

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 4, 2025 from 4:00 to 5:00 pm~~
- ~~February 18, 2025 from 5:00 to 6:00 pm~~
- March 4, 2025 from 4:00 to 5:00 pm
- March 18, 2025 from 5:00 to 6:00 pm
- April 1, 2025 from 4:00 to 5:00 pm
- April 15, 2025 from 5:00 to 6:00 pm
- May 6, 2025 from 4:00 to 5:00 pm
- May 20, 2025 from 5:00 to 6:00 pm
- June 3, 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
  - Maria Avila
  - Kim Baltierra
  - Jennifer Cowger
  - Rocky Daly
  - Tim Gong
  - Eman Hamad
  - Jennifer Hartman
  - Mandy Nathan
  - David Sutcliffe
  - Martha Tankersley
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Yoon Son Ahn
  - Monica Colvin
  - Avery Cook
- **UNOS Staff**
  - Nicole Brown
  - Matt Cafarella
  - Cole Fox
  - Lindsay Larkin
  - Eric Messick
  - Holly Sobczak
  - Kaitlin Swanner
  - Sara Rose Wells
- **Other Attendees**
  - Shelley Hall
  - Jim Kim