OPTN Heart Committee Meeting Summary February 20, 2024 Conference Call

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

Introduction

The Heart Committee (Committee) met via WebEx teleconference on 02/20/2024 to discuss the following agenda items:

- 1. Welcome and agenda review
- 2. CD of Hearts Request for Feedback and Values Prioritization Exercise public comment update
- 3. Public comment proposal: Ad Hoc Multi-Organ Transplantation (MOT) Committee: *Modify Effect* of Acceptance Policy
- 4. Public comment request for feedback: MOT Committee: *Identify Priority Shares in Kidney Multi-Organ Allocation*
- 5. Availability of 2-Year Monitoring Report of Pediatric National Heart Review Board on SharePoint site
- 6. Open Forum

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

1. Welcome and agenda review

Members were reminded about the upcoming in-person meeting scheduled for March 29th in Houston, Texas. They were encouraged to complete all travel plans as soon as possible.

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

An updated was provided about the public comments received to date regarding the Request for Feedback document. Members were also informed of the number of Values Prioritization Exercises that had been completed to date.

Summary of discussion:

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. Committee members were told 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. Key themes included concerns about impacts on pediatric candidates and the lack of inclusion of post-transplant survival attributes. Several members who presented at OPTN regional meetings shared the questions and comments they received. One member pointed out that if the adult and pediatric statuses are the foundation of the current heart allocation system, how can the Committee address the use of exceptions to those statuses in the continuous distribution allocation framework? The member said that the use of exception requests for statuses 2, 3, and 4 are where it is less clear exactly how sick / medically urgent a candidate truly is. Another member added that when a patient is supported by a heart device, their outcome is more

dependent on any device complications they experience than it is on their underlying physiology. A question for consideration is whether the Committee should continue moving forward with the approach of transitioning the existing statuses to a medical urgency rating scale, with an eye towards addressing physiology in the future, or address physiology now. The Chair reminded the members that a journal article about creating a potential risk score was distributed previously and members should review that for possible discussion at the March 29th in-person meeting.

There were 230 responses so far to the Values Prioritization Exercise. Committee members were encouraged to complete the exercise. 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.

Next steps:

It was stated that the OPTN Contractor staff would continue sharing new comments with the Committee as such comments are received. The members were reminded that at a Committee meeting following the end of public comment on March 19th, a summary document of the public comments received for the Request for Feedback document will be provided to them. The results of the Values Prioritization Exercise will be shared in the May – June, 2024 timeframe because the analysis takes more time.

3. Public comment proposal: Ad Hoc Multi-Organ Transplantation (MOT) Committee: *Modify Effect of Acceptance Policy*

The Committee received a presentation of the proposal from the MOT Chair. The proposal's intent is to clarify when a single organ offer acceptance takes priority over required multi-organ transplant shares.

Summary of discussion:

The MOT Chair reminded the Committee members that current policy establishes several required multi-organ shares. However, OPOs are continuing to report that it is unclear if and when multi-organ shares take precedence ahead of single-organ offers. Specifically, the proposal seeks to clarify that when the single organ is declined after an organ has been accepted, the OPO is not required to allocate the required multi-organ share because the second organ is now no longer available.

The Committee Chair stated that the proposed changes made sense. For instance, the next transplant program on the list with a heart-kidney candidate does not have to accept the heart being offered then. The program could decide to wait. Additionally, there is the kidney safety net policy for a heart recipient to pursue if the program does not get both the heart and kidney to perform a simultaneous transplant. A Committee member stated that in terms of a timeframe, it appears that there should be flexibility for OPOs within such a timeframe reflecting the nuances of a given OPO geographically. That being said, the member also mentioned support for exploring ways to safely shorten the timeframe associated with the allocation process.

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.

4. Public comment request for feedback: MOT Committee: *Identify Priority Shares in Kidney Multi-Organ Allocation*

The Committee received a presentation of the proposal from the MOT Chair. The MOT Committee is seeking feedback concerning how to stratify which organs should be offered to which candidates when multiple organs are available, especially as this applies to kidney-pancreas candidates who are on the waiting list.

Summary of discussion:

The MOT Chair said that concerns have been expressed that current multi-organ policies may disadvantage candidates in need of a single kidney, as well as candidates who need both a kidney and pancreas. Specifically, the MOT Committee is interested in feedback regarding: should multi-organ candidates be prioritized when there's only one kidney available, and should kidney-pancreas candidates be considered multi-organ candidates and be prioritized among other multi-organ combinations?

The Committee members appreciated the MOT Committee's efforts to collect public feedback regarding whether policy should direct the order in which OPOs allocate organs, especially transplants involving kidney-alone and kidney-pancreas candidates. Two members discussed the proposal's request for feedback questions in terms of lifesaving transplants versus non-lifesaving transplants, and that kidneypancreas transplants are not lifesaving in the way a high-status heart-kidney transplant is. As such, kidney-pancreas transplants should not be prioritized ahead of other multi-organ transplants, and should instead be considered along with kidney-alone transplants. It was pointed out that safety net policy exists by which a heart recipient who also needs a kidney gets priority for a kidney under certain conditions. The group was asked if the pathway to obtaining a heart and a kidney transplant provided by the safety net policy is adequate enough to meet the needs of heart-kidney candidates. The Committee members responded it does not. Two Heart Committee members pointed out that published data exists showing that heart transplant recipients who require dialysis postoperatively are at the greater risk of mortality in the first three months after transplant. Because heart transplant recipients are likely to still be recovering three months post-transplant, they are not great candidates for use of the heart-kidney safety net established in OPTN policy. A member asked that the MOT Committee consider a pathway by which the adult heart candidates at highest daily risk of mortality (currently status 1 candidates), can be prioritized to receive the second kidney from a heart and kidney donor even after one kidney has already been allocated to an MOT candidate.

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.

5. Availability of 2-Year Monitoring Report of Pediatric National Heart Review Board on SharePoint site

Committee members were notified that the 2-Year Monitoring Report associated with the creation and implementation of the National Heart Review Board (NHRB) for Pediatrics is available on the Committee's SharePoint site. This represents the last monitoring report for NHRB for Pediatrics. Members were encouraged to review the monitoring report and submit any questions or comments to the OPTN Contractor staff.

6. Open Forum

There were no speakers for the open forum discussion period.

Upcoming Meetings

- 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

- o Rocky Daly
- o JD Menteer
- o Tamas Alexy
- o Amrut Ambardekar
- o Kim Baltierra
- o Jennifer Carapellucci
- o Jennifer Cowger
- o Tim Gong
- o Eman Hamad
- o Jennifer Hartman
- o Glen Kelley
- o Earl Lovell
- o Cindy Martin
- o Fawwaz Shaw
- o Christy Smith
- o Martha Tankersley
- **HRSA Representatives**
 - o Jim Bowman
- SRTR Staff

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- o Yoon Son Ahn
- o Katie Audette
- o Monica Colvin
- UNOS Staff
 - o Kelsi Lindblad
 - o Alina Martinez
 - o Eric Messick
 - o Sarah Roache
 - o Laura Schmitt
 - o Holly Sobczak
 - o Kaitlin Swanner
 - o Sara Rose Wells
- Other Attendees
 - o Lisa Stocks
 - o Daniel Yip