

OPTN Heart Transplantation Committee

Meeting Summary

June 20, 2023

Conference Call

Richard Daly, MD, Chair

Jon David Menteer, MD, Vice Chair

Introduction

The Heart Transplantation Committee (the Committee) met via GoTo teleconference on 06/20/2023 to discuss the following agenda items:

1. Farewell to departing members
2. Continuous Distribution: Review Committee's 06/14 decision regarding Proximity Efficiency rating scale
3. Action Item: Review revised proposed policy related to adult heart status 2 mechanical devices and Committee vote
4. Reminder about regional meetings and presentations

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

1. Farewell to departing members

The seven members whose terms are ending on June 30, 2023 were thanked for their service.

2. Continuous Distribution Rating Scales: Proximity Efficiency

The Committee discussed proximity efficiency as a measure of success as to be used in upcoming mathematical optimization exercises.

Summary of discussion:

Support staff provided a review of the proximity efficiency information the Committee discussed as part of the June 14 meeting. The Committee agreed that priority points for proximity efficiency would be available within a range of 500 nautical miles between transplant and donor hospitals. Beyond 500 nautical miles, the priority would decrease linearly until it reached 0% at 1500 nautical miles.

The Committee confirmed their agreement on this approach and emphasized the importance of determining how success would be measured for all attributes. Support staff mentioned measuring success based on the decrease in nautical miles traveled at transplant for proximity efficiency, and informed the Committee the decided rating scales, rationale for the chosen rating scales, as well as how the Committee will measure success will be utilized in forthcoming mathematical optimization exercises. Support staff cited giving priority to transplants that are occurring closer between transplant and donor hospitals and decreasing the nautical miles traveled at transplants to be possible ways of measuring success for the mathematical optimization.

A committee member mentioned inclusion of pediatric patients and the challenges they face in traveling long distances for transplants, noting that transplant hospitals in more densely populated areas will be advantaged in this scenario. This committee member also expressed concerns about potential disadvantages for smaller pediatric transplant hospitals located in remote areas. Citing the previous

committee meeting, support staff acknowledged that traveling longer distances for infant hearts was a well-known practice, and another committee member noted the attribute would not disincentivize these transplants as they are so rare. Multiple committee members agreed that they would not be dissuaded by distance to procure an infant heart.

A committee member responded by asking if the proximity attribute for these infant cases is an effective attribute based on the current discussion, and if these candidates should be given proximity efficiency points regardless of actual proximity to better serve this population. Support staff noted the infants will still have their medical urgency points and pediatric priority points, which will likely be substantially more than the proximity efficiency points. In these cases, proximity efficiency will not take points away, it just will not add many points to their overall score.

Next steps:

Citing the current discussion, support staff noted they will take the Committee's agreement on using a decrease in nautical miles traveled at transplant for a measurement of success of the proximity efficiency attribute to the Chair and Vice Chair.

3. Amend Adult Heart Status 2 Mechanical Device Requirement

Following the Committee's June 14, 2023 vote to approve the proposed policy language, a clarifying question arose concerning the extension requirements. The Committee agreed that in order to extend the assignment, a transplant program must demonstrate that the candidate continued to be supported by the qualifying inotropic therapy and failed to be weaned from either the percutaneous endovascular mechanical circulatory support device or the intra-aortic balloon pump depending on the status assignment. The Committee voted to approve the revised policy language for submission to the OPTN Executive Committee.

Summary of discussion:

The Committee revisited the proposed policy language. At question was the extension language determining how an adult status 2 candidate who was assigned to the status by meeting the "CPR shock" requirements found in the percutaneous endovascular mechanical circulatory support device criteria or the intra-aortic balloon pump criteria. The previous version of the proposed policy did not include a pathway to extend the status of a candidate who had received one of the two mechanical devices as a result of: receiving CPR, having a systolic blood pressure less than 70 mmHg, having arterial lactate greater than 4 mmol/L, or demonstrating aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L. The revised policy proposal clarifies that such a candidate must be on the qualifying inotropes and fail the device wean to be eligible for an extension. The Committee members felt the clarification was important in order to maintain the intent of the proposed changes that inotropic therapy had been tried and shown to be unsuccessful before the transplant program could implant a qualifying mechanical device. The members concurred with the proposed revisions as because the changes were consistent with the intent of the process.

The members also discussed amending the extension language by referring back to the section of the proposal containing the qualifying inotropic therapy requirements. The members indicated that such a reference would be consistent with how similar references are made in policy.

4. Reminder about regional meetings and presentations

The Committee members were reminded that the next round of regional meetings starts August 2023, and shown a slide with the meeting dates, regions, and locations of the meetings. The regional representatives were told that they are responsible for presenting the information about the

Committee's two public comment proposals, the Amend Adult Heart Status 2 Mechanical Device Requirements, and the Continuous Distribution of Hearts: Concept Paper. Support staff stated that they would provide the presentation material to the representatives ahead of time and schedule prep calls with them.

Upcoming Meetings

- July 18, 2023, teleconference, 5 pm ET

Attendance

- **Committee Members**
 - Tamas Alexy
 - Amrut Ambardekar
 - Jen Cowger
 - Jennifer Carapellucci
 - Timothy Gong
 - Glen Kelley
 - Earl Lovell
 - Nader Moazami
 - John Nigro
 - Jonah Odim
 - Martha Tankersley
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Grace Lyden
 - Yoon Son Ahn
 - Monica Colvin
 - Bryn Thompson
- **UNOS Staff**
 - James Alcorn
 - Alex Carmack
 - Mariah Huber
 - Elena Liberatore
 - Kelsi Lindblad
 - Alina Martinez
 - Eric Messick
 - Laura Schmitt
 - Holly Sobczak
 - Susan Tlusty
 - Sarah Rose Wells
- **Other Attendees**
 - Kim Baltierra
 - Samantha DeLair
 - Robert Goodman
 - Shelley Hall
 - Eman Hamad
 - Jennifer Hartman
 - Lindsay Robertson
 - Daniel Yip