OPTN Heart Committee Meeting Summary November 1, 2023 Conference Call

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

Introduction

The Heart Committee ("Committee") met via WebEx teleconference on 11/01/2023 to discuss the following agenda items:

- 1. Continuous Distribution (CD) of Hearts: Medical Urgency Rating Scale
- 2. Review of Objectives of Time on Left Ventricular Assist Device (LVAD) Attribute

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

1. Continuous Distribution (CD) of Hearts: Medical Urgency Rating Scale

The Committee worked to finalize and align the medical urgency criteria rating scales for adult and pediatric patients.

Summary of discussion:

In general, the Committee agreed on the overall shape of the continuous medical urgency scale and the alignment of current status groups along the scale. For the most part as of now, the Committee will keep each of the clinical criteria associated with its status. However, because the use of 'statuses' is being eliminated with CD, the groupings need a new description. The Committee considered assigning a percentage of points to the IABP criteria that is different than the percentage assigned to the other criteria in the second highest medical urgency grouping. The Committee discussed possibly wrapping up the percentage point estimates as suggested by the Vice Chair, aligning with the following disaggregation:

- First attempt:
 - Medical urgency group 1 = 100 percent
 - Medical urgency group 2 = 80 percent
 - Medical urgency group 3 = 50 percent
 - Medical urgency group 4 = 30 percent
 - Medical urgency group 5 =15 percent
 - Medical urgency group 6 =0 percent
- Second attempt,
 - Medical urgency group 1 = 100 percent
 - Medical urgency group 2 = 60 percent
 - Medical urgency group 3 = 40 percent
 - Medical urgency group 4 = 20 percent
 - Medical urgency group 5 = 10 percent
 - Medical urgency group 6 = 0 percent

The Committee members agreed with the second attempt, in part because the percentages work better with the additional priority the members want to give for time on LVAD. There was general agreement within the Committee to keep the current medical urgency status groupings (1-6 for adults and 1A-1C for pediatrics) and associated criteria, but to spread them along a continuous scale rather than discrete categories. This could help with understanding implementation. In addition, several questions were posed to the Committee related to medical urgency groupings. The Committee reached consensus on awarding waiting time and 5 points a year with the cap of 30 points, with other groupings to be discussed in future meetings.

Additionally, the Committee noted that there should be meaningful separation between groupings based on risk and urgency rather than just waitlist mortality. In response to the pediatric proposal changes, the Committee agreed that it was "directionally correct." There was some debate around whether the maximum medical urgency points should be capped at 100% or allow possibilities of earning more points through multipliers. Additionally, the Committee agreed to iterate and set appropriate conceptual directions that could be modeled and optimized.

Next steps:

Next steps are to finalize the pediatric medical urgency scale and determine optimal weighting of the various factors in the overall allocation score. The committee will continue working with the goal of identifying and defining the information needed for future modeling.

2. Review of Objectives of Time on LVAD Attribute

The Committee discussed including additional prioritization on the medical urgency rating scale for time a candidate has spent with an implanted LVAD, and how the additional prioritization might be calculated.

Summary of discussion:

The Committee discussed consideration for prioritizing adult heart status 4 candidates who have been supported by a LVAD at some point while registered on the waiting list. The Committee agreed that VAD patients should be given additional prioritization points based on their time on the device, likely starting at 5 points per year on the device. This is to help address the issue of VADs becoming "bridges to complications" rather than bridges to transplant. In addition to the points for VAD waiting time, they agreed that patients with durable VADs should get priority points based on time on device to address complications. However, there was some discussion around whether status 4 LVAD waiting time should count as its own attribute or be incorporated into the medical urgency attribute. Following this discussion, the Committee decided to include it as a part of the medical urgency rating scale. There were also differing opinions expressed about how many priority points VAD waiting time should be worth with suggestions ranging from 5 to 10 points per year. The final consensus was 5 points per year. A member asked whether VAD patients' risk could be quantified and modeled over time to determine equivalent medical urgency statuses. The Chair responded that medical urgency prioritization is based on more than just mortality risk, reflecting concerns like patient hope and quality of life.

Next steps:

The Committee members agreed to include priority for waiting time on LVAD with the medical urgency rating scale and will continue refining the idea moving forward.

Upcoming Meeting

• November 21, 2023

Attendance

- Committee Members
 - o Rocky Daly, Chair
 - o J.D. Menteer, Vice Chair
 - o Tamas Alexy
 - o Amrut Ambardekar
 - o Jennifer Carapellucci
 - o Timothy Gong
 - o Eman Hamad
 - o Glen Kelley
 - o Earl Lovell
 - o Cindy Martin
 - o John Nigro
 - o Cristina Smith
 - o Martha Tankersley

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi
- SRTR Staff
 - o Yoon Son Ahn
 - Katie Audette
 - o Grace Lyden

UNOS Staff

- o James Alcorn
- o Alex Carmack
- o Cole Fox
- o Gabrielle Hibbert
- o Emily Howell
- o Kelsi Lindblad
- o Alina Martinez
- o Eric Messick
- o Holly Sobczak
- o Sarah Rose Wells
- Other Attendees
 - o Shelley Hall
 - o Samantha Taylor