OPTN Heart Committee
Meeting Summary
August 2, 2023
Conference Call

Richard Daly, MD, Chair
Jondavid Menteer, MD, Vice Chair

Introduction

The Heart Committee met via Webex teleconference on 08/02/2023 to discuss the following agenda items:

1. Review / determine outcome metrics and plain language purposes for each attribute for inclusion in future mathematical analyses
2. Feedback from Region 2 meeting and public comment concerning:
    a. Amend Adult Heart Status 2 Mechanical Device Requirements
    b. Continuous Distribution of Hearts

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

1. Review / determine outcome metrics and plain language purposes for each attribute for inclusion in future mathematical analyses

Discussion Summary

The Committee reviewed and discussed the plain language purposes and optimization metrics for each attribute. The purposes and metrics will be used as part of the future mathematical optimization analysis that the Committee heard about during the 07/18/2023 meeting. As part of the Committee's early work on continuous distribution in 2022, the members had identified attributes and discussed reasons why the attributes should be included in the first iteration of the new allocation framework. Some of that information is useable for this discussion, but there are some differences that will also need to be addressed.

The Committee members were told that the optimization metrics allow for optimizing a certain outcome and determining if the chosen rating scale and associated weights achieve the attribute's intended purpose. There was a short description of the different types of metrics that are being considered. For example, there are Organ Allocation Simulation metrics that are system level and stratified by different characteristics, such as age, race/ethnicity, and geographic area. There are also post-implementation metrics. These are used as a resource to understand whether an implemented policy is achieving its intended objective. For today's purpose, the Committee will be discussing optimization metrics. Such metrics attempt to answer questions such as, does this policy scenario accomplish the goal for a given attribute? And, is the selected rating scale or weight successful?

The Chair pointed out that, on the surface, the purposes associated with each attribute seem fairly obvious and more discussion seems like a repetition of work the Committee has already completed. However, the reason the Committee is being asked to do this now is that if the purposes can be made more accurate for the purpose of mathematical optimization, then it will simplify the analysis and result in the Committee getting the types of outcomes and information for which they are looking. The Chair

added that the Committee could choose a number of different metrics, but having too many metrics results in the modeling trying to satisfy all of the factors that have been identified, which ends up limiting the value of the information provided back to the Committee. To reiterate, the Committee is being asked to choose an optimization metric that will satisfy the goal that is trying to be achieved. Then when modeling occurs, it will provide information about the level of prioritization an attribute should receive compared to others. Additionally, the Committee should have this discussion so that members have the chance to voice their opinions about the optimization metrics.

The Committee was presented with the draft plain language purposes and optimization metrics for each attribute for consideration. Contractor staff stated that the purposes and metrics had been shared with other contractor staff for feedback. In their comments, those contractor staff had suggested that for the medical urgency-related attributes the use of counts of waiting list deaths might be more useful in the mathematical optimization that waiting list rates.

A Committee member stated that when considering the use of counts versus rates, that the counts must have a defined period of time, and asked if more information could be shared about why counts would be more appropriate.

Contractor staff responded that there has been much discussion around the idea recently with the other organ committees as they work on continuous distribution allocation frameworks. Contractor staff said it does not have to strictly be counts, it could also be a cumulative incidence. Both address the idea that more transplants reduce deaths. Because wait list mortality rate censors at transplant, it is actually more a measure of how sick candidates are while they are waiting for a transplant. For instance, a particular subgroup can experience an increase in transplants, but while they are waiting, they remain equally sick. The policy is not guaranteed to change who is waiting for a transplant. When the contractors perform modeling, there is a set cohort of candidates that is used in the simulations. This creates a bound on the absolute number of deaths that could occur.

The member replied that the candidates with higher waiting list mortality rates are sicker than candidates with lower rates. The differences in the rates are important because it helps demonstrate whether candidates are being assigned to the appropriate statuses according to their level of sickness. As a result, if the Committee is not considering the criteria, such as ventricular tachycardia, cardiac index, LVAD complications, defined in a way to reflect a level of risk, then the Committee won't be able to identify the types of issues candidates have that need to be accounted for within the allocation framework in terms of defining the level of risk. Contractor staff stated that in terms of the output from the simulations, the policy (defined as the attributes and the assigned weights) is changing the availability of transplants as opposed to the providing more of an analysis of medical urgency within various candidate populations.

The Chair brought up that what would be helpful in terms of considering medical urgency is knowing the mortality within each criterion within each status. Moving forward with continuous distribution, the qualifications for medical urgency priority/points will be based on a candidates' criterion. A Committee member stated that the current criterion within the statuses have a lot of granularity in terms of defining how sick someone is to be assigned to that criterion. The criterion differentiate the candidates from one another. That same level of differentiation is going to be replicated within the continuous distribution allocation framework. As a result, the members want to be sure that the steps they take in establishing the attributes, for example, ensuring candidates with Intra-Aortic Balloon Pumps (IABP) can be compared against candidates receiving a single high dose inotrope, and the waiting list mortality rates demonstrate those difference and help with such comparisons.

Contractor staff asked if that type of information and those types of comparisons can be made with existing data? The simulation modeling, on the other hand, is considering something different, mainly what is the optimal combination of heart-related attributes and weighting or prioritization that will result in more transplants? Another contractor staff person reminded the group that when the policy changes implemented in 2018 were being considered, the Committee and others identified the groups of patients at highest risk of death, and then next highest risk group, and son on, and then that information was used to help with the simulation performed at that time. The Vice Chair came back to the fact that there is a fixed cohort of patients used in the simulation model and because of that the modelers can use the fixed count of waitlist deaths as a surrogate for instance.

It was also discussed that the simulation is performed in a way that candidates are being added to and removed from the cohort as the simulation occurs. In this way, the simulation is meant to reflect the actual process. It was discussed that it might be useful to have a demonstration of how the simulation functions and where within the simulation, deaths are occurring. For example, is a death happening in the simulation right after a candidate joins the list because they are not being assigned to the appropriate priority, or is happening gradually over time? Nonetheless, a waitlist mortality rate/deaths per active patient years is a measure of how sick a candidate is; however, it is not necessarily going to be impacted by an allocation policy change. It does not change how sick a patient is to have a different policy. The same set of cohorts are being used in the simulation regardless of the policy. On the other hand, if those candidates are able to be transplanted at a faster rate, there will be fewer total deaths.

It was also mentioned that for the optimization metrics the goal is to choose one metric that is going to optimize both the rating scale, and then also find the ideal policy to the combination of all the different attributes and rating scales and weight together. The Chair asked what additional information the Committee needs to provide in order to move this forward. Contractor staff suggested that if the Committee agrees with the purposes and metrics provided, then we can move forward. The metrics provided have been used in other allocation frameworks for optimization purposes.

The Committee tentatively concurred with the proposed purposes and optimization metrics and reserved the right to ask more questions about how those will work within the allocation framework they are developing.

Next Steps

The plain language purposes will be shared again with the Committee at the next meeting.

2. Feedback from Region 2 meeting and public comment concerning:

- Amend Adult Heart Status 2 Mechanical Device Requirements
- Continuous Distribution of Hearts

Discussion Summary

While still early in the public comment period, support staff gave a quick overview of the feedback received for the two public documents. The update included information submitted to the OPTN website as well as the OPTN Region 2 meeting, which had occurred earlier in the week. It was mentioned that the OPTN Region 4 meeting is scheduled for the next day.

For the Amend Adult Heart Status 2 policy proposal, two comments were received through the OPTN website. One comment raised the potential for a significant increase in adult status 2 exception request if the proposed changes were approved, and requested that the Committee prepare a guidance document addressing arrhythmias. The other comment raised a concern that the proposal exposes

patients to undue risk by requiring inotropic therapy prior before an IABP can be implanted, and also dictates clinical care. A commenter at the OPTN Region 2 meeting also questioned the step-wise approach in the proposal. Other public comments about the proposal included the need to potentially address the timeframe that a candidate is experiencing cardiogenic shock. The Committee members talked about potential changes, but any such changes are likely to result in more prescriptive requirements for programs.

It was mentioned that few comments were received about the continuous distribution of hearts concept paper.

Next Steps

Contractor staff will continue monitoring the submitted comments and OPTN regional meeting discussions and sharing that information with the Committee members.

Upcoming Meeting(s)

- August 15, 2023 (teleconference)
- September 6, 2023 (teleconference)
- September 22, 2023 (in-person)
- October 4, 2023

Attendance

- **Committee Members**
  - Rocky Daly, Chair
  - J.D. Menteer, Vice Chair
  - Kim Baltierra
  - Jen Carapellucci
  - Jennifer Cowger
  - Tim Gong
  - Eman Hamad
  - Jennifer Hartman
  - Glen Kelley
  - Earl Lovell
  - John Nigro
  - Cristy Smith
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Kala Rochelle
- **SRTR Staff**
  - Yoon Son Ahn
  - Monica Colvin
  - Grace Lyden
- **UNOS Staff**
  - James Alcorn
  - Alex Carmack
  - Cole Fox
  - Elena Liberatore
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Laura Schmitt
  - Holly Sobczak
  - Kim Uccellini
  - Sara Rose Wells
  - Ashley Woodards
- **Other Attendees**
  - Shelley Hall
  - Ted Papalexopoulos
  - Daniel Yip