OPTN Heart Transplantation Committee
Meeting Summary
February 28, 2023
Conference Call

Rocky Daly, MD, Chair
JD Menteer, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee, the Committee, met via Citrix GoTo teleconference on February 28, 2023, to discuss the following agenda items:

1. Status Update: ABOi Public Comment Feedback
2. Continuous Distribution: Consideration for Days Alive on Durable MCS (Waiting time on LVAD)

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

1. Status Update: ABOi Public Comment Feedback

The staff representative from the OPTN Contractor reviewed the public comment feedback received on the Committee's ABOi Offers proposal. OPTN Regions 2, 3, 4, 5, and 10 were all largely supportive of the proposal. The 11 comments submitted to the OPTN Website have been supportive of the proposal, this includes comments submitted by the OPTN Pediatric Transplantation Committee and the Childhood Cardiomyopathy Foundation. While the general themes of the comments have been supportive, some comments have suggested the Committee consider taking steps to expand eligibility even more by eliminating ishemagglutintin titer cut-off as an eligibility criteria and to consider increasing the age for identification as "Primary" blood type group from less than one year old to less than two years old. Staff will draft a public comment update document for the Committee to consider prior to the March 29, 2023, meeting. The Committee will be able to vote on any potential changes at that time. Staff reminded the Committee that public comment remains open until March 15, 2023, and committee members are allowed to submit comments as individuals and their programs are also able to submit their own comments.

Summary of discussion:

The Chair of the Committee noted that many of the comments have been focused on the question of 'why is the policy not looser' and reminded the Committee of the decision to keep the parameters of the policy tight in order to keep community support.

2. Continuous Distribution: Consideration for Days Alive on Durable MCS (Waiting time on LVAD)

The Committee discussed waiting time on LVAD and days alive on durable MCS as a possible attribute for continuous distribution prior to voting on the attribute. The Committee voted unanimously in support of the concept of capturing waiting time on LVAD as a potential attribute.

Summary of discussion:

The Chair began the discussion by thanking the committee member who had researched and prepared a document for the Committee concerning this potential attribute. The Chair then reminded the Committee that days on LVAD is not currently in policy and added it is one of the more major changes to

policy the committee is undertaking along with continuous distribution itself. The device technology that exists right now is not viewed as a bridge to transplantation but incorporating this into policy would help to change that perception and incentivize the use of technology. Additionally, the Chair highlighted that addressing diversity and disparity issues can be difficult in allocation because access is a different problem. The Chair suggested the Committee needs to rediscuss the issues around disparity and the data that may be out there, noting that this will likely be on the agenda of a future meeting.

The Vice Chair stated they had read the document, and that while it is very well done and detailed, other workgroups will not be going into the same level of granularity. The Vice Chair expressed some concern that the length of future documents by the committee for the committee if all go into the same level of detail as the document concerning LVAD. The Vice Chair then asked if the LVAD document should be shortened prior to being incorporated into the continuous distribution proposal. The Chair responded that out of all the things the Committee will be incorporating into continuous distribution, waiting time on LVAD may be the most controversial and therefore would need the most support and granular detail. The Chair continued that if this is going to be incorporated into the medical urgency attribute of continuous distribution it is critical that the Committee's thoughts be documented on this issue. The Vice Chair agreed and then asked Staff for their opinion on the matter. Staff responded that while there may be a need to shorten the document itself, the detail provided is good because this is an important issue that is a substantial shift from what is in current policy. Staff continued that the detail in the document is going to be useful once the Committee begins discussing rating scales.

Staff noted that liver, kidney, and pancreas committees have all included, or are planning to include, waiting time as an attribute but listing it under patient access rather than medical urgency. The Chair said the Committee may still do that as well, but the level of impact on the composite allocation score might be different to prevent this from limiting the impact it will have on the patients on LVAD.

A member stated that this is a sensitive topic because while the Committee wants to give credit to patients who have been on LVAD for an extended period of time, those patients tend to be more stable and less urgent and do not tend to qualify for medical urgency. Weighing these patients against those who need an immediate transplant and who are hospitalized needs to be addressed. The Chair acknowledged this but pointed out that the longer a patient is on LVAD the greater the risk of complications.

The Committee member who drafted the document asked the Committee to be mindful of four key concepts that are laid out for incorporating time on support. The member said that no one is arguing that patients with giant cell myocarditis and an RA of 20 is the same as a patient who is at home on a VAD, however, transplant programs have dictated a care plan for a patient that has made a huge impact on that patient's future potential of survival and quality of life post-transplant. This is because those patients on a VAD are at home living a relatively stable life without potential for transplant. This was an attempt to come up with a compromise agreement that awards points for time on VAD that will plateau as to not disadvantage immediately medically urgent patients.

A committee member suggested that the bigger issue may be there are some flaws in current allocation that need to be addressed and reviewed. The committee member who drafted the document agreed with the member's sentiment but pointed out that this is what the committee has been tasked with regarding continuous distribution. The committee member responded by stating that giving status 2 priority to patients has incentivized getting patients as status 2 when those patients are more like status 3; removing that incentive could allow for more transplant opportunities for LVAD patients. The committee member who drafted the document responded my agreeing in theory but again suggested that considering time on LVAD is the current task that needs to be addressed by the committee.

Another member pointed out that continuous distribution could give the committee an opportunity to address these things by adjusting the medical urgency scales for allocation, but taking on all the definitions might be too big of an ask for the first version of continuous distribution but addressing IABP and LVAD would be appropriate. A committee member cautioned against creating a system that could incentivize one thing over another, which is what is currently happening with IABP and in turn has made that the first course of action far too often without trying anything else. The member continued that they support including LVAD in continuous distribution because often these are patients who may not have support at home and the LVAD might be the only reasonable option for treatment prior to transplant.

The committee member who drafted the document stated that programs and doctors will probably still try to figure out ways to increase likelihood of getting a transplant for their patient in the future, but that should not prevent the committee from addressing what they can now. The member highlighted that currently in the United States medical fellows are not going into programs. Low VAD numbers, and a decrease in heart transplants for black Americans, considering the disparities and access to care issue is critical for the committee to consider. Comparing VAD patients to others in more critical need might not be far, but patients on VAD might not have the same access to and being on VAD should not limit a patient's opportunity for a transplant.

The Vice Chair asked the committee if any member is opposed to including the concept of granting points for time on VAD, no committee member responded as opposed. The Vice Chair continued that since the committee is in agreement on this point the conversation should be about how many points should these patients receive and in what attribute should this be placed under. Another member responded with their belief that this attribute would be widely supported within the transplant community because so many people have the same concern regarding LVAD patients never getting transplanted. The Vice Chair agreed and pointed out that it would be more difficult to do nothing after seeing the survival curve for patients on LVAD whose risk increases.

A member asked if the time on VAD be continuously incremental, or should it plateau after a certain period of time, or maybe even lose points after a certain amount of time. The committee member who drafted the document said that plateauing the points after an extended period of time makes the most sense and cautioned against the points decreasing saying this would be unfair for patients who are on LVAD the longest. The Vice Chair suggested that centers and doctors are going to have to discuss with their patients if a transplant is necessary and if so when, being on LVAD does not mean that a transplant is always going to be the best option.

The committee member who drafted the document asked the committee when should days on LVAD start counting, would it be from the time you started on VAD even if you were not listed or does it start from the moment you are listed? A member pointed out that for kidney it is the moment the patient starts dialysis, and the time is backdated once they are listed. Another member stated that this makes sense and should be replicated.

A member suggested that there are multiple ways to allocate points for time on VAD, a gradual increase, a dramatic increase that levels off over time, a small increase over the course of months that increases more dramatically over time could all be justified. The committee member who drafted the document reminded the committee that modeling has yet to be done, and that should help answer these questions. Another member suggested that new data is going to be needed prior to modeling to know exactly what to model. Another member said it would be important to keep in mind, and to know, which patients are going to be displaced by this attribute.

The Vice Chair stated their support for waiting time on LVAD to be included under the medical urgency attribute, agreeing with the Chair.

The Ex-Officio Chair reminded the committee the OPTN Contractor Staff will be drafting the concept paper for public comment. This means certain components of the document the committee is currently reviewing may not make it into the final official document for a variety of reasons. The Ex-Officio Chair cautioned the committee against getting too focused on specifics within the current document because it can be changed. The Chair reminded the committee that the level of detail in documents that come from committee workgroups is going to depend on the complexity of the attribute they are tasked with reviewing.

Staff asked the committee member who drafted the document to explain why the recommendation was made to provide greater prioritization for time on MCS when the document earlier suggested that there should be a reason why the candidate is getting sicker and needs the prioritization. The committee member who drafted the document responded that the longer a patient is on LVAD the risk increases of a device complication or an infection, and this is an attempt to be proactive rather than reactive to a device complication.

The Committee voted on including this concept as an attribute in the first iteration of Heart Continuous Distribution. The vote was unanimous with 15 voting yes.

Upcoming Meeting

- March 21, 2023; 5:00 pm – 6:00 pm et; virtual conference call
- March 29, 2023; in-person meeting; Richmond, Virginia

Attendance

- **Committee Members**
  - Rocky Daly
  - JD Menteer
  - Adam Schneider
  - Tariq Ahmad
  - Amrut Ambardekar
  - Glenn Kelley
  - Timothy Gong
  - Jennifer Cowger
  - Jonah Odim
  - Jose Garcia
  - Martha Tankersley
  - Nader Moazami
  - John Nigro
  - Cristy Smith
  - Tamas Alexy
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Alina Martinez
- **SRTR Staff**
  - Grace Lyden
  - Monica Colvin
  - Yoon Son Ahn
  - Katherine Audette
- **UNOS Staff**
  - Eric Messick
  - Alex Carmack
  - Kelsi Lindblad
  - Laura Schmitt
  - Mariah Huber
  - Sara Rose Wells
- **Other Attendees**
  - Daniel Yip