OPTN Heart Transplantation Committee
Meeting Summary
May 16, 2023
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via Citrix GoTo teleconference on May 16, 2023, to discuss the following agenda items:

1. Regional Meeting Schedule
2. Review and Vote on Policy Proposal Related to Adult Heart Status 2 Mechanical Devices
3. Continuous Distribution Rating Scales: Proximity Efficiency

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

1. Regional Meeting Schedule

Contractor staff shared the upcoming OPTN Regional Meeting Schedule and reminded the Committee there will be multiple presentations for Regional Representatives to make at these meetings.

Summary of discussion:

There was no discussion on this item.

2. Amend Adult Heart Status 2 Mechanical Device Requirement

The Committee discussed the proposal that was developed and recommended by the Intra-Aortic Balloon Pump (IABP) Subcommittee, *Amend Adult Heart Status 2 Mechanical Device Requirements.*

Summary of discussion:

A member suggested to including in the Committee's regional meeting presentations the statistic that 83 percent of candidates were never Status. The Vice Chair raised a question about the purpose behind using seven days compared to using 48 hours. The member replied, saying that they did not know the significance of the seven days and although they would be supportive of the change to 48 hours, there is no existing data to support that change right now. The Chair suggested that the Committee could discuss this in the future. The member agreed and hoped this project will give the Committee data to address this in continuous distribution and potentially analyze the days of support. A member brought up a potential point of argument as being: 'the continuous infusion of inotropes to prove the candidate's clinical condition could not be stabilized'. The member said the Subcommittee could not find an answer to that question and thus it is not in policy right now.

An incoming committee member asked if a candidate has a balloon pump and does not meet the stated criteria, are they Status 3? A member responded by explaining that if a candidate does not match the criteria, then the transplant program may submit an exception request. The incoming Committee member further clarified their question by asking if having a balloon pump no longer has a status by itself and a member of the Subcommittee affirmed this and explained that all percutaneous devices must demonstrate inotropic medical failure. A member then expressed hope that the review boards will

be strict in approving exception requests. The incoming committee member raised a concern that if everybody must ask for an exception, they will just ask for Status 2 as opposed to Status 3. The member explained that there must be clear descriptions as to why clinicians did not try medical therapy first and yet the shock criteria was not met. They welcomed others' thoughts on adding balloon pump with no medical therapy, preconditions as a Status 3, however they are unsure if it will pass.

A member discussed a concern that the subcommittee had, being that smaller individuals who do not need non-balloon pump support may be disadvantaged. Another member explained that the small individual can get medical therapy. A member affirmed, but raised the concern that once they fail medical therapy, the individual will then move onto balloon pump. A member further clarified the individuals' earlier concerns, saying that they are asking if people want to support a candidate with a balloon pump over medical therapy, can we put a balloon pump by itself without qualifying medical therapy as a Status 3? A committee member recommended that instead of saying medical therapy, high dose inotropes might be a better option, allowing for more flexibility. The member suggested to add policy language that states "if the candidate does not qualify for the above balloon pump will go to Status 3".

Another member said that they do not think that transplant programs should be able to implant a balloon pump without the candidate having receive some inotropic support and expressed that they think there should be criteria as to why a balloon pump is being put in. A committee member reminded everyone that Status 3 is not just inotropes and that typical inotropic therapy is a Status 4 assignment, and if a candidate is on inotropes and is failing, they are a Status 3. A member disagreed, and another member explained that they were unsure if candidates should be Status 3 with just the balloon pump. A committee member worries that there will be an incredible number of exceptions written. A member emphasized the importance of transplant programs including supporting data in the exception request, and that RRBs should not support the request without such supporting data. Another member responded, explaining the need for a guidance document for exceptions.

A member asked if Regional Review Boards are given guidance stating that 90% of approvals for exception is too high. A member expressed their feelings that the RRB training is weak and that it should be more granular, especially because they sent the exception guidance to the review boards and exceptions got higher and felt that the guidance document was ignored. They personally felt that there must be more rigorous recommendation to review boards to give them the strength to say no to exception requests. A different committee member suggested an email from each regional member to the boards themselves, to avoid coming off as an overarching guideline. They further elaborated by saying that communication from each regional representative would be useful by explaining that the 90% exception approval must be thought about more critically. A member responded and said that awareness should be spread across different groups and to understand how bad this is, to find some kind of way for repercussion.

The incoming committee member affirmed that this is a problem but emphasized that not having a place "for balloon pump to land" without meeting these high criteria will just open to a whole bunch of exceptions, which are likely to be approved, thus defeating all the work that the subcommittee did. They continued to say that the previous guidance document given to the review board did not help. A member emphasized that if a clinician chooses to support a candidate with a balloon pump with no criteria, they land in Status Three. They believe that it will curtail the exception issue a bit, but it is also telling them that they do not need to try medical therapy and you can go right to the device.

Staff suggested that there could be a specific question in the public comment document if there should be consideration for Status 3. Another committee member raised the concern about an Impella CP in a candidate who has not had inotropes is any better than a balloon pump. They elaborated that some

individuals may say yes, but others may disagree. A member reminded the Committee that whatever the policy language says must be applied to all of them. A member clarified that the proposal is saying that before patients get any temporary support device, they must meet the hemodynamic criteria plus failed inotropes. A member said they have concerns about putting this question out for public comment, just pertaining to balloon pumps, as it will merit a response that not all percutaneous and endovascular devices are the same and therefore, if balloon pumps are going to be considered Status 3 with no other medical attempts first, then the policy language should be the same for the other percutaneous devices. It was worrisome to a member that the language may become too granular, as there is not extensive data analytics to create new policy. They worry that if it gets too granular, the community will not support the proposal at all. They highlighted that the intention in this proposal is to address a gap in current policy that is causing unintended use of Status 2 and acknowledged that not everything can be accomplished that the Committee would like with this proposal. The Chair agreed with the member, saying that the Committee needs to accomplish what they can in a brief time here. They emphasized that they know the data will get some information about the results of this and how that impacts behavior, which will help the committee with getting this better. A member said, "it's a step closer to where we want to be and a step away from where we are," which is how the Committee should view it. The Chair said this is making it more palatable, which would impact the other projects that are being worked on by the Committee. The member suggested the Committee consider what feedback should be requested during public comment.

The Committee voted on the following:

- Amending the Adult Heart Status 2 Mechanical Device Requirement proposed policy language
    - Support- 11; Abstain-0; Oppose- 0

Next steps:

The proposal will be submitted for public comment in July 2023. The Committee will review community feedback on the proposal.

3. Continuous Distribution Rating Scales: *Proximity Efficiency*

The Committee reviewed general concepts related to Proximity Efficiency, reviewed pre-meeting input, discussed primary considerations, and identified a potential rating scale for future review and describe why it is appropriate for heart allocation policy.

Summary of discussion:

The Chair of the Committee said one respondent must always fly, since they are geographically isolated, as the nearest donor center would be about 80-100 nautical miles (NM) away. The Chair then said it is difficult to get a uniform answer.

A member explained there is a difference between flying via airplane versus a helicopter regarding timing. The Chair mentioned the concern of road conditions and that there are other factors to consider. A member asked if there was any potential for inequity if you are stuck geographically. They gave the example of some states being more geographically isolated than others, such as Oregon, in which transplant programs would need to constantly be flying. Their main point is if there is anything impacting some centers in a negative way when talking about distance. The Chair responded by saying that the balance is between adequate sharing, which was not present when donation service area (DSA) was part of the allocation criteria which was noticeably clear, and has since improved, and balancing that with having planes fly across the country, whether that be New York to California or Minnesota to Texas. The Chair then said the other question is to not pay any attention to proximity, which the only disadvantage to that is a lot of expenses, flying back and forth across the country for these things. They

continued, saying we are not sure where OCS perfusion technology will fall through yet, which is why it might be best to leave that aside for this phase. The Chair continued to say balancing sharing along with avoiding driving long distances may be the best way to think about this.

The Vice Chair expressed concern about waiting a week with all the discussion of the individual donor, and we know that there is a distribution of donors that comes up. The Chair said that transplant programs know that they do not have to go out 1500 NM to get a donor heart even if they could, because there is a 99% likelihood of there being a donor within 500 NM in the next 5 days. The chair continued, saying if the MIT staff have analytics to get the information of the probability of the next donor coming up within 500 NM within X number of times. The Vice Chair said it does not seem rational to have no proximity score. They added that to give the exact same number of points to somebody who is 2000 NM away as somebody whose next door, does not make any sense. They said the other Committees seemed to have deemed it irrational to make this a major source of points, as we do not want to build so much inequity into the system that you can't get a donor across the country and if you're from a couple of states away, if that is your only source of organs. They suggested making this a small number of points, starting with a small circle around the donor hospital, potentially being 5 points. They also said that some cities use helicopters because of traffic issues, even if it is only fifteen miles, so assigning a threshold for distance is difficult, as it varies from city to city.

Next steps:

The Committee will continue their conversation about proximity efficiency, where they hope to continue the engagement from this meeting. The Committee will continue to provide input prior to meeting discussions.

Upcoming Meeting(s)

- June 14, 2023 @ 4pm EST (teleconference)
- June 20, 2023 @ 5pm EST (teleconference)

Attendance

- **Committee Members**
  - Rocky Daly
  - JD Menteer
  - Adam Schneider
  - Dmitry Yaranov
  - Fawwaz Shaw
  - Earl Lovell
  - Glen Kelley
  - Hannah Copeland
  - Jennifer Carapellucci
  - Jennifer Cowger
  - John J Nigro
  - Jose Garcia
  - Robert Goodman
  - Shelley Hall
  - Tamas Alexy
  - Timothy Gong
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Grace Lyden
  - Katharine Audette
  - Monica Colvin
- **UNOS Staff**
  - Alex Carmack
  - Alina Martin
  - Eric Messick
  - Holly Sobczak
  - James Alcorn
  - Laura Schmitt
  - Mariah Huber
  - Sara Rose Wells
- **Other Attendees**
  - Cindy Martin
  - Daniel Yip
  - S. DeLair