OPTN Heart Transplantation Committee
Meeting Summary
September 6, 2023
Conference Call

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

Introduction

The OPTN Heart Transplantation Committee met via Webex teleconference on 09/06/2023 to discuss the following agenda items:

1. Discussion of policy proposal, *Amend Adult Heart Status 2 Mechanical Device Requirements*
2. OPTN Efficiency Task Force
3. Reminder of 09/22 in-person meeting and closing remarks

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

1. Discussion of policy proposal, *Amend Adult Heart Status 2 Mechanical Device Requirements*

The Committee members received an update on the themes to-date from public comment and potential proposal changes based on the comments.

Summary of discussion:

The primary agenda item for the Committee's discussion involved the policy proposal *Amend Adult Heart Status 2 Mechanical Device Requirements* and the public comments submitted to the OPTN website and provided during the regional meetings about the proposal. Information was shared with the members illustrating sentiment about the proposal classified by OPTN region and OPTN member type. (Regional meeting sentiment is intended to reflect the OPTN member organizations' intensity of support or opposition to a proposal. However, it is not intended as a vote of approval or rejection.) At this stage of public comment, eight regional meetings had been completed. Of the regions that had met, the sentiment intensity was generally supportive of the proposal. The vice chair stated that Region 5 attendees benefited from the information included in the presentation, because it addressed many of the early concerns about the impact of the proposed changes.

Before discussing the general themes identified from the public comments, OPTN Contractors staff shared information about the types of changes to the policy proposal that the Committee can make based on the concept of 'logical outgrowth.' Specifically, it must be demonstrated that the OPTN community was given fair notice of the proposed change, such that the community could reasonably anticipate what would be the final version of the policy proposal. Additionally, the final policy proposal needs to demonstrate that it is an outgrowth of the initially proposed policy, and not only an outgrowth of the comments. Contractor staff shared the targeted questions that were included in the public comment proposal and pointed out that regional meeting comments and comments submitted to the OPTN website aligned with the questions. The feedback provided by the community matched well with the questions in the proposal.

Following the discussion of logical outgrowth, OPTN contractor staff presented the general public comment themes to the Committee, as well as potential changes to the policy proposal that the members might want to consider as a result of the themes. The three main themes were:

- Whether there should be a pathway to having a percutaneous endovascular mechanical circulatory support device (MCSD) or intra-aortic balloon pump (IABP) implanted for patients not on inotropes,
- The concern regarding candidates experiencing arrhythmias because of inotropes, and
- Increased specificity addressing the amount of time a candidate needs to be receiving inotropic therapy in order to qualify for initial assignment at status 2, and the time on inotropes to qualify for a status extension.

Additional public comments addressed concerns associated with the use of a LVAD as bridge-to-transplant and that the proposal is too prescriptive about how transplant programs should manage their patients' care.

OPTN Contractor staff told the Committee that the goal for today was not necessarily to determine what the final policy language should be, but more about whether the Committee members are interested in exploring such a change in more detail.

The Committee members first discussed whether a pathway to having a percutaneous endovascular MCSD or IABP implanted is needed for patients without requiring the patient to fail inotropic therapy in order to qualify for adult heart status 2. It was previously suggested that the Committee might want to consider allowing candidates to initially qualify at status 3 under such circumstances. A Committee member explained the option for consideration. For example, if a candidate is receiving single, low dose inotropic therapy, but the candidate's clinical situation is not stabilized by the therapy, should a pathway be created in status 3 for such a candidate to receive a percutaneous endovascular MCSD or IABP? The member raised the question as a potential way to decrease exception requests, because a transplant program is going to submit an exception request for a candidate who is receiving inotropic therapy but is still failing clinically and does not meet the proposed status 2 eligibility criteria. Without an option to assign candidates who are experiencing the described circumstances to a lower priority status, the volume of submitted exception requests is going to increase substantially. As a result, the proposed policy change may not accomplish what the Committee is intending. A member stated that there are some patients who are potentially less sick than someone with a percutaneous endovascular MCSD or IABP, who are sicker than patients on inotropes, but who are not sick enough to qualify for status 2. Unfortunately, there is no place currently to assign those candidates.

The members were reminded that the purpose of this proposal was to better align assignments to adult heart status 2 with the high medical urgency that status 2 was initially intended to capture. In order to accomplish the purpose, the Committee landed on using eligibility criteria that already exists in adult heart status 3 policy to demonstrate the candidate failed status 3 criteria and then the program can provide a justification for assigning the candidate to status 2.

A member asked whether status 3 was possible if the candidate did not meet the status 2 requirements but was on temporary, mechanical support. Other members stated that is not the case. Under current policy, assignment at status 3 is only possible if a candidate was already assigned to status 2 using the criteria for percutaneous endovascular MCSD or IABP and the transplant program chose not to extend the assignment or the extension request was denied.

It was also pointed out that much of the current environment with exceptions is the responsibility of the members of the Regional Review Boards (RRB). It was stated that the RRBs need to start making

decisions that are more closely aligned with the existing criteria, and stop granting every exception request. It was recommended that in addition to the policy proposal, creating guidance to help the RRB members adjudicate exception requests is also needed. Because whatever granularity the Committee comes up with, there will be push back from parts of the community because the granularity won't match some clinical scenario. Additional RRB guidance could take the form of communicating information such as, what is an acceptable attempt at providing inotropic therapy, and what is a truly dangerous arrhythmia. A Committee member stated that due to the amount of time it takes RRBs to make decisions, there may also be an uptick in the number of candidates who are transplanted at a denied status. It was mentioned that the educational offerings to the RRB members should be improved to make clearer that the members are responsible for enforcing the criteria. A Committee member also commented that, perhaps each of the regional representatives on the Heart Committee ought to proactively and preemptively meet with the members of the RRBs to emphasize the importance of the criteria in policy and guidance to head off the types of exception requests the Committee discussed today.

The members strongly indicated their belief that there would be fewer exception requests and approvals if the previous exception review process was adopted under which review boards reviewed the requests submitted within their own regions and transplant programs had to make their case for an exception as part of a conference call involving the review board members.

Another member stated that the Committee should not be so concerned about the potential for an increase in exception requests that the Committee does not move forward with the policy. The Committee should still move forward with the proposed changes, and then make adjustments as necessary in the future.

The members also briefly discussed the public comments regarding how the policy changes might impact candidates with arrhythmias. It was pointed out that adult heart status 2 policy already addresses ventricular tachycardia (VT) and ventricular fibrillation (VF); however, it was mentioned that the eligibility criteria within that policy is very strict for a patient who is already on inotropic therapy. A Committee member asked whether the policy proposal should include the existing, standard definition of sustained ventricular tachycardia (VT) being 30 seconds or longer? It was suggested that the proposal could be amended to include something like “a contraindication to chronic inotropes is inotrope induced sustained VT greater than 30 seconds with a normal potassium (K) and magnesium (Mg).”

Next steps:

OPTN Contractor staff pointed out that the Committee had identified how the proposal might be amended for clarity and how certain public comments might be addressed. The Committee has indicated that increased guidance to RRB members and the heart transplant community generally will be beneficial, along with greater clarity of the eligibility criteria, but not changing the current version of the policy proposal.

2. OPTN Efficiency Task Force

A short summary of the task force’s objectives was provided. The objectives include prioritizing ways of decreasing non-use of donor organs, identifying ways to scale up and replicate successful OPTN member processes, and establishing consistency in allocation practices. Actions the task force might include are: updating or clarifying existing processes in OPTN policies, addressing new processes where no policies exist, and modifying programming to systems, tools, and reports.

A question was asked about the status of the Committee’s project idea to address the concerns associated with candidates’ lengthy time on the waitlist assigned to adult heart status 4 with a Left

Ventricular Assist Device (LVAD). Members of a subcommittee have been identified, but a project form has not been completed and submitted to the Policy Oversight Committee for review and approval.

At this point, it is unclear how many meetings would be necessary to produce a thoroughly documented and researched project form that can be submitted to POC. Whether the project will move forward is also influenced by the decisions and priorities of the efficiency task force. The task force is looking across all of the OPTN Committees for opportunities to improve efficiency in allocation, and while such opportunities are pursued, may ask for other project work to be paused. Because the task force's priorities are still being worked out, it is too early to tell what impact those decisions will have on future project activity.

3. Reminder of 09/22 in-person meeting and closing remarks

The Committee members were reminded of the in-person meeting scheduled for 09/22/2023 in Detroit, Michigan. Because of the date of the in-person meeting, the Committee's meeting that was scheduled for 09/19/2023 was cancelled. Members were asked to check their calendars and confirm that the 09/19 meeting was not appearing. If it is, members should email the OPTN Contractor staff.

Upcoming Meetings

- September 22, 2023 – In-Person Meeting (Detroit, MI)
- October 4, 2023 – 4:00 pm
- October 17, 2023
- November 1, 2023 – 4:00 pm
- November 21, 2023
- December 6, 2023 – 4:00 pm
- December 19, 2023

Attendance

- **Committee Members**
  - J.D. Menteer, Vice Chair
  - Tamas Alexy
  - Kim Baltierra
  - Jennifer Carapellucci
  - Jennifer Cowger
  - Timothy Gong
  - Eman Hamad
  - Jennifer Hartman
  - Glen Kelley
  - Cindy Martin
  - Nader Moazami
  - Cristy Smith
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Monica Colvin
  - Grace Lyden
- **UNOS Staff**
  - Alex Carmack
  - Terry Cullen
  - Cole Fox
  - Emily Howell
  - Shelby Jones
  - Lindsay Larkin
  - Kelsi Lindblad
  - Alina Martinez
  - Lauren Mauk
  - Eric Messick
  - Rebecca Murdock
  - Susan Tlusty
  - Kim Uccellini
- **Other Attendees**
  - Shelley Hall
  - Stephanie DeLair
  - Stephanie Taylor