OPTN Thoracic Organ Transplantation Committee
Heart Subcommittee
Meeting Summary
February 27, 2020
Conference Call

Shelley Hall, MD, Subcommittee Chair

Introduction

The Thoracic Committee's Heart Subcommittee met via Citrix GoTo teleconference on 02/27/2020 to discuss the following agenda items:

1. Public Comment Update
2. Separate Heart and Lung Committees
3. Presentation of *One-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System*
4. Future Meeting Dates

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

1. Public Comment Update

UNOS staff provided an update on public comment, noting that response to the National Heart Review Board for Pediatrics proposal has been positive. UNOS staff said the OPTN has received detailed feedback that the Workgroup will need to go through after public comment closes on March 24, 2020. UNOS staff shared the schedule of presenters for the remaining regional meetings.

2. Separate Heart and Lung Committees

UNOS staff notified the Subcommittee that the OPTN Board of Directors will vote on the establishment of separate heart and lung committees on March 10, 2020. If approved, implementation is projected for July 1, 2020, and the OPTN will initiate the committee nominating process for both.

3. Presentation of *One-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System*

UNOS staff briefed the Subcommittee on findings from the one-year monitoring report on changes to the heart allocation system. The report did not include data relating to the removal of donation service area (DSA) from allocation, which was implemented in January 2020. The slides from the presentation are available on the OPTN website at the following link:
https://optn.transplant.hrsa.gov/media/3662/subcommittee_presentation_022720.pdf

The main findings from the report are as follows:

- Use of venoarterial extracorporeal membrane oxygenation (VA ECMO) and intra-aortic balloon pumps (IABPs) increased in the post-implementation era
- There was no significant change in waitlist mortality post-implementation but the new statuses more accurately stratified candidates by medical urgency
- There was a dramatic decrease in median waiting time for medically urgent candidates
- Transplant rates increased for medically urgent candidates

- There was no significant difference in six-month graft or patient survival
- There were 300-400 exception requests per month, almost all of which were approved
- There was no clear impact on pediatric heart candidates

Summary of discussion:

The Subcommittee's discussion of the report focused on patient outcomes and status exceptions.

Patient Outcomes

The Chair said it was a positive sign that 6-month survival did not decline as it is usually a good indicator of 12-month survival. However, the report did not show the expected decrease in waitlist mortality. A member noted that six-month patient survival rates were almost as high for Status 2 recipients as for Status 4 recipients, whereas survival rates were worse for Status 1 and Status 3 recipients. The Chair asked the Subcommittee to consider whether their goal is equality in patient survival, no matter how sick the patient is, or if they should expect to see survival stratified by status at transplant. The Chair noted that the direction that policy is moving is towards equal survival rates, regardless of status.

Status Exceptions

The Subcommittee discussed the large increase in Status 2 exceptions and whether the Subcommittee should take further action to address this trend. The Chair noted that some of the candidates applying for Status 2 exceptions in the post-implementation era may not have submitted exceptions in the pre-implementation era because they would not have survived long enough on the waitlist to get a transplant, and instead received a durable ventricular assist device (VAD). The Subcommittee noted that there was a significant difference in the number of VAD patients that received transplants between eras, as about 80% of transplant recipients had a left ventricular assist device (LVAD) at transplant in the pre-implementation period compared to about 47% in the post-implementation period. A member expressed concern that this gives programs more incentive to apply for a Status 2 exception while keeping a candidate on a balloon pump instead of inserting a VAD. The Chair responded that since the number of donors is limited, the community has to decide whether to accept this incentive and transplant more Status 2 candidates, or whether the Subcommittee should take more action to control this trend in order to transplant more Status 4 candidates [which includes many VAD patients].

A member said that the Subcommittee needs to consider that candidates face increased risk of complications the longer they are on a VAD, which has a negative impact on their morbidity relative to other Status 4 candidates. The Chair noted that when the Subcommittee starts working on developing a heart allocation score, there is community interest in assigning points for duration of time on VAD because of that increased risk. This is similar to the policy for renal transplant, where candidates receive points based on length of time on dialysis.

Members identified additional data that would help inform their discussion. One member asked if there was information available on the reasons provided for exception requests, and whether the percentage of recipients who received transplants with exceptions was greater in the post-implementation era. UNOS staff noted that this information was outside the scope of the report. A member asked if it would be possible to analyze the waitlist mortality of Status 2 candidates to see if there was a difference between candidates supported by balloon pump versus those not on balloon pump. This data could indicate whether or not the current rate of exceptions is appropriate or if these candidates should be placed at Status 3, but the Chair said it would be challenging to interpret. UNOS staff said that the sample size might be too small at this stage but this analysis could be conducted in the future.

The Chair expressed support for the Subcommittee's approach to address Status 2 exceptions through guidance that helps to standardize exception requests; clarify criteria indicative of VAD

contraindications; and ensure that patients are only placed on ECMO or IABP when they really need these devices. The Subcommittee also discussed other approaches to educating the community, like sharing examples of appropriate or inappropriate exception requests. The Chair said the Subcommittee needs to empower the regional review boards to ask for data and to decline exception requests if appropriate. The Chair noted that requiring transplant programs to submit the data listed in the guidance document may help, but UNOS staff noted that the guidance document will not impose a requirement for transplant programs to submit this information.

The Chair noted that another issue that should be addressed in the guidance document is to recommend that programs submit hemodynamic criteria within seven days of listing instead of within seven days of administering inotropes. The Chair explained that otherwise transplant programs may place candidates at risk by withholding inotropes until their hemodynamic criteria worsens, and that this situation applies to the bulk of the Status 4 exceptions group. The Chair suggested that the Subcommittee consider changing policy to require programs to submit hemodynamic criteria within seven days of listing rather than putting it into guidance. UNOS staff noted that such a policy change would need to go through the approval process as a new project.

A member brought up the issue of recurrent extensions for candidates at Status 1, 2 and 3, noting that candidates should not be "parked" on inotropes or on a device to maintain a certain status. The Chair asked about the possibility of limiting extension requests to one. UNOS staff noted that this would be a major policy change requiring public comment, and that policy changes typically are not made based on one year of monitoring data. UNOS staff suggested that the Subcommittee review data evaluating duration of status based on exceptions as a next step.

A member expressed concern about placing limits on exception requests, noting that the Subcommittee should not assume that IABP support is not in the best strategy for acutely ill patients. The member suggested that the current two-week designation for IABP support is somewhat arbitrary and that the Subcommittee does not have data to show whether patients who stay on IABP or patients who receive a VAD as a bridge to transplant have better outcomes in the long term. The Subcommittee agreed to continually assess this question to make the best use of available organs.

The Chair suggested that the Subcommittee move forward with the guidance document to keep a spotlight on this issue. UNOS staff noted that the Subcommittee can include questions for feedback when the guidance document goes out for public comment, including whether 14 days is the appropriate timeframe for IABP support for Status 2 candidates.

Next steps:

UNOS staff will share a draft of the policy proposal for the Status 2 exception guidance with the Subcommittee prior to the Thoracic Committee meeting on April 17, 2020. The goal is to release the guidance document in the fall public comment starting in August. The Chair asked Subcommittee members to provide examples of review board cases of exceptions or extensions that were either well-presented or poorly presented that can be included in a monthly email blast to educate the community.

Upcoming Meetings

- March 26, 2020
- April 17, 2020 in-person meeting