OPTN Thoracic Organ Transplantation Committee
Meeting Summary
April 17, 2020
Conference Call

Ryan Davies, MD, Chair
Erika D. Lease, MD, Vice Chair

Introduction

The Thoracic Organ Transplantation Committee (Committee) met via Citrix GoTo teleconference on 04/17/2020 to discuss the following agenda items:

1. Thoracic Committee Leadership
2. Public Comment Review: National Heart Review Board (NHRB) for Pediatrics
3. Policy Oversight Committee (POC) Update
4. Update on Heart-Specific Member Questions Related to COVID-19 Circumstances
5. Heart Subcommittee – Guidance for Exception Requests Related to Status 2 Candidates Supported by Intra-Aortic Balloon Pump (IABP)
6. Heart Subcommittee – Future Projects
7. Other Subcommittee Business

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

1. Thoracic Committee Leadership

UNOS staff welcomed Committee leadership and outlined upcoming leadership changes as the Committee separates into the Heart and Lung Transplantation Committees in July 2020.

2. Public Comment Review: National Heart Review Board (NHRB) for Pediatrics

The Chair led the Committee in a discussion of the NHRB for Pediatrics proposal, which will create a National Heart Review Board responsible for reviewing and determining status 1A and 1B exception requests for pediatric candidates. The Chair shared feedback received during public comment and proposed changes recommended by the OPTN Pediatric Heart Workgroup (Workgroup).

Summary of discussion:

The Chair shared that public comment sentiment was generally supportive, with no votes opposing the proposal. There was strong support for the creation of a NHRB for pediatrics with members with pediatric heart experience, given that the current lack of pediatric expertise leads to high rates of approval for exception requests. The OPTN Pediatric Committee, the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and The Organization of Transplant Professionals (NATCO) supported the proposal. There was general support for the plan to select reviewers through a randomized selection of members from programs that conduct pediatric heart transplants, though some comments suggested that board representation should be based on program volume or regional differences. In general, public comment feedback acknowledged the importance of resolving exception requests quickly and supported the proposed 3-day turnaround time for reviewing exception requests.

Based on public comment feedback, the Workgroup considered possible changes to operational programming to maintain consistency with other organ review boards; board composition; program size and geography as additional selection criteria for reviewers; metrics associated with removal for failure to vote in a timely manner; and the timing of reviews.

The Chair asked the Committee if they favored each program having a representative on the NHRB for Pediatrics, from which a subset of reviewers would be assigned for each request. An alternate approach would be to establish a review board of nine reviewers for two years, which would lead to less representation but perhaps more consistency in decision making. The Workgroup recommended allowing each program to have a representative on the review board. The Committee had no comments or objections to this approach.

The Chair asked the Committee if they agreed with the Workgroup recommendation that a NHRB Chair position is not needed at this time. The Workgroup felt that a chair would not be needed since a chair would primarily be helpful for leading conference calls, which will not be required under the new electronic voting system. Any outstanding appeals will be referred to a subgroup of the Pediatric and Thoracic/Heart Committees, which already have chair positions. There were no comments or objections from the Committee.

The Chair asked the Committee if they agreed with the Workgroup recommendation to incorporate diversity of program size as a criterion in the random selection of reviewers, such that there would be three reviewers each from small, medium, and large programs. A member expressed support for representation based on program size, since larger programs have a greater depth of experience. The Chair noted that Workgroup members from smaller programs also thought this approach would be useful since there may be differences in patient management between smaller and larger programs. There were no objections from the Committee.

The Chair asked the Committee if they support replacing a non-responsive reviewer with another randomly selected reviewer. This approach is more aligned with the voting practices of the National Liver Review Board, and UNOS staff recommended this approach for operational and programming consistency. Nine reviewers will be randomly selected from the overall pool, which includes a representative from each program. If one of the initial nine reviewers does not vote, the case will go to another randomly selected reviewer. Alternate reviewers from the same program will be used only if the primary is unavailable. There were no objections from the Committee.

The Chair asked the Committee whether they agreed that three days was the appropriate timeframe for a reviewer to submit a response. Committee members expressed support for this approach.

The Chair asked the Committee if they agreed that, if a representative misses more than three voting deadlines in a 12-month period, the Heart Transplantation Committee Chair may remove the representative from the NHRB. There were no objections from the Committee.

A member asked for an estimate of the number of reviews conducted each year. The Chair said that there are about 40 initial requests per year, but since extensions requests must be reviewed every two weeks, there are probably a few hundred total per year. Each reviewer will probably review 1 out of every 10 exception requests. The Chair said that the Committee may want to consider modifying policy in the future so that extension requests do not need to be reviewed every two weeks for cases that do not warrant review that frequently, like candidates who need to be placed at a status by exception due to their anatomy.

The Chair asked the Committee if they agreed with the Workgroup's recommendation for the same group of nine individuals to review subsequent appeals or extension requests following an initial case.

The Chair noted that while allowing different reviewers to see how others voted previously on a case may enhance the overall consistency of the NHRB, the Workgroup felt that it would be more efficient for the same set of reviewers to handle cases. There were no comments or objections from the Committee.

The Workgroup previously voted to submit the policy and operational guidelines with these revisions to the Committee, and recommended that the Committee submit the proposal to the OPTN Board of Directors (BOD) for approval at their June 8, 2020, meeting. A motion was made and seconded to submit the National Heart Review Board for Pediatrics proposal to the BOD in June 2020. The Committee voted and unanimously approved sending the proposal to the BOD (no abstentions).

Next steps:

The Workgroup is preparing a guidance document for the NHRB for Pediatrics which is expected to be released for public comment in August 2020 and submitted to the BOD in December 2020.

3. Policy Oversight Committee (POC) Update

The Vice Chair presented an update on the work of the POC. Members collaborating with other committees also gave an update on the progress of their workgroups.

Summary of discussion:

A member shared an update on the Multiorgan Workgroup. With the elimination of Donation Service Areas (DSAs) in allocation, all multiorgan policies need to be updated to provide more guidance to organ procurement organizations (OPOs) to improve consistency in multiorgan allocation. The guidance is based on recommendations from the Ethics Committee to ensure that multiorgan policies prioritize candidates with medical urgency. Committee members recommended to the Multiorgan Workgroup that candidates assigned to heart status 1, 2 or 3 that also need a liver should receive multiorgan offers within a 500 nautical mile (nm) radius. However, if the multiorgan candidates are assigned to a heart status greater than 1, the Workgroup proposed that the liver could be offered alone to a liver candidate assigned to status 1a, 1b, a MELD (Model for End-Stage Liver Disease) score of 35 or higher, or a MPaT (Median Pediatric End-Stage Liver Disease at Transplant) score of 35 or higher. The members also recommended that lung-liver candidates with a LAS (Lung Allocation Score) of 35 or 40 should be offered a liver within a 250 nm radius. The Multiorgan Workgroup will look at medical urgency issues for other heart and lung candidates next, and then move onto abdominal organs.

The Vice Chair shared that the Histocompatibility (Histo) Committee is interested in partnering on a project on sensitized candidates. The Histo Committee is working on a survey to gather sensitization information from thoracic organ transplant programs. The survey could inform data collection that could feed into the continuous distribution project. There will be opportunities for members from both committees to participate.

A member asked if there is any work looking at data collection on organ perfusion. The Vice Chair explained that POC did not select organ perfusion as a strategic priority for the OPTN at this time, but the Heart and Lung Committees still have the opportunity to work on projects that are a priority for members.

4. Update on Heart-Specific Member Questions Related to COVID-19 Circumstances

Members of the Lung Subcommittee were offered the opportunity to leave the meeting as the rest of the agenda focused on activities of the Heart Subcommittee (Subcommittee).

UNOS staff presented an update on OPTN actions related to COVID-19. UNOS staff also shared a summary of ongoing discussions between UNOS, the Subcommittee, and leadership regarding

hospitalization requirements for heart candidates to qualify for statuses 1, 2 and 3. UNOS received seven member questions between March 16 and April 10 asking whether the hospitalization requirement for Status 3 exception could be waived due to COVID-19 concerns. Prior to this meeting, Committee leadership, the Subcommittee, and the President of the BOD had all agreed that the hospitalization requirement should not be waived.

The Subcommittee Chair reiterated her stance, noting that status 3 is supposed to apply to candidates at imminent risk of death, and the risk of gaming would be substantial if the requirement were waived. Several Subcommittee members expressed their concurrence.

5. Heart Subcommittee – Guidance for Exception Requests Related to Status 2 Candidates Supported by Intra-Aortic Balloon Pump (IABP)

UNOS staff led the Subcommittee in a review of the draft guidance document for exception requests related to status 2 candidates supported by IABP.

Summary of discussion:

A member said it was confusing that Table 1 shows that 227 candidates were added to the waitlist at status 2 by exception, but Table 3 shows that 548 candidates received transplants while at status 2 by exception. Separately, the member recommended adding to the guidance document that a very small number of status 2 candidates ultimately transition to status 3, which shows that there is a problem with the exception process. The member also recommended using the same numbers consistently throughout the document and not to approximate (e.g. refer to 227 people vs. "approximately 220").

Under the recommendations section, it says that, "Without the sufficient, objective data identified in the guidance document, candidates will be appropriately categorized as status 3." UNOS staff asked the Subcommittee whether this statement could be read as a requirement instead of guidance. The Subcommittee Chair said that it is fine as written, as it just reiterates the existing policy that those who do not meet status 2 criteria drop to status 3. Another member suggested clarifying the language in the guidance document to indicate that it references existing policy.

A member asked what "Low SvO_2 PA sat" refers to under Section 2 of the document, and whether it refers to a central venous sample or a pulmonary artery sample. The Subcommittee Chair felt that a central venous sample would be appropriate but asked the Subcommittee whether pulmonary artery should be specified. The member suggested changing the wording to "low SvO_2 or PA sat" to provide the option to collect either sample. The Subcommittee Chair agreed with this language.

UNOS staff suggested providing an example of the evidence needed to demonstrate that a candidate applying for a status 2 exception has similar medical urgency to candidates who qualify for Status 2 by criteria, and/or to justify why the candidate needs a transplant sooner. The Subcommittee Chair agreed to work with UNOS staff on developing an example.

A member said that the last sentence in the conclusion, "However, the guidelines are not prescriptive of clinical practice," was unclear. The Subcommittee Chair agreed that it was already stated in the beginning of the document, and that the community understands that guidance documents do not mandate clinical practice. The Subcommittee agreed to remove this statement.

Next steps:

The Subcommittee Chair asked that members review the next draft so that it can be finalized for public comment. UNOS staff said that the Subcommittee will need to vote during their May 28th meeting to send the guidance document out for public comment from August to October 2020. The guidance

document would go to the BOD for review in December 2020, and would go into effect immediately following Board approval.

6. Heart Subcommittee – Future Projects

Status 4 Criteria

The Subcommittee discussed criteria for adult heart status 4 in relation to *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*. UNOS staff explained the history of the current policy language and noted that there has been some confusion from members regarding the criteria requiring "cardiac index of less than 2/2 L/min/m^2 within 7 days prior to submission of the *Heart Status 4 Justification Form*." A member said that the Subcommittee's intent is to indicate to transplant programs that candidates should not be weaned off of inotropes in order to conduct a right heart catheterization to prove that the patient has a cardiac index indicating cardiogenic shock. The member noted that the challenge is clearly expressing this intent in policy language. The Subcommittee proposed changing the language to "cardiac index of less than 2/2 L/min/m^2 within 7 days prior to inotrope administration or while on inotrope infusion as specified below."

A member proposed modifying the status criteria to be valid for 180 days. The Subcommittee Chair said that her program conducts a right heart catheterization every 90 days but asked members about their programs. Most members said that their programs use 180 days as a standard. A member said that their program uses 90 days but that 180 days is reasonable for the policy requirement.

Extension Criteria Requirements

The Subcommittee discussed member questions regarding inconsistent extension criteria requirements. For example, for candidates on IABP, the transplant program may apply to the review board to extend the candidate's status every 14 days if the candidate remains supported by the IABP. In contrast, for candidates with ventricular tachycardia (VT) or ventricular fibrillation (VF), the status can be extended by the transplant program every 14 days by submitting another *Heart Status 2 Justification Form*. The Subcommittee reviewed the policy language for the extension criteria for status 1 and status 2 candidates to identify sections that need clarification or standardization.

A member asked how many candidates in status 1 to status 3 were granted extensions based on the one-year heart allocation policy monitoring report.[1] UNOS staff reported there were 26 status 1, 286 status 2, and 192 status 3 candidates that had an extension at the time of transplant within one year.

Policy 6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)

The Subcommittee reviewed the policy, noting that if candidates fail to wean from ECMO, they can be extended if they continue to meet extension criteria. Theoretically, candidates can keep reapplying for the extensions, but most of the time they get too sick to keep extending while on ECMO. A member noted that the number of candidates who get a transplant while at status 1 by extension is pretty small. The Subcommittee agreed not to make any changes to this policy.

Policy 6.1.A.ii Non-dischargeable, Surgically Implanted Non-Endovascular Biventricular Support Device

The Subcommittee Chair asked surgeons in the group to explain what information should be provided in order to appropriately justify extending a candidate at this status, noting that there are no specific

[1] OPTN Thoracic Transplantation Committee. One-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System https://optn.transplant.hrsa.gov/media/3701/data_report_thoracic_committee_heart_subcommittee_20200227_rpt1_revised_508_compliant.pdf. Published 2020. Accessed April 17, 2020.

criteria listed in policy. A member said that there needs to be evidence that they are unable to move the candidate to a dischargeable device. Members agreed that all transplant programs should not be expected to have a full artificial heart. Members noted that this issue probably is not that common.

A member asked if the extension timelines should be standardized across heart statuses, since it is 7 days for ECMO and 14 days for this category. The Subcommittee Chair suggested that all status 1 extensions should be for 7 days. A member agreed that this process should be standardized. A member said that ECMO was 7 days because they were concerned about gaming and other devices were 14 days because they were surgical. Members agreed with changing the extension timeline to 7 days.

One member asked if this condition had a longer extension because these candidates have contraindications to a ventricular assist device (VAD). A member explained that this condition may need a bit more time to be ready for a transplant, because after 7 days, the candidate is just starting to recover from cardiogenic shock and the surgical interventions. The member was not opposed to changing one or the other so that the extension timelines are standardized. The Subcommittee agreed to add a requirement to the policy language for submission of a clinical narrative describing the candidate's need for an extension, including if the candidate cannot transition to a VAD. UNOS staff noted that some of the inconsistency lies in whether requests go to the regional review board. The Subcommittee Chair recommended that members talk to their peers to get a sense of whether these changes would be supported by the community.

Policy 6.1.A.iii: Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia

Currently, this status can be extended by the transplant program every 14 days by submission of another *Heart 1 Status Justification Form* if the candidate must remain hospitalized on continuous intravenous antiarrhythmic therapy. The Subcommittee Chair thought that there should be some sort of limit to this type of extension. A member responded that sometimes candidates really need those therapies. The Subcommittee Chair said that programs should be attempting to wean patients off those therapies. A member noted that the bar is pretty high to be in a position to get this therapy so these patients are pretty sick. The member thought that the likelihood that people are abusing this policy is low. UNOS staff noted that this is a small population of candidates. The Subcommittee agreed not to make changes to this policy, particularly since it is a small population of candidates.

Policy 6.1.B.i: Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)

The Subcommittee had no changes to this section as they are working on a guidance document to address candidates in this situation.

Policy 6.1.B.ii: Total Artificial Heart (TAH), BiVAD, Right Ventricular Assist Device (RVAD), or VAD for Single Ventricle Patients

The Subcommittee had no changes to this section as they agreed that candidates with these devices implanted should be assigned to status 2. The Subcommittee discussed whether any additional clarification was needed regarding BiVADs, and how that differs from the surgically implanted, non-dischargeable policy section. The Subcommittee agreed that it is appropriate for BiVAD to be called out separately in this section since a patient may have two devices inserted, one as an LVAD and one as an RVAD, which would be a dischargeable situation.

Policy 6.1.B.iii: MCSD with Malfunction

The Subcommittee had no changes to this section.

Policy 6.1.B.iv: Percutaneous Endovascular Mechanical Circulator Support Device

The Subcommittee noted that the guidance document being drafted for IABP candidates may also apply to this category, even though the IABP candidates are really driving the need for the guidance document. The Subcommittee agreed that the guidance document can be broadened to cover more status 2 candidates than just IABP, including this category of candidates.

Policy 6.1.B.v: IABP

This section of policy is being addressed by the guidance document.

Policy 6.1.B.vi: VT or VF

The Subcommittee Chair noted that the way the policy language is worded, the candidates need to meet the same criteria to submit another justification form for an extension, unless the Subcommittee wants to create a separate extension form. The policy language reads that the candidates must experience VT or VF episodes within every 14 days, but no new information needs to be submitted in the justification form. UNOS staff noted that the population of candidates in this category is small, and a member noted that it is hard for candidates to meet these criteria. The Subcommittee agreed to add policy language clarifying that a candidate qualifies for an extension under this section of policy if the candidate remains on intravenous (IV) antiarrhythmics.

Next steps:

At the next Heart Subcommittee meeting on April 23rd, the Subcommittee will continue reviewing extension criteria for heart statuses 3 through 6. Following the extension criteria review, the Subcommittee will finalize the guidance document regarding status 2 exceptions, which will be expanded to apply to candidates with percutaneous devices.

7. Other Subcommittee Business

The Subcommittee Chair noted that with the upcoming expansion of the Heart Subcommittee to a full Heart Transplantation Committee, there will be a lot more representation from members around the country. The Subcommittee Chair said that since this will add more opinions to the discussion, the work may move more slowly on some of the projects, but this will ultimately make for better policy.

Upcoming Meetings

- April 23, 2020 – Heart Subcommittee
- May 28, 2020 – Heart Subcommittee

Attendance

- **Committee Members**
  - Ryan Davies, Chair
  - Erika Lease, Vice Chair
  - Marie Budev
  - Staci Carter
  - Rocky Daly
  - Greg Ewald
  - Shelley Hall
  - Jonathan Hammond
  - Matthew Hartwig
  - Steven Kelban
  - Arun Krishnamoorthy
  - Jasleen Kukreja
  - Donna Mancini
  - Dan McCarthy
  - Mike McMullan
  - Tania Sherrod
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Monica Colvin
  - Melissa Skeans
  - Maryam Valapour
- **UNOS Staff**
  - James Alcorn
  - Nicole Benjamin
  - Julia Chipko
  - Craig Connors
  - Shannon Edwards
  - Rebecca Goff
  - Lauren Mauk
  - Eric Messick
  - Elizabeth Miller
  - Janis Rosenberg
  - Leah Slife
  - Kaitlin Swanner
  - Susan Tlusty
  - Sara Rose Wells
  - Amber Wilk
- **Other Attendees**
  - Champa Andresen
  - Selim Arcasoy
  - Alan Betensley
  - Masina Scavuzzo

- Stuart Sweet