

**OPTN Thoracic Committee
Pediatric Heart Workgroup
Meeting Summary
April 7, 2020
Conference Call**

Ryan Davies, MD, Chair

Introduction

The Pediatric Heart Workgroup of the Thoracic Committee met via Citrix GoTo teleconference on 04/07/2020 to discuss the following agenda items:

1. Public Comment Update
2. Discuss Certain Operational Components Identified in the National Heart Review Board (NHRB) for Pediatrics Proposal

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

1. Public Comment Update

UNOS staff shared an overview of the feedback received during the public comment period on the NHRB for Pediatrics proposal. The Workgroup did not have any questions or comments.

2. Discuss Certain Operational Components Identified in the NHRB for Pediatrics Proposal

The Chair led the Workgroup in a discussion of operational components to consider modifying in the NHRB for Pediatrics proposal based on feedback received via public comment.

Summary of discussion:

The Workgroup discussed whether each pediatric heart transplant center should have a representative on the NHRB for Pediatrics with a subset of nine program representatives reviewing each request. A member asked for clarification about how the nine reviewers would be selected and expressed concern about consistency. UNOS staff said that the recommended approach for consistency across review boards is to use the National Liver Review Board's (NLRB) model as a guide, in which all programs have a primary representative with the opportunity to be selected for any given case. The Chair noted that one dramatic difference between the NLRB and NHRB for Pediatrics is that the NLRB does not include a representative from every center. UNOS staff clarified that every liver transplant program has an opportunity to assign a reviewer to each of the three liver review boards, though not every program has opted in. For the NHRB for Pediatrics, the nine reviewers would be selected by random from the national pool of reviewers. If a reviewer does not vote in the designated time frame, they would be replaced by someone else in the pool who would also be randomly selected. The Workgroup supported this approach.

The Workgroup discussed whether the NHRB for Pediatrics should have a chair who serves for longer than the one-year term of the representatives. The Workgroup Chair noted that having a chair of the NHRB could provide some consistency across reviews. The Chair asked the Workgroup to consider whether this chair should serve at the discretion of the Heart Committee Chair for up to two years, and if the chair should vote on all cases. Alternatively, the NHRB for Pediatrics chair could vote on any ties and guide phone calls as needed. A member noted that it seems like a good idea on paper but that it

would be hard to find someone with the requisite experience and the time to fill this role. Another member said that a chair can be helpful as a voice of guidance and consistency for the regional review boards when cases go to a phone call on appeal, but that a chair may not be necessary for the NHRB for Pediatrics since the voting will be handled electronically. UNOS staff noted that cases only go to a phone call at the highest level of appeal, which is a workgroup of the Thoracic Committee. The Workgroup decided that the NHRB for Pediatrics does not need a chair.

The Workgroup discussed whether geography or program size should be considered for representation on the NHRB for Pediatrics to ensure some degree of diversity. The Chair noted that geographic diversity could not be defined by region since one region only has one program, but said that one option would be to ensure representation from programs east of the Mississippi River and west of the Mississippi River. A member said it was important to have representation from larger-volume centers, intermediate-sized programs, and smaller programs on all review boards to ensure a diverse range of experience. Another member said that program diversity is important, particularly if larger centers are more prone to suggest inserting a ventricular assist device (VAD) instead of granting an exception, when smaller programs might not be comfortable with that approach. The member said that program diversity is more important than geography. UNOS staff noted that UNOS does not currently have a method of defining or identifying programs as small, medium and large. The Chair suggested that the groups could be defined by transplant volume over the last three years; that the group assignments could be updated every three years; and during that time period, every review board would have three members from each of those three groups. The Workgroup members agreed that review boards should have diverse representation based on program size.

The Workgroup discussed the voting process. The Workgroup agreed that a non-responsive reviewer would be replaced by another randomly-assigned reviewer if the vote is needed, rather than switching from a primary reviewer to an alternate reviewer at the same center. The Chair noted that it is up to the program to report that their primary representative is not available so that cases can be assigned to the alternate representative from their center. The Workgroup also discussed the timeframe for voting and how long reviewers have to submit a response. UNOS staff noted that NLRB members have seven days to respond to exception requests, though the mean response time is five days. The Workgroup agreed that three days is a reasonable timeframe for the NHRB for Pediatrics because they want a quick response time on these cases. One member suggested that UNetSM send daily reminder emails when a vote is pending, and UNOS staff confirmed that this would be an option.

The Workgroup discussed the threshold for removing reviewers from the NHRB for Pediatrics. There was general agreement in public comment that missing three voting deadlines within a 12-month period is an appropriate threshold for removal from the NHRB for Pediatrics, though the NLRB is currently proposing new criteria that uses missing “more than 5% of the cases assigned” as the threshold for removal. The Chair suggested using three misses. A member agreed since 5% could only be one case for some members. The Workgroup agreed that this is reasonable.

The Workgroup discussed whether the same group of nine reviewers would follow the case through the process, including extension requests. The Chair noted that a benefit to sending the case to the same reviewers is that it may promote quicker response time due to familiarity with the case, but the benefit with sending those cases to a new set of reviewers could lead to broader consistency by allowing reviewers to see how others are voting on cases. The Chair said it is probably more efficient to have the same group of reviewers on extension requests, particularly if the group is reviewing requests every two weeks for candidates with anatomy that qualifies them for subsequent extensions. The Workgroup agreed with this approach.

With these decisions made, the Workgroup voted unanimously to send the proposal forward to the Thoracic Committee.

Next steps:

UNOS staff will follow up on the possibility of implementing program diversity in review board representation. The Thoracic Committee will vote at their meeting on April 17 to send the proposal to the OPTN Board of Directors for approval in June 2020.

During their next meeting on April 28, the Workgroup will continue reviewing guidance for pediatric heart exception requests. The Chair will send an updated draft in advance of the call.

Upcoming Meetings

- April 17, 2020 – Thoracic Committee meeting
- April 28, 2020 – Workgroup meeting