

**OPTN Thoracic Organ Transplantation Committee
Pediatric Heart Workgroup
Meeting Summary
April 29, 2020
Conference Call**

Ryan Davies, MD, Chair

Introduction

The Pediatric Heart Workgroup of the Thoracic Organ Transplantation Committee met via Citrix GoTo teleconference on 04/29/2020 to discuss the following agenda items:

1. Discuss Potential Transition Procedures for National Heart Review Board for Pediatrics Proposal
2. Pediatric Guidance Document

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

1. Discuss Potential Transition Procedures for National Heart Review Board for Pediatrics Proposal

To meet requirements of the OPTN Final Rule for revisions to organ allocation policies, UNOS staff asked the Workgroup to consider whether a transition procedure is necessary for implementation of the National Heart Review Board (NHRB) for Pediatrics proposal. UNOS staff asked the Workgroup (1) whether there are any groups/populations that may be treated less favorably under the policy changes, and if so, (2) whether a transition procedure for these populations is necessary.

Summary of discussion:

The Chair noted that the purpose of the proposal is to ensure that the most medically urgent candidates are getting exception requests. A member asked if there would be a way to assess whether anyone who did not receive an exception prior to the policy change would receive an exception after the policy change. The Chair recommended encouraging transplant programs to apply again for exceptions after the NHRB is implemented if they feel that a candidate was inappropriately denied an exception under the Regional Review Board (RRB) infrastructure. UNOS staff affirmed that UNOS can send a notice to members with this recommendation. The Chair and UNOS staff noted that the current population of people with pending exceptions is very small – only four candidates. The Workgroup did not have any further concerns or recommendations.

The Chair explained the transition plan for cases that are open at the time of implementation, noting that UNOS will remove those cases from RedCap and redistribute them through UNetSM. UNOS will notify NHRB members of the cases and the potential for short decision timelines. All new requests will then be routed through UNetSM.

Next steps:

UNOS staff will ensure the appropriate communications are sent to OPTN members prior to and during implementation of the NHRB for Pediatrics.

2. Pediatric Guidance Document

The Chair led the Workgroup in a discussion of the draft pediatric guidance document, including guidance for single ventricle heart disease candidates, re-transplant candidates, and other categories.

Summary of discussion:

Single Ventricle Heart Disease Candidates

The Chair explained that he has been contacted regarding incongruity in current policy for single ventricle candidates. A candidate who is listed at 17 years old as a Fontan, without being on inotropes in the hospital, is assigned to pediatric status 2, but if the candidate is 18 years old at the time of listing, the candidate is assigned to adult status 4, which is broadly equivalent to pediatric status 1B. The Chair asked the Workgroup if pediatric Fontan candidates should be listed at pediatric status 1B, since very few candidates get transplants at pediatric status 2. The Chair noted that most of these candidates either get approved for pediatric status 1B by exception, or the candidates receive an exception for pediatric status 1A after being admitted to the hospital and administered inotropes.

The Chair explained that he wrote the guidance broadly so that if the candidate is admitted and experiencing complications, then pediatric status 1A is appropriate, but if the candidate is not admitted but is a Fontan with complications like PLE (protein-losing enteropathy) or plastic bronchitis, then pediatric status 1B is appropriate. The Chair noted that these recommendations are not based on knowing the waitlist mortality of this category of candidates but are in response to concerns expressed to the Chair. The Chair noted that candidates who are age 18 and older who have congenital heart disease have waitlist mortality more similar to pediatric status 1B candidates than to other candidates in adult status 4, which is broadly equivalent to pediatric status 1B.

A member noted that the guidance document for adult congenital heart disease says that single ventricle candidates admitted to the hospital with complications like PLE can be upgraded to status 3 by exception. The member asked how adult status 3 compares to pediatric heart classifications. The Chair said status 3 is roughly equivalent to the bottom half of pediatric status 1A, which is why he thought pediatric status 1A would be the right classification for this category of candidates, though he noted that it may be too aggressive. Members agreed with this approach, noting that this would be a small population of patients, many of whom would already be in the hospital and qualify for a higher status by meeting other criteria.

The Chair noted that he did not list Fontan explicitly in the draft guidance and asked if the category should be broadened to include all congenital heart patients, but said that might be too broad. The Chair noted that there are particular challenges with transplanting sick Fontan patients, and while the population of Fontan candidates admitted to the hospital but not on inotropes is small, the preference is generally to get them a transplant sooner rather than waiting for them to decline to the point that they need inotropes. A member agreed, noting that there is a window of frailty in which they quickly become unsuitable candidates from a surgical standpoint. The Chair noted that if these candidates are not assigned a higher status before they are admitted to the hospital with inotropes, then the post-transplant survival for these candidates may be low. Members agreed, noting that donor selection for these candidates is tighter due to previous surgeries and reconstruction, and many of these candidates have antigens.

A member asked whether there is any other congenital heart disease other than single ventricle that could have a complication that places a candidate in the hospital but not on inotropes. A member suggested that restrictive candidates may fall into this situation, but those candidates are generally younger, sick, and not in quite in the same situation as a late adolescent. The Chair noted there are a lot of congenital patients who aren't explicitly covered by policy and merit exceptions, but since the cases can be so heterogeneous, the NHRB will help with figuring out the appropriate exceptions.

Re-transplant Patients

The Chair asked whether the Workgroup should provide guidance for assigning higher status to re-transplant patients, or if it is too hard to provide guidance to review boards for re-transplant candidates because the cases are too variable. The Chair said that re-transplants are assigned to pediatric status 2 unless they qualify for higher status by other means, noting that it may be appropriate to leave these cases to the review boards as they may be too hard to categorize. The Chair noted that re-transplant candidates are often physiologically like restrictive candidates, so the criteria used in the guidance for restrictive candidates may apply to re-transplant candidates. A member said that the re-transplant patients that are really ill and need a lot of support are those who have suffered an arrest event, and if they survive one arrest event, they are not likely to survive a second. The member said that it might be hard to provide guidance on this issue but it is an important consideration. A member agreed that arrest might warrant a 1A exception, and suggested that 1B could apply to candidates experiencing other symptoms suggesting that they are close to cardiac arrest, like non-sustained ventricular arrhythmias or unexplained syncope. Another member suggested considering the candidate's level of sensitization, or some measure of graft vasculopathy or percentage of coronary artery disease, that would warrant a 1B or 1A exception before the candidate is administered inotropes or considered for a high-risk VAD.

The Chair suggested that the Workgroup draft guidance for re-transplant patients and solicit feedback. The Chair said it can be challenging to incorporate sensitization but he would look into including something on graft vasculopathy. The Chair said it is worth trying to include something in the guidance document for re-transplant candidates, and if it is not favorably received in public comment, then the Committee can remove it.

Other Categories

The Chair asked the Workgroup whether there are any other categories of patients that should be included in the guidance document. A member asked whether there are any dual-organ scenarios that should be addressed, like heart-lung. Currently, the heart must pull the lungs, so the candidates generally must be assigned to pediatric status 1A to get a good lung offer. The member noted that a candidate from their transplant program in this situation did receive an exception. A member noted there are challenges with heart-liver patients as well, particularly in candidates with advanced liver disease. The Chair agreed that dual-organs are a challenge, and said that there is not a lot of guidance on this topic because there are a lot of factors that go into it. UNOS staff noted that there are other projects looking into multiorgan allocation, including thoracic organs. A member noted that taking a multi-disciplinary look at this issue is outside the scope of the Thoracic Committee.

Next steps:

The Chair said he will send an updated draft to the Workgroup prior to the next meeting on May 26, which is the Workgroup's last chance work on the guidance document before it goes to the Thoracic Committee for a vote to release for public comment in August 2020. The Chair noted that the Workgroup will not need to meet regularly once the guidance is released for public comment, but that the Workgroup should reconvene following public comment to review feedback and make changes as necessary.

Upcoming Meeting

- May 26, 2020