OPTN Heart Transplantation Committee
Meeting Summary
March 21, 2023
Conference Call

Richard Daly, MD, Chair
JD Menteer, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee, the Committee, met via Citrix GoTo teleconference on 03/21/2023 to discuss the following agenda items:

1. Continuous Distribution: Consideration of Pediatric Medical Urgency
2. Status update: Public comment feedback regarding ABOi Offers Proposal
3. Closing Comments

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

1. Continuous Distribution: Consideration of Pediatric Medical Urgency

The Vice Chair presented on pediatric medical urgency as it pertains to continuous distribution and the medical urgency attribute. The Committee will review adult medical urgency at a later, as yet unspecified, date.

Summary of discussion:

The Chair noted that pediatric medical urgency in heart does not clearly align with adult medical urgency, and the Vice Chair had been working on how best to approach pediatric medical urgency. The Chair introduced the Vice Chair to present the findings and recommendations.

The Vice Chair began the presentation by asking Staff to review the topics for consideration regarding continuous distribution. These topics include the size of the impacted population, where consensus exists around proposed solutions, what data the OPTN currently collects, and the impact this could have on other organs. For pediatric medical urgency the consideration was: should the concept of addressing pediatric medical urgency as part of overall medical urgency be addressed in this version of Continuous Distribution of Hearts? Staff then reminded the Committee they are addressing pediatric medical urgency as part of the overall medical urgency attribute in this version of continuous distribution.

The Vice Chair noted that along with members of the Committee, the OPTN Pediatrics Committee and members of the Pediatric Heart Transplant Study Group were also included in the group that developed these recommendations. These groups were included in order to gain their buy-in early in the process and to access data they might have that the Committee may not have on hand. The Vice Chair reiterated that there will be one medical urgency attribute that merges pediatric and adult medical urgency in continuous distribution. Medical urgency will be one of five attributes used to match donors and recipients in continuous distribution, the others being post-transplant survival, candidate biology, patient access, and placement efficacy. The current pediatric urgency status systems differs significantly from the current adult system. The Committee is seeking to improve allocation fairness by improving comparability of the two systems with each other. If no changes are made, the pediatric urgency status

1A will be mapped to a certain number of points in continuous distribution, likely more than an adult status 3 but less than adult status 1.

The Vice Chair continued, that each attribute is then assigned a weight for how much impact it can have on the overall score of a candidate in continuous distribution. They explained further that, historically, heart has weighed medical urgency higher than other organs groups and they would be allowed to do so in continuous distribution. The Vice Chair did note that at this point in the development on continuous distribution the Committee is not considering the weight, of an attribute just the components making up the attribute. The Vice Chair then explained that points do not have to be given in a strictly linear fashion. They can be assigned on a curve, capped, and other non-linear fashions, but at this point in the process the Committee is not developing a rating scale but is instead developing an attribute for a concept paper.

The Vice Chair explained the process the group followed in considering pediatric medical urgency. The group began by aligning adult status based on medical urgency and then inserted where they believed pediatrics would fit on that scale and where there would need to be a split. For example, status 1A in pediatrics would be below status 1 for adult, but above certain status 2 criteria depending on factors like waiting time and distance. The group discussed the fact that since there is a status 1 for adults that would get all the medical urgency points, perhaps there should be a pediatric status that would do the same. Committee leadership has been operating with a linear curve in mind for medical urgency, with the most urgent getting more points and a decrease in points for less medically urgent based on pre-transplant mortality.

The Vice Chair explained that based on mortality data, the group was able to identify a pediatric group that should have full medical urgency points. The group would consist of pediatric candidates on extracorporeal membrane oxygenation (ECMO), single ventricular assist devices (SVAD), ventricular assist devices (VAD) with life threatening arrhythmias. This was used as a starting point. The group then began to sort other pediatric candidates on to the scale.

The group then examined current guidance for pediatric heart exception request. Currently a pediatric candidate with dilated cardiomyopathy on inotropes is thought to align with status 1B. The group carved out this pediatric group of candidates who are under five kilograms as a single group because they have approximately 40 to 50% VAD mortality rate and should therefore be status 1A. Additionally, candidates under ten kilograms, roughly the size of a typical one year old, who are supported on high dose inotropes and who have other qualifications like renal insufficiency may also qualify for status 1A. Similarly, if the candidate has hypertrophic cardiomyopathy and they are on inotropes with high PVR along with other risk factors they too would be status 1A.

If the candidate has single ventricle congenital heart disease (CHD) and is experiencing complications from CHD (including but not limited to: protein-losing enteropathy, plastic bronchitis, or Fontan circuit thrombosis) and they are admitted to the transplant hospital they may qualify for status 1A. If the candidate has been palliated through a Fontan procedure and has ongoing complications of the Fontan and is actively receiving therapy for that complication but not require hospital admission, they may qualify for status 1B. If the candidate has prior heart transplant and evidence of chronic rejection or significant coronary allograft vasculopathy and a history of recent cardiac arrest, or signs or symptoms placing patients at high-risk for sudden cardiac death, they may qualify as status 1A. Yet if they have a history of revascularization (either surgical or transcatheter) for coronary allograft vasculopathy they may qualify as status 1B.

The group also looked at the guidance for adult hypertrophic/restrictive (HCM/RCM) cardiomyopathy exceptions request in an attempt to align pediatric guidance. Adults with CHD and no other qualifiers

can be adult status four, and the group tried to align pediatrics the same way. This was done to remove any advantage to listing a candidate before or after their eighteenth birthday.

The group developed a linear curve that aligned certain pediatric patients with adult statuses based on waitlist mortality for medical urgency:

- Adult Status 1; pediatric candidates on ECMO, SVAD, VAD with life threatening arrhythmia
- Adult Status 2; pediatric candidate with CHD on inotropes, Ductal dependent Single V (stent or PGE1), Inotrope and vent dependent, nondischargeable VAD, Poor VAD cand: RCM/HCM inpatient <10kg, inotropes inpatients <10kg; Severe CAV inpatient, RCM/HCM on HD inotropes or syncope etc or PVR>6 Wui, single ventricle other complications inpatient
- Adult Status 3; pediatric Inpatient dischargeable VAD, DCM high dose inotropes inpatient, HCM/RCM inpatient other, Outpatient VAD, < $1.3m^2$
- Adult Status 4; pediatric Outpatient VAD, < $1.3m^2$
- Adult Status 5; pediatric Multiple organ listing, not meeting higher criteria.
- Adult Status 6; Other pediatric candidates, not meeting higher criteria.

The Vice Chair noted the group tried to use evidence-based information and expert opinions when forming this curved ranking. They also tried to make small incremental changes that are understandable. The Vice Chair then reviewed the one-pager explaining the medical urgency for pediatric candidates which contains all the previous mentioned information.

Several committee members commented how easy the information is to understand and thanked the Vice Chair for presenting the information.

The Chair reminded the Committee that they have not yet determined what kind of scale they are going to use for medical urgency in continuous distribution, but this sets up an exponential curve. They also pointed out that it makes sense to keep all the criteria lumped together, but they do not have to, this is just a starting point for the first version of continuous distribution.

Staff asked the Vice Chair to elaborate on the expert opinions that were used by the workgroup. The Vice Chair responded that in an effort to find the top 5% of high-risk pediatric candidates, mechanical devices continuously raised to the top because they can be difficult to place. Additionally waiting time is often an issue with pediatrics. These were expert opinions used to place this group of pediatric candidates at the top of the medical urgency scale. As was the expert opinion on outpatient VADs which was used to inform the group on how these machines work, especially for small patients. The group did not want to put these patients down in status four but it was clear they should not be at the top, expert opinion was important in placing these patients and where the cutoffs should be.

A member pointed out that these are just concepts, and weights and rating scales have not been established. These concepts were developed for the forthcoming public comment paper.

The Vice Chair asked if the committee should vote on this now, or if they should wait so the committee has more time to examine the one pager and then vote at the in-person meeting. The Chair asked the Committee if anyone felt like they need more time for review. One member respond that they do not need more time, and the placement of each status makes sense. No other committee member commented. Staff suggested the Committee should vote now rather than later. The Chair asked for a motion, which was made.

The vote to include the pediatric medical urgency component within the Medical Urgency Attribute for Continuous Distribution of Heart was unanimous.

2. Status update: Public comment feedback regarding ABOi Offers Proposal

Staff provided a status update regarding the Committee ABOi Offers Proposal.

Summary of discussion:

Staff provided some background information about the ABOi offers proposal that had been out for public comment in the most recent cycle. The proposal received strong support from the public. One pediatric transplant program reached out with a request for an urgent exception or appeal pathway to allow a candidate to immediately receive ABOi offers; this was for a current status 1A candidate over two years old and willing to accept an ABOi offer. This candidate would qualify under the policy proposal but not under the current policy at that time. OPTN Presidents were supportive of quick action to implement aspects of the proposal for this candidate and other like them.

The OPTN Executive Committee approved key aspects of the ABOi policy proposal to allow ABOi heart and heart-lung offers. This increased the age limit from registered prior to "2 years old" to "18 years old", kept current status 1A and status 1B qualifying requirement. These were implemented immediately upon approval. Programs must contact the Organ Center directly regarding their candidates in order to register and start receiving offers. The Committee will bring the remaining aspects of the proposal to the OPTN Board of Directors at the June 2023 meeting. One program is known to have already registered their candidate under this change.

Staff shared that during public comment this proposal received 248 total comments, with an average sentiment score of 4.0 out of 5. There was only one "opposed" vote received based on member type, this came from an Organ Procurement Organization (OPO) in OPTN Region 7. Staff reached out to the OPO directly to see why they were opposed but no response was received. Overall, there was support for the proposal. Feedback from public comment included transplant program continuing to be responsible for determining whether ABOi is appropriate for their candidates. Additional steps that were suggested during public comment included steps to increase access; eliminate requirement that isohemagglutinin titer cut-off be less than 1:16, eliminate 30-day titer reporting requirement, and increase age to "less than 2 years old" for classification as primary blood type group. Staff will share all public comments with Committee members, provide an opportunity to consider post-public comment changes. Committee will vote at the in-person meeting on March 29, 2023, regarding components of proposal not already implemented, and that proposal will be submitted to the OPTN Board of Directors for approval at their June 26 meeting.

The Chair commented they were surprised to see so many comments regarding how restrictive the proposal is, considering how concerned the Workgroup had been that if the proposal was not restrictive it would not gain support in the public. The Chair suggested that perhaps the 1 to 16 cutoff could be eliminated and left up to the center. Staff suggested it might make more sense to raise the cutoff rather than eliminating it altogether. Staff also pointed out that there were some good arguments made for the elimination of 30-day titer requirement; if those are outpatient and they are very young then it can be difficult to bring those candidates in to get blood drawn every 30 days. The Vice Chair responded that those still may be critical as data suggests for ABOi candidates.

3. Closing Comments

Staff reminded the Committee about the upcoming in-person meeting on March 29, 2023, and the Committee dinner the night before the meeting. Staff also notified the committee that the April meeting has been rescheduled for April 25, 2023, due to a scheduling conflict with a conference most on the committee will be attending.

The Chair adjourned the meeting.

Upcoming Meeting(s)

- March 29, 2023; in-person
- April 25, 2023, virtual
- May 16, 2023, virtual

Attendance

- **Committee Members**
  - Richard Daly
  - JD Menteer
  - Shelley Hall
  - Jennifer Carapelluci
  - Hannah Copeland
  - Timothy Gong
  - Glen Kelley
  - Earl Lovell
  - John Nigro
  - Jonah Odim
  - Adam Schneider
  - Cristy Smith
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Grace Lyden
  - Monica Colvin
  - Yoon Son Ahn
  - Katherine Audette
- **UNOS Staff**
  - Eric Messick
  - Laura Schmitt
  - Sara Rose Wells
  - Alex Carmack
  - Alina Martinez
  - Holly Sobczak
  - Kelsi Lindblad
  - Kimberly Uccellini
  - Mariah Huber
- **Other Attendees**
  - Robert Goodman
  - Eman Hamad
  - Daniel Yip