

OPTN Heart Transplantation Committee

Meeting Summary

June 3, 2025

Conference Call

J.D. Menteer, MD, Chair

Hannah Copeland, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 06/03/2025 to discuss the following agenda items:

1. Welcome, introductions, and agenda review
2. Overview of letter from the Cardiovascular Surgery Center of Puerto Rico and the Caribbean Heart Transplant Program (PRCC) requesting Heart Committee consideration of a variance from OPTN heart allocation policy
3. Continue discussion and consideration of Heart Committee action associated with pediatric MCS equipment shortage
4. Other Committee business
5. Open forum
6. Closing remarks

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

1. Welcome, introductions, and agenda review

The Chair welcomed the Committee members and shared that there was good news regarding the shortage of pediatric mechanical circulatory support equipment and added that Committee leadership's call with staff of the Cardiovascular Surgery Center of Puerto Rico and the Caribbean Heart Transplant Program (PRCC) would be discussed.

2. Overview of letter from the Cardiovascular Surgery Center of Puerto Rico and the Caribbean Heart Transplant Program (PRCC) requesting Heart Committee consideration of a variance from OPTN heart allocation policy

The Chair summarized Heart leadership's discussions with members of the Cardiovascular Surgery Center of Puerto Rico and the Caribbean Heart Transplant Program (PRCC), who had contacted leadership about the potential for pursuing a variance from heart allocation policy until PRCC's mechanical circulatory support (MCS) program was implemented.

Summary of discussion:

No decisions were made as part of this agenda item.

The Chair detailed for Committee members how PRCC reached out to Heart leadership describing the issues the program faces and asking for the opportunity to meet with leadership and describe their circumstances. The Committee reviewed correspondence from the PRCC, which had expressed concern

over the inability to retain donor hearts for local transplant candidates due to the absence of a mechanical circulatory support program. In their correspondence with Heart leadership and then on a call with leadership on 05/29/2025, PRCC leaders expressed concern that donor hearts originating from Puerto Rico were frequently allocated to urgent candidates on the U.S. mainland, leaving local candidates with limited access to transplantation. The program staff highlighted the inability to retain donor organs for local use, citing the absence of a mechanical circulatory support (MCS) program as a key barrier. As a result of not having a MCS program, PRCC is only able to list and transplant patients at adult heart statuses 4 and 6. When PRCC leaders initially contacted Heart leadership it was to request a variance from OPTN allocation policy to ensure donor hearts stayed in Puerto Rico at least until PRCC's MCS program has been implemented.

On 05/29/2025, Committee leadership held a conference call with PRCC representatives to better understand the challenges the program faces. During the conversation, it became evident that PRCC had not been utilizing the exception request process to advocate for their hospitalized patients who, while medically urgent, do not meet the standard criteria for higher statuses due to the lack of MCS availability. The Committee provided detailed guidance on how to submit exception requests for such patients and emphasized that the review board would consider the unique limitations faced by the program.

Following a discussion with PRCC representatives, it was determined that the program had not been utilizing exception requests for patients who were hospitalized but did not meet criteria for higher statuses due to lack of MCS access. Committee leadership provided guidance on submitting exception requests and offered ongoing support. Leadership emphasized that regional review board reviewers would consider the unique limitations faced by the program when adjudicating such exception requests. It was agreed that no formal variance was necessary at this time as the existing exception pathway could likely address PRCC's concerns.

Next steps:

Committee leadership promised to monitor the situation informally and welcomed future updates from PRCC concerning the outcomes of their initial exception requests.

3. Continue discussion and consideration of Heart Committee action associated with pediatric MCS equipment shortage

The Committee continued its discussion on how best to address the national shortage of pediatric MCS equipment, supplies, and support systems. Ultimately, the Committee approved adding language to the *Guidance for Pediatric Heart Exception Requests* document for National Heart Review Board (NHRB) for Pediatrics reviewers to consider when adjudicating a pediatric exception request. The Committee concurred that the added language should be sufficiency to ensure candidates impacted by such a MCS shortage will maintain access to the appropriate therapy for their condition.

Summary of discussion:

Decision #1: The Committee approved the proposed update to the *Guidance for Pediatric Heart Exception Requests* document for submission to the OPTN Board of Directors.

The Committee members continued their urgent deliberation on the national shortage of pediatric MCS equipment. Currently, implanting a durable MCS device is the primary therapy for certain small pediatric heart candidates. However, there is only one durable MCS device available for such patients and the

device is currently experiencing supply issues. For example, there is a critical and ongoing issue involving the unavailability of the older IKUS driver units, which are no longer in production. The newer generation driver remains under FDA review and is only accessible through clinical trials, limiting its availability to a small number of centers. Additionally, there is a temporary disruption in the supply of cannulas and pumps, which is expected to be resolved at the manufacturing level in the near term.

This shortage has created a significant barrier to care for pediatric candidates who would otherwise be eligible for MCS and, by extension, Status 1A listing. To address this, the Committee proposed pursuing an emergency action by the OPTN Board. The action would update the existing pediatric heart exception guidance document to inform NHRB reviewers about the additional circumstances they should consider when adjudicating such exception requests. The goal of the guidance update is to ensure that patients who are clinically deteriorating and would typically receive a VAD—but cannot due to equipment shortages—can still be considered for Status 1A by exception.

The Chair and OPTN contractor staff let the members know that prior to the Committee meeting, OPTN leadership indicated that they supported pursuing the update as an emergency action in order to take advantage of the 06/09/2025 OPTN Board meeting. OPTN leadership asked the Heart Committee to give the OPTN Pediatrics Committee members the opportunity to review and comment on the final version of the guidance update as soon as possible. OPTN leadership also requested that the Heart Committee establish a plan to perform a review / evaluation of the guidance update no more than 90 days after the changes become effective, in part to determine if the MCS device shortage still exists.

The Committee reviewed and refined proposed language for the guidance update. Key elements of the revised language include:

- Applicability to candidates who do not meet existing size-based criteria but are experiencing poor systemic perfusion while supported by high-dose inotropes.
- A requirement that no acceptable alternative MCS device is available due to a recognized national shortage.
- Reference to existing criteria in Table 1 of the guidance document to ensure consistency and clarity for reviewers.

The Committee debated the placement and tone of the language, ultimately agreeing to insert it directly below the existing table to maintain a subdued but accessible presence in the document. Members emphasized the importance of not undermining the intent of the 2016 allocation changes, which deprioritized the medical urgency of stable inotrope-dependent cardiomyopathy patients due to their waitlist mortality rates which were better than certain other status 1A candidates. A member asked whether the Committee needs to define a “recognized national shortage?” Other Committee members responded that because the proposed change involves updating guidance, that the NHRB reviewers should be aware of such shortages.

The Vice Chair of the OPTN Pediatric Transplantation Committee also participated in the Heart Committee’s discussions and provided feedback regarding the proposed policy language, as well as asking about the timing of when the information would be shared with the Pediatrics Committee members. OPTN contractor staff said the updated guidance language would be provided shortly after the meeting.

Thirteen of the 15 Committee members participating in the meeting voted to approve the proposed language and agreed to submit it to the OPTN Board for emergency action. (The two other Committee members did not indicate a preference.) The update will be shared with the Pediatric Committee for expedited review. The emergency guidance will be subject to a 12-month expiration period, with a 90-

day reevaluation window to assess whether the shortage persists. Members also expressed interest in making the guidance permanent if the shortage continues or if similar issues arise in the future.

Next steps:

The guidance will be shared with the Pediatric Committee for expedited review and feedback in order to include a summary of the feedback to the OPTN Board of Directors when the updated guidance document is presented for their consideration as an emergency action on 06/09/2025.

4. Other Committee business

The Committee received an update regarding how the policy changes associated with the *Escalation of Status for Time on Left Ventricular Assist Device* proposal might be implemented in the OPTN Board of Directors approves the proposal on 06/09/2025. Committee members were reminded that implementation of phase 2 would occur 18 months after the implementation of phase 1. The 18-month interval was included as a way to allow the Committee to receive monitoring results associated with the changes. If the monitoring results indicated the objectives were not being achieved or the results pointed to unintended consequences, the 18-month interval provided the Heart Committee with a window to seek OPTN Board action to prevent phase 2 from being implemented.

Following discussions with OPTN leadership leading up to the OPTN Board meeting, OPTN leadership agreed that the Heart Committee was best situated to determine a sunset date for Phase 1 based on at least six months of monitoring data, although the timeframe could be longer. OPTN leadership indicated that a data-driven solution would be best. They also acknowledged that this approach provides flexibility and ensures that Phase 2 will not be indefinitely delayed. The resolution language the OPTN Board will consider also states that if the Heart Committee recommends a sunset date, but the Board does not act on the Committee's recommendation within three months of submission, the recommendation will take effect automatically.

Committee members expressed support for this approach, noting that it addresses prior concerns about the potential for Phase 2 to be stalled. The update was well received, and no objections were raised.

5. Open forum

No requests from the public were received prior to the meeting asking to address the Committee during open forum.

6. Closing remarks

The Chair thanked the members for their engagement and contributions. The meeting adjourned with a reminder of the next scheduled session in two weeks.

Upcoming Meetings

- ~~July 2, 2024 from 4:00 to 5:30 pm~~
- ~~July 16, 2024 from 5:00 to 6:00 pm~~
- ~~August 7, 2024 from 4:00 to 5:00 pm~~
- ~~August 20, 2024 from 5:00 to 6:00 pm~~

- ~~September 4, 2024 from 4:00 to 5:00 pm~~
- ~~September 17, 2024 from 5:00 to 6:00 pm~~
- ~~October 2, 2024 from 4:00 to 5:00 pm~~
- ~~October 9, 2024 from 9:00 am to 4:00 pm (In-person meeting, Detroit, MI)~~
- ~~October 15, 2024 from 5:00 to 6:00 pm~~
- ~~November 6, 2024 from 4:00 to 5:00 pm~~
- ~~November 19, 2024 from 5:00 to 6:00 pm~~
- ~~December 4, 2024 from 4:00 to 5:00 pm~~
- ~~December 17, 2024 from 5:00 to 6:00 pm~~
- ~~January 1, 2025 from 4:00 to 5:00 pm~~
- ~~January 21, 2025 from 5:00 to 6:00 pm~~
- ~~February 4, 2025 from 4:00 to 5:00 pm~~
- ~~February 18, 2025 from 5:00 to 6:00 pm~~
- ~~March 4, 2025 from 4:00 to 5:00 pm~~
- ~~March 18, 2025 from 5:00 to 6:00 pm~~
- ~~April 1, 2025 from 4:00 to 5:00 pm~~
- ~~April 15, 2025 from 5:00 to 6:00 pm — Cancelled~~
- ~~April 18, 2025 from 11:00 am to 4:00 pm~~
- ~~May 6, 2025 from 4:00 to 5:00 pm~~
- ~~May 20, 2025 from 5:00 to 6:00 pm~~
- ~~June 3, 2025 from 4:00 to 5:00 pm~~
- June 17, 2025 from 5:00 to 6:00 pm

Attendance

- **Committee Members**
 - J.D. Menteer
 - Hannah Copeland
 - Maria Avila
 - Kim Baltierra
 - Jennifer Cowger
 - Kevin Daly
 - Rocky Daly
 - Jill Gelow
 - Eman Hamad
 - Earl Lovell
 - Mandy Nathan
 - John Nigro
 - Jason Smith
 - David Sutcliffe
 - Martha Tankersley
- **HRSA Representatives**
 - None
- **SRTR Staff**
 - Yoon Son Ahn
 - Monica Colvin
 - Avery Cook
 - Grace Lyden
- **UNOS Staff**
 - Matt Cafarella
 - Kelsi Lindblad
 - Eric Messick
 - Leah Nunez
 - Laura Schmitt
 - Sara Rose Wells
- **Other Attendees**
 - Neha Bansal