

## OPTN Heart Transplantation Committee

### Meeting Summary

August 5, 2025

Conference Call

J.D. Menteer, MD, Chair

Hannah Copeland, MD, Vice Chair

### Introduction

The OPTN Heart Transplantation Committee met via WebEx teleconference on 08/05/2025 to discuss the following agenda items:

1. Welcome, announcements, and agenda review
2. Evaluating pediatric MCS device and supply shortage associated with *Guidance for Pediatric Heart Exception Requests*
3. Next project considerations
4. Open forum
5. Closing remarks

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

#### 1. Welcome, announcements, and agenda review

The meeting commenced with review of the agenda. Members were reminded that the session was being recorded and live-streamed.

#### Summary of discussion:

No decisions were made as part of this agenda item.

The OPTN contractor shared with the Committee members that the next public comment period was rescheduled to run from 08/27/2025 through 10/01/2025, shortening the original timeline. OPTN contractors staff also stated that OPTN committee nominations opened on 08/01/2025 and will close on 08/20/2025. Vacancies on the OPTN Heart Committee exist in regions 3 and 5. Members were encouraged to identify and refer qualified candidates to submit information for consideration to serve on an OPTN committee. Due to changes in the appointment process, individuals who submitted volunteer interest forms prior to 01/01/2025 must now submit new forms.

OPTN Contractor staff let the members know that a transition from the use of WebEx to Microsoft Teams for Committee meetings is planned by the end of September, 2025. Members experiencing technical difficulties with Teams were advised to seek support in advance.

OPTN contractor staff reminded the members that implementation of the revised eligibility criteria included in the Heart's Committee's Amend Adult Heart Status 2 Mechanical Device Requirements remains scheduled for 09/17/2025. The OPTN members will be notified of the changes and implementation date by way of the following:

- A pre-implementation notice approximately 30 days prior to 09/17/2025,
- A system-wide notice on the day of implementation, and

- Targeted communication to transplant programs with affected candidates 14 days before the change.

Clarifications of the revised policy were provided regarding requalification requirements. Candidates currently assigned under the impacted criteria (Intra-Aortic Balloon Pump (IABP) and percutaneous endovascular Mechanical Circulatory Support Devices (MCS)) will not need to requalify until their current assignment or extension expires. New candidates must meet the updated criteria immediately upon assignment.

Next steps:

Committee members were reminded to be aware of the public comment period.

## **2. Evaluating pediatric MCS device and supply shortage associated with *Guidance for Pediatric Heart Exception Requests***

The Committee revisited the emergency guidance issued for pediatric Status 1A candidates unable to receive ventricular assist devices due to equipment shortages.

Summary of discussion:

Decision #1: The Committee members agreed that the guidance modification should remain in place and be revisited on a regular basis in the future.

The Committee revisited the emergency guidance modification issued for pediatric Status 1A candidates unable to receive ventricular assist devices due to supply shortages. The modified guidance went into effect on 06/12/2025. The pediatric devices addressed by the modification were officially listed on the FDA's medical device shortage list as of mid-July. Staff will collaborate with leadership to prepare a formal response to the OPTN Board by the September 10 deadline, as required when the emergency proposal was approved.

Next steps:

The Committee agreed to maintain the emergency guidance for pediatric Status 1A candidates due to the ongoing FDA-listed device shortages. Members also agreed to revisit this issue in future meetings to assess whether the guidance should be extended or rescinded based on updated supply chain information. OPTN contractor staff will collaborate with Committee leadership to prepare and submit a formal reevaluation report to the OPTN Board by 09/10/2025, as required by the original approval conditions.

## **3. Next project considerations**

The Committee held a detailed discussion regarding future project priorities, particularly in light of OPTN budget constraints and the need for cost-effective policy development. Several potential initiatives were considered.

Summary of discussion:

Decision #1: The Committee members agreed to continue discussing potential project ideas.

Because the Committee was discussing starting new projects while their continuous distribution work is on hold, OPTN contractor provided a brief overview of the OPTN policy development process. The

overview identified the parts of the development process requiring approval of an OPTN entity to move forward, when public comment/input would be required, OPTN Board approval steps, and potential implementation considerations. The Chair reminded the members that the OPTN Board is working on a much tighter budget outlook than in previous times and project cost-effectiveness will be top of mind when OPTN Policy Oversight Committee (POC), Executive Committee, and Board of Directors consider projects for approval.

The Chair identified several potential project ideas for Committee consideration. The first idea involved addressing the issue with exception requests and the regional review board practices and policies. A second idea involved determining how the Committee could improve access to transplant opportunities for highly sensitized heart candidates. A third potential project involved new data collection and enhancements to existing data collection to improve granularity of information. A fourth option involves the potential for developing and/or implementing a medical urgency risk score.

The Committee first discussed the potential of initiating a project addressing exception request and Heart review board practices. There was consensus that the current system involving status exception requests and review boards is under strain, with concerns about equity, transparency, and consistency. Members expressed concern over the increasing volume and perceived misuse of exception requests. The discussion highlighted systemic issues including:

- Excessive waiting times prompting exception requests for patients who might not meet formal criteria,
- Lack of consistency and transparency across regional review boards,
- Thoroughness of reviewer training, and
- Absence of consequences for the misuse exception requests.

Multiple members emphasized the need for reform, citing public scrutiny and internal dissatisfaction. Proposed areas of focus included:

- Transitioning from retrospective to prospective review processes,
- Eliminating the current regional review boards and creating a national adult heart review board, modeled after the pediatric structure,
- Enhancing reviewer education and guidance,
- Establishing 'term limits' for exception statuses,
- Implementing structured data requirements for exception request submissions,
- Clarifying permissible clinical circumstances under which exceptions should be submitted, particularly in cases where mechanical circulatory support is declined.
- Revising operational guidelines administering voting thresholds and reducing approval rates for questionable requests, and
- Creating forums for discussions of complex cases and retrospective audits.

There was broad support for addressing both exception criteria and review board structure concurrently. Members suggested forming subgroups to tackle each component in parallel, with the goal of submitting a comprehensive policy proposal.

The Committee also discussed the potential integration of a medical urgency risk score into the heart allocation framework. Preliminary work by SRTR staff using national datasets was acknowledged. A future presentation is planned to evaluate the feasibility of incorporating blood and device variables into a predictive model. Members expressed interest in pursuing this initiative as a complement to existing status-based criteria.

The Committee agreed to pursue further discussion of a comprehensive policy initiative addressing both exception request reform and review board restructuring. Members acknowledged the complexity and timeline of the policy development process and emphasized the importance of delivering a meaningful and effective solution.

#### Next steps:

During the next few meetings, the Committee will refine and prioritize potential policy initiatives. Among the potential initiatives, SRTR staff will be invited to present preliminary findings on urgency risk modeling using national datasets. This presentation will inform whether the Committee pursues formal development of a hybrid scoring system. The Committee will continue refining the scope and goals of the projects being considered. Additionally, preliminary data gathering to support formal project endorsement by the OPTN POC.

#### **4. Open forum**

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

#### **5. Closing remarks**

The meeting concluded with appreciation for member contributions and a reminder of upcoming meeting dates. Members were also encouraged to review meeting materials and upcoming proposals.

#### **Upcoming Meetings**

- ~~July 1, 2025 from 4:00 to 5:30 pm~~
- ~~July 15, 2025 from 5:00 to 6:00 pm~~
- ~~August 5, 2025 from 4:00 to 5:00 pm~~
- August 19, 2025 from 5:00 to 6:00 pm
- September 2, 2025 from 4:00 to 5:00 pm
- September 16, 2025 from 5:00 to 6:00 pm
- October 7, 2025 from 4:00 to 5:00 pm
- October 21, 2025 from 5:00 to 6:00 pm
- November 4, 2025 from 4:00 to 5:00 pm
- November 18, 2025 from 5:00 to 6:00 pm
- December 2, 2025 from 4:00 to 5:00 pm
- December 16, 2025 from 5:00 to 6:00 pm
- January 6, 2026 from 4:00 to 5:00 pm
- January 20, 2026 from 5:00 to 6:00 pm
- February 3, 2026 from 4:00 to 5:00 pm
- February 17, 2026 from 5:00 to 6:00 pm
- March 3, 2026 from 4:00 to 5:00 pm
- March 17, 2026 from 5:00 to 6:00 pm
- April 7, 2026 from 4:00 to 5:00 pm

- April 21, 2026 from 5:00 to 6:00 pm
- May 5, 2026 from 4:00 to 5:00 pm
- May 19, 2026 from 5:00 to 6:00 pm
- June 2, 2026 from 4:00 to 5:00 pm
- June 16, 2026 from 5:00 to 6:00 pm

## Attendance

- **Committee Members**
  - J.D. Menteer
  - Hannah Copeland
  - Maria Avila
  - Kim Baltierra
  - Jennifer Cowger
  - Rocky Daly
  - Tim Gong
  - Eman Hamad
  - Jennifer Hartman
  - Earl Lovell
  - Mandy Nathan
  - Jason Smith
  - Dmitry Yaranov
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Cole Fox
  - Eric Messick
  - Laura Schmitt
  - Sara Rose Wells
- **Other Attendees**
  - None