

OPTN DAC Committee

Meeting Summary

November 14, 2023

Conference Call

Sumit Mohan, MD, MPH, Chair
Jesse Schold, PhD, M.Stat, M.Ed, Vice Chair

Introduction

The Data Advisory Committee (“Committee”) met via WebEx teleconference on 11/14/2023 to discuss the following agenda items:

1. Welcome, Reminders, and Follow-up from 11/13/2023 Meeting
2. Organ Procurement Transplantation Network (OPTN) Project Check-in: Amend Adult Heart Status 2 Mechanical Device Requirements
3. Membership and Professional Standards Committee (MPSC), Concept Overview: Organ Procurement Organization (OPO) Performance Monitoring Metrics and Closing Remarks

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

1. Welcome, Reminders, and Follow-up from 11/13/2023 Meeting

The Chair welcomes the committee and announces updates from the previous DAC meeting on 11/13/23.

Summary of discussion:

The Chair began with announcements made during the 11/13/2023 meeting and calls for interested candidates to apply to be Vice Chair. The Chair noted that there is a deadline of 8 weeks for pre-listing data collection efforts and appeals that were discussed with the Committee by HRSA staff during the 11/13/2023 meeting. Further noting that this is an important opportunity for the Data Advisory Committee (DAC) to actively support the transplant community. The Chair also announced the need for the workgroup, for which members will do a lot of early work individually before joining together during an in-person meeting. The proposal that the workgroup will work on will be discussed by the DAC. Those interested in the workgroup should email the OPTN Contractor.

A member started the discussion on manual data collection, with the Chair responding that this will be one of the investigative questions. The Vice Chair noted that in the creation and research process, there will be inconsistencies between transplant centers, but understanding the knowledge gaps is crucial. The Vice Chair made a call for subject matter experts within the workgroups. Another member asked for clarification on the final deliverable, with the Chair responding that the deliverable will be a list of variables and data elements that is provided to HRSA staff. A member asked about offering to do a crosswalk of what HRSA provided and the pre-waitlist data elements and the Chair noted that the data has not yet been collected. The Chair also noted that there will be an option for everyone to weigh in. Another member cautioned that DAC and the Membership and Professional Standards Committee should ensure not to duplicate efforts around what they provide back to HRSA staff.

The Chair noted that this will be more than a research effort. The Vice Chair notes that support is strong for the project, although there needs to be more clarification and research into the documentation. Another member mentioned that some transplant centers only get phone calls referring potential

patients, as opposed to written or electronic documentation from which data or information can be extracted. The member noted that there needs to be definition on the term “referral” and what the purpose of collecting referral data is. The Chair noted again that these questions will be investigated by the workgroup. Another member stated that it would be helpful to have documentation on the variables that were presented by HRSA staff during the 11/13/2023 meeting. The OPTN Contractor stated that a draft will be distributed. The Chair acknowledged that these questions will be answered by workgroups members with specific expertise. Another member asked about disparities, which the Chair responded to by stating the fact that this research will be inclusive of disparities and will not address the broader themes.

Next steps:

The committee will look for interested members for Vice Chair and will work toward assembling the Pre-Waitlist Data Collection workgroup.

2. OPTN Project Check-in: Amend Adult Heart Status 2 Mechanical Device Requirements

The Vice Chair of the OPTN Heart Transplantation Committee, presented on updates to the Heart Committee’s project following public comment and asked for discussion.

Summary of discussion:

The Vice Chair of the Heart Committee updated the DAC on the progress of the proposal, shared the Committee’s post-public comment policy proposal changes and the impact of the changes on data collection. The Vice Chair of the Heart Committee described to the DAC members that the purpose of proposal is to accomplish the following:

- Better align the two adult status criteria with status 2 eligibility criteria to reflect the high medical urgency associated with adult status 2.
- Address substantial increases in use of intra-aortic balloon pump (IABP) therapy within adult heart status 2 since policy changes were implemented in October 2018.
- Prevent the potential for increases in the use of status 2 through the percutaneous endovascular mechanical circulatory support device criteria.
- Increase access for other status 2 candidates and improve waitlist outcomes.

The impacts of this data collection will be the following:

- Replicating existing OPTN data fields used for collecting information about inotropic therapy as part of the adult heart status 3 requirements.
- Data collected are pharmacological in nature (e.g., dosing levels) and will be used to assess findings and to verify eligibility for assignment at adult heart status 2.
- New data elements will be introduced to accommodate the additional pathways needed to collect the data.

The proposed data solution is to add fields in the OPTN Waiting List to support eligibility requirements of two heart statuses. These effects will impact the OPTN Computer Systems and Waiting List. There will be various tools that have been assessed to align with OPTN data collection principles. This alignment will add eligibility requirements to adult heart status 2 criteria to reflect intended medical urgency of such criteria. It will also clarify expectation of medical urgency for patients to be assigned to adult heart status 2. The proposed data collection involves replicating existing OPTN data fields in the OPTN Waiting List system and associated data within the inotropic therapies and hemodynamic monitoring. New data elements will be introduced to accommodate the additional pathways needed to collect the data.

The public comment feedback to data is mostly supportive of changes. Among the themes of public comment were the concern for patients developing arrhythmias while attempting inotropic therapy and the need for the Committee to avoid being too prescriptive in policy. The Committee initially considered revising regional review board guidance materials to address issues that may come through exception requests. Post-public comment the committee reached consensus on the eligibility criteria needed to address candidates who might develop arrhythmias when attempting the required inotropic therapy. The Committee used existing policy language associated with adult heart status 4 to indicate what circumstances can be considered as resulting in arrhythmias or similar issues. In response to the proposed changes, transplant programs will need to do the following:

- Inform and educate staff about the changes.
- In initial assignments of candidates to adult heart status 2 criteria transplant hospitals will need to report various data.
- For extending candidates assignments, reporting failure to wean candidates from device support while supported by or attempting to initiate inotropic therapy will also need to be reported.

The DAC Chair asked whether these changes will alter the definitions and the Heart Committee Vice Chair of the Heart Committee noted that the replicated data elements won't change definitions but other changes will create new data elements that need new definitions. The Chair of the DAC committee noted some concerns about the repurposing and the Vice Chair of the Heart Committee explained why it may not be problematic. The Chair asked for clarity and the OPTN Contractor shared examples of how the changes would appear. Another member asked about how heart candidates currently registered on the waiting list might be impacted by the change. The Vice Chair noted that such candidates would be able to remain at status 2 until their extension date arrived. Each candidate who experiences that circumstance will need their transplant program to submit an initial justification form in order for that candidate to qualify. The OPTN Contractor explained what the data collection looks like currently in the OPTN Waiting List and what it would look like if the proposed changes were implemented. The OPTN Contractor noted that the proposed changes will capture the appropriate information. Another member asked about definitions and the Vice Chair noted that they will not be overly prescriptive. The member retorted that it may help to add more qualifiers to be helpful for the end-user. This member also asked about what could be removed from data collection to offset any new collection, and the OPTN Contractor noted that the opportunity to remove data elements was not what the Heart Committee wanted to accomplish. The Vice Chair mentioned that eliminating existing data collection may not be the best way to approach the issue the Committee is trying to solve. The Chair noted and supported this. A comment was made about the process for this and what went into the decision.

Next steps:

There were no next steps discussed. The DAC supported the Heart Committee's modifications post public comment.

3. MPSC, Concept Overview: OPO Performance Monitoring Metrics and Closing Remarks

The OPTN Contractor presented updates and a concept overview of the OPO performance monitoring metrics.

Summary of discussion:

The OPTN Contractor introduced the activities of the MPSC's workgroup. The workgroup's objective is to provide the DAC with an update and progress report on the concept paper that will go out for public comment from January to March of 2024. The purpose of the concept paper is to standardize and collect

data within the OPO electronic donor record (EDR) systems and to share improvements on collection for the development of OPO performance. It will impact OPTN data collection by bringing in additional data into the OPTN Computer System that will be assessed in the future. The concept paper will describe data requirements for collecting potential donor and donor referral data in the upstream OPO EDR systems. The OPO community will need to partner and prioritize this work with the EDR vendors to modify their current data collection. This proposed data solution will help design the data collection module for the OPO EDR systems and this model will be used to efficiently feed data into the OPTN Computer System.

The data collection instruments that are impacted are the OPTN Computer System and the extended impact will be assessed upstream from OPO data requirements with EDR vendors. However, there is anticipation of impact from the OPTN Death Notification Registration (DNR) form and potentially other donor related forms in OPTN Donor Data and Matching system (known as DonorNet®). In addition to being in alignment with the OPTN data collection principles (it aligns with a variety of indicators included the OPTN Final Rule), various other alignments are presented that are needed to support the new development of these metrics. The OPTN Contractor showed a proposed timeline and milestones. Two DAC representatives will continue to participate in the OPO performance monitoring enhancement workgroup and provide comments during the 12/13/2023 Committee meeting. As this work moves into an official data collection project proposal, the workgroup will re-engage with DAC.

The Chair thanked the presenter and asked about whether an API will capture data that could be eliminated. The staff member clarified that it has been hard for donor hospitals to adopt this, and that the workgroup will consider asking for feedback about requesting data from transplant hospitals. The Chair notes that this should be looked at again for opportunities and partnerships and noted that the Centers for Medicare and Medicaid Services (CMS) is potentially the end-user. The OPTN Contractor mentioned that there may need to be a commitment from CMS. The Chair called for more questions – a member asked about potential barriers with creating APIs with vendors. The OPTN Contractor mentioned that it is difficult to capture buy-in from donor hospitals, but that OPOs would support this measure. Another member asked about authority and the member noted that it may be CMS or another organization. The DAC Vice Chair asked whether CMS is aware of the project. The OPTN Contractor mentioned that CMS is aware and that they have had discussions with various CMS departments. The Chair asked about ease of use and the OPTN Contractor considered this for future discussion. Lastly, the Chair asked additional questions. The OPTN Contractor clarified the committee project and initiative.

Next steps:

The Chair made a note that this project needs to be completed within 8 weeks and calls for committee members to email the OPTN Contractor if they are interested in working on this workgroup.

Upcoming Meeting

- December 13, 2023

Attendance

- **Committee Members**
 - Sumit Mohan
 - Jesse Schold
 - Rebecca Baranoff
 - Kate Giles
 - Dustin Goad
 - Paul MacLennan
 - Christine Maxmeister
 - Meghan Muldoon
 - Hellen Oduor
 - Jennifer Peattie
 - Juie Prigoff
 - Alicia Skeen
 - Allen Wagner
- **HRSA Representatives**
 - Adriana Martinez
 - Chris McLaughlin
- **SRTR Staff**
 - Avery Cook
- **UNOS Staff**
 - Brooke Chenault
 - Jonathan Chiep
 - Gabrielle Hibbert
 - Nadine Hoffman
 - Michael Hollister
 - Houlder Hudgins
 - Sevgin Hunt
 - Krissy Laurie
 - Kerrie Masten
 - Eric Messick
 - Sara Moriarty
 - Sharon Shepherd
 - Holly Sobczak
 - Kaitlin Swanner
 - Kim Uccellini
 - Sara Rose Wells
 - Joann White
 - Divya Yalgoori
- **Other Attendees**
 - Marie Budev
 - Rocky Daly
 - J.D. Menteer