

**OPTN Data Advisory Committee
Meeting Summary
November 18, 2024
Conference Call**

**Jesse Schold, PhD., M.Stat., M.Ed.
Lisa McElroy, MD MS FACS**

Introduction

The OPTN Data Advisory Committee (the Committee) met via WebEx teleconference on 11/18/2024 to discuss the following agenda items:

1. Welcome, Reminders, and Agenda Review
2. Status update regarding Living Donor Committee's Living Donor Candidate Donation Decision and Operationalization project
3. Share DAC Chair's presentation to the OPTN Board
4. HHS Directive status update: Pre-waitlist data collection and Ventilated patient referral collection
5. Revisit project ideas identified during DAC's 09/10/2024 meeting
6. Open Forum
7. Closing Remarks

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

1. Welcome, reminders, and agenda review

The Chair welcomed the members and provided a brief overview of the agenda items.

2. Status update regarding Living Donor Committee's Living Donor Candidate Donation Decision and Operationalization project

The OPTN Living Donor Committee (LDC) was directed by OPTN leadership to initiate a data collection project. The LDC created a workgroup, consisting of members of multiple OPTN committees, to develop the project. Two Committee members are serving on the workgroup. They have shared some concerns about the proposed effort from the perspective of the OPTN Data Collection Principles and other DAC-related considerations. LDC had targeted submitting the proposal for public comment in January 2025.

Summary of discussion:

Decision #1: The Committee agreed to continue supporting the concept of the Living Donor Committee's project.

The LDC project aims to collect comprehensive data on potential living donors to understand the transplant process better. During previous meetings of the LDC workgroup, concerns were raised about the project's scope and the feasibility of transplant programs being able to carry-out some of the proposed collection and reporting.

The Committee members learned that the LDC's data collection proposal has been postponed and will not be included in the January 2025 public comment cycle. Instead, LDC will work more closely with the

Committee in order to refine the proposed data collection components. Specific concerns with the project included too much information being requested and the bandwidth of programs to collect it. The need for pragmatic approaches to data collection was emphasized, considering the availability of information at different points in time.

Next steps:

The Committee expressed support for the concept of the project and volunteered to partner with the LDC to find practical ways to collect the needed data fields.

3. Share DAC Chair's presentation to the OPTN Board

The DAC Chair provides the OPTN Board of Directors (BOD) with an annual update about the Committee's past activities presents, as well as providing information about the Committee's future activities. Information included in the presentation is drawn from the Annual Data Review Report and the Annual Data Quality Report. This presentation and the previous year's were used by the Committee Chair to identify opportunities the Committee members believe are important for improving the overall OPTN data collection effort. The Chair presented to the Committee the same information and recommendations that will be presented to the OPTN BOD on 11/21/2024.

Summary of discussion:

Decision #1: The Committee agreed to include some additional talking points in the Chair presentation to the Board.

As the DAC Chair walked through the presentation slides, the Committee members were reminded that DAC endorsed ten data collection proposals from other OPTN committees and six updates to OPTN data definitions during the previous year. In addition, the Committee received a report detailing the two-year monitoring results associated with the Modify Data Submission Requirements (also referred to as the Data Lock) project.

Among the activities identified for improving OPTN data collection and data quality, the Committee recommends aligning with the BOD and HRSA to champion data efforts, enhancing data collection, and addressing known barriers to data quality. The Committee recognizes the need for the OPTN to be nimbler in responding to changes in clinical practice, similar to how the data collection process was modified during the pandemic. For example, the systematic collection of machine perfusion-related data has not started despite previous BOD approval. The lack of data is a barrier to understanding quality and outcomes in the transplant system. The Committee recommends developing solutions to move forward more quickly in such instances.

The Chair discussed how the OPTN might be able to improve its responsiveness to data needs in part by strengthening the connections between the BOD, HRSA, other entities and the Committee. Such coordination could improve the OPTN registry and data governance activities. Among other efforts, the BOD could oversee data strategy and foster connections with HRSA, groups like the Office of the National Coordinator for Health Information Technology (ONC), and similar entities. To this end, the Committee members discussed the need to create a role on the BOD or reporting to the BOD with a specific data-related skillset to share information about the OPTN data registry and support securing resources for broader initiatives. The role could be modeled after the responsibilities of a chief informatics officer, for example. The current BOD members and their expertise should be considered when identifying potential champions for the Committee's initiatives.

Other members recommended involving Electronic Health Record (HER) vendors in the planning and implementation process of any changes the BOD makes. Additionally, Committee members said that specific data sources should be considered for collaboration efforts. Among such sources, the Committee cited the Centers for Medicare and Medicaid Services' (CMS) death record information and the End Stage Renal Disease Quality Reporting System (EQRS).

Next steps:

Contractor staff will post the Chair's BOD presentation on the Committee's SharePoint site, along with the Annual Data Review Report and the Data Quality Report for members to review. The Committee members agreed to schedule planning sessions in the coming year to further discuss and develop an infrastructure for bi-directional communication with the BOD. OPTN Contractor staff agreed to provide a Vimeo hyperlink to the BOD meeting for Committee members to watch the discussion and to provide a hyperlink to the list of current BOD members.

4. HHS Directive status update: Pre-waitlist data collection and Ventilated patient referral collection

Members were provided with an update on the status the OPTN response to the HHS Directive. The discussion covered the posting of the OPTN packages, communication efforts, preparation of the OPTN response, and the timeline for feedback and implementation. Concerns about the data collection mechanism were raised, and the importance of community engagement and feedback was emphasized.

Summary of discussion:

No decisions were made as part of this agenda item.

Members were told that two notices were posted on the Federal Register (FR) concerning OPTN data collection efforts. One of the Federal Register Notices (FRN) includes six BOD-approved projects. This FRN was posted on 10/31/2024 with the 60-day comment period closing on 12/31/2024. This FRN is following the typical Office of Management and Budget (OMB) process for changes to OPTN data collection, except for the delay in submission. The other FRN was related to the HHS Directive, which is referred to as the process data package in the FRN announcement. The process data package consists of three drafted directive forms: two for pre-waitlist and one for ventilated patients. It was posted on the FR on 11/04/2024 and its 60-day public comment period ends on 01/03/2025. An email from the OPTN President was sent on 11/08/2024 to about 4,000 individuals in the community notifying them of the posting and the OPTN's intent to respond. Additionally, DAC members and members of the two OPTN workgroups involved with the Directive were emailed the HRSA drafted forms and instructions. A spreadsheet comparing the information on the pre-waitlist forms submitted by the DAC and the forms posted by HRSA as part of the FRN was included as part of the email to the group.

The Chair reminded the Committee members that the mechanism for how the new data fields will be collected, such as quarterly submission on individual forms, is a key part of the draft response. Members were reminded that the OMB public comment process is a little different than the process the OPTN uses. The OMB process focuses more on what date needs to be collected than how the data should be collected. Feedback on the data collection cadence can be included in the OPTN response. Committee members were asked to review the data collection forms and instructions and provide feedback by 11/25/2024 at 12:00 pm (ET). This will give OPTN contractor staff time to review and incorporate any new information before the next workgroup meeting.

A DAC Committee meeting is scheduled for 12/04/2024 to align on the feedback and draft the response. Members of the two workgroups have been asked to join. The meeting will be used to finalize the drafted OPTN response. The plan is for the DAC Chair to present the drafted OPTN response to the OPTN

Executive Committee during their 12/12/2024 meeting and obtain approval on the behalf of the OPTN BOD. If that is successful, the next step will be to submit the OPTN response to the HRSA mailbox before 12/20/2024. The OPTN President will issue a memo to the community once the response is submitted.

There were concerns about the mechanism for collecting data, specifically whether it would involve quarterly submissions or individual forms. The FRN does not acknowledge DAC's previous suggestion for a quarterly cadence with regard to data submission requirements. However, the recommendation will be included in the response. The response will request HRSA clarify the submission process for this new data collection.

Next steps:

OPTN contractor staff reminded the members that on 11/15/2024 they were emailed HRSA's proposed data collection forms and instructions and asked to provide feedback. Members were asked to share their feedback about the data collection forms with OPTN contractor staff, who will summarize the information as part of the prep work for the OPTN response.

5. Revisit project ideas identified during DAC's 09/10/2024 meeting

Discussion of the other agenda items took up most of the meeting time and there was no discussion of potential projects. The Committee will revisit the project ideas at a future Committee meeting.

Summary of discussion:

No decisions were made as part of this agenda item.

Next steps:

The Committee will revisit the potential project ideas at a future meeting.

6. Open forum

No requests from the public to address the Committee during open forum had been received.

7. Closing remarks

The Chair thanked the Committee members for sharing their ideas about the BOD presentation and the HHS Directive. The Chair acknowledged the members' comments emphasizing the importance of partnerships, data modernization, and stakeholder engagement in improving transplant data quality and processes. The Chair reminded the members to email any additional ideas to the OPTN contractor staff.

Upcoming Meetings (Meetings start at 3:00 pm (ET) unless otherwise noted)

- ~~July 8, 2024~~
- ~~August 12, 2024~~
- ~~September 10, 2024 – In-person meeting, Detroit, MI, 8:00 am – 3:00 pm (ET)~~
- ~~October 21, 2024~~
- ~~November 18, 2024~~
- December 9, 2024 11:00 am (ET)
- January 12, 2025
- February 10, 2025
- March 10, 2025
- April 14, 2025

- May 12, 2025
- June 9, 2025

Attendance

- **Committee Members**
 - Jesse Schold
 - Rebecca Baranoff
 - Kate Giles
 - Michael Ison
 - Paul MacLennan
 - Michael Marvin
 - Christine Maxmeister
 - Nancy McMillan
 - Jennifer Peattie
 - Julie Prigoff
 - Meghan Schaub
 - Alicia Skeen
 - Lindsay Smith
 - Allen Wagner
- **HRSA Representatives**
 - Adriana Alvarez
- **SRTR Staff**
 - Avery Cook
 - Jon Snyder
- **UNOS Staff**
 - Brooke Chenault
 - Jonathan Chiep
 - Huong Cunningham
 - Michael Hollister
 - Jesse Howell
 - Eric Messick
 - Lauren Mooney
 - Nadine Rogers
 - Sharon Shepherd
 - Kimberly Uccellini
- **Other Attendees**
 - None