

OPTN Data Advisory Committee

Meeting Summary

January 22, 2024

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 1/22/2024 to discuss the following agenda items:

1. Welcome and Reminders
2. Review HRSA Request
3. Feedback on Ventilated Referrals Data Collection
4. Feedback on Pre-Waitlist Data Collection

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

1. Welcome and Reminders

OPTN contractor staff began by informing participants that the meeting is being recorded and livestreamed, with instructions on how to access the livestream on Vimeo. Staff emphasized ensuring accessibility for committee members and others interested in observing. The Chair thanked everyone for joining the meeting. He stated that the meeting’s focus would be primarily on the Health Resources and Services Administration (HRSA) directive, specifically on pre-wait-listing data collection and additional data collection related to potential donors.

Summary of discussion:

The Committee did not make any decisions.

2. Review HRSA Request

Committee members reviewed a request from HRSA related to feedback regarding ventilated referral notification data collection and referral evaluation registration data collection.

Presentation summary:

On November 13, 2023, the OPTN Contracting Officer’s Representative (COR) from HRSA attended the DAC meeting and requested the following:

- Feedback on the drafted ventilated referral notification data collection
- Feedback on the drafted referral and evaluation pre-registration data collection
- OPTN COR shared DAC’s feedback will be considered when:
 - Finalizing the HHS Secretarial Directive – coming in early 2024
 - HRSA intends to include the new data collection forms in the 2023 OPTN Data System package

HRSA and the Committee agreed to a feedback deadline of January 31, 2024.

Summary of discussion:

The Committee did not make any decisions.

3. Feedback on Ventilated Referrals Data Collection

Members discussed the feedback and tool that the Membership and Professional Standards Committee's (MPSC) Organ Procurement Organization (OPO) Performance Metric Workgroup have created regarding ventilated referrals data collection.

Presentation Summary:

A participant summarized the feedback from the MPSC Workgroup, highlighting the shared goal of collecting high-quality data throughout various donation phases. The participant emphasized the importance of refining data fields for meaningful collection, suggesting improvements and making recommendations based on their experience with data collection tools. He then proceeded to discuss the draft data collection, noting the addition of 64 fields, with 28 already being collected on the Death Notification Registration (DNR) Form. He focused on the 36 new data fields, including two optional ones, which he stressed require significant discussion and additional work on what information should be collected because such information is not already collected.

Summary of discussion:

Decision #1: The DAC endorsed submitting the presented Workgroup feedback on Ventilated Referrals Data Collection to HRSA.

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A Committee member raised a critical point about the need for clarification regarding certain aspects of the workbook and data definitions. He expressed concerns about the ambiguity in data definitions, emphasizing the necessity of a clear process to obtain this clarification to facilitate progress and ensure consistency in data collection methods. A participant acknowledged the complexity of providing specific answers in the absence of a clear directive but underscored the importance of providing detailed feedback from the Committee once the directive is established. The participant explained that much of the substantial public comment and feedback would be provided through the Office of Management and Budget (OMB) process, as opposed to the typical OPTN public comment process. He emphasized that granular feedback will be essential for refining the data collection process and that engaging in discussions with CMS and HRSA will be pivotal in resolving issues effectively.

The Chair further emphasized the significance of developing robust data definitions to guarantee accuracy and consistency in reporting. He also suggested ongoing conversations between the OPO Workgroup, HRSA, and CMS to refine data elements continuously. The Chair stressed the importance of ensuring that the data collection process remained flexible to accommodate future adjustments based on evolving needs and insights. A HRSA representative assured the group that the best opportunities for feedback on the directive would be during the two identified comment periods which will then be reviewed by HRSA and CMS. He underscored HRSA's openness to refining the data collection process based on the feedback received, highlighting the collaborative approach to achieving accurate, timely, and meaningful data.

Following the additional questions and comments, the DAC decided to endorse the submission of the Workgroup's feedback on Ventilated Referrals Data Collection to HRSA.

Next steps:

The DAC Chairs will be sharing this feedback with HRSA on 1/31/2024. Next steps will also include developing a community communication plan, submitting public comment to the Federal Register, and developing an evaluation and monitoring approach.

4. Feedback on Pre-Waitlist Data Collection

Committee members discussed the Pre-Waitlist Data Collection Workgroup’s feedback for submission to HRSA.

Presentation Summary:

OPTN contractor staff outlined the discussion on pre-waitlist data collection, a topic associated with many members of the DAC. She discussed the Workgroup’s agreed-upon guidelines for data collection, emphasizing that data will be collected moving forward from a chosen point in time, not retrospectively. The data collection will be reported to the OPTN on a quarterly cycle rather than in real-time. There will be options to submit bulk data or participate in manual entry at predefined intervals. The main types of events, referral, evaluation, and transplant program selection are identified, each with start and end triggers. Once event closure takes place, transplant programs will not be able to edit the data.

For the referral event, the Workgroup identified 27 elements for collection, while for the evaluation-program selection event, there were 32. Nearly half of these identified data elements are currently collected on the Transplant Candidate Recipient (TCR) form. Additionally, five of the 12 new elements identified are collected at both referral and evaluation stages. After discussing the matter during breakout sessions at the in-person meeting, they concluded that there were no organ-specific data requirements for tracking at these two events.

Summary of discussion:

<p>Decision #2: The DAC endorsed submitting the presented Workgroup feedback on Pre-Waitlist Data Collection to HRSA.</p>
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A member wondered if a potential recipient’s OPTN Waiting List addition date would be a better data point compared to the selection committee decision element. He stated that this might be an easier way to capture relevant data. A Committee member recommended against using the OPTN Waiting List addition date because not every selection committee decision will lead to a waitlist addition. She added that even for those that are approved, the approval date might not necessarily be the same as the waitlist date.

A participant wondered when the Electronic Health Record (EHR) vendors would be brought into the conversation. She stated that they would not be able to pilot these changes until the EHR is built out first. The member questioned whether it would be possible to have a direct meeting between DAC and EHR vendors regarding this project.

In the conversation, a Committee member suggested revising the language for the selection committee decision label to "first final decision" or "final decision" to ensure clarity, given the variety of decisions made within the selection committee process. The Chair responded, affirming that "accepted," "approved," or "declined" are definitive responses, however, deferrals do not constitute final decisions. They agreed on the need for clarity in framing the data definitions to capture the correct information.

Members affirm the possibility of changing the label to "first final decision," reflecting the initial definitive decision resulting from referral and evaluation activities. The Committee agreed to continue to discuss this matter later.

A member also added that important conversations for the future will need to consider the viability of a pilot phase prior to the changes going live. He thinks that a pilot phase would be useful to understand areas that need to be improved; however, the logistics of such a pilot would still need to be identified. In addition, he said that they should consider providing a feedback platform for transplant centers regarding pre-waitlist data. This feedback tool could help transplant centers use meaningful data and may also assist in tracking their performance.

Following the additional questions and general feedback on the matter, the DAC decided to endorse the submission of the presented Workgroup feedback on Pre-Waitlist Data Collection to HRSA.

Next steps:

The next steps for the pre-waitlist data collection are very similar to those involving the ventilated referrals. The DAC Chairs will be sharing this feedback with HRSA on 1/31/2024. Next steps will also include laying out a community communication plan, submitting public comment to the Federal Register, and developing an evaluation and monitoring approach.

Upcoming Meeting

- February 12, 2024

Attendance

- **Committee Members**
 - Sumit Mohan
 - Jesse Schold
 - Dustin Goad
 - Paul MacLennan
 - Michael Marvin
 - Christine Maxmeister
 - Meghan Muldoon
 - Hellen Oduor
 - Jennifer Peattie
 - Julie Prigoff
 - Alicia Skeen
 - Al Wagner
- **HRSA Representatives**
 - Adriana Alvarez
 - Chris McLaughlin
- **SRTR Staff**
 - Avery Cook
 - Ajay Israni
 - Jon Snyder
- **UNOS Staff**
 - Laura Cartwright
 - Brooke Chenault
 - Jonathan Chiep
 - Kevin Daub
 - Samya Dyer
 - Cole Fox
 - Nadine Hoffman
 - Michael Hollister
 - Sevgin Hunt
 - Beth Kalman
 - Sara Langham
 - Eric Messick
 - Heather Neil
 - Joel Newman
 - Laura Schmitt
 - Sharon Shepherd
 - Kim Uccellini
 - Niyati Upadhyay
 - Divya Yalgoori
 - Anne Zehner
- **Other Attendees**
 - Rick Hasz