OPTN Data Advisory Committee
Meeting Summary
December 4, 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 12/04/2024. The purpose of the meeting was to refine Committee leadership's draft OPTN response to the Federal Register Notice (FRN) *Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx-New* that was published on 11/14/2024. (The FRN can be accessed here: https://www.federalregister.gov/d/2024-25522) The Committee was joined by members of their Pre-Waitlist Data Collection Workgroup (Pre-Waitlist Workgroup) and members of the Membership and Professional Standards Committee's (MPSC) OPO Performance Monitoring Enhancement Workgroup (OPO Workgroup). The meeting attendees discussed the following agenda items:

1. Welcome, meeting objectives, and next steps
2. Ventilated Patient Referral data collection form and instructions
3. Pre-Waitlist Referral and Evaluation data collection forms and instructions
4. Questions and comments
5. Public Forum
6. Closing Remarks

Discussions focused on collecting meaningful and standardized data to support organ donation and transplantation performance improvement. Attendees evaluated the submitted feedback about the pre-waitlist referral collection form, the pre-waitlist evaluation collection form, the ventilated patient referral collection form, and the instructions associated with each in order to ensure alignment with the Committee's objectives.

The following is a summary of the discussions that took place between the members of the Committee and both workgroups.

1. Welcome, meeting objectives, and next steps

The members of the Committee and the two Workgroups were welcomed and a brief overview of the agenda items was provided. The meeting was convened to finalize the Organ Procurement and Transplantation Network's (OPTN) draft response to the Health Resources and Services Administration (HRSA) data directives addressing ventilated patient data collection and pre-waitlist data collection. HRSA published their proposed data collection forms and instructions in the Federal Register 11/04/2024.

2. Ventilated Patient Referral data collection form and instructions

This part of the meeting focused on enhancing data collection for ventilated patients to identify opportunities for performance improvement in Organ Procurement Organizations (OPOs). The data collection aims to include demographic information and OPO process data on ventilated patients with a

documented pronouncement of death. Those in attendance strongly stated their commitment to improving data collection for ventilated patients and enhancing the performance of OPOs.

Summary of discussion:

Meeting attendees reviewed the definition and scope of “ever ventilated” patients. They wanted to ensure consistency in data collection. Concerns were raised about the burden OPO staff would encounter tracking ever-ventilated patients who have absolute contraindications to donation, such as metastatic cancer. Patients with absolute contraindications have no potential for donation. It was recommended to clarify the death record review requirements by focusing on collecting what is identified as essential data, while minimizing unnecessary reporting.

Concerns were expressed about the variability in interpretation and implementation of data collection processes across OPOs.

The meeting participants emphasized using a hierarchical, algorithmic approach to data collection to ensure objective and reproducible data. The OPO Workgroup had developed an algorithmic approach as part of a public comment proposal they had developed, but which was not released for public comment.

The group discussed the criteria for including patients in the ventilated patient data collection, emphasizing the need for clear definitions. The group agreed that these criteria should be considered: patients must be deceased, declared dead by brain or cardiac death criteria, and have been ventilated during their terminal hospital admission.

Those in attendance discussed what they believed to be the challenges with HRSA proposed data collection form and instructions. They also identified clarifications they believe are needed. For example, there was agreement that the term "ever ventilated" needs a clear definition to avoid inconsistencies in data collection. The requirements for death record reviews need further clarification, including the criteria and timing for such reviews. The group expressed concern that without clarification, the information provided as a result of the death record reviews will probably be reported inconsistently by the OPOs. For example, there was a question as to whether the OPTN response should reference the Code of Federal Regulation requirements for death record reviews and validate whether there is agreement that the death record reviews are only occurring based upon the CFR requirements and not for a larger population? Concerns were raised about the data collection burden on OPOs, especially for patients who are not potential donors. Similarly, a question was raised about whether the definition of a documented pronouncement of death refers to the event being documented in the hospital record or in the OPO donor record? Which entity records such information also impacts who will be counted or not counted as a potential donor. OPOs are likely to capture the date and time of death differently. Another member said that it should be death in the referring institution and perhaps the tweak should be ‘death in an acute care facility that has the potential for donation?’ The members also asked about the advantages and disadvantages with recommending collection of a timeframe from extubation as another way to identify the potential for donation? The group pointed out that it is these types of questions that lead them to question whether HRSA’s proposed VPF data collection form will result in information that can be used to effectively measure OPO performance? While raising these questions, the group reiterated their support of HRSA’s efforts to ensure the collection of reliable and timely data to accurately measure OPO performance.

The participants identified some specific data fields and instructions they believe need additional work. The collection of home zip codes was debated, with concerns about data accuracy and relevance for non-donors. The need for consistent and clear instructions on collecting race and ethnicity data was highlighted. The relevance of collecting gender identity data was questioned, given its current lack of impact on donation and transplantation processes. These fields for height and weight were discussed in

terms of their availability and accuracy, especially for non-donors. The process for documenting legal authorization for organ donation and the impact of family objections were discussed.

The matter of hospital interference and reporting was of particular interest to those in attendance. The term "hospital interference" was debated, with suggestions that the OPTN response recommend that HRSA consider using less pejorative language. The need for clear definitions and standardized criteria for reporting hospital interference was emphasized. The process for reporting and remediating hospital interference was discussed, including who should receive reports and what constitutes acceptance and remediation.

The group discussed the various outcomes for case disposition, such as medical rule out, family decline, and allocation exhaustion. The need for clear definitions and mutually exclusive categories was highlighted to ensure consistent data collection. For example, a member stated medical rule out is just a big catch-all category as it appears on the proposed collection form and appears to have been determined without understanding how OPOs make such decisions. As a result, there needs to be guidance about the expectations and more granularity about what is actually being requested. Some attendees indicated their thinking that the proposed collection will result in data that is less helpful than what is currently being collected.

The group had several recommendations for inclusion in the draft OPTN response. They agreed on the need for clear definitions and standardized criteria for all data fields to ensure consistent and accurate data collection. Specific terms like "ever ventilated," "hospital interference," and "case disposition" require detailed definitions.

They emphasized the importance of minimizing the data collection burden on OPOs while ensuring the collection of meaningful and accurate data. The need for a logical flow in the data collection process was highlighted, with suggestions to align with existing data collection tools and standards. They recognized the need for ongoing collaboration with HRSA and other stakeholders to refine the data collection process and address any challenges. The importance of involving hospitals in the data collection process and ensuring their awareness and cooperation was emphasized.

Next steps:

The group identified the need for HRSA to draft detailed definitions for key terms and criteria to be included in the data collection process. These definitions will be reviewed and refined in collaboration with HRSA and other stakeholders. OPTN contractor staff will incorporate the group's feedback in the draft response to ensure the final data collection process is comprehensive and practical. An implementation plan will be developed to ensure a smooth transition to the new data collection process. This plan will include timelines, training for OPO staff, and mechanisms for ongoing review and improvement.

3. Pre-Waitlist Referral and Evaluation data collection forms and instructions

The current DAC Chair and the previous DAC Chair reminded those in attendance that HRSA had accepted the vast majority of the pre-waitlist data collection recommendations submitted by the Pre-Waitlist Data Collection Workgroup in January 2024. The Chairs wanted to make sure that the draft OPTN response reflected the OPTN's desire to partner with HRSA to ensure that the pre-waitlist data fields identified for collection are the most appropriate for achieving both HRSA's goals and the goals of the OPTN.

Summary of discussion:

Decision #1: The members agreed to submit the draft OPTN response to the OPTN Executive Committee, with some revisions.

Participants noted the need for improved guidance and granularity in the reporting of medical rule-outs and patient outcomes. Discussions highlighted the necessity for clear, universal definitions to avoid inconsistent data practices. Examples included defining "absolute contraindications" and aligning reporting criteria across organizations.

The participants acknowledged that HRSA had incorporated most of the DAC's Pre-waitlist Data Collection Workgroup's recommendations, with a few differences. There was agreement that HRSA's actions were a positive outcome.

In terms of differences, HRSA made changes to DAC 's recommendations for how cancellation reasons should be reported. HRSA also removed one of DAC's recommended date fields. It was unclear why the field was removed. There was agreement from those in the meeting that DAC should ask HRSA to clarify the reason or reasons for removing the recommended field.

The DAC Chair stated that it was important for the OPTN response to reiterate the Committee's recommendation for a quarterly data collection cycle, which should include an option for transplant programs to perform a bulk submission if they have the ability to do so. For programs unable to submit a bulk upload, then the data can be submitted manually in three to five intervals. The Chair also asked that the OPTN response emphasize the Committee's recommendation for implementing batch reporting rather than real-time reporting as a way to reduce the administrative burden on transplant programs while also improving data quality. OPTN contractor staff also highlighted that after a transplant program has submitted their data, it becomes final and cannot be retrospectively edited. This should help ensure the integrity of the data.

Several other key points were discussed regarding the pre-waitlist data collection proposed by HRSA. The Chair highlighted that the OPTN response should address the importance of also capturing death records in order to understand the populations at risk for progressing across the stages of referral, evaluation, registration on the waitlist, etc. The Chair added that without knowing what the denominator of patients is, the collected information will result in highly skewed estimations of timing and processes of care. It is likely that HRSA will use the pre-waitlist data to determine how quickly patients progress from referral to evaluation, and so on. Without information about those who do not progress to the next phase due to death, then any analysis will produce a biased estimate of the timing of moving through phases. Additionally, transplant programs do not holistically have information about patients who do not progress from one stage to another. As a result of these and other factors, the OPTN response needs to clearly explain the potential gaps and share what the edge cases could be.

Also highlighted was the potential for rolling out the pre-waitlist data collection through a pilot or "run-in" period to address unforeseen challenges and refine the collection process before large-scale implementation. Those in attendance thought it important for the OPTN response to suggest that a pilot phase would help all sides work through any unforeseen issues before a full rollout occurred. The Chair noted that a pilot may or may not be an option depending on how HRSA intends for implementation to occur, but added that there is utility in avoiding large-scale issues that could result from a single, full rollout. This could also help involve other stakeholders, particularly the electronic medical record (EMR) vendors who could make data collection and submission as seamless as possible for transplant programs to implement.

A DAC member asked about how the collected information will be shared with transplant programs? For example, how will the information be shared and with whom shall it be shared? There was consensus on

the importance of HRSA sharing collected data with transplant centers to help them benchmark their processes and improve patient outcomes. The Committee recommended that this be explicitly stated in the draft OPTN response. As such, the OPTN response might also want to address the need for additional resources needed to support benchmark reporting.

The current DAC Chair and the previous DAC Chair emphasized the need for the OPTN response to reflect a cooperative and non-confrontational tone in order to facilitate meaningful discussions with HRSA and make the progress both sides want to accomplish. At the same time, those in attendance agreed that creating separate closing remarks for the pre-waitlist forms and the ventilated patient form was appropriate due to the different statuses of the forms HRSA published as part of the Federal Register notice. The members agreed that the pre-waitlist data collection forms as published in the notice were mostly ready to move forward, with minor suggestions from the OPTN for improving the forms. Those in attendance concurred that the OPTN response needs to highlight that the ventilated patient referral form published in the notice needs more work before it becomes final. The members expressed concerns that the form is unlikely to achieve its objective. They indicated that, among other issues, there remain issues around the viability of OPOs to collect some of the data fields, including both the timing of when some of the data is available and whether other data is available at all, as well as some of the definitions need clarifying to ensure the community's consistent understanding and reporting of the requested information. The DAC Chair pointed out that it is unlikely DAC would endorse the current version of the ventilated patient form if it were presented to the Committee as part of their regular review of data collection projects.

Next steps:

OPTN contractor staff will revise the Committee's drafted OPTN response based on the suggestions made and share the updated version with the Committee members within the next few days.

4. Questions and comments

The DAC highlighted the need to differentiate their feedback between the pre-waitlist and ventilated patient data collection. While the pre-waitlist data collection was deemed largely ready for implementation, the ventilated patient data collection required significant refinement. The group emphasized the need for a clear, cooperative approach in presenting the pre-waitlist recommendations to foster productive dialogue with HRSA and ensure alignment with the OPTN's overarching goals.

Summary of discussion:

The meeting participants agreed that without additional guidance from HRSA, there is a risk of collecting incomplete or inconsistent data due to a lack of standard definitions and reporting frameworks. Moreover, the risk of not receiving such guidance could derail the potential benefits of the proposed collection. In addition, the potential administrative burden of tracking non-essential data points, could detract from obtaining critical information about donation and transplantation efforts. There was also discussion that OPOs must receive the resources and clarity needed to implement data collection efficiently.

Those attending the call agreed that the draft OPTN response should include detailed definitions and standards to address the inconsistencies that have been documented. They also agreed that the response should emphasize the importance of stakeholder collaboration with HRSA to refine the data collection tools and processes. Finally, the OPO Workgroup members recommended including in the response the tools, such as the algorithm, and the public comment proposal they developed as reference material for developing robust data collection methodologies. The algorithm was developed as a hierarchical tool, to help reduce the amount of open-ended interpretations that OPOs have to make

and do make, especially when the facts of different cases are similar. The group wanted to underscore that the algorithm was intended to demonstrate a potential solution that would help OPOs consistently interpret the instructions, which in term would lead to better quality data being collected. The decision was made to include with the OPTN response the OPO Workgroup's public comment document describing the algorithm. At the time, the document was not published for public comment at HRSA's request because the Data Directive was forthcoming.

The meeting concluded with acknowledgments of the committee's efforts under a compressed timeline. Final steps involve review and approval by the OPTN Executive Committee and submission to HRSA before the 12/2-/2024 deadline. The DAC expressed hope for increased engagement and responsiveness from HRSA in the future.

Next steps:

DAC leadership and the leader of the OPO Workgroup will work with OPTN contractor staff to prepare materials for review by the OPTN Executive Committee (ExCom) as part of their 12/12/2024 meeting. ExCom is expected to vote on whether or not to submit the response to HRSA by the 01/03/2025 deadline.

5. Public Forum

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

6. Closing Remarks

The Committee Chair thanked everyone for participating throughout the meeting. The Chair said that Committee leadership will ensure all feedback is comprehensively addressed in the draft response submitted to ExCom. The Committee will also need to provide clear timeline and Summaries of any additional discussion items. The Chair also said that it is important for HRSA to provide clear timelines and expectations regarding how the OPTN will implement the changes after the HHS Directive is approved.

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 4, 2024 10:30 am – 2:30 pm (ET) – HHS Data Collection Directive Meeting
- 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
  - Cassie Hertert
  - Paul MacLennan
  - Christine Maxmeister
  - Sumit Mohan
  - Jennifer Peattie
  - Julie Prigoff
  - Meghan Schaub
  - Alicia Skeen
  - Lindsay Smith
  - Allen Wagner
- **HRSA Representatives**
  - Marilyn Levi
  - Arjun Naik
- **SRTR Staff**
  - Avery Cook
  - Ryutaro Hirose
  - Jon Miller
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - Lloyd Board
  - Marty Crenlon
  - Huong Cunningham
  - Richard Hennings
  - Jesse Howell
  - Robert Hunter
  - Krissy Laurie
  - Eric Messick
  - Lauren Mooney
  - Heather Neil
  - Joel Newman
  - Nadine Rogers
  - Laura Schmitt
  - Sharon Shepherd
  - Holly Sobczak
- **Other Attendees**
  - MPSC's OPO Performance Monitoring Enhancement Workgroup
    - Rick Hasz
    - Kristine Browning
    - Chris Curran
    - Theresa Daly
    - Micah Davis

        - Kyle Herber
        - Christy Keahey
        - Lori Markham
        - Luis Mayen
        - Debbi McRann
        - Cliff Miles
        - Malay Shaw
        - Carrie Thiessen
    - DAC's Pre-Waitlist Data Collection Workgroup
        - Leigh Ann Burgess
        - Ashley Cardenas
        - Karl Neumann
        - Martha Tankersley