OPTN Data Advisory Committee
Meeting Summary
December 9, 2024
Conference Call

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Introduction

The OPTN Data Advisory Committee (the Committee) met via WebEx teleconference on 12/09/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Summary of DAC Chair's discussion with the OPTN Board of Directors on 11/21/2024 and feedback received
3. Finalize draft OPTN response to 60-day Federal Register Notice: Process Data for Organ Procurement and Transplantation Network (OMB No. 0906-xxxx-New)
4. Public forum
5. Closing remarks

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

1. Welcome and agenda review

The Chair welcomed the members and highlighted the two main items for discussion. First, the Chair said the Committee would use the meeting to finalize the responses to the Federal Register Notice regarding data collection. Second, the Chair said he would provide the Committee with a summary of his conversation with the OPTN Board of Directors.

2. Summary of DAC Chair's discussion with the OPTN Board of Directors on 11/21/2024 and feedback received

The Chair summarized his presentation of the Committee's annual deliverables to the OPTN Board of Directors and the discussions of the Committee's recommendations. OPTN contractor staff provided feedback based on Board members' comments during the meeting.

Summary of discussion:

No decisions were made as part of this discussion.

The presentation stressed the need for ongoing improvement and supplementation of the OPTN data collection process. The Board members expressed support for the Committee's recommendations. The OPTN President requested that the Committee draft a briefing paper formalizing the recommendations from the presentation in order to establish a precedent for future Board discussions and resource prioritization. The former OPTN President emphasized the importance of data quality and highlighted the recommendation that HRSA and the OPTN need to find ways to act more quickly when it comes to

implementing data collection changes. The former OPTN President mentioned the delays in project implementation due to the requirement of OMB approval before changes can be implemented.

The Board members appeared receptive to creating a data champion role who could serve as a liaison between the Board and the Data Advisory Committee to assist with the promotion of data collection needs. Additionally, the Board members appeared to agree that they will consider candidates for the data champion role and how the potential changes in the new OPTN Board composition may impact such a role. The Chair expressed gratitude to the OPTN Board members and for considering the Committee's recommendations, especially the theme of an expedited process for implementing data collection changes.

OPTN contractor staff attempted to supplement the Chair's description of the Board meeting with additional details. For example, the OPTN President acknowledged that the comprehensiveness of the presentation and said it provides a good roadmap for the future. The OPTN President also mentioned that the OPTN Board had already started some conversations during their prep for the board meeting with HRSA around improving the timing associated with the OMB cycles. OPTN contractor staff are also following-up to find out if any OPTN Board members indicated an interest in serving as the data champion. In addition, the immediate past OPTN President pointed out that some of the projects the OPTN Board approved in 2022 and 2023 have yet to be implemented because they are awaiting OMB approval. HRSA did not submit the projects as part of the OMB approval process following Board approval because they wanted to include them with the Data Directive data forms to create a more streamlined process. However, HRSA decided to forego combining the projects and the Directive, and the projects are part of a separate Federal Register Notice.

OPTN contractor staff also shared other OPTN Board members' comments from the Chair's presentation. A member who was supportive of a data champion asked if the OPTN Board support contractor group could provide that function, but no answers were provided. Another member cautioned against creating a dedicated Board role and pointed out that other subject matter areas and patient populations are not largely represented on the Board either. A Board member called out being mindful of small programs without adequate resources to perform the amount of data collection and reporting being discussed. A Board member asked that they would like to have some concrete examples included in the proposed briefing paper that would help explain and expand upon the challenges DAC identified regarding data.

The Committee also discussed the notification that was sent to OPTN members regarding the creation of a nominating committee that will gather information about key criteria for Board members to have, as well as to recommend individuals for consideration as part of a new Board.

Next steps:

The Committee will develop a briefing paper documenting their recommended changes for the OPTN Board's consideration. OPTN contractor staff will assist with developing the briefing paper. The Committee will follow-up regarding a potential data champion on the Board.

3. Finalize draft OPTN response to 60-day Federal Register Notice: Process Data for Organ Procurement and Transplantation Network (OMB No. 0906-xxxx-New)

The Committee reviewed the draft OPTN response and agreed with the information in the response. The Chair underscored that the draft response makes clear that the OPTN and the Committee support HRSA's effort implement collection of pre-waitlist and ventilated patient referral data. The Chair

reminded the members that on 12/12/2024 the response will be presented to the OPTN Executive Committee (ExComm) for their approval to submit it as the OPTN's formal response to HRSA.

Summary of discussion:

Decision #1: The Committee agreed to submit their draft OPTN response to the OPTN Executive Committee for approval.

The Chair summarized the draft response as it addresses both the pre-waitlist data collection and the ventilated patient referral data collection. The draft response is comprised of a high-level summary addressing the entire Directive, and individual sections addressing the proposed pre-waitlist referral form, the pre-waitlist evaluation form, the ventilated patient referral form (VPF), and the instructions created for each form. The Chair emphasized that DAC is supportive of the overall goal of HRSA's proposed data collection. He stated that the draft response endorses HRSA's proposed pre-waitlist data collection as it appears in the 60-day Federal Register Notice (FRN) because it is very consistent with what DAC proposed originally. At the same time, the response recommends improvements to the ventilated patient referral (VPF) data collection and makes clear that the Committee is willing to partner with HRSA to make necessary changes.

The Chair covered the timeline of Directive-related activities, which started in late 2023. He also emphasized the amount of work performed by the Committee and two workgroups in developing proposed data collection tools at HRSA's request. He acknowledged that HRSA incorporated much of the Committee's recommendations for pre-waitlist data collection, while accepting few of the recommendations related to the VPF. The Chair stated that the expectation is that HRSA, as part of their 30-day FRN, will publish a response addressing all public feedback received as part of the 60-day FRN.

For the pre-waitlist data collection, the Chair reminded the members that HRSA is proposing collection of two categories of information, data associated with the referral stage and data associated with the evaluation stage. Some of the specific recommendations included in the draft response are: establishing start and end triggers for referral evaluations, no editing of data after event closure, and batch reporting as a way to collect higher quality data. The Chair added that the draft response suggests minor modifications to HRSA's proposed collection data. For example, HRSA's proposed data collection excluded some variables DAC originally recommended. The draft response emphasizes why those variables are meaningful. The draft response also addresses other DAC recommendations that are absent from the 60-day FRN. For instance, there is no information about the mode of data collection. The Chair said the draft response explains the Committee's rationale for suggesting the data be collected in a particular way, in particular the importance of batch reporting knowing that this is going to increase the value and quality of the data. The Chair added that batch reporting is even more justifiable because real time data is not necessary to affect what the Committee perceived to be the intent of the data. The Chair said the draft response addresses the importance of including the use of supplemental data, specifically death data, to measure key timing and processes of care events.

In recommending improvements to HRSA's proposed VPF collection, the draft response points out that any data collection should be detailed and use discrete data already available, in order to support careful interpretation. The draft OPTN response again highlights support for HRSA's effort while providing recommendations for how the proposed data collection might be improved in order to efficiently and effectively measure OPO performance. The Chair stated that the draft response recommends significant additional is required to make the ventilated patient referral data useful for the intended purposes. The Chair added that as currently proposed, the Committee would not be willing to endorse the data collection if it were an OPTN project being presented to them. The Chair said that the

hope is that the HRSA will want to engage with Committee to improve the VPF, and that the MPSC's OPO Workgroup has offered several times to work with HRSA. In particular, the OPO Workgroup developed a sophisticated algorithm that is believed to meet HRSA's intended goals of collecting ventilated patient data while also collecting many of the salient data fields that are currently available through existing workflows and electronic medical records. The draft response suggests that the data proposed for collection lacks necessary granularity and consistency, making it difficult to document medical rule outs, for example. To address the concern separate forms reflecting current processes of care and data submission are recommended.

The Chair continued that for both the pre-waitlist and ventilated patient referral data, the draft response highlights that the data should be sufficiently detailed to support careful, reliable, and reproducible interpretation necessary to match any appropriate study design. To assist in this effort, the draft response recommends using discrete data that is already available and incorporating current processes of care and current electronic medical records as possible. The draft response points out that the data that currently exists through normal workflows and those discrete data will have more objectivity than data that is either not currently collected or is less objective in its current form. Some of the VPF-specific comments point out that some of the data proposed for collection is unknown in certain circumstances or in certain flow of data for certain subsets of the population and thus presents substantial challenges to be collected.

On the pre-waitlist side, there were two specific variables the Committee had originally proposed that HRSA did not include with the 60-day FRN and the Committee has not received specific feedback as to the rationale for their removal. The data involve the start and end trigger dates for the pre-waitlist referral stage and the pre-waitlist evaluation stage. The start and end dates are particularly relevant for the intended goals of understanding the timing of patients' processes of care on the pre waitlist side and reasons why patients might not proceed farther in the process.

The Chair continued by highlighting the VPF-related feedback provided in the draft response. As mentioned, the Chair said that there are significant concerns with the proposed VPF collection that would likely result in DAC not endorsing the proposal if it were an OPTN data collection project. Among the high-level concerns are that the data are unlikely to meet HRSA's intended goals, in part because they lack the necessary granularity. The proposed medical rule out reasons are a good example. The Chair stated that there is a long history of why the OPTN needs to know whether potential donors are medically suitable or not. The proposed data will not allow for objective, consistent documentation of medical rule outs. In addition, some of the choice list values and the logical data flow are not consistent given the current processes of care for potential donors. There are several key pieces of information that will likely be reported as unknown simply because some information is not known early in the potential donor processes for ventilated patients. Those pieces of information are identified in the draft response. Because the data will not be available at the timeframes identified in the proposed data collection, there will be a high percentage of data fields with unknown information that will not be useful for the intended purposes. Another concern is that populations targeted by some of the proposed fields are unclear and will require clarification and standardization. Otherwise, individual OPOs may interpret what to collect and report differently resulting in inconsistent data.

The draft response recommends a more holistic approach to the VPF data collection. The Chair pointed out that the product developed by the OPO Workgroup was not incorporated to a large degree in the proposed data collection form. The OPO Workgroup's product has been iterated on several times and was proposed to HRSA in January 2024 as part of an effort to start an ongoing conversation with HRSA about the rationale for all the data proposed for collection. However, the proposed data collection does not include the OPO Workgroup's suggestions. The draft response illustrates some of the benefits

associated with the OPO Workgroup's product, such as how their proposed data collection can be incorporated with electronic donor records. As a result, it is concordant with current data systems and could potentially reduce some of the data burden experienced by OPOs. It would also likely result in more objective data through the current flow of processes of care. The Workgroup's product could result in standardized documentation of the referrals. The logic behind what the Workgroup proposed is important because it helps guide the OPOs' responses in a way that results in elements being collected that are reflective of prior responses.

The draft response also points out that the proposed VPF data collection would aggregate patient-specific demographic and clinical data with process- and hospital-specific into one form, which will lead to problems in the future. Some of the proposed data collection is fairly ambiguous and will likely be reported inconsistently, so significant clarification is needed to ensure accurate and consistent data reporting on behalf of the OPOs. Additionally, different types of the proposed data are unlikely to be available within the same time frame. Having data that is reflective of when more information is known makes sense to the normal processes, rather than aggregated into one collection form. The draft response recommends creating separate forms reflective of current processes of care.

Other important aspects of the pre-waitlist data collection addresses in the draft response include that transplant programs should not be able to edit data after event closure, which is consistent with the Committee's decisions regarding the data lock generally. Like the expectations around other OPTN data, the intent is for the pre-waitlist data to be collected and reported correctly the first time which should be achievable given the proposed reporting cadence. The Chair then discussed the proposed quarterly data collection cycle and how transplant programs will have the options to submit their pre-waitlist data either in bulk or manually at predefined intervals.

The Chair also discussed the importance of including secondary death information as part of the pre-waitlist effort. The secondary death information is necessary to help ensure the appropriate patient denominator is known and used in analyses in circumstances where a transplant program is unaware of a patient death during on the stages. The OPTN will want to know the number of patients at risk for progressing through each stage. Without knowing the appropriate denominator of patients who are available to progress to that next stage, the time from referral to evaluation cannot be accurately calculated. It is fair to assume that HRSA and the OPTN will want to know how quickly patients are progressing through these stages, and if there are differences in the amount of time by transplant program, patient populations, etc.

Other high-level suggestions in the draft response include requesting that HRSA provide more information about how the OPTN should address the proposed policy changes specific to the Directive as well as in the future. Because the Directive does not follow the OPTN policy development and public comment processes, the draft response requests clarification concerning HRSA's expectations around future policy changes related to the Directive's data collection. For example, OPTN *Policy 18: Data Submission Requirements* may be the most appropriate vehicle for such policy revisions in the future. The draft response also highlights the Committee's interest in setting implementation plans and timelines and collaborating with vendor stakeholders. There is general agreement that the data reporting should be highly dependent on APIs and as such should engage the EDR and EMR vendors. The draft response also discusses the potential for implementing a pilot effort prior to full implementation to identify and address any unforeseen challenges. The draft response also discusses how the proposed data collection could be of high value to transplant programs and OPOs via benchmark reporting. During DAC's original development of the proposed data collection elements, there was very consistent messaging from those involved that the data can be very valuable for internal quality assurance and improvement processes.

Next steps:

The Chair discussed how a formal OPTN response must be submitted to HRSA within the next ten days. After the formal response is submitted, the Committee wants to have it posted to the Directive toolkit on the OPTN website in order to continue being as transparent with the OPTN community as possible. A request will be submitted to the OPTN President asking that the OPTN community be notified about submission of the formal response. Following closure of the 60-day FRN, HRSA will have time to review the public feedback before publishing the 30-day FRN.

4. Public forum

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

5. Closing remarks

As part of the closing remarks, the Chair stated that more information will be shared with the Committee about the nominating committee for the new OPTN Board composition. OPTN contractor staff were asked to share the email about the nominating committee with the DAC members. The Chair also thanked the members for their work and efforts in creating a comprehensive and thorough draft response for HRSA's proposed pre-waitlist and ventilated patient referral data collection, especially given the short-timeline the Committee had to produce the response. The next Committee meeting is scheduled for 01/13/2025.

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
  - Kate Giles
  - Cassie Hertert
  - Michael Marvin
  - Christine Maxmeister
  - Nancy McMillan
  - Jennifer Peattie
  - Julie Prigoff
  - Alicia Skeen
  - Lindsay Smith
  - Allen Wagner
- **HRSA Representatives**
  - None
- **SRTR Staff**
  - Avery Cook
  - Jon Miller
- **UNOS Staff**
  - Brooke Chenault
  - Jonathan Chiep
  - Huong Cunningham
  - Cole Fox
  - Jesse Howell
  - Eric Messick
  - Lauren Mooney
  - Nadine Rogers
  - Laura Schmitt
  - Sharon Shepherd
- **Other Attendees**
  - Rick Hasz