

**OPTN DAC Committee
Meeting Summary
November 13, 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 11/13/2023 to discuss the following agenda items:

1. Discuss Pre-Waitlist and Organ Procurement Organization (OPO) Performance Metric Data Collection and Closing Remarks

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

1. Discuss Pre-Waitlist and Organ Procurement Organization (OPO) Performance Metric Data Collection and Closing Remarks

The Committee discussed potential pre-waitlist data collection and the collection of “ventilated death” data that is associated with the work being performed by the Membership and Professional Standards Committee’s (MPSC) OPO performance monitoring metric workgroup. The pre-waitlist and ventilated death data collection efforts were brought to DAC by representatives of the Health Resources and Services Administration (HRSA).

Summary of discussion:

The Chair welcomed members to the meeting, announced a secondary meeting with an expanded agenda, and welcomed a HRSA representative to address the Committee about the request. The Chair further stated that HRSA’s request represents an important, positive step related to pre-waitlist and OPO metric data performance data collection for the overall transplant ecosystem. The Chair concluded with a reminder that there will be a meeting tomorrow.

The HRSA Contracting Officer Representative (COR) explained the Final Rule, its relationship to data collection involving pre-waitlist activities, and HRSA has not historically exercised the authority to collect such data. The COR also said that there are 2 data collection efforts that will be discussed. The HRSA representative started by discussing the request involving pre-waitlist data collection, stating that the OPTN has the authority to allow data to be collected at the point of referral. Previously, DAC and two other OPTN Committees, the Minority Affairs Committee (MAC) and the Transplant Administration Committee (TAC), were involved with developing a pre-waitlist data collection proposal. The three OPTN committees proposed to begin collecting information on the current transplant candidate referral form, which HRSA staff indicated they would like DAC to revisit.

The COR showed a copy of a prototype kidney referral evaluation registration form that HRSA staff have been revising as an example of how such data might be collected in the future. The HRSA representative noted implementation of the data collection changes being discussed during the meeting would need to be negotiated with the contractor and the changes could be implemented immediately, meaning that

this policy change would not undergo the general policy approval process, including not submitting a proposal for public comment.

Because HRSA requests quick feedback concerning the new data collection, the COR asked if DAC could complete their review by the December meeting. Due to that timing, HRSA could insert those data elements into the next round of the Office of Management and Budget (OMB) data package that would then be released as part of an OMB public comment period. However, it is important to note that this would take it out of the OPTN's normal public comment process, but not out of public comment totally because the OMB approval process requires a 60-day public comment notice in the Federal Register and then an additional 30-day public comment period for the forms to be available for review. With this timing, it might be too late to get into the winter OPTN process, although it may overlap. HRSA staff also indicated that while the prototype form being shared is kidney-specific, data collection would be for all organs. HRSA staff also indicated that in their proposed changes, they removed the organ register field and the date of listing field.

The HRSA COR also started a presentation about adding information on ventilated death referrals and other data that HRSA may want to add related to Death Notification Registration (DNR). There is a significant amount of information listed. Additionally, this would need an electronic process where things are revised to pull data and submit expectations and modifications through APIs. There were questions about starting in this way and working from there. The intention is to start collection of information on deceased donors. The HRSA COR noted that the information currently collected is not sufficient to meet regulatory requirements, according to the Centers for Medicare and Medicaid Services (CMS). The COR said that it would be great if DAC can provide feedback regarding both the pre-waitlist data collection and the ventilated death data collection back to HRSA by January of next year. The Chair asked about the availability of the data and whether they will be offered to DAC as well as calling to answer questions from the wider group.

Members discussed the potential changes to pre-waitlist data and a member asked about the required fields for the time of referral indicated on the spreadsheet provided by HRSA staff. A HRSA representative responded that that is not indicated on the spreadsheet and notes that it does not reflect the form or the process. Another Committee member asked about how to populate the forms in a logistical manner. The members think about what date to use and how to define referral. Another member shared the sentiment for needing to define the term 'referral.' The HRSA COR discussed the potential for inequity and equity noting that the point of referral is the point at which a patient first gets into the transplant system. The Chair pointed out the fact that the DAC has requested authority to collect this information for multiple years and that there needs to be a denominator in reference to organ allocation. The Chair continued by providing an example from the kidney transplant community, noting the mismatch between the waitlist and the population denominator for the other organs – with heart, lung, and liver there is little understanding as to what the population denominator is and who is being referred in evaluation. The Chair also mentioned the lack of transparency in the process, suggesting that the best way to look at this is to decide and identify which are meaningful variables.

The HRSA representative mentioned how the authority to define and modify the data would be within DAC's purview. In addition, the HRSA representative noted that HRSA is working with CMS to figure out how CMS can address its data collection as well. A member noted that it may be easier to do a crosswalk of all the forms to see what is missing and what is not missing. Another member mentioned needing a definition of 'evaluation.' The Vice Chair thanked the HRSA representative for presenting the new change. The Vice Chair also mentioned broader areas that need to be addressed, need for iteration, and the potential limitations and opportunities. The OPTN Contractor made a reference to the potential inequity. The Chair mentioned that to make these changes the other OPTN committees need to also

weigh in. The Vice Chair mentioned that a duplication of work does not need to happen and that it is doable to meet the deadline. The OPTN Contractor asked about how to collect data more efficiently and the HRSA representative responded that collecting it with APIs might be appropriate. In reference to the OPO membership data collection, DAC has not done a lot of work but can still play a supportive role. The Vice Chair supports this initiative.

Next steps:

Questions and comments will be circulated among the Committee members, and then be forwarded to one of the HRSA representatives. The Chair will navigate delegations and possibly convene a workgroup for further discussion and iterations.

Upcoming Meeting

- November 14, 2023

Attendance

- **Committee Members**
 - Sumit Mohan
 - Jesse Schold
 - Rebecca Baranoff
 - Dustin Goad
 - Paul MacLennan
 - Michael Marvin
 - Christine Maxmeister
 - Meghan Muldoon
 - Hellen Oduor
 - Jennifer Peattie
 - Juie Prigoff
 - Alicia Skeen
 - Allen Wagner
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Adriana Martinez
 - Chris McLaughlin
- **SRTR Staff**
 - Katie Audette
 - Ajay Israni
 - Maryam Valapour
- **UNOS Staff**
 - James Alcorn
 - Asma Ali
 - Sally Aungier
 - Roger Brown
 - Alex Carmack
 - Brooke Chenault
 - Jonathan Chiep
 - Robert Emerson
 - Bonnie Felice
 - Cole Fox
 - Darby Harris
 - Richard Hennings
 - Gabrielle Hibbert
 - Nadine Hoffman
 - Michael Hollister
 - Houlder Hudgins
 - Sevgin Hunt
 - Robert Hunter
 - Sara Langham
 - Krissy Laurie
 - Lauren Mauk
 - Kieran McMahon
 - Eric Messick

- Sara Moriarty
- Jacqui O’Keefe
- Sarah Payamps
- Kelley Poff
- Amy Putnam
- Laura Schmitt
- Sharon Shepherd
- Kaitlin Swanner
- Susan Tlusty
- Kim Uccellini
- Suhuan Wang
- Tamika Watkins
- Joe Watson
- Sara Rose Wells
- Steve Wendt
- Divya Yalgoori
- **Other Attendees**
 - Alejandro Diez
 - PJ Geraghty
 - Rick Hasz
 - Sanjay Kulkarni