

**OPTN Data Advisory Committee
Pre-Waitlist Data Collection Workgroup
Meeting Summary
January 9, 2024
In-Person Meeting, Richmond, VA**

**Sumit Mohan, MD, MPH, Chair
Jesse Schold, PhD, M.Stat, M.Ed, Vice Chair**

Introduction

The Data Advisory Committee (DAC) Pre-Waitlist Data Collection Workgroup (“Workgroup”) met in-person and via WebEx teleconference on 01/09/2024 to discuss the following agenda items:

1. Welcome, introductions, logistics, Agenda review: HRSA’s request and today’s goals
2. Review drafted definitions and trigger points and capture feedback
 - a. Referral
 - b. Evaluation
 - c. Selection Committee

The following is a summary of the Workgroup discussions.

1. HRSA’s request to the DAC, DAC’s deliverable and value of new data collection

The Chair stated that the Workgroup has been assembled to address a HRSA request for pre-waitlisting data. There is a long-standing interest in identifying the denominator for the need for organ transplantation. There is some sense of what the denominator is with regard to kidney transplantation because the ESRD population is known. However, that is not really an adequate measure of the denominator, and it is a much harder number to come by for the other organs.

The group is being asked to understand what such a denominator looks like, recognize who is being referred for organ transplantation, and what is the pathway from referral all the way to waitlist registration? The effort is an attempt to start capturing data regarding how selective programs are being when referring patients for transplantation, and what is happening during the evaluation process. The group has not been convened to discuss the question of ‘why?’ – such as, what is the value of the data being collected, what will it be used for, etc.? The why questions are outside the Workgroup’s purview. The Workgroup has been tasked with what does the referral, evaluation, and program selection committee look like, how does the Workgroup accomplish the goal of identifying such data, how is the data collect in a way that is successful and effective, and meets the needs of the transplant community.

Another aspect of the HRSA request is to try and identify the potential organ donor pool. The OPTN Organ Procurement Organization (OPO) Committee has taken the lead on that request, and DAC is engaged with them on the effort.

The Chair also told the participants that the timeline associated with both requests is quite condensed, at least in part leading to the need for the in-person meeting. DAC was asked in late November 2023 to try and put this together. The Chair said the objective is to complete the work by the end of January 2024. The deliverables created for both requests will not follow the traditional OPTN public comment process, nor will they be reviewed by the OPTN Board of Directors for approval. The deliverables will be

submitted for public comment as part of the OMB submission process, and that is when the public will have an opportunity to submit comments. The OPTN will make an effort to ensure the transplantation community is aware of when the OMB public comment period occurs and leverage the opportunity to comment on the deliverables. As a result of the compressed timeline, an objective of the in-person meeting is to close to the final version of the data elements needed and what the definitions should be. There will be a limited amount of time for this Workgroup to review its efforts before sharing them with DAC for endorsement and submission to HRSA.

A Workgroup member suggested that it would be helpful for the Workgroup moving forward if the members could learn more about HRSA's ask of the Data Advisory Committee. For instance, what data elements did HRSA identify as examples or suggestions? The Chair responded that HRSA first provided a very preliminary draft data collection example based on the elements associated with the OPTN Computer system, specifically the data elements identified with transplant candidate registration activities. The Workgroup moved away from that initial draft data collection resource because members began to see referral and evaluation as slightly different processes than what is associated with candidate registration on the waiting list. The Chair also emphasized that what the Workgroup is addressing is not focused solely or even primarily on research needs. Instead, the Workgroup's primary goal is to get data that will improve the primary understanding of the denominator or the need in the transplant community. This includes identifying variations in care, identifying opportunities for improvement. Workgroup members are asked to think about this in terms of 'if the data were available at a national level, what value would it have and that will help inform the discussions and choices the Workgroup will make. Data burden is a real concern when thinking about the potential data elements, so the group needs to be cognizant of how the burden is managed.

A stakeholder representative recommended that the Workgroup be fairly parsimonious about the initial data elements identified, while at the same time the group needs to develop a very complete definition of referral, completed referral, and evaluation, start of evaluation, completion of evaluation, etc. so that consistent data can be captured across transplants.

The Health Resources and Services Administration (HRSA) Contract Officer reiterated the comments of the stakeholder representative. And added, that the point of this effort is to start collecting information about patients at the time they are referred to transplant so that the community understands what happens to such patients on their journey from referral to listing on the waitlist. Pre-waitlist data is expected to help provide information on verification of who gets referred by whom, who gets evaluated, and eventually who gets placed on the waiting list. Over time, these data will facilitate the OPTN's ability to address disparities that may be identified through those data. As a result, this effort is intended to help create a baseline that will permit the tracking of an individual through the transplantation process. HRSA recognizes that the data at the beginning may not be as available as was hoped, but that as an individual moves their way through the process more data are available and collected consistently so that as the baseline is started it is accurate and that it can be expanded in the future.

A member of the OPTN Transplant Coordinator Committee said that in reviewing the information shared with Workgroup members ahead of the meeting, it appears that there may be some effort to establish a new requirement involving the amount of time a program has to register a candidate on the waitlist after determining they should be added to the waitlist. The Chair responded that it isn't the goal of this effort to establish such a timeframe, but at the same time, it is not clear why a transplant center would identify a patient for listing but then not list the patient within some relatively short period of time following that decision. The TCC member said that it has not been a requirement previously, but if that is the case it also seems to fall outside the purview of just data collection mentioned previously. The Chair said that this effort is about trying to capture what the process is, but having said that, if there are

transplant centers that for whatever operational reasons choose not to waitlist a patient even though they've been approved at selection and there is a gap, that is helpful to know and this group would want to understand that.

The Chair then provided an overview of the value of collecting pre-waitlist data. A goal of the Workgroup is to provide a broader understanding of and greater transparency into access to transplant, in order to understand the patient journey from referral on. The data can provide some level of insight into the denominator of potential transplant patients. In addition, pre-waitlist data collection is within the purview of the OPTN. This effort should be considered as a first step and future efforts will try to build upon what is established now. Collection of the data will allow transplant centers to see what practices other centers are doing and perhaps learn from them. So, it will allow for reporting and benchmarking, and the information will be used to make things more transparent for patients.

2. Review drafted definitions and trigger points and capture feedback

The Workgroup discussed various data elements for inclusion into the pre-waitlist data dictionary, triggering events, and preventing data burden. Workbook materials were updated in real time throughout the meeting and those artifacts are posted on the DAC's Sharepoint site and the Workgroup's Team site. The artifacts will be reviewed at the final workgroup meeting on January 16, 2024.

Summary of discussion:

The Chair began the discussion by level setting and providing context to the Workgroup members. HRSA staff noted that the overarching goal of the directive is to capture the descriptive journey of the referral to the evaluation whether deferred or denied. In addition, the Chair noted that the goal should be to avoid data loss by using an agreed upon framework for reporting data, in addition to avoiding subjective definitions so that transplant centers can have a richer data set. To begin discussing the data elements, the Chair started to discuss the impetus for triggering in-patient referrals, probing the Workgroup members to discuss what triggers an in-patient referral. Support staff noted that there were already various forms of triggers such as telephone calls and other modalities that did not need to be discussed again.

Further, the Chair then steered the question to what triggers a new consultation. A member noted that all the modalities will create an 'action,' but that about 50% of the conversations an episode is not created because it's just a conversation. Members noted that incentives for initiating triggers should be defined as well as merging with the process that larger centers do with their modalities. The Chair noted that a referral should constitute basic information that leads to a conversation, with the goal of capturing as much information as possible. Another member noted that they use Transchart to document every referral and that they receive referrals through transconnect, fax, call, or request made through in-patient service even if they are transferred from outside the center. In response, a HRSA representative noted that the goal is to get a sense of who is referred into the system and to document who is sent to the center but does not move forward so that they can share that with CMS; the reason being is to document what is coming to you even if you are unable to create that clinical relationship. The Chair then asked whether the group should implement a referral reason from the referral provider. In response, multiple Workgroup members replied "no." Another member noted that patient education also needs to be a part of the referral process. A member of HRSA noted that they need to know if someone does not move forward because that is valuable information. In addition, the HRSA member clarified that the Workgroup members should be thinking about this process as first being broad then detailed. The Chair noted that there was consensus on capturing as much information as possible at the start of referral.

The Chair then transitioned the conversation to discuss the role of data burden, noting that these changes may take time and may require more labor – but need to be completed because the data needs to be consistent. A member noted that it is hard to hire and retain staff to collect this level of detailed data. The Chair decided to table the conversation and make note that the members should think about data burden during the rest of the meeting.

To ensure that duplicative data can be tracked accordingly, the Chair brought up the need for a unique identifier and further questioned the members on their stance on Social Security Numbers (SSNs) as a unique identifier. The Chair also noted that full addresses and zip codes will be collected. A member noted that patients move, which change addresses making it hard to review. Another member noted that as part of a consortium of centers that collect and report data specific to kidney patients, centers who do not wish to provide SSNs can enter 000-00-000. The member advocated for collecting SSN data. The Chair posed whether the inclusion of SSN data could be optional at referral and a member noted that it is only required at waitlisting. A member provided context as to why their program stopped collecting SSN data, in that the federal government is recommending not collecting SSN data to help reduce the potential of data breaches. In response, a member questioned whether a randomizer application could be used to create unique identifiers rather than using incomplete or incorrect SSNs. Support staff noted that this process could be laborious. HRSA staff stated that the OPTN is already collecting social security number at the point of registration. HRSA staff noted that whatever identifier is used it needs to be used throughout the entire process. The Chair tabled the discussion on utilizing a unique identifier but noted that there was consensus for including date of referral as a data point.

The Workgroup members then discussed the cancellation code choice list, with the Chair inquiring what needed to be included or revised. A member noted that ‘age’ and ‘immigration status’ were not present on the list and advocated for them being added. Some members noted that systemic barriers should be worded differently to be more inclusive and less dismissive. The Chair noted that the language and data definitions would be reviewed later. The Chair asked whether evaluation has to include an evaluation start date. A member noted that if a center noted that consent started prior to the evaluation date, the center can be out of compliance and the Centers for Medicare and Medicaid Services (CMS) will hold that against the center. Support staff noted that the next day’s meeting will include discussing evaluation, start trigger, and end trigger definitions.

Next steps:

The Workgroup members will continue discussing and revising various referral and evaluation data elements for inclusion into the pre-waitlist data dictionary and the triggers that start and end the events.

Upcoming Meeting

- January 10, 2024

Attendance

- **Workgroup Members**
 - Sumit Mohan
 - Jesse Schold
 - Marie Budev
 - Leigh Ann Burgess
 - Ashley Cardenas
 - Jennifer Cowger
 - Kate Giles
 - Adrian Lawrence
 - Christine Maxmeister
 - Karl Neumann
 - Hellen Oduor
 - Jennifer Peattie
 - Emily Perito
 - Julie Prigoff
 - Reem Raafat
 - Neil Shah
 - Martha Tankersley
 - Megan Urbanski
- **Stakeholder Members**
 - Kenneth Brayman
 - Gaurav Gupta
 - Krista Lentine
 - Rachel Patzer
- **HRSA Representatives**
 - Adriana Alvarez
 - Chris McLaughlin
- **SRTR Staff**
 - Ryo Hirose
 - Jon Snyder
- **UNOS Staff**
 - Brooke Chenault
 - Jonathan Chiep
 - Bonnie Felice
 - Cole Fox
 - Darby Harris
 - Gabrielle Hibbert
 - Nadine Hoffman
 - Houlder Hudgins
 - Sevgin Hunt
 - Beth Kalman
 - Krissy Laurie
 - Eric Messick
 - Lauren Mooney
 - Heather Neil
 - Laura Schmitt

- Sharon Shepherd
- Kim Uccellini
- Divya Yalgori
- Anne Zehner