OPTN Data Advisory Committee
Pre-Waitlist Data Collection Workgroup
Meeting Summary
January 10, 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 Workgroup ("Workgroup") met via WebEx teleconference and in-person on 01/10/2024 to discuss the following agenda items:

1. Discuss drafted definitions and trigger points for referral, evaluation and selection committee events
2. Discuss shared data collection for each event
3. Breakout and discuss organ specific data collection
4. Review output from breakout groups
5. Summarize the outcomes

The following is a summary of the workgroup discussions.

1. Discuss drafted definitions and trigger points for referral, evaluation and selection committee events

The workgroup discussed the start and end triggers and various data elements for inclusion into the pre-waitlist data dictionary. 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 discussion started with making adjustments to the start and end triggers for referral and discussing the cancellation reasons for referrals not proceed to an evaluation event. The workgroup members then moved to discussing the spreadsheet and agreed to require a social security number (SSN), but to implement a workaround for those that do not have an SSN such as '000-00-000.' The members also agreed to list race, ethnicity, and birth sex as optional or potentially do something similar to the waitlist by including a 'not available' option. However, a member of HRSA expressed concern that having something optional will lead to it not being reported. The workgroup then agreed to report it if they have the information and chose a 'not available' option if they do not have the information. Other elements such source of payment will also utlize 'unknown' if not available. The source of payments will be uploaded by bulk upload. A support staff noted that Transplant Candidate Registration (TCR) form does not currently collect secondary insurance, however if it's in your Electronic Medical Record (EMR) system then it is worth capturing. The workgroup memebrs agreed to additiionally remove referral reason and organ, since it is more important to know which program. They discussed having the option to multi-select organs because it may change over time and centers will need to link to specific organ

types for waitlisting patient. However, there was no consensus on whether an update to the referal would be needed if a multi-select choice list were introduced.

The group then moved to discussing the evaluation trigger,with some members noting that they would not schedule a patient if they had not consented. Some members noted that members should use their center's definition for start date. Other members noted that it is crucial to see which patients move forward and which do not. A support staff member noted that it could be reported as including: date of first visit, patient consent, or something else entirely. Another member noted that it could capture multple dates but this would increase date burden.

Batch Reporting

The Vice Chair then provided an overview of batch reporting, noting that there are 3 points, referral, closed, and active. A member noted that they may want more real time data collection later, but that this mockup of the batch reporting cadence was a good start. Other members agreed with the approach. Another member noted that some of the data may be useless because there is no retrospective information. The Vice Chair noted that it may capture the prevalnt population first and then could capture the end date of evaluation and not the start date. A HRSA member noted that it may not be possible to do something retrospectively and that could be helpful if the DAC would document why to collect the data prospectively is preferred in a short statement. The Chair noted that they work recommend having a hard start date for the prospective population.

The workgroup members then transitioned to discussing evaluation requirements, noting that everything on referral should be on the evalutation requirements as well. A member noted that there should be one record for a distinct patient for a distinct transplant center, with the option to update static fields. Other members noted that there is a challenge in EPIC where data gets written over and it would be a heavy workload to collect all the information. Other members noted that this may be too dynamic to repliacte in practice. A member noted that there could be danger to data integrity, where information is duplicated. However, the Chair noted that in this context, it is not of any concern if it is used for the waitlist. A support staff member noted that there is audit history, but once the referral has ended it is can be locked and that the only way to tie the evaluation data to the referral is through the Medical Record Number (MRN) which is unique to each transplant center. A support staff member noted that there should be capture of separate records for referral and evaluation. The members then discussed the choice list for contraindications, noting that they would only capture reasons for the rest of the population, even when some patietns are approved for other contraindications. The members agreed to work on this during the organ breakouts.

Next steps:

There was general consensus around this approach and the Workgroup members said they would discuss it more at the next Workgroup meeting.

2. Discuss shared data collection for each event

The Workgroup discussed the start and end triggers and various data elements for inclusion into the pre-waitlist data dictionary. 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:

Members shared that all patients in the evaluation phase of care are presented to the Selection Committee for review, even those cases were the patient decides to withdraw or the patient dies. In

cases of withdrawal or death, the selection committee action might be just notifying the members about the patient's situation, but the case is still presented to the selection committee. Therefore, the end of the evaluation event aligns with the Selection Committee's decision (Approve or Decline). Due to this discovery during the session, we combined the evaluation and selection committee events together and defined the start and end triggers accordingly. If a patient is approved by the selection committee, they move forward to being placed on the waitlist and if the patient is declined (even for withdraw or death) there is a selection committee decline reason(s)

Members agreed that data capture should remain at a summary level rather than collecting detailed clinical data elements. There was agreement to review the selection committee decline reasons to identify all the common reasons that are shared across organs such as mental health reasons or financial/insurance reasons.

Next steps:

There was agreement with the data collection approach described during the discussions. There was also agreement that consideration be given to involving the entities that develop the electronic health records used by the transplant programs, and also to consider opportunities to implement pilot project as a way to ensure that larger IT implementation efforts are meeting the intended goals.

3. Breakout and discuss organ specific data collection

The workgroup broke out into 2 breakout groups, 'abdominal' and 'thoracic' to further determine if there are organ specific reasons a selection committee would decline patients moving forward to the waitlist. 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 noted that breakout groups would focus on the abdominal and thoracic organs and determine if there was any organ specific reasons that should be added to the shared selection committee closure reasons. Members of the breakout groups noted that if this choice list was going to be submitted for public comment it could affect the division of categories further. A HRSA member noted that the DAC could consider this as an ongoing project rather than something to be accomplished all at once. However, the HRSA member also noted that the DAC may not have the capacity to review this choice list and that they could go the OPTN Board with a statement about what is needed to modernize it along with the recommendations that the DAC will provide to HRSA at the end of the month. The Chair noted that both HRSA and CMS need to weigh in on what needs to be brought to the EMR vendors. The HRSA member responded to the Chair's comments and requested they be sent to HRSA for review.

Next steps:

The workgroup will meet again on January 16th to finalize their recommendations. On January 22nd the full DAC will meet and the workgroup will share their recommendations. It was noted that a communication plan needs to be developed to share information across the community about this new data collection being proposed and how the community can comment on it via the Office of Management and Budget's public comment period when the OPTN data collection package is on the federal register. Staff will take the lead on developing a communication plan.

4. Review output from breakout groups

Summary of discussion:

After reconvening from the breakout groups, the workgroup members discussed their findings, noting that no organ specific closure reasons were identified for thoracic or abdominal organs outside of keeping cardiovascular and kidney diseases. The thoracic breakout group discussed active infections and maliginancies in relation to contraindications, noting that some lung patients being on ECMO along with other reasons may be reason to not move a patient forward. The workgroup members agreed to add choice options for diseases that could occurThe choice list for selection committee closure was updated and reviewed for completeness.

The Chair noted that DAC put VCA organs out of scope for this exercise, due to their small volume and unique referral and evaluation process, and DAC would follow-up with the VCA committee in the near future to discuss.

Next steps:

Based on the feedback, the Workgroup members agreed that they did not need to create separate data collection tools for abdominal and thoracic organs. The consensus was that a single tool/form could be provided to HRSA to assist with developing the future directive.

5. Summarize the outcomes

Summary of discussion:

The workgroup began closing out the discussion by noting they had aligned on requiring quarterly data submission. A member recommended aadding 'patient referred too early' to the referral close reason however it was countered that the reason should be 'too well' which is on the choice list. It was noted that the evaluation could close up on patient request, death, or selection committee decision. Specifically in regard to the selection committee decision, members noted that if an evaluation status was active it means it is still in process and if it is closed, this means there should be a closure reason(s). The Chair tabled the discussion on waitlisting patients within 48 hours after the selection committee decision since that is not an OPTN or CMS policy.

Next steps:

For the January 16th meeting, the OPTN Contractor will update the materials that were discussed and modified as part of the January 9th and January 10th in-person meetings and share the materials with the Workgroup members. Workgroup members were asked to consider how the OPTN might be able to operationalize all of the decisions that were made as part of today's meeting and be ready to discuss them as part of the January 16th meeting. The Chair also indicated that he hopes the information discussed during both in-person meetings and the decisions made will be socialized with the societies who had made members attending the meetings, specifically the American Society of Nephrology (ASN), American Society of Transplant Surgeons (ASTS), and the American Society of Transplantation (AST).

Upcoming Meeting

- January 16, 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
- **Stakeholder Members**
  - Kenneth Brayman
  - Garrett Erdle
  - Gaurav Gupta
  - Molly McCarthy
  - Rachel Patzer
- **HRSA Representatives**
  - Adriana Alvarez
  - Chris McLaughlin
- **SRTR Staff**
  - Ryo Hirose
  - Ajay Israni
  - Jon Snyder
  - Nick Wood
- **UNOS Staff**
  - Brooke Chenault
  - Jonathan Chiep
  - Cole Fox
  - Bonnie Felice
  - Darby Harris
  - Gabrielle Hibbert
  - Nadine Hoffman
  - Houlder Hudgins
  - Sevgin Hunt
  - Beth Kalman
  - Eric Messick
  - Lauren Mooney
  - Heather Neil
  - Laura Schmitt

- Sharon Shepherd
- Kaitlin Swanner
- Kim Uccellini
- Divya Yalgoori
- Anne Zehner