OPTN Data Advisory Committee
Meeting Summary
February 12,2024
Teleconference

Sumit Mohan, M.D, M.P.H., Chair
Jesse Schold, PhD., M.Stat., Vice Chair

Introduction

The OPTN Data Advisory Committee met via Webex teleconference on 02/12/2024 to discuss the following agenda items:

1. Overview of MPSC Referral Process
2. DTAC, Project Check-in: MPSC Referral Requirements for Communicating Post-Transplant Disease
3. HHS Directive Update and discussion with Committee and Pre-Waitlist Data Collection Workgroup members

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

1. Overview of MPSC Referral Process

OPTN Contractor staff provided the Committee with an overview of how the process works when the OPTN Membership and Professional Standards Committee (MPSC) refers a potential issue or concern to to another OPTN Committee for consideration as a potential project. MPSC identifies such issues or concerns through multiple sources, including case reviews and a determination is made that policy can be improved in order to resolve the issue. Committees receiving MPSC referrals are asked to review the information provided by MPSC, determine whether it is appropriate for the committee to initiate a policy project or data collection project, and report back to MPSC about the committee's decision.

2. DTAC, Project Check-in: MPSC Referral Requirements for Communicating Post-Transplant Disease

The Committee reviewed and discussed DTAC's proposal to address the MPSC Referral DTAC received regarding Communicating Post-Transplant Disease.

Data summary (as applicable):

Policy 15.5 A Transplant Program Recreations for Post-Transplant Discovery of Donor Disease or Malignancy and Policy 15.5B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy create confusion about what infectious disease results transplants programs need to report for lung transplantation (Phase 1). Forty-five-day follow-up on potential disease transmission events is a manual process that is currently handled via secure email to transplant programs (Phase 2). This impacts data collection since forty-five-day recipient follow-up needs to be automated through the OPTN Computer System.

The current forty-five-day follow up process of reporting events of potential disease transmission events are submitted to the OPTN Patient Safety Portal. Upon receipt of these events, OPTN Contractor triage, evaluate, and assess to determine validity and urgency. Following a development of a case packet of information related to the sick recipient and other applicable donor information needed for the DTAC review. The OPTN Contractor contacts all programs that transplanted an organ from the involved donor,

to obtain information related to each recipient and the pathogen reported. After follow-up is complete, the information is added to the case packet and posted for DTAC to review and adjudicate. Currently, the forty-five-day follow-up information is requested in custom, individual emails to each transplant program that received an organ.

There are several pain points to this process. Presently, it is a very manual and time-consuming process for staff. In addition, 50% of cases require second and/or additional requests to obtain this information on at least one recipient involved in the case, which can lead to unresponsiveness. Secure emails add extra obstacles for both DTAC members and OPTN Contractor staff to navigate. Thus, increasing time contacting programs via email. This affects the OPTN's ability to report data that the community can use in the future to determine potential policy modifications.

The Data Collection idea was to structure the process to conduct the forty-five-day follow-up for recipients of a potential disease transmission event (PDTE) such as: bacterial, viral, fungal, endemic, parasitic, and malignancy. This will create efficiencies and more secure data collection for confidential medical peer review completed by the DTAC. And the aim is to develop a more structed data collection process for members.

The data collection idea aligns with the following OPTN Data Collection Principles and DTAC case review allows the committee to monitor donor-derived disease transmission events and formulate education and OPTN Policy accordingly.

Summary of discussion:

The Chair discussed concerns surrounding the forty-five-day follow-up since that does not currently align with any of the other reporting timeframes currently found in Policy 18: Data Submission Requirements, advising that a window around a period should be implemented. A member then advised that they are already asking for this information as part of a safety portal and its information after a discreet event that happens where we want to know the status of the patient. Hence, informing that it does not need to be reported exactly at the forty-five-day mark since it's not being done that way. The reason behind this is that there is a significant amount of back and forth that occurs which is what this project is seeking improvement in.

The Chair raised an important question on how this information pertains to patient safety and how to find a way to standardize the data capture. Accordingly, creating a system that allows events to be predictable/systemic which the DAC committee would support. However, the concern stems from the operations details. Such as having a pathway where if something were to happen to a recipient such as them having an infection that stemmed from the donor organ. The sense of urgency and communication back to the potential recipients from that organ is unclear. Thus, creating a complementary process.

The Committee concluded to endorse this proposed data collection effort.

Next steps:

DTAC will submit the proposal for POC review on 03/18/24 with the intention of submitting a public comment document addressing phase one as part of the July-September 2024 cycle. DTAC will come back to DAC for future reviews as necessary.

HHS Directive Update and discussion with Committee and Pre-Waitlist Data Collection Workgroup members

The Committee reviewed and discussed the feedback that was shared with HRSA as well as discussed HRSAs recently issued Secretarial directive to the OPTN President and Executive Director. The Committee lastly reviewed the OMB public comment cycle.

Data summary (as applicable):

DAC chairs and MPSC Workgroup Chair shared feedback with HRSA on 01/31/24. HRSA Issued Secretarial directive to the OPTN President and Executive Director on 02/05/24. A Copy of the directive and attachments have been uploaded to the DAC SharePoint site.

More information will be forthcoming on the OMB public comment cycle. OMB public comment consists of a two-step process. The first being the posting of a notice on the federal register for 60 days announcing changes to the OPTN Data System package. The second step in the process involves posting a notice on the federal register for 30 days including details of all the changes to the data collection form packages. The OPTN Contractor will submit public comments during both the 60-day and 30-day cycles. OMB review and approval typically occurs after the 30-day FRN step. During OPTN Regional meetings, HRSA staff have the 30-day cycle which is projected to occur in the summer 2024.

Summary of discussion:

A member of the committee proposed the following item regarding whether HRSA is still in agreement with the proposed data reporting requirement of every 3 months as well as what data points were going to be proposed. Another member of the committee advised the directive itself was not specific to the frequency of submission of the data. The plan would be to provide what was recommended as part of DAC work. A HRSA representative advised to submit any recommendations or any comments during the public comment period and HRSA will consider them.

The Chair briefly spoke that there is concern as it pertains to DAC work efforts to get a deadline that was set by HRSA themselves with the assumption that it was critical to the directive. However, now it is not critical. The Chair continued with his case that HRSA would then be posting to the Federal Register what information HRSA had originally submitted to DAC as potential data elements for collection and asked DAC to provide improvements to, which was not what DAC had recommended. Therefore, once the comments start to flow in, they will be commenting on a wrong set of recommendations since they are not commenting on the DAC-identified data elements or the DAC batch submission idea that was proposed. The Chair highlighted that within the regional meeting presentations there was already one that was inaccurate, which added to the concern that there will be inconsistences between what is being presented and how that will cause negative feedback about the proposal and ultimately an objection from the council. This is because the original modification that HRSA has presented is not a practical solution for what's needed. A member of the committee suggested taking this feedback to HRSA and seeing if they can make a statement regarding this matter.

The Vice Chair wanted more information on whose requirements it is that this is being presented at the regional meetings and to see if we can delay that process given its not aligned with what DAC has suggested. A member of the committee advised that we could attempt to ask HRSA if that can be adjusted but ultimately, it's their decision if they want comments on it. The Chair made final remarks that the communication strategy should be clear so that all those involved can understand what to expect.

Upcoming Meeting(s)

- March 11, 2024 (teleconference)
- March 22, 2024 (In-person meeting, Houston TX)

Attendance

- **Committee Members**
  - Sumit Mohan
  - Jesse Schold
  - Rebecca Baranoff
  - Jamie Bucio
  - Kate Giles
  - Dustin Goad
  - Michael Ison
  - Paul MacLennan
  - Michael Marvin
  - Christine Maxmeister
  - Meghan Muldoon
  - Hellen Oduor
  - Jennifer Peattie
  - Julie Prigoff
  - Alicia Skeen
  - Allen Wagner
- **HRSA Representatives**
  - Adrianna Alvarez
- **SRTR Staff**
  - Avery Cook
  - Ajay Israni
  - Jon Snyder
- **UNOS Staff**
  - Asma Ali
  - Lloyd Board
  - Brooke Chenault
  - Viktoria Filatova
  - Richard Hennings
  - Nadine Hoffman
  - Michael Hollister
  - Houlder Hudgins
  - Sevgin Hunt
  - Beth Kalman
  - Sara Langham
  - Krissy Laurie
  - Kerry Masten
  - Eric Messick
  - Lauren Mooney
  - Laura Schmitt
  - Holly Sobczak
  - Susan Tlusty
  - Kim Uccellini
  - Tamika Watkins
  - Joe Watson
  - Joann White

    - Divya Yalgoori
    - Anne Zehner
- **Other Attendees**
    - Lara Danziger-Isakov