

OPTN Data Advisory Committee

Meeting Summary

January 9, 2023

Conference Call

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

Introduction

The Data Advisory Committee (DAC) met via Citrix GoToMeeting teleconference on 01/09/2023 to discuss the following agenda items:

1. Public comment proposal review
2. Closing remarks

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

1. Data Collection Project Review

Representatives from the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC), OPTN Kidney Transplantation Committee, and OPTN Operations and Safety Committee provided an update on the data collection components of their proposals in preparation for public comment. The update is part of the check-in process to ensure a consistent, systematic approach to assessing data and data collection instruments.

OPTN Ad Hoc Disease Transmission Advisory Committee – Improve Deceased Donor Evaluation for Endemic Diseases

Overview of proposal:

The purpose of this proposal is to require universal screening for Strongyloides and targeted screening for Chagas for deceased donors. This will require additional data collection in the OPTN Donor Data and Matching System to collect the following:

- Was the donor born in a country currently classified as endemic for Chagas by the CDC?" Cascades to DDR
- Add 'Chagas Ab Screen' and 'Strongyloides Ab' with other infectious disease testing options
- Add 'Chagas Ab Diagnostic' that replicates SARS-CoV-2 test reporting

Summary of discussion:

A member asked what happens if an OPO does not know where a potential donor was born. The DTAC Chair responded that if that information is unknown, it should be treated as if the donor was not born in a country classified as endemic for Chagas by the Centers for Disease Control (CDC).

A member asked about the disease transmission concerns and if this occurs frequently. The DTAC Chair noted that Chagas and Strongyloides are the two most common parasitic infections reviewed by the DTAC. The screening results are typically received post-transplant and therapy can be provided to the recipient. The DTAC Chair noted that screening for Chagas is a two-step screening process, with the initial screening done before transplantation while waiting for confirmatory testing.

A member asked another question about the birth country. For example, how impactful is that information if a donor has been outside their birth country for 50 years and why not use travel information. The DTAC Chair responded that country of origin was the best indicator based on published literature and reported infections. She added that donors can have these parasites present for a long time and they can cause risks to immunosuppressed recipients.

A member asked about the burden on OPOs to perform and report these infectious disease results. The DTAC Chair noted that many OPOs are already performing these tests.

A member asked if these proposed requirements would be the same for living donors. The DTAC Chair noted that it would not be a requirement for living donors since there are not many transmissions from living donors. The DAC Chair suggested aligning deceased donor and living donor requirements to avoid confusion.

A member requested this information also be collecting in the deceased donor registration form and be aligned with how this testing is captured in electronic medical records.

OPTN Kidney Transplantation Committee – Align OPTN Kidney Paired Donation Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements

Overview of proposal:

This proposal will establish a requirement for annual donor re-evaluation for OPTN Kidney Paired Donation Pilot Program (KPDPP) donors in order to increase the likelihood of match success. The proposal will also align the OPTN KPDPP blood type A, non-A1 and AB, non-A1B matching eligibility requirements with those in OPTN Kidney Policy.

The data collection modifications include the following:

Remove the following data elements:

- If the candidate is blood type B, is the candidate willing to accept an A2 or A2B donor – Yes/No
- If candidate is willing to accept an A2 or A2B donor, enter IgG antibody titer – 1:1, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, >1:64
- Titer date – MM/DD/YYYY

Replace with one single data element:

- Does the candidate meet criteria for A2 or A2B (including patient consent) – Yes/No

Summary of discussion:

One member asked if this proposal applies to all living donors or just those participating in the OPTN KPD program. Staff confirmed that there are specific living donor policies that address all living donors.

Another member asked if the infectious disease testing was only performed again once there is a match. Staff noted that the proposed requirements to re-evaluate living donors every year would include infectious disease testing. She further added that infectious disease is typically done as part of the initial evaluation and then again prior to donation.

The DAC Chair expressed some concerns about the 395-day re-evaluation requirement because it could be close to the donation date. He also opined that every 6 months might be a more appropriate timeframe. Staff noted that transplant programs would be notified a month prior to the re-evaluation date and there is a 30-day grace period to complete the evaluation.

OPTN Operations and Safety Committee – Optimization of Offer Filters

Overview of proposal:

The purpose of this proposal is to develop a more broadly utilized offer filter model that will create multi-factorial offer filters to filter off organ offers more precisely. The data collection component will include the addition of a data field in the OPTN Waiting List to allow transplant programs to exclude candidates from the offer filters applied to them.

Summary of discussion:

The DAC Chair expressed concern about the language used to describe the default filters and the process for excluding candidates. Staff noted that the presentation focused on the proposed data solution, which would allow transplant programs to specify if a candidate would be excluded from all offer filters. Currently, the offer filters are applied at the program level and feedback during public comment included recommendations to allow for the exclusion of certain candidates based on medical urgency or other factors. Staff noted that the presentation for the upcoming public comment period will be updated to provide more clarity and prevent similar confusion. This includes clarifying program specific filters and candidate exclusions.

The DAC Chair also expressed concerns about the offer filters being re-evaluated and turned back on every 90 days. Several DAC members agreed that this would create a burden on kidney transplant programs. Transplant programs do not have the staff to re-evaluate their waiting lists against the filters every 90 days. Another member suggested allowing transplant programs to adjust filters at any time in order to do what is best for patients.

The DAC Chair suggested that the Operations and Safety Committee bring this proposal back to the DAC with clarifications. He opined that the DAC does not support this proposal as currently written.

2. Closing Remarks

Committee members were reminded of the in-person meeting scheduled for February 2, 2023 in Chicago, IL.

Upcoming Meetings

- February 2, 2023 (In-person, Chicago)
- March 13, 2023

Attendance

- **Committee Members**
 - Sumit Mohan
 - Jesse Schold
 - Rachel Patzer
 - Daniel Stanton
 - Farhan Zafar
 - Macey Levan
 - Jamie Bucio
 - Lauren Kearns
 - Christine Maxmeister
 - Maryam Valapour
 - Michael Marvin
 - Rebecca Baranoff
 - Paul MacLennan
- **HRSA Representatives**
 - Adriana Martinez
- **SRTR Staff**
 - Ajay Israni
 - Jon Snyder
- **UNOS Staff**
 - Anne Zehner
 - Brooke Chenault
 - Eric Messick
 - Kayla Temple
 - Joann White
 - Joel Newman
 - Krissy Laurie
 - Lauren Mauk
 - Michael Ghaffari
 - Michael Hollister
 - Nadine Hoffman
 - Robert Hunter
 - Serena Straub
 - Sevgin Hunt
 - Sharon Shepherd
 - Suhuan Wang
 - Susan Tlusty
 - Taylor Livelli
- **Other Attendees**
 - Lara Danzinger-Isakov