

**OPTN Data Advisory Committee
Meeting Summary
September 29, 2020 11:00 AM EST
Conference Call
Rachel Patzer, Ph.D., Chair
Sumit Mohan, M.D., M.P.H., Vice Chair**

Introduction

The Data Advisory Committee (DAC) met via Citrix GoToMeeting teleconference on 09/29/2020 to discuss the following agenda items:

1. Public Comment Proposal Review: Further Enhancements to the National Liver Review Board (NLRB)
2. Public Comment Proposal Review: COVID-19 Emergency Policies & Data Collection
3. Public Comment Proposal Review: Incorporating COVID-19 Related Organ Failure in Candidate Listings
4. Public Comment Proposal Review: Align OPTN Policy with US Public Health Service (PHS) Guideline, 2020
5. Q4 Data Definition Review
6. Primary Graft Dysfunction Project Check-in #1

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

1. Public Comment Proposal Review: Further Enhancements to the National Liver Review Board (NLRB)

The Liver & Intestinal Organ Transplantation Committee presented *Further Enhancement to the National Liver Review Board* proposal. The proposal seeks add additional data modification to current portopulmonary hypertension (POPH) exception criteria.

Summary of discussion:

A member asked what happens when “No” is selected as a response for the question regarding assessment of other causes of pulmonary hypertension. Staff responded that the candidate would not automatically be approved for the exception. The exception would be routed to the NLRB for review.

Another member stated the definitions are clear and acceptable. The member added that someone reading this, who is not familiar with pulmonary hypertension would find these definitions helpful and easy to follow.

There were no additional comments or questions.

2. Public Comment Proposal Review: COVID-19 Emergency Policies & Data Collection

DAC was presented emergency actions the Executive Committee enacted in response to COVID-19.

Summary of discussion:

Members support this proposal and agreed the actions the Executive Committee took were appropriate and effective in providing administrative relief during the pandemic. There was some support from

members for retrospective data reporting after amnesty expires, emphasizing the need for accuracy and validity of these data, to maintain the integrity of OPTN data, future modeling, and evaluation. Additionally, members emphasized the need for completeness of the data where possible. DAC recommended ending amnesty at the end of 2020. If retrospective reporting becomes required, DAC recommended implementing a data entry due date 90 days after the end of the amnesty period.

There were no additional comments or questions.

3. Public Comment Proposal Review: Incorporating COVID-19 Related Organ Failure in Candidate Listings

The Lung Transplantation Committee presented *Incorporating COVID-19 Related Organ Failure in Candidate Listings* proposal. The proposal seeks to add the coronavirus disease 2019 (COVID-19) related organ failure options in candidate listings. The purpose of this proposal is to better track candidates listed due to COVID-19.

Summary of discussion:

Members of DAC strongly support this proposal as written for lung and heart. Members cautioned adding this for other organs if there are not clear data on the impact of COVID-19 as a direct cause of organ failure for other organs. DAC questioned why the OPTN was not collecting more detailed information on candidate/recipients related to COVID testing results and infection. DAC suggested member education encouraging utilization of both primary and secondary causes of death data collection to show complete impact of COVID-19 on recipient outcomes.

There were no additional comments or questions.

4. Public Comment Proposal Review: Align OPTN Policy with US Public Health Service (PHS) Guideline, 2020

The Disease Transmission Advisory Committee presented *Align OPTN Policy with US Public Health Service Guidelines, 2020* proposal. The purpose of this proposal is it to align OPTN policies with updated PHS Guidelines for assessing solid organ donors and monitoring transplant recipients for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) infection.

Summary of discussion:

DAC supports this policy. DAC supports the collection of the individual risk factors in the definition.

There were no additional comments or questions.

5. Q4 Data Definition Review

The DAC reviewed and discussed data definitions shown in the following tables. Members were asked for their feedback and whether or not they endorse the proposed changes. The table includes the members' endorsement decision, as well as any proposed changes.

Data Element	Endorsed by DAC	Member Question	Proposed Additional Language	Changes Proposed after Discussion
FEV1, FVC, FEF25-75	Yes	Is it reasonable to enter data from a spirometry test instead of pulmonary function test (PFT)?	Adds “Note: Examples of pulmonary function tests include spirometry, lung volume test and diffusing capacity for carbon monoxide (DLCO).”	Adds “Results exclude home spirometry test.”
Prior Cardiac Surgery	Yes	How many procedures count as “Prior Cardiac Surgery”, specifically, PCI with stenting and ablations?	Adds “This should capture previous non-transcatheter, non-endovascular, open (sternotomy, thoracotomy) cardiac surgeries which complicate the transplant surgery, increasing the risk of bleeding and primary graft dysfunction.”	Changes to “Cardiac surgery refers to open chest (sternotomy, thoracotomy) procedure (excluding transcatherter and endovascular which complicate...”

Summary of discussion:

Under the FEV1, FVC, FEF25-75 definition, members agreed to add a statement which excludes home spirometry testing.

Under the Prior Cardiac Surgery definition, a member suggested rewording the proposed clarification, “Cardiac surgery refers to open (sternotomy, thoracotomy) cardiac procedures, excluding transcatherter and endovascular...”. Members agreed.

DAC endorsed both proposed data definition clarifications.

6. Primary Graft Dysfunction Project Check-in #1

The Heart Transplantation Committee presented their first check-in to DAC. This new project aims to collect primary graft dysfunction (PGD) related data to allow for outcome monitoring and future policy development.

Summary of discussion:

The proposal seeks to add new data elements to existing Heart Transplant Recipient Registration (TRR) form, and potentially eliminate collection of some data elements. The Heart Transplantation Committee is defining the framework of the project in order to identify appropriate heart-specific data elements and values. They are discussing the following data elements:

- PGD (yes or no)
- Left Ventricular Ejection Fraction
- Right Atrial Pressure
- Pulmonary Capillary Wedge Pressure
- Cardiac Index

- Support device (yes or no), if yes, type of device
- Whether to not include mild PGD-LV criteria when identifying potential data elements

Members agreed with this proposed data collection effort. Members suggested defining the elements first. A member stated support for having a criteria based definition of PGD. There were no other questions or comments.

DAC endorsed this proposed data collection effort.

Upcoming Meetings

- October 26, 2020 (teleconference)
- November 9, 2020 (teleconference)

Attendance

- **Committee Members**
 - Anna Mello
 - Benjamin Schleich
 - Bilal Mahmood
 - Colleen O'Donnell Flores
 - Daniel Stanton
 - Farhan Zafar
 - Heather Hickland
 - Kristine Browning
 - Lauren Kearns
 - Macey Henderson
 - Melissa McQueen
 - Rachel Patzer
 - Sandy Feng
 - Sumit Mohan
- **HRSA Representatives**
 - Adriana Martinez
 - Chris McLaughlin
- **SRTR Staff**
 - Bertram Kasiske
 - Jon Snyder
 - Michael Conboy
 - Nick Salkowski
- **UNOS Staff**
 - Adel Husayni
 - Brooke Chenault
 - Carly Engelberger
 - Christopher Sweeney
 - Courtney Jett
 - Craig Connors
 - Darby Harris
 - Elizabeth Miller
 - Emily Ward
 - Eric Messick
 - Grace Acda
 - James Alcorn
 - Janis Rosenberg
 - Joann White
 - Kaitlin Swanner
 - Kim Combs
 - Kim Uccellini
 - Kristine Althaus
 - Lauren Mauk
 - Matt Cafarella
 - Matthew Prentice
 - Meghan McDermott

- Nicole Benjamin
- Pete Sokol
- Randall Fenderson
- Sarah Taranto
- Shannon Edwards
- Susan Tlusty
- **Other Attendees**
 - Marian Michaels
 - Maryam Valapour
 - Marie Budev