

**OPTN Data Advisory Committee
Meeting Summary
August 10, 2020 3:00 PM 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 08/10/2020 to discuss the following agenda items:

1. Broader Distribution Data Collection Update
2. OPTN Lung Committee COVID-19 Data Collection Project
3. Public Comment: Vascularized Composite Allograft (VCA) Data Collection Modifications
4. Public Comment Vascularized Composite Allograft (VCA) in UNet

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

1. Broader Distribution Data Collection Update

DAC received an update on the Broader Distribution Data Collection project. The purpose of this project is to develop a data collection proposal that will promote effective data collection in evaluating the logistical impact of broader distribution.

Summary of discussion:

As organs progress towards adopting the broader distribution framework, the Operations & Safety Committee (OSC) found the need to evaluate data collection in order to better understand the logistical impact of broader distribution. OSC formed the Broader Distribution Data Collection Workgroup (the Workgroup), which DAC will co-sponsor. The Workgroup will look at existing data related to ischemic time and perfusion across organs, forms, and systems. Members will be evaluating data based on currency, consistency, specificity, and objectivity.

There were no questions or comments.

Next steps:

The first Workgroup meeting will occur on August 18, 2020.

2. OPTN Lung Committee COVID-19 Data Collection Update

The Lung Transplantation Committee updated the DAC on new COVID-19 data collection. The purpose of the proposal is to establish a standard diagnosis for lung candidates listed due to COVID-19 infection as well as establish a process to track candidate listings for COVID-19 related organ failure.

Summary of discussion:

The proposal impacts data collection by adding two diagnosis codes, "COVID-19: acute lung disease" and "COVID-19: chronic lung disease", to the dropdown menu for listing lung candidates. This proposed data collection will impact the Lung Candidate Add/Edit within Waitlist. It will also update the Lung Diagnosis

Code field in the Transplant Candidate Registration (TCR) and Transplant Recipient Registration (TRR) forms within TIEDI. The proposal requests feedback from the community regarding if this data should be collected for other organs. The proposal aligns with OPTN Data Collection Principles by developing transplant, donation, and allocation policies as well as fulfilling the requirements of the OPTN Final Rule.

A member asked if there is data collected on the timing of the transplant relative to the infection of COVID-19. Staff responded that the transplants which have been performed occurred after the patient recovered from COVID-19 but still had significant damage. The member clarified that the proposal should consider what other questions need to be asked in conjunction to gain a better understanding of the status of the patient at the time of transplant. Another member agreed and suggested to add data regarding the date of the polymerase chain reaction (PCR) test to be able to have meaningful interpretations. Other members agreed.

Another member suggested a better definition for “COVID-19: chronic lung disease”. The member explained it could be interpreted as a patient with COVID-19 that has an underlying chronic lung disease. It could also be interpreted as a patient that had COVID-19 and is need of a transplant a year after recovery because of the effects of COVID-19.

A member suggested that the Lung Transplantation Committee should work with the Disease Transmission Advisory Committee (DTAC) to create additional questions. Staff responded that DTAC has been consulted and expressed concern with adding additional questions because there is not a lot of data around this topic. DTAC viewed this proposed data collection as addressing damage caused by COVID-19 not actively positive patients, as DTAC assumed surgeons would not want to transplant actively positive patients. The member suggested the data collection should consider the possibility that, in the future, a COVID-10 positive, asymptomatic patient could undergo a transplant.

The Vice Chair agreed that it seems reasonable to start documenting COVID-19 related transplants across organs.

Does the OPTN Data Advisory Committee endorse this proposed data collection effort?

Yes – 100% (11), No – 0% (0)

Next steps:

The proposal will be reviewed by the Policy Oversight Committee (POC) on August 12, 2020.

3. Public Comment: Vascularized Composite Allograft (VCA) Data Collection Modifications

The Chair of the VCA Committee presented the Modify Data Collection on VCA Living Donors proposal. The purpose of this proposal is to require data submission for living VCA donors, including the Living Donor Registration (LDR) and Living Donor Follow-up (LDF). The proposal also adds new data elements to the LDR and LDF specific to living donors, particularly uterus.

Summary of discussion:

Changes to the proposal since previous update to DAC:

- Added “induced abortion” as a proposed data element on the Pre-donation LDR form
- Added “reoperation” and “any readmission after initial discharge” as proposed data elements on the Post-operative LDR form
- Added “complications since other VCA donation” as a proposed data element on the LDF form

There were no comments or questions.

Public Comment Sentiment Vote:

Strongly Support- 64% (7), Support – 27% (3), Neutral/Abstain – 9% (1), Oppose – 0% (0), Strongly Oppose 0% (0)

4. Public Comment: Vascularized Composite Allograft (VCA) in UNet

The Chair of the VCA Committee presented Programming VCA Allocation in UNet proposal. The purpose of this proposal is to enable VCA to be programmed in UNet for consistency and efficiency.

Summary of discussion:

Currently, VCA allocation and data collection occur in a stand-alone system. Programming VCA allocation in UNet will allow organ offer and acceptance functionality and requirements for organ procurement organizations (OPOs) and transplant hospitals. VCA data submission will include Potential Transplant Recipient (PTR), Donor Histocompatibility (DHS), Recipient Histocompatibility (RHS), and Transplant Candidate Registration (TCR) forms. VCA programming in Waitlist will allow for waitlist removal, screening criteria, listing candidates, and accrual of unlimited waiting time while inactive. This proposal does not include new data collection.

There were no comments or questions.

Next steps

The Refusal Codes Workgroup will be approved soon and a first meeting scheduled.

Upcoming Meetings

- September 29, 2020 (teleconference)
- October 12, 2020 (teleconference)

Attendance

- **Committee Members**
 - Alicia Redden
 - Benjamin Scleich
 - Bilal Mahmood
 - Daniel Staton
 - Farhan Zafar
 - Heather Hickland
 - Kristine Browning
 - Lauren Kearns
 - Macey Henderson
 - Melissa McQueen
 - Rachel Patzer
 - Sandy Feng
 - Sumit Mohan
- **HRSA Representatives**
 - Adriana Martinez
- **SRTR Staff**
 - Bertram Kasiske
 - Nick Salkowski
- **UNOS Staff**
 - Adel Husayni
 - Courtney Jett
 - Elizabeth Miller
 - Kaitlin Swanner
 - Kim Uccellini
 - Lauren Mauk
 - Leah Slife
 - Meghan McDermott
 - Pete Sokol
 - Randall Fenderson
 - Sarah Taranto
 - Scott Castro
 - Tina Rhoades
- **Other Attendees**
 - Sandra Amaral