

Meeting Summary

OPTN Data Advisory Committee Meeting Summary May 8, 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 05/08/2023 to discuss the following agenda items:

- 1. Check-in 1: Standardize the Patient Safety Contact Notification Process
- 2. Check-in 1: Amend Adult Heart Status 2 Mechanical Device Requirements
- 3. Check-in 1: Continuous Distribution of Kidneys and Pancreata

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

1. Check-in 1: Standardize the Patient Safety Contact Notification Process

A representative from the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) presented the Committee's new project, *Standardize the Patient Safety Contact Notification Process*.

Overview of Proposal:

Currently, the patient safety contact (PSC) is not actively monitored. Organ procurement organizations (OPOs) have submitted concerns that PSCs do not include accurate information. Third party organizations listed as PSC have not answered or instructed the OPO to contact someone else. Feedback from the OPTN Membership & Professional Standards Committee (MPSC) cited the need for consistency in the type of contact provided since the current contact varies which causes confusion. The DTAC is proposing that transplant programs will be responsible for regular auditing of the PSC in the OPTN computer system.

Summary of discussion:

A member stated that this has also been an issue identified in the community. The member added that one suggestion is to have validiation measures because a large issue is PSC information for individuals who have since left the respective institution.

The DAC endorsed the DTAC's new project.

Next steps:

A member of the DAC will join the DTAC's new Workgroup to help address the problem. The DTAC will continue to check-in with the DAC as the project develops.

2. Check-in 1: Amend Adult Heart Status 2 Mechanical Device Requirements

A representative from the OPTN Heart Transplantation Committee presented the Committee's new project, *Amend Adult Heart Status 2 Mechanical Device Requirements*.

Overview of Proposal:

The Heart Transplantation Committee's new project seeks to better align mortality rates within adult status 2 heart allocation by reserving intra-aortic balloon pump (IABP) exception for candidates most in need. This will allow for more equitable distribution of hearts within status 2. Data on inotrope use will be required to be collected for status 2 exceptions to ensure proper alignment of status 2 candidates without disadvantaging patients in need of an IABP.

Summary of discussion:

The Vice Chair asked for the estimated number of cases this project would affect. The representative of the Heart Transplantation Committee stated that it is estimated to affect 60 to 80 percent of current status 2 population.

The Vice Chair emphasized the importance of objective data for purposes of policy and the necessity to collaborate with the DAC.

The DAC endorsed the Heart Transplantation Committee's new project.

Next steps:

The Heart Transplantation Committee will continue to check-in with the DAC as the project develops.

3. Check-in 1: Continuous Distribution of Kidneys and Pancreata

The DAC reviewed the OPTN Kidney Transplantation and Pancreas Transplantation Committees' data collection efforts related to the continuous distribution of kidneys and pancreata projects.

Overview of Proposal:

Implementation of the kidney and pancreas continuous distribution projects will require data collection across several difference considerations:

- Kidney Minimum Acceptance Criteria (KiMAC) Screening Criteria
 - o Data collection related to screening elements utilized by the KiMAC tool
 - Currently being discussed by the KiPa Utilization Considerations Workgroup
- Kidney and Pancreas Review Boards
 - o Data collection related to exception requests
 - Currently being discussed by the KiPa Review Boards Workgroup
- Pancreas and Kidney Medical Urgency
 - Currently being discussed by the Pancreas and Kidney Committees, respectively

Summary of discussion:

The Chair asked for more information on the difference between KiMAC and organ offer filters. Staff explained that transplant programs are required to provide KiMAC on a yearly basis while organ offer filters currently are not required. Additionally, KiMAC is answered on the program-level while organ offer filters are answered on the program-level with candidate-based exclusion criteria. KiMAC is applied after a match is run and before national offers are sent but organ offer filters are applied and updated as offers are sent out. Another difference is that KiMAC is applied for offers outside of 250 nautical miles and excludes "top of the match" candidates while organ offer filters are applied to all offers unless a candidate meets the filter exclusion criteria.

The Chair expressed concern that KiMAC and organ offer filters are duplicative rather than complementary. The Chair suggested that transplant programs need to understand how these tools work together to benefit organ offer acceptance rates and how it fits in with transplant program

processes. The Vice Chair agreed that these tools seem convoluted, and it may be difficult for transplant programs to understand how to utilize these overlapping systems. The Vice Chair recommended that the Kidney and Pancreas Transplantation Committees monitor this during implementation to ensure that the intended endpoints are being met. The Vice Chair suggested that DAC should continue to be involved in how this data is developed and codified.

The Chair suggested that the Kidney and Pancreas Transplantation Committees consider using the creation of medical urgency forms as an opportunity to collect data to gain an understanding of the impact of the policy.

The Vice Chair stated that a monitoring plan and identification of unintended consequences is an important consideration in the development of this work. The Vice Chair stated that the language for how medical urgency is defined will also be very important.

The DAC endorsed the Kidney and Pancreas Transplantation Committees' development of data collection related to the continuous distribution projects.

Next steps:

The Kidney Transplantation and Pancreas Transplantation Committees will continue to check-in with the DAC as the data collection efforts related to the continuous distribution projects continue to be refined.

Upcoming Meetings

• June 12, 2023 (teleconference)

Attendance

Committee Members

- Bilal Mahmood
- o Christine Maxmeister
- Daniel Stanton
- o Hellen Odour
- o Jesse Schold
- o Macey Levan
- o Michael Marvin
- o Michael Ison
- o Paul MacLennan
- Sumit Mohan

• HRSA Staff

o Adriana Martinez

• SRTR Staff

- o Ajay Israni
- o Jon Snyder

UNOS Staff

- o Alex Carmack
- o Brooke Chenault
- o Eric Messick
- o Joann White
- o Joel Newman
- o Jonathan Chiep
- o Kayla Temple
- o Kieran McMahon
- o Kim Uccellini
- o Laura Schmitt
- o Lindsay Larkin
- o Meghan McDermott
- o Michael Hollister
- o Nadine Hoffman
- o Sara Langham
- o Serena Straub
- Sevgin Hunt
- o Sharon Shepherd
- o Suhuan Wang
- o Susan Tlusty
- o Tamika Watkins
- o Taylor Livelli