

**Data Advisory Committee
Meeting Minutes
April 29, 2019
Conference Call**

**Sandy Feng, MD, PhD, Chair
Rachel Patzer, MD, MPH, Vice Chair**

Introduction

The Data Advisory Committee (DAC) met via Citrix GoTo teleconference on 04/29/2019 to discuss the following agenda items:

1. SRTR Presentation: Data Quality Changes Identified from 2015-2016
2. Review Data Advisory Committee's Decisions

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

1. SRTR Presentation: Data Quality Changes Identified from 2015-2016

Staff from the Scientific Registry of Transplant Recipients (SRTR) presented an overview of data changes that occurred post-implementation of new risk-adjustment models for kidney transplant recipients for the spring 2015 program-specific reports (PSRs). The presentation was originally made to DAC in 2015 and was important in getting the Modifying Data Submission project started.

Summary of discussion:

Due to the high volume of data changes that occurred, SRTR staff contacted OPTN Membership and Professional Standards Committee (MPSC) staff about these changes at the time the analysis was performed. However, SRTR staff did not believe that any direct follow-up was done on the part of the MPSC to determine why transplant centers had changed their data. Committee members asked for clarification regarding how EBV status is collected and transferred between OPTN forms. UNOS staff clarified that this donor data is derived from Deceased Donor Registrations (DDRs) and that Organ Procurement Organizations (OPOs) are able to change "donor status", sometimes done at the behest of transplant centers. SRTR staff also stated that the OPOs were not making data changes across all transplant centers, but rather only at specific centers in their DSAs. Due to this, Committee members voiced concern that some OPOs and transplant centers might be "colluding" together to improve PSR data. One Committee member stated they were not surprised about these results because it may have helped "marginal" transplant centers improve their risk-adjustment scores. This Committee member hypothesized that there were different transplant centers adjusting their data each year, depending on how well they performed. SRTR staff stated that if centers can be prevented from making such huge data changes, this could help increase quality data. For example, in order to prevent transplant centers from gaming the system, SRTR staff suggested enacting a data lock that forces transplant centers to initially enter quality data. This would also allow the SRTR to disband the PSR review period because quality data would already be available. Another Committee member also clarified that some transplant centers employ businesses to help them improve their PSR data (e.g. entering serum albumin values as opposed to leaving these fields unmarked will increase their PSR scores). Committee members agreed that data changes could be allowed for erroneous or inaccurate data, but not for making transplant centers "look better".

Another Committee member voiced concerns about shortening the data lock timeframe because this may result in the OPTN collecting low quality data. Furthermore, the Committee members opined that the DAC will need to agree on an initial submission date, prior to determining a lock date. Prior to the initial time frame, Committee members suggested that transplant centers be allowed to review their data prior to locking their data. SRTR staff also clarified that the DAC should not focus merely on the data variables used in the PSRs, because these variables may change over time.

2. Review Data Advisory Committee's Decisions

UNOS staff summarized and reviewed the Committee's prior policy decisions related to OPTN Policy 18: *Data Submission Requirements*.

Summary of discussion:

There were no questions or concerns from Committee members about any prior policy decisions made to OPTN Policy 18: *Data Submission Requirements*.

Due to spare time, UNOS staff discussed feedback received from other OPTN Committees about the timeframes in OPTN Policy 18.1: *Data Submission Requirements*. One Committee member asked whether there should be a two- step timeframe or a one-step timeframe for locking the data. One concern was that if there was one-step timeframe, this may inadvertently lead to lower quality data. However, SRTR staff stated that a two- step timeframe process might lead to more difficulties, and thereby advocated for only one-timeframe. On the otherhand, Committee members stated that similar to clinical trials, any "preliminary data" prior to the lock would not be used to inform the policy-making process. In this way, OPTN policy can state that members will not receive unlocked data. Due to the complexity of these questions, the Committee decided to further discuss a one-step versus step-process at the DAC in-person meeting whereby more members can provide feedback.

Next, UNOS staff clarified that the current policy proposal will be limited to evaluating the timeframes for TEIDI forms. Committee members advocated that histocompatibility and OPO representatives be available at the DAC in-person meeting in order to provide feedback on these timeframes. UNOS staff responded that they will follow-up to determine if a histocompatibility representative can attend the meeting. Another Committee member suggested that they review the data reports at the in-person meeting, and UNOS staff responded that this could be done.

Next steps:

The Committee agreed to re-consider a one-step versus two-step locking process at the DAC in-person meeting.

Upcoming Meetings

- May, 2019
- May, 2019

Attendance

- **Committee Members**
 - Sandy Feng, Chair
 - Rachel Patzer, Vice-chair
 - Maryl Johnson
 - Sumit Mohan
- **HRSA Representatives**
 - Shannon Dunne
 - Joyce Hager
 - Janet Kuramoto-Crawford
- **SRTR Staff**
 - Alyssa Herreid
 - Ajay Israni
 - Bert Kasiske
 - Nick Salkowski
- **OPTN/UNOS Staff**
 - Hannah Byford
 - Eric Messick
 - Leah Slife
 - Sarah Taranto