OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

**Data Advisory Committee
Meeting Minutes
April 8, 2019
Conference Call**

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

Introduction

The Data Advisory Committee (DAC) met via Citrix GoToTraining teleconference on 04/08/2019 to discuss the following agenda items:

1. Modify Data Submission Policies- Data Lock

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

1. Modify Data Submission Policies- Data Lock

DAC discussed the principles and implementation of a potential data lock.

Data summary:

The Committee reviewed UNOS analysis comparing TIEDI form submission rates by the expected date of submission and within 90 days of the expected date of submission.

Summary of discussion:

UNOS staff began discussion regarding OPTN Committee outreach efforts, including an overview of the conversations held with the Living Donor Committee (LDC) and the Histocompatibility Committee. During conversation with other OPTN Committees, a member asked for clarification on the current data check process and questioned its level of rigor. The member also asked if the process was consistent with the Centers for Medicare and Medicaid Services (CMS). UNOS Staff responded that CMS has a 90 day deadline. UNOS staff added that within UNet there are ongoing efforts to improve documentation and members' ability to enter data more accurately. Furthermore, there are some data integrity checks on the TIEDI forms, where submitted values that do not meet pre-defined upper and lower boundaries result in the user receiving an error message.

Also during the other OPTN Committee meetings, UNOS staff asked for feedback on which data should be locked and when it should be locked following submission and validation. At the time, there was no feedback for this specific question, but these topics came up later in the discussion. In continuing the discussion, UNOS staff reported that due to the performance variance amongst transplant centers, more information is needed to find solutions. The current idea is to work with engaged and timely OPOs to find answers. In response, a member suggested involving organ specific Committees as the data lock is developed, because organ-specific data drives SRTR reports on the transplant center side (such as outcomes). The member stated that the community might become concerned with a data lock due to its potential effect on transplant program performance. This member encouraged upfront engagement with stakeholders in order to bring them into these discussions sooner rather than later.

Another member asked if the DAC should look to another similar database and examine its data lock practices. UNOS staff responded that they have looked to the literature on this topic to find examples of comparable databases with locks, but that it was difficult to identify the standards

used (such as what data was locked and the timeframes used for the lock). A member reported that the DAC may have difficulty finding information on data locks.

There was also concern from Committee members as to when the data will be locked. For example, data for kidney patients is only collected once a year and a data lock with a tight timeframe may unintentionally shut out this information, thereby decreasing the data's accuracy. There are also times where data may need to be updated in TIEDI. UNOS staff then asked the Committee how they would plan an update before the lock is implemented. A suggestion was for the lock to be in parallel with data entry that is pertinent and required. This might give the transplant community confidence that the intention behind the process of the lock is to their benefit, not detriment. Another member spoke on increased functionality of the TIEDI system and suggested having more pop-ups that ask users to check their data's accuracy before final submission. Another suggestion was to implement additional reporting tools that could search for and require users to check on any logged information that looks out of the ordinary. However, other Committee members were concerned that human error will be an issue as long as there is manual entry. In order to eliminate this issue, the DAC would have to find another way to get data into the system. UNOS staff asked the Committee if there was a way to move forward and focus on the data integrity component of the project. A Committee member suggested starting with forms that are simple in nature, such as the Transplant Candidate Registration (TCR) form because it covers a specific point in time.

Another Committee member commented that the creation of a data lock is an opportunity to make correct changes to the system. While figuring out the logistics is challenging, it was felt that the Committee should focus on the transplant community and to introduce the data lock in the most acceptable way while obtaining data that is useful.

In conclusion, Committee members supported having a data lock with exceptions that would allow edits through back up documentation.

Next steps:

UNOS staff asked Committee members to think about the best way to review change requests for next meeting.

Upcoming Meetings

- April 15
- April 22
- April 29
- May 1 (In-person)

Attendance

- **Committee Members**
  - Nicole Berry
  - Richard Hasz
  - Maryl Johnson
  - Sumit Mohan
  - Marian O'Rourke
  - Jesse Schold
- **HRSA Representatives**
  - Shannon Dunne
  - Janet Kuramoto-Crawford
  - Chris McLaughlin
  - Raelene Skerda
- **SRTR Staff**
  - Alyssa Herreid
- **OPTN/UNOS Staff**
  - Hannah Byford
  - Kimberli Combs
  - Catherine Monstello
  - Lauren Parker
  - Leah Slife
  - Kim Uccellini
- Other Attendees
  - Laura Vinson