OPTN Data Advisory Committee
Meeting Summary
October 18, 2021
Conference Call

Rachel E Patzer, MD, PhD, Chair
Sumit Mohan, MD, MPH, Vice Chair

Introduction

The Data Advisory Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/18/2021 to discuss the following agenda items:

1. Improving the MELD Score
2. Biopsy Standardized Format for Pathology Report
3. Refusal Codes Update
4. Data Collection Review: Follow Up from 9/13 Discussion

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

1. Improving the MELD Score

Data Summary:

The Liver Committee presented on their proposal being submitted to the Board of Directors, *Improving the Model for End Stage Liver Disease (MELD) score*, which will address the sex-based disparity in the liver allocation system. Since the implementation of MELD, women have decreased odds of liver transplantation within three years compared to men. Similarly, they are three times as likely to die awaiting transplant or be removed from the waitlist for being too sick to transplant. The root cause of this disparity is twofold, the presenter noted. First, women tend to be shorter than men, which means size is a larger constraint. Second, women have lower muscle mass, which disproportionately skews their creatinine scoring within MELD. Between two identical and equally sick candidates, the candidate with the higher muscle mass will obtain a higher MELD score.

The proposed solution from the Liver Committee is to add either 1.33 or 1.40 MELD points to any female candidate that is registered for a Liver. However, the Liver Committee is also aware that instances may arise where the candidate's sex at birth, the only currently recorded indicator of sex, does not align with their current sex. To address this discrepancy, the Liver Committee proposes adding a new data field asking if the candidate's current sex and sex at birth are the same. The Liver Committee will not define what sex and will allow it to be self-reported by the patient, which is line with the current reporting of race and ethnicity to the OPTN. The presenter then requested any feedback from the Committee, noting the importance of the issue and the need to provide appropriate accommodations for all patient populations.

Summary of discussion:

The Chair presented two questions to the presenter; first, are there any other areas that they feel should capture candidate sex data outside of the candidate registration form, if it is liable to change over time? Second, will this information be a required field for candidate registration? To the first question, the presenter noted that they had not addressed how any change in sex after registration or

transplant would be indicated across forms, but also estimated that it would be exceedingly unlikely at present for this circumstance to arise. To the second question, the Liver Committee assumed there would likely be missing data, but did not make a decision whether it would be a required field or not. A Committee member inquired whether any consideration had been given as to whether candidates could "modify the system", by that meaning identifying as female on registration to gain the proposed 1.33 or 1.40 MELD points granted to female candidates. The presenter noted that yes, in theory, someone could use this tactic to gain a fairly small number of points, but it was very unlikely that candidate who would otherwise identify as male, with the oversight of their physician and transplant surgeon, would register as female. The Vice Chair also asked whether the Liver Committee had considered using Glomerular Filtration Rate (GFR) as a measurement to adjust for creatinine values, but the presenter replied that obtaining a GFR weekly for 14,000 candidates would be untenable. Following that, and with no further questions, the DAC endorsed the project.

Next steps:

The Liver Committee will consider the Committee's feedback.

2. Biopsy Standardized Format for Pathology Report

The Committee received an update on the Standardized Pathology Report project developed by OPTN Kidney Transplantation Committee's Biopsy Best Practices Workgroup, and provided feedback.

Data Summary:

The Biopsy Best Practices Workgroup was founded with the goal to standardize biopsy practices, including reducing unnecessary biopsy performance and improving consistency and quality of biopsy analysis and reporting. The latter part of this goal will be done through the implementation of a standardized biopsy form across Organ Procurement Organizations (OPOs). The Standardized Pathology Report project will reduce inconsistencies in biopsy reporting and quality of analysis, increase efficiency in allocation, and establish biopsy data collection on a wide scale. The Standardized Pathology Report utilizes parameters and response options that balance provision of clinical useful information and usability for pathologists with and without renal training. For example, certain parameter response options are percentage-based categories of a certain granularity, rather than abstract qualifiers. This project aims to update the "Organ Data" field on DonorNet will to improve biopsy reporting with the inclusion of both external sampling characteristics and biopsy parameters. The Standardized Parameters include:

- Biopsy Type and Tissue Preparation Technique
- Number of Glomeruli
- Number of Glomeruli Sclerosed, and Percent Glomerulosclerosis (GS)
- Nodular GS
- Interstitial Fibrosis and Tubular Atrophy (ITFA)
- Vascular Disease
- Cortical Necrosis
- Fibrin Thrombi

This standardization of data aligns with two OPTN Principles for Data Collection – develop transplant, donation and allocation policies, and ensure patient safety when no alternative sources of data exist.

Improving the quality of data used to evaluate organ offers and tracking biopsy data in a standardized format will help improve recipient placement and clinical care post-transplant. It was also noted that none of these elements have will to require additional or invasive testing to obtain, nor involve any

measurement not commonly performed. The Committee was then presented with the opportunity to provide feedback on the proposed data elements and standardization methods.

Summary of discussion:

A Committee member inquired what would happen if a pathologist did not completely fill out the form, given that that would result in incomplete data for the system. UNOS staff responded by saying that one potential idea that the Kidney Committee discussed was to have a sample version that is downloadable from DonorNet to provide to the pathologist, as most pathologists do not have access to DonorNet. However, the Biopsy Best Practices Workgroup had not discussed the potential outcomes of a pathologist not filling out the form to completion. The Vice Chair also wondered whether standardization would fix the reliability issue seen in biopsy data sets currently. They acknowledged that standardization was a good place to start, but may not be the root cause of all the inaccurate information. Staff shared that the scope of the Biopsy Best Practices Workgroup's projects is standardizing the biopsies that do occur, noting that , "standardizing how the data is reported and what data is recorded for the biopsies that do happen will be…largely beneficial". The Vice Chair responded that, in terms of standardization, part of the process includes understanding the context and information of the donor that is being biopsied. For example, between two donors, one 25 years old and the other 65, 20 percent Glomerulosclerosis mean very different things. With that in mind, the Vice Chair questioned whether there were any resources that would help inform pathologists in their understanding of a specific biopsy. A number of Committee members also voiced concerns that pathologists simply would not fill out the report, as they have had experiences where pathologists perform biopsies and do not create a written report afterwards. To both of these, the presenter said they would bring the feedback back to the workgroup. Finally, a member asked whether the Banff guidelines had been considered in this project. Staff shared that the Workgroup's developed the standardized report under the principle that biopsies should be utilized to help place an organ with the recipient that will receive the most benefit. The Banff criteria were established with the goal of determining organ viability, and so were not appropriately aligned with the goal of improved organ evaluation and appropriate recipient placement.

Next Steps:

The Kidney Biopsy Best Practices Workgroup will consider the Committee's feedback.

3. Refusal Codes Update

The Committee reviewed an update to Refusal Codes project. The project updates organ offer refusal codes to improve data quality, real-time offer decision making, organ refusal reasoning, and transplant quality review. As it stands, current offer refusal codes are frequently lumped into the 830 refusal code, which does not provide clarity as to the true refusal reason. This does not change anything significant within the DonorNet system beyond updated codes for clarity, and it will add a search functionality for these codes. For some of the codes, free text will be required to be entered to support the refusal reasoning. The presenter also commented that no bypass codes will be touched in this process outside of code 799, which notes that the candidate was bypassed. This was done due to the prevalence of code 898 being used both as a refusal code and a bypass code.

Implementation is scheduled to go into effect December 2, and a full summary of the codes can be found on OPTN. Beta testing of the refusal codes will be done in November, and a number of Committee members volunteered to help with that effort.

4. Data Collection Review: Follow Up from 9/13 Discussion

This agenda item was not discussed due to time constraints.

Upcoming Meetings

- November 8, 2021
- December 13, 2021

Attendance

- **Committee Members**
  - Rachel Patzer
  - Sumit Mohan
  - Kristine Browning
  - Jamie Bucio
  - Heather Hickland
  - Lauren Kearns
  - Krishnaraj Mahendraraj
  - Melissa McQueen
  - Alicia Redden
  - Benjamin Schleich
  - Daniel Stanton
  - Farhan Zafar
  - Bilal Mahmood
- **HRSA Representatives**
  - Adriana Martinez
- **SRTR Staff**
  - Bert Kasiske
  - Jon Snyder
- **UNOS Staff**
  - Lloyd Board
  - Matt Cafarella
  - Brooke Chenault
  - Abby Fox
  - Courtney Jett
  - Lindsay Larkin
  - Lauren Motley
  - Samantha Noreen
  - Matt Prentice
  - Sharon Shepherd
  - Leah Slife
  - Kayla Temple
- **Other Attendees**
  - James Trotter