OPTN Data Advisory Committee
Meeting Summary
July 12, 2021
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 7/12/2021 to discuss the following agenda items:

1. Welcome
2. Data Definition Clarification Review
3. HLA Equivalency Tables Update 2021
4. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation
5. Updating Alcohol-Associated Diagnoses on the Transplant Candidate Recipient (TCR) and Transplant Recipient Registration (TRR) Forms

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

1. Welcome

The Chair welcomed a new member to the Committee.

The Chair and UNOS staff reminded members that the DAC in-person meeting will be held on August 11, 2021 in Chicago, IL. The members were also presented with the regional meeting schedule and were encouraged to register and attend.

UNOS staff invited members to volunteer on the OPTN Fiscal Impact Workgroup by reaching out to their primary point of contact.

2. Data Definition Clarification Review

UNOS staff provided an overview of the process for clarifying data definitions. The current retrospective process was initiated in 2018 and allows for data element definitions to be further refined over time when additional clarity is requested by members or staff.

UNOS staff noted that improving data element definitions is a performance standard within the OPTN contract for the DAC. This revision process seeks to improve the quality of OPTN data as clear data definitions allow for more consistent data reporting by OPTN members.

The Committee's role in the review process is to consider and endorse proposed data definition changes. UNOS staff noted that the proposed data definitions were previously presented to DAC leadership for initial feedback. The Committee reviewed and discussed the following data definitions:

Number of previous solid organ transplants

A member submitted a question about how to indicate the number of previous transplants when listing a patient for a kidney transplant. The patient had previously received a kidney-pancreas transplant on

the same day. The current definition in Waitlist[sm] states that multi-organ transplants should be counted as one prior transplant. The proposed revised definition states that "All prior transplants involving any combination of kidney, liver, pancreas, heart, lung, intestine, or VCA organs, including transplants performed outside the U.S., should be provided. All multi-organ transplants in which the organs came from the same donor (including but not limited to liver-kidney, kidney-pancreas, heart-lung, or kidney-pancreas-intestine transplants) should be counted as ONE prior transplant." This field is required.

A SRTR representative questioned why multi-organ transplants count as one transplant. A member commented that the intention for collecting the information this way is to understand the number of donors a recipient has received organs from as this impacts the recipient's sensitization. A member noted that information is collected on the number of organs transplanted when the recipient is removed from the waitlist. UNOS staff agreed to follow up with the SRTR representative to confirm this data element's intent.

Height/Weight

An OPTN member submitted a question about how to enter additional height or weight measurements when captured on different dates as there is only one date field for both height and weight provided in TIEDI®. The proposed revision adds "Note: Use the most recent value for height/weight when/if multiple measurements are taken" to the definition.

Gender

UNOS staff noted that the DonorNet® and TIEDI® definitions for "gender" were updated in 2019 to reflect the intent of capturing sex at birth. UNOS Information Technology (IT) staff will begin a programming effort to make label changes to replace "gender" with "birth sex" beginning with Waitlist[sm]. The proposed revised definition for this field in Waitlist[sm] is "Indicate if the patient is Male or Female. Report patient sex (male or female), based on biologic and physiologic traits at birth." This will make the definition consistent across the multiple UNet[sm] applications.

 A member asked why the label was being changed to "birth sex" rather than "sex at birth." UNOS staff noted that IT staff reviewed how this information is captured in other registries and "birth sex" was commonly used. UNOS staff agreed to confirm this.

The Committee endorsed the three data definition clarifications.

3. HLA Equivalency Tables Update 2021

The Histocompatibility Committee Vice Chair provided an overview of this proposal, which will update and align human leukocyte antigen (HLA) data collection within UNet[sm] for donors, candidates, and recipients. This proposal will also include the addition of required HLA-DPA1 typing.

The Vice-Chair presented the current HLA typing/reporting requirements and an overview of the proposed changes.

Summary of discussion:

A member commended the Histocompatibility Committee for adding DPA1 but questioned why HLA typing was only required for abdominal organs. She noted that there are highly sensitized heart and lung candidates and it sometimes requires a virtual crossmatch for donors. The Histocompatibility Committee Vice Chair noted that the Committee is discussing requiring that donor HLA data be entered for all organs prior to the match run and will be requesting feedback from the Organ Procurement Organization (OPO) Committee.

The Chair asked about the 20% of labs that are not currently collecting this HLA-DPA1 information and asked how many labs are reporting HLA data through Application Programming Interfaces (APIs). The Histocompatibility Committee Vice-Chair noted that APIs are currently being developed and are targeted to go live in the fall. He commented that the reason some labs may not currently be reporting this information is likely due to some of the data elements not being required. He also noted that newer HLA typing techniques provide results that are more comprehensive and the development of APIs should make the reporting of additional typing results easier.

The DAC endorsed this proposal.

4. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

UNOS staff presented an overview of a project, sponsored by the newly formed Multi-Organ Transplantation Committee, to establish eligibility criteria and safety net for heart-kidney and lung-kidney allocation. The purpose of the project is to ensure clinical justification for allocating multiple organs to one candidate while also protecting access for single heart and lung recipients who do not regain kidney function and may need a kidney transplant in the future. Transplant programs will need to provide data to the OPTN in order to confirm a candidate meets eligibility criteria or qualify for the safety net. These eligibility criteria may mirror what is collected for simultaneous liver-kidney (SLK) candidates. This proposal will require changes to the heart, lung, kidney, and liver candidate forms in Waitlist[sm].

Summary of discussion:

UNOS staff shared what is currently collected relating to SLK allocation on the liver and kidney candidate forms to provide an example of what could be proposed as part of this new project. The Vice Chair questioned the use of creatinine clearance as part of the eligibility criteria for SLK. He recommended considering the use of cystatin, rather than creatinine, as a marker for kidney function as a lot of patients that may be impacted are cachectic. The Vice Chair also noted that the use of continuous renal replacement therapy (CRRT) as a component of eligibility criteria may cause reluctancy in removing patients from this therapy. UNOS staff noted that creatinine clearance is included in the current SLK policy but will bring these concerns back to the Multi-Organ Committee.

A member asked if there would be a caveat in the safety net policy if the heart-kidney candidate is in the operating room and the kidney transplant cannot be performed due to patient instability. UNOS staff agreed to bring this concern back to the Multi-Organ Committee for consideration as the project progresses.

The DAC endorsed this project.

5. Updating Alcohol-Associated Diagnoses (ALD) on the TCR/TRR

The Liver and Intestinal Organ Transplantation Committee Vice Chair presented a proposal to update the list of diagnoses on the Transplant Candidate Registration (TCR) and Transplant Recipient Registration (TRR) to allow for more complete data collection on candidates with alcohol-associated liver diseases. He noted that the Committee is not proposing new data collection but is seeking to update the current data fields by replacing "alcoholic" with "alcohol-associated" to align with updated terminology.

Summary of discussion:

A SRTR representative asked if this proposal is changing the associated codes or only updating the description associated with the codes. He questioned if the updated descriptions are describing the same condition or if there needs to be differentiation from the former codes. The Liver and Intestinal Organ Transplantation Committee Vice Chair noted that the change is intended to update the

terminology. He shared that the current diagnoses on the forms are outdated and confusing which prohibits accurate data collection on these candidates. The Chair agreed that updating these descriptions would provide value.

The DAC endorsed this project.

Upcoming Meetings

- August 11, 2021
- September 13, 2021
- October 11, 2021

Attendance

- **Committee Members**
  - Rachel Patzer
  - Sumit Mohan
  - Alicia Redden
  - Anna Mello
  - Bilal Mahmood
  - Colleen Flores
  - Daniel Stanton
  - Farhan Zafar
  - Heather Hickland
  - Jamie Bucio
  - Kristine Browning
  - Melissa McQueen
- **HRSA Representatives**
  - Adriana Martinez
- **SRTR Staff**
  - Bert Kasiske
  - Jon Snyder
  - Nick Salkowski
- **UNOS Staff**
  - Abigail Fox
  - Betsy Gans
  - Brooke Chenault
  - Courtney Jett
  - Darleen Arrowood
  - Kaitlin Swanner
  - Kiana Stewart
  - Kimberly Uccellini
  - Kristine Althaus
  - Laura Schmitt
  - Lauren Mauk
  - Leah Slife
  - Matt Prentice
  - Matthew Cafarella
  - Nicole Benjamin
  - Robert Hunter
  - Ross Walton
  - Sarah Konigsburg
- **Other Attendees**
  - John Lunz
  - Scott Biggins