

**OPTN Data Advisory Committee  
Meeting Summary  
December 13, 2021  
Conference Call**

**Rachel Patzer, MD, PhD, Chair  
Sumit Mohan, MD, MPH, Vice-Chair**

## **Introduction**

The Data Advisory Committee (Committee) met via Citrix GoToMeeting teleconference on 12/13/2021 to discuss the following agenda items:

1. Check In #2 Multi Organ Committee – Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation
2. Data Definitions

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

### **1. Check In #2 Multi Organ Committee – Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation**

The Multi Organ Committee (MOC) met with the Committee to re-evaluate the data elements that were being impacted by their proposal. This was a follow-up meeting from their initial estimate of which data elements would be touched.

#### Data elements impacted:

- Systems: Waitlist
- Forms: Heart Candidate, Lung Candidate, Kidney Candidate
- Fields: Diagnosis, Chronic Kidney Disease (CKD) diagnosis date; CKD qualifying criteria, Sustained Acute Kidney Injury (SAKI) test or treatment date, SAKI qualifying criteria, Diagnosing nephrologist

The MOC proposes mirroring the eligibility criteria currently existing for simultaneous liver-kidney (SLK).

#### Summary of discussion:

The Vice-Chair raised concerns that there was not enough detail to measure kidney function, saying that creatinine clearance can be based off of measured creatinine or calculated creatinine. Given the amount of bias built into the calculation, they assumed that the proposal would require everyone to use one approach. Furthermore, they added that there may be other evaluation metrics that would be less prone to error than creatinine-based ones, and wondered if the MOC had considered those. The presenter responded that the MOC had consulted with subject matter experts from the Kidney Committee, as well as Heart, Lung, and Liver. In addition, they had aligned their proposal with a proposal from the Kidney Committee on calculated creatinine in comparison to measured creatinine. The Vice-Chair concluded by saying that creatinine-based estimates are not validated in candidates with heart failure or liver disease, and while that’s not necessarily a problem, the potential for error with solely a creatinine-based estimate system is much higher. They also added that, when considering a candidate’s

dialysis time, it is not uncommon for candidates to receive dialysis for volume management, rather than kidney function management. To that regard, they felt that the requirements should indicate dialysis time specific to kidney function management.

The Chair inquired which committees the MOC had consulted with to develop the requirements, to which the presenter responded they had representation from the Heart, Lung, Liver, Ethics, Patient Affairs, and Transplant Coordinators Committees. These, they noted, had approved the proposed requirements, which in a large part mirrors the current SLK requirements. It was further explained that the MOC had examined the SLK data collection, and they felt that the data collection was still relevant to heart-kidney and lung-kidney and no fields were irrelevant. At present, they also wanted to have the policies in alignment, rather than have to reconsider SLK requirements if heart-kidney or lung-kidney were different. In the future, an effort could be made to update the requirements for all three.

The presenter also received a question on triple-organ transplants, but stated the MOC had not considered that far ahead. They did note that they would return to their committee with that question.

#### Next steps:

The MOC will consider the Committee's feedback.

## **2. Data Definitions**

The Committee reviewed the progress made on the data definitions clarifications review process. Currently, there is a lack of standardization or subject matter expertise opinion amongst the data definitions. This is the second time the Committee has received an update on the project.

#### Data summary:

The Committee had already reviewed the relevant data and was only being asked for feedback on the proposed updates to fields. The Committee was asked to consider how clear, easy to find in a chart, and objective the definition was. Of the four definitions that had been updated, they were: Ventilator support, Working for Income, Diabetes, and Date: Last Seen, Retransplanted, or Death (Recipient and Living Donor).

#### Summary of discussion:

A member noted that, within the definition for Working for Income, the terminology "just prior to time of donation" was still vague. They requested more specificity, and suggested the possible change with specific time frame. The member also noted that the member question that prompted the change did not address living donors, but was driving a change on the Living Donor Follow-Up (LDF) form. The presenter clarified that the LDF was being updated in order to remain consistent with the Transplant Recipient Registration (TRR) form, where the same field is also found. There was concern voiced with this mirroring, as the member pointed out there are distinct differences between living donors and transplant recipients, notably that, at the time of donation, living donors are expected to be very healthy, whereas at the time of transplant, transplant recipients are likely very sick. By this, they meant that there could be confounding factors when the same logic is applied to two distinct groups. While they agreed with the definition in the context of a transplant recipient, they questioned whether it could be applied with the same phrasing to living donors.

A second member also confirmed that, for consistency's sake, "just prior to time of donation" could be changed to "at the time of transplant".

A member inquired whether the "Date: Last Seen, Retransplanted, or Death" field on the TRR required a doctor to have seen them, or whether anyone could document the last seen date. They explained that

lots of kidney patients are assessed with a phone call to understand general levels of health; the presenter clarified that this field was looking for the patient status, rather than their graft status, which could be evaluated based off of general levels of health. Another member asked and received confirmation that this meant a provider would be able to document evaluating a patient who arrives for a non-transplant related medical visit, such as a vaccine. As an aside, they expressed that they were in favor of designating only transplant program personnel to be able to evaluate the patient. There was also discussion of the field title's reference to being "seen", as that could reflect the last date known alive, or last time evaluated by transplant professional. There was concern from a member that this could be vague; the presenter did note that at present, they were not able to update the field title, but they could add it to a list of enhancements for the future.

Finally, a member commented that the update to the "Last Seen, Retransplanted, or Death" field on the LDF made the field easier to understand, as well as circumvented the problems with "seen" as noted on the TRR. They did add that there could be a potential addition to include the family, in the case of donor death.

The Committee agreed to the proposed updates that received no concerns, but will re-review data definitions that need updating due to Committee feedback.

Next steps:

Changes will be considered based off of Committee feedback to the data definition fields examined.

#### **Upcoming Meeting**

- January 10, 2022

## Attendance

- **Committee Members**
  - Rachel Patzer
  - Sumit Mohan
  - Kristine Browning
  - Jamie Bucio
  - Colleen Flores
  - Lauren Kearns
  - Krishnaraj Mahendraraj
  - Anna Mello
  - Alicia Redden
  - Benjamin Schleich
  - Daniel Stanton
  - Farhan Zafar
- **HRSA Representatives**
  - Adriana Martinez
- **SRTR Staff**
  - Bertram Kasiske
  - Melissa McQueen
  - Jon Snyder
- **UNOS Staff**
  - Kristine Althaus
  - Lloyd Board
  - Brooke Chenault
  - Cole Fox
  - Olga Kosachevsky
  - Lauren Mauk
  - Eric Messick
  - Samantha Noreen
  - Matthew Prentice
  - Laura Schmitt
  - Sharon Shepherd
  - Leah Slife
  - Susan Tlusty
  - Kimberly Uccellini
  - Ross Walton
- **Other Attendees**
  - Nadine Hoffman
  - Ryo Hirose