

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

**Rachel Patzer, Ph.D., Chair  
Sumit Mohan, MD, MPH, Vice Chair**

## **Introduction**

The Data Advisory Committee (DAC) met via Citrix GoToMeeting teleconference on 09/13/2021 to discuss the following agenda items:

1. Social Determinants of Health Project (SDOH) Update
2. Lung Allocation Score (LAS) Refinements and Clean-Up
3. Data Definition Clarification Review
4. Call for Volunteers – DAC and Transplant Coordinators Committee Workgroup

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

### **1. Social Determinants of Health Project Update**

UNOS Research staff provided an overview of this project to assess the feasibility of acquiring third party social determinants of health data that could be linked to OPTN data, such as zip code, primary source of payment, education level and work for income.

UNOS Research also provided an overview of the two active projects that includes the following:

- Analysis of relationship between kidney candidates and their communities
- SDOH variables and waiting list outcomes

#### Summary of discussion:

The Chair commented that this is important work to address some of the issues previously discussed by the OPTN Minority Affairs Committee, including the collection of individual income data.

The Chair asked if there was a plan to use the data to analyze equity between transplant centers. UNOS Research staff noted that an equity analysis would go through the committee project process where there is a research question and a plan is developed to perform the analysis on behalf of the committee.

UNOS Research staff noted that the current project focuses on the procurement of data and the feasibility of collecting data from other sources. The next step is to perform several analyses to understand the “phenomenon of interest data” and potentially use the data to inform future projects that might have similar questions.

The Chair asked if there was funding from the Health Resources and Services Administration (HRSA) or other sources to repeat this data linkage and how that will look over time. UNOS Research staff responded that there is the potential for future data linkage; however, they are currently working on the two projects mentioned previously.

The Chair inquired about the need to provide evidence of institutional review board (IRB) approval in order for others to use the data to perform their own analyses. UNOS Research staff responded by explaining the privacy and security requirements from the third party vendor, and the need for any analysis to be conducted by the UNOS Research department through the standard committee process for data requests. However, the exact process for how that would work is still being determined.

A member asked about the size of the cohort and UNOS Research staff noted that it included 112,000 individuals on the waitlist during 2020.

Another member asked about the ability to provide center-level data. UNOS Research staff noted that the analysis could not be performed at the center level; it could be done at the donation service area (DSA) or county level. The intent was to look at geographies for public sources of data, such as estimates of end stage renal disease in chronic kidney disease and other types of co-factors.

The Chair commented about the importance of data as the DAC fulfills its role in evaluating projects. The Chair and Vice Chair both expressed interest in the DAC being involved in future conversations about this project.

#### Next steps

UNOS Research staff agreed to work with the DAC to schedule follow-up calls.

## **2. Lung Allocation Score (LAS) Refinements and Clean-Up - Lung Committee**

The Lung Committee Chair provided an overview of this project as part of a required DAC check in and endorsement process. The purpose of this proposal is to update data fields used to calculate the LAS, collect data that may identify trends in waitlist mortality and post-transplant survival, and clarify a number of identified variables based on questions from the community and LAS post-implementation data trends.

#### Summary of discussion:

A member noted an appreciation for the proposed changes, particularly the options for reporting supplemental oxygen. The member inquired about when the data is entered, there is not an option to complete one or the other according to what data is required.

The Lung Committee Chair asked if the member was referring to how the system is going to use the appropriate oxygen entry for the highest lung allocation score. She noted that currently there seems to be consistency where if a patient requires oxygen at rest if provides them with a higher allocation score than if they were on 15 liters at exertion. The system will certainly factor in what will give them the highest lung allocation score until there is additional data.

The member asked if there were any considerations for allowing different evaluation dates for each of the values. The Lung Committee Chair noted that when providing that information it is typically collected at the same time.

A member expressed appreciation for the changes to how the diabetes information is collected. She raised the question about how diabetes information is collected elsewhere and if there is a way to ensure consistency and accurate data collection. DAC leadership agreed that it is important to look at changes holistically across organ systems as data collection changes are proposed for a particular organ system.

UNOS staff noted that it would be a good practice for committees proposing data collection changes to evaluate how a particular data element is collected across all organ systems.

A member commented about the need to consider all the new options for assisted ventilation. She noted that it would be beneficial to the community to provide guidance to help coordinators choose the right options to ensure that patients are best represented by the information being submitted.

The Lung Committee Chair noted that there have been discussions about collecting data on different oxygen deliver, such as regular nasal cannula versus high flow oxygen.

The DAC endorsed the data collection effort and will be provided with future updates on this project.

### **3. Data Definition Clarification Review**

UNOS staff presented an overview of the process for reviewing data definitions as well as the DAC's role in providing subject matter expertise to help clarify data definitions. UNOS staff presented the proposed changes to the following data definitions for review:

- NAT (Nucleic Acid Test) Results
- Cigarette Use (>20 pack years) – Ever
- Ventilator Support

Summary of discussion:

#### ***NAT (Nucleic Acid Test) Results***

This data field is located on the transplant recipient registration (TRR) form. A member submitted the following question:

- This is to clarify if we can use ribonucleic acid (RNA) and deoxyribonucleic acid (DNA) tests to satisfy NAT results which is required documentation in the TIEDI TRR forms for Heart/Lung/Liver and Kidney Transplant Recipients.

UNOS staff provided the following proposed changes (shown with underlines) to the data definition, which would be added for human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV):

#### **Viral Detection**

HCV NAT: Select the NAT results from the list. This field is **required**.

**Positive**

**Negative**

**Not Done**

**UNK/Cannot Disclose**

Definition: (Hepatitis C Virus) - Inflammation of the liver due to the hepatitis C virus which is usually spread via blood transfusion (rare), hemodialysis, and needle sticks. The damage hepatitis C does to the liver can lead to cirrhosis and its complications as well as cancer. Transmission of the virus by sexual contact is rare. At least half of hepatitis C patients develop chronic hepatitis C infection. Diagnosis is made by blood test. Treatment and probably cure is via antiviral drugs and is effective in over 90% of patients. Chronic hepatitis C was frequently treated with injectable interferon, in combination with antiviral oral medications, but now is most often treated with oral antivirals alone.

**Note:** Serology refers to tests that detect the presence of an antibody to an infection. NAT (nucleic acid test) detects virus nucleic acid, either DNA or RNA.

For an equivocal (or indeterminate) result that changes to either positive or negative, change the result to the newer more specific value even though it may be a different test date. For a result that was originally equivocal (or indeterminate) or remains equivocal (or indeterminate) after repeated testing, record as "UNK/cannot disclose".

The Vice Chair provided a suggested change that would provide a clearer definition regarding DNA and RNA NAT testing, instead of adding more text in the middle of the definition.

Below is the proposed modification (shown in underlines) that was supported by the DAC members:

**Viral Detection:**

**NAT (Nucleic Acid Test) Results:**

**HIV NAT:** Select the NAT (RNA) results from the list. This field is required.

**Positive**

**Negative**

**Not Done**

**UNK/Cannot Disclose**

Definition: (Human Immunodeficiency Virus) - The virus that causes AIDS, which is the most advanced stage of HIV infection. HIV is a retrovirus that occurs as two types: HIV-1 and HIV-2. Both types are transmitted through direct contact with HIV-infected body fluids, such as blood, semen, and genital secretions, or from an HIV-infected mother to her child during pregnancy, birth, or breastfeeding (through breast milk).

**HBV NAT:** Select the NAT (DNA) results from the list. This field is **required**.

**Positive**

**Negative**

**Not Done**

**UNK/Cannot Disclose**

Definition: (Hepatitis B Virus) - A virus which primarily causes inflammation of the liver. The hepatitis B virus can be transmitted in several ways including blood transfusion, needle sticks, body piercing and tattooing using unsterile instruments, dialysis, sexual and even less intimate close contact, and childbirth. Symptoms include fatigue, jaundice, nausea, vomiting, dark urine, and light stools.

**HCV NAT:** Select the NAT (RNA) results from the list. This field is **required**.

**Positive**

**Negative**

**Not Done**

**UNK/Cannot Disclose**

Definition: (Hepatitis C Virus) - Inflammation of the liver due to the hepatitis C virus which is usually spread via blood transfusion (rare), hemodialysis, and needle sticks. The damage hepatitis C does to the liver can lead to cirrhosis and its complications as well as cancer. Transmission of the virus by sexual contact is rare. At least half of hepatitis C patients develop chronic hepatitis C infection. Diagnosis is made by blood test. Treatment and probably cure is via antiviral drugs and is effective in over 90% of patients. Chronic hepatitis C was frequently treated with injectable interferon, in combination with antiviral oral medications, but now is most often treated with oral antivirals alone.

**Note:** For an equivocal (or indeterminate) result that changes to either positive or negative, change the result to the newer more specific value even though it may be a different test date. For a result that was originally equivocal (or indeterminate) or remains equivocal (or indeterminate) after repeated testing, record as "UNK/cannot disclose".

### ***Cigarette Use (>20 pack years) – Ever***

This data field is located on the deceased donor registration (DDR) form. A member submitted the following question:

- Help documentation does not specify what to choose if the donor used 20 pack years. Could this be clarified?

UNOS staff provided the following proposed changes (shown with underlines) to the data definition:

**Cigarette Use (>20 pack years) - Ever:** If the donor has ever used cigarettes for more than 20 pack years, select **Yes**. If the donor has never used cigarettes, or used for 20 pack years or less, select **No**. If cigarette usage is unknown, select **UNK**. Vaping and e-cigarette usage is not collected in this field. This field is **required**.

Pack years refers to the number of packs of cigarettes the donor smoked per day multiplied by the number of years. For example, a donor smoking 2 packs of cigarettes per day for 10 years equals 20 pack years. Another example is  $1\frac{1}{2}$  packs per day for 10 years equals 15 pack years.

The Vice Chair commented that the use of the word "ever" is confusing and should only be if the donor has use cigarettes for more than 20 years. UNOS staff noted that it is part of the data field and would need to be changed as a separate improvement that is outside the scope of the process. UNOS staff agreed to document the concern for future reconsideration throughout the system.

### ***Ventilator Support***

This data field is located on the transplant recipient registration (TRR) form. A member submitted the following questions:

- Does this field include the time the patient was intubated for surgery? For example, if a patient got a transplant on 12/20 and then was extubated on 12/21 would that fall into the <=48 hrs category? If the patient had a transplant on 12/20 and then was extubated on 12/20 and then was discharged would that be no for ventilator support?
- Or is the ventilator question relevant after the patient is extubated for transplant?

- Also is this invasive ventilation?

UNOS staff noted that consulting with clinical experts as part of the review process. Following consultation with Lung Committee leadership, the following changes (shown with underlines) are being proposed for the data definition:

**Ventilator support** (Lung and Heart/Lung Only): If the recipient did not receive ventilator support, select **No**. If the recipient received invasive mechanical ventilation outside of the operating room, select the total time on ventilator support. If the duration is unknown, select **Ventilator support, duration unknown**. If ventilator support status is unknown, select **Unknown Status**. This field is required.

- **No**
- **Ventilator support for <= 48 hours**
- **Ventilator support for > 48 hours but < 5 days**
- **Ventilator support >= 5 days**
- **Ventilator support, duration unknown**
- **Unknown Status**

**Note:** Report the total cumulative amount of time during the postoperative period that the recipient was on ventilator support, regardless of the clinical reason the recipient was intubated.

A member commented that it still seems confusing on whether you are trying to determine pre OR versus post OR ventilator support. Is the intent is to collect ventilator support prior to transplant and combined support post-transplant? She noted that the “note” seems to imply that it is only post-transplant.

UNOS staff suggested that this feedback be provided to the Lung Committee leadership to determine if additional clarification is needed. DAC leadership supported that plan.

The DAC approved the changes to the NAT (Nucleic Acid Testing) results and Cigarette Use (>20 pack years) – Ever data definitions. The DAC supported providing feedback to the Lung Committee on the data definition for ventilator support.

#### **4. Call for Volunteers – DAC and Transplant Coordinators Committee Workgroup**

UNOS staff discussed the ongoing process improvements for the review of data collection. One new process that was identified was to better engage external subject matter experts by establishing a workgroup made up of representatives from transplant hospitals and organ procurement organizations. This group would meet quarterly with the first meeting being scheduled for February 2022.

UNOS staff requested that members have experience entering or validating data entry or oversee data entry teams. Member were asked to contact UNOS staff with questions or to volunteer for this workgroup.

#### **Upcoming Meetings**

- October 11, 2021
- November 8, 2021
- December 13, 2021

## Attendance

- **Committee Members**
  - Rachel Patzer
  - Sumit Mohan
  - Alicia Redden
  - Anna Mello
  - Bilal Mahmood
  - Colleen Flores
  - Daniel Stanton
  - Jamie Bucio
  - Krishnaraj Mahendraraj
  - Kristine Browning
  - Lauren Kearns
  - Macey Levan
  - Melissa McQueen
- **HRSA Representatives**
  - Adriana Martinez
  - Chris McLaughlin
- **SRTR Staff**
  - Bert Kasiske
  - Ajay Israni
- **UNOS Staff**
  - Abby Fox
  - Andrew Placona
  - Anne Zehner
  - Alex Garza
  - Bob Carrico
  - Brooke Chenault
  - Robert Hunter
  - Elizabeth Miller
  - Kimberly Uccellini
  - Krissy Laurie
  - Kristine Althaus
  - Lauren Mauk
  - Leah Slife
  - Nicole Benjamin
  - Olga Kosachevsky
  - Samantha Noreen
  - Sara Rose Wells
  - Susan Tlusty
  - Tatenda Mupfudze
- **Other Attendees**
  - Erika Lease