

**OPTN Data Advisory Committee  
Meeting Summary  
February 8, 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 2/8/2021 to discuss the following agenda items:

1. Refusal Codes
2. Amnesty Policy Updates
3. AHIRC Non-Citizen/Non-Resident (NCNR) Guidance Document

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

### **1. Refusal Codes**

UNOS staff provided an update on the Refusal Codes project.

#### Summary of discussion:

The proposed refusal codes are being presented to other committees in order to collect feedback. So far feedback has been collected from the DAC, the Organ Procurement Organization (OPO) Committee, the Transplant Administrator Committee, and the Operations and Safety Committee. The remaining presentations will be completed in February and March.

The IT Roadmap was presented and it was shared that work to implement the new refusal codes could begin as early as May.

Refusal code definitions still need to be developed and will be worked on by the internal team and workgroup members.

### **2. Amnesty Policy Updates**

UNOS staff provided an update on *Action 2: Relax Data Submission Requirements for Follow-up Forms* of the COVID-19 Emergency Policies implemented in April 2020. DAC members were asked to provide feedback and recommendations for ending form submission amnesty.

#### Summary of discussion:

There is a recent decrease in the number of Transplant Recipient Follow-up (TRF) forms in amnesty status. This decrease may be attributed to communications and weekly reports sent to transplant hospitals. Transplant hospitals have been diligently working to submit forms retrospectively.

A member asked who receives the amnesty reports. Transplant administrators, primary surgeons, and primary physicians at each transplant program receive the reports by email. There has been a high level of engagement with members.

Some members have reported that they were unaware that the forms would leave their queue once reaching amnesty status and are now returning to complete these forms. The additional communications have increased the number of forms being validated each week.

Currently, the only required fields on the TRF are date of death or graft failure and report of death or graft failure. Reporting the cause is not required. There are concerns about transplant programs not reaching out to transplant recipients post-transplant since the follow up forms are not currently required. This could potentially limit the number of deaths or graft failures identified.

Currently, no data is required on the living donor follow-up (LDF) and post-transplant malignancy (PTM) forms. However, adverse outcomes within two years for living donors is still required to be reported through the patient safety portal.

Most recent patient and graft status with date last seen (including those alive with functioning graft) from six month, one, two, and three year follow-up forms are currently not being collected during amnesty but are needed for performance metrics. Additional data not required under amnesty are still needed for general monitoring of post-transplant quality of life, reporting and policy analysis, as well as understanding the impact COVID-19 has had on the system.

The Executive Committee reviews the form amnesty data at every meeting in order to monitor and consider when it would be appropriate to end amnesty. UNOS staff asked the DAC members to provide their opinion on whether to sunset the amnesty policy and begin requiring retrospective form submission.

The Chair emphasized that the DAC is charged with upholding data quality and that the data included on the forms in amnesty are critically important for a number of reasons including performance monitoring, research, and policy making. The DAC leadership is supports ending amnesty.

A member agreed with the recommendation to sunset amnesty and noted that most transplant programs have adjusted their processes to ensure the data is collected. Other members agreed. A member supported ending amnesty and commented that programs are now able to safely access patients to collect data. She suggested providing clear expectations and timelines so programs can prepare and raised concern about a potential timeline coinciding with the March 1st implementation of the Public Health Service (PHS) guideline policy modifications.

The Chair suggested a timeline in which members would receive notice that amnesty is ending in 30 days on March 1<sup>st</sup>, amnesty would end April 1<sup>st</sup>, and then there would be a 90 day period for submitting retrospective data. A member commented that this is reasonable but to consider data coordinators' availability and suggested extending the timeframe for retrospective form submission. Another member recommended extending the retrospective data collection period to the end of the year. The members agreed that advance notification is essential.

UNOS staff asked how much time is appropriate between the end of the retrospective data submission period and the implementation of the data lock policy. UNOS staff also commented that the Membership and Professional Standards Committee (MPSC) recommended setting milestones during the retrospective data collection period and invited the DAC members to provide comment. The Chair asked the Scientific Registry of Transplant Recipients (SRTR) representatives if there were any concerns with the timeline presented. The SRTR representative commented that what is practical for programs needs to be considered and commented that older forms should be prioritized when completing the retrospective data submission.

The Chair suggested encouraging programs to prioritize the submission of older forms in communications from the OPTN. The members discussed setting milestones based on the age of the

forms. The Ex Officio raised a concern about being able to regiment submission through these milestones and suggested instead raising their awareness and requesting older forms be submitted first. If a milestone, for example, is to submit forms that are older than six months by a specific date, this may be the majority of the forms that need completion and may be impractical.

The Chair asked about the portion of forms in amnesty and if there is any relationship with a program's size. UNOS staff shared that majority of TRFs in amnesty are from larger programs. The Ex Officio commented that the impact of COVID may have varied for programs of different sizes.

The member discussed a 60-day timeframe for retrospective data submission. The Vice Chair and members supported a 60-day window for retrospective data submission. A member raised a concern about members submitting incomplete or erroneous data if overly rushed to submit due to the timeframe being too short.

When considering if all fields should be required for retrospective submission, a member commented that lab data collected late may not be useful. The SRTR representation commented that late data is better than no data and raised a concern relating to the potential to miss incidences of graft failure if data is not submitted.

The Chair summarized the recommendations received stating that the DAC recommends ending amnesty as soon as possible, provide as much advance notice as possible, allow 60 days for retrospective data collection in which older forms are prioritized, and provide clear communication on expectations, deadlines, and available tools.

#### Next steps:

DAC's recommendations and concerns will be shared with the Executive Committee to help inform next steps of ending amnesty.

### **3. AHIRC Non-Citizen/Non-Resident (NCNR) Guidance Document**

The Vice Chair of the Ad Hoc International Relations Committee (AHIRC) provided an overview of the *Non-citizen/Non-resident Guidance Document* project and requested feedback from the DAC regarding best practices to promote accurate collection of citizenship status on the transplant candidate registration (TCR).

#### Summary of discussion:

The Vice Chair of AHIRC shared that the results of an information request from 2020 identified that nearly 45% of programs the responded did not know whether their NCNR candidate's home country had a transplant program, 50% of programs did not know whether their NCNR candidate sought a transplant in their home country before coming to the U.S., and a couple of programs contacted UNOS stating that they had been inaccurately capturing citizenship status. The programs requested guidance on how to categorize patients as NCNR to improve data quality. The Vice Chair of AHIRC also noted that there are significantly fewer completed follow up forms for NCNR recipients.

To help address these issues, AHIRC intends to develop and publish a guidance document to educate transplant programs on the differences between candidates traveling to U.S. for transplant and NCNR candidates traveling to U.S. for reason other than transplant.

The members discussed the sensitive nature of collecting citizenship data, how this data is reported and collected, and how this information is used. There may be hesitation for the candidate to share this information with health care providers because there is concern about the information being shared with law enforcement or misused in other ways. The Chair suggested adding information about why this

data is collected and how it will be used. A member commented that this data may be used by transplant programs in determining if the patient will have ongoing access to immunosuppressants. Another member commented that citizenship data is submitted on Centers for Medicare and Medicaid Services (CMS) forms.

The members discussed the purpose for collecting this data. UNOS staff shared that there is OPTN policy that requires AHIRC to review and report on this data. The Ex Officio commented that if the form corresponds to a policy, then the policy should be considered when assessing modifications to the form.

The members discussed if “Non/U.S. Citizen/ Non-U.S. Resident, Traveled to U.S. for Transplant” and “Non/U.S. Citizen/ Non-U.S. Resident, Traveled to U.S. for Reason Other Than Transplant” needs to be differentiated or could be collected as a singular category “Non/U.S. Citizen/ Non-U.S. Resident.”

The Vice Chair of AHIRC asked if the DAC members were concerned about the lack of follow up on NCNR recipients. The Vice Chair of DAC commented that follow up may not be needed if the patient is able to receive post-transplant care where they live after surgery. The Ex Officio commented that having the follow up forms completed does not speak to the care the person is receiving, it only indicates that the form was completed.

Next steps:

DAC members were invited to provide more feedback by email.

**Upcoming Meeting**

- February 18, 2021
- March 8, 2021

## Attendance

- **Committee Members**
  - Alicia Redden
  - Anna Mello
  - Benjamin Schleich
  - Bilal Mahmood
  - Colleen O'Donnell Flores
  - Daniel Stanton
  - Farhan Zafar
  - Kristine Browning
  - Leah Slife
  - Macey Levan
  - Melissa McQueen
  - Rachel Patzer
  - Sandy Feng
  - Sumit Mohan
- **HRSA Representatives**
  - Adriana Martinez
  - Chris McLaughlin
- **SRTR Staff**
  - Alicia Redden
  - Bert Kasiske
  - Maryam Valapour
  - Nick Salkowski
- **UNOS Staff**
  - Adel Husayni
  - Alex Tulchinsky
  - Brooke Chenault
  - Charles Fenderson
  - Courtney Jett
  - Kiana Stewart
  - Kim Uccellini
  - Lauren Mauk
  - Matthew Prentice
  - Meghan McDermott
  - Nicole Benjamin
  - Peter Sokol
  - Rebecca Brookman
  - Robert Hunter
  - Roger Brown
  - Sarah Konigsburg
  - Sarah Taranto
  - Susan Tlusty
- **Other Attendees**
  - Pramod Bonde