OPTN Executive Committee
Meeting Summary
March 1, 2021
Conference Call

David Mulligan, MD, Chair
Matthew Cooper, MD, Vice Chair

Introduction

The Executive Committee (EC) met via teleconference on 03/21/2021 to discuss the following agenda items:

1. New Project for Approval
2. OPTN Response to CMS Public Comment on OPO Medicare/Medicaid Conditions for Coverage
3. Data Review: COVID-Related Policies Currently in Effect
4. Data Collection Amnesty Policy Data Review and Discussion
5. Adjourn

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

1. New Project for Approval

The Policy Oversight Committee (POC) Chair presented one new project recommended for approval. The new project comes from the Ad Hoc International Relations Committee (AHIRC) related to a guidance document on non-citizen (NC) and non-resident (NR) data collection. There is a lower rate of post-transplant care data submission for NC/NR transplant patients and concerns were raised regarding capturing citizenship and residency status. The goal of this project is to provide guidance on collection of the data to improve accuracy and quality of the data collected from transplant candidates, especially NC/NR candidates.

The AHIRC was initially concerned with follow-up care, because if patients are not in the country during their post-transplant period, it will be more difficult to collect data. However, the POC discussed the scope of the guidance document, and determined that it can help identify best practices to ensure patients are tracked and followed up on concerning data collection, but should not give guidance on follow-up care itself.

The Data Advisory (DAC), Ethics, Minority Affairs, and Transplant Administrators Committees (TAC) will be collaborating on this project. The AHIRC has the bandwidth to take on this project at this time. The project falls under the category of "Promoting living donor and transplant recipient safety" in the Strategic Plan because the quality of the data collection helps inform patient care. It does not fall under one of the Strategic Policy Priorities. Resources needed are minimal because this project is a guidance document.

One Committee member noted that there previously was a guideline that if greater than 5% of a center's transplants were foreign citizenship status, the center would be subject to an audit. The POC chair explained that over the years those audits were not consistently done and that policy no longer exists. She further explained that about five years ago there was a push to change that policy to residency status, rather than citizenship status, which was more relevant because of the concern of candidates coming into the U.S. solely for the purpose of transplantation. One Committee member felt

the number of NC/NR transplants very low and has almost no relevance from a statistical point of view. The POC Chair clarified that the purpose of the guidance document is to improve accuracy and quality of the data collected is because those data will impact the way the care and follow-up for this category of patients is evaluated. The UNOS CEO noted that the number of NC/NR patients is relatively low, a little over 1% of total transplants, or approximately 350 transplants a year. The EC Chair supported the project, as it will help with evaluation of NC/NR patients. One Committee member commented that the document should be applicable to a range of transplant programs.

It was asked if there is any type of follow-up agreement to encourage patients to return to the US for follow-up. The POC chair explained that the purpose of the guidance document is only to identify best practices for follow-up and data collection. There is no policy about follow-up for this specific group of patients.

Another Committee member expressed concern over the title of the project, as it conveys the idea that the document involves determining who can or cannot get a transplant. Rather, the title should convey the efforts to improve patient safety with follow-up. The term "non-resident" is well defined in the policy, but the AHIRC could consider modifying the title.

A motion was made and seconded for the Executive Committee to approve the Non-Citizen/Non-Resident Guidance Document project as recommended by the POC, along with the recommendation that the project title be modified.

A vote was taken and results were as follows: 100% yes; 0% no; 0% abstained.

2. OPTN Response to CMS Public Comment on OPO Medicare/Medicaid Conditions for Coverage

The EC Chair explained that during the Trump administration CMS issued a final rule that included performance monitoring metrics on the basis of regulation and certification for OPO organizations. The EC approved the public comment submissions to CMS in September 2019 and January 2020, which included feedback from MPSC and OPO committees. The Biden administration delayed implementation of this and other regulations and opened a 30-day public comment, closing 3/4/2021.

The current draft of the response from the OPTN to CMS for public comment includes six major points: 1) to set a performance bar for reevaluation on a four-year cycle, 2) improve coordination between CMS, HRSA and OPTN, 3) develop a plan for management of service areas in OPO If decertified and limit number of OPOs that can become decertified in a year, 4) leverage existing data sharing innovations, 5) remove external disincentives to transplanting organs from older donors and DCD donors, and 6) enable OPOs to merge and share services.

UNOS staff explained that the letter is thematically consistent with the first two letters that were approved by the EC, but with some adjustments. The letter now offers suggestions for CMS to make some adjustments that would be consistent with the OPTN's original recommendations.

There were questions about why a new public comment was opened, and the UNOS CEO explained that the current administration could have withheld implementation without asking for public comment, so this is a sign that a substantive review may be taking place. The POC chair added that CMS is specifically looking for issues of law, fact, and policy. This will be the focus of the comment period.

One Committee member asked whether it is known by CMS, HRSA and the OPTN that enhanced coordination between the groups would be beneficial, since examples of poor communication are not provided in the letter. The EC Chair noted that he has met with officers from CMS and HRSA and feels they acknowledge there are delays and that improvements in communication are needed. One Committee member pointed out the wording in the response is for "improved coordination," as an

attempt to build on what's already there, to try to work together as a community and as regulatory bodies to improve organ donation and transplantation.

One comment was that the written response reiterates statements made before, but in a much more concise and precise manner. The previous response document was much longer and was rewritten to hone in on specific points from contributions from many people, so this response will probably come across better than the more extensive document did a year ago.

One Committee member noted that the public comment document that was responded to before did not have many of the details that were in the final regulation, which is important for people who may be new to this discussion. The 75% decertification threshold and a few of the other details around the Final Rule were not in the original proposal that was sent out for public comment. This time there is more for the OPTN to react to and the response can therefore be more specific. There was further agreement that the response was well written and responds accurately. Another Committee member noted that the letter is a rational response.

A motion was made and seconded for the Executive Committee to approve the Response to CMS (OPO Metrics), as presented.

A vote was taken and results were as follows: 100% yes; 0% no; 0% abstained.

3. Data Review: COVID-Related Policies Currently in Effect

The UNOS Manager of Research Science presented the COVID-19 policies data review. Policy 1, updates to candidate data during COVID-19, continues to have low usage. Analysis of policy 3, modify wait time initiation for non-dialysis kidney candidates, shows that the number of non-dialysis kidney registrations has remained stable at one-third. Overall, there has been a decline in COVID-19-related organ offer refusals since the beginning of the pandemic, with a slight increase in fall 2020 through the beginning of 2021. Most refusals were related to OPO or transplant center operations. COVID-19-related waitlist deaths for kidney and liver showed a similar pattern, slightly increasing in late fall 2020 through early 2021.

Policy 4, incorporating COVID-19 infectious disease testing into DonorNet, was made permanent on 1/27/2021. Discrete testing fields are currently not required in the system, but in instances where a donor has no testing reported, the UNOS data quality team reaches out to the OPO to confirm that testing was done and to encourage them to enter data into DonorNet. 86% of donors had test results indicated in the discrete infectious disease testing field, and there were 63 positive COVID test results for 45 unique donors.

In summary, the number and percent of candidates carrying labs forward remains very small across organs. New adult kidney waiting list registration counts are continuing to rebound. The COVID-19-related waiting list/post-transplant deaths were most highly reported for kidney candidates and recipients. All OPOs are reporting COVID-19 testing and 100% of donors have been tested for COVID-19.

4. Data Collection Amnesty Policy Data Review and Discussion

The UNOS Principal Research Analyst went over specifics regarding COVID-19 Policy 2: Relax Data Submission Requirements for Follow-up Forms (Amnesty Policy).

Pre-COVID, around 7,000 to 8,000 recipient follow-up forms were validated each week. There was a brief spike in March with a dip to about 6,000 forms a week until December 2020. There was an increase in forms December 2020 through early February 2021 as staff began to complete retrospective data submission. In the most recent two weeks, it stabilized to about 8,000 forms a week, similar to pre-COVID. At the end of February 2021 it was close to 8,500 forms.

When comparing the December 2020, January 2021, and February 2021 data reports, the total number of forms in amnesty has stabilized at just over 50,000, with more than 48,000 of those being transplant recipient follow-up forms (TRF). The total percentage of forms in amnesty has continued to drop, now at 12.5% of expected TRF and living donor forms (LDF) for the period in amnesty status. The median number of forms per center in amnesty is down to 22 with the median percentage at 3.8% and a high of 2,427 forms expected at a single center. Eleven centers have more than 1,000 TFRs in amnesty, representing 38% of the total number of forms in amnesty on 2/21/2021. The OPTN is sending out a report to all hospitals to help them better identify the forms they have outstanding in amnesty.

The Committee reviewed potential next steps. The date of death or graft failure and report of death or graft failure fields are still being collected while the forms are in amnesty. In order to look at performance metrics and outcomes for a center, the report of patient and graft status, including date for recipients without failure or death, is needed, and is more in-depth data. This is currently not collected in amnesty.

The DAC, Membership and Professional Standards (MPSC), TAC, and Transplant Coordinators (TCC) Committees have also been reviewing these data and considering the impact of amnesty. They looked at several options going forward and each wanted to provide feedback to the EC. All four committees were supportive of ending amnesty on April 1, 2021. There was mixed support for what to do with the retrospective data for these forms. The DAC supported complete retrospective data submission, while the other three supported not requiring or limiting the required retrospective data. Five potential options going forward were presented in a memo to the EC, but the focus today will be on Options 1 and 2. Option 1 was collecting all data on all the forms and Option 2 was collecting all the data on recipient malignancy forms (PTM) and LDF forms and focusing on outcomes data from TRF.

The EC will decide today on whether to end amnesty or continue the policy further, whether to require complete retrospective data or limit the field, and to determine a timeline for form completion. Chris McLaughlin commented that HRSA has been supportive of extra flexibility in managing the follow-up visits and collecting the data. In review of recent data, the majority of centers are now completing the forms and retrospectively completing the follow-up forms in amnesty status, which is an important achievement. But given the requirements of the Final Rule and the importance of the data, HRSA does recommend that the OPTN return to its standard data submission requirements, eliminating the amnesty option, as well as requiring retrospective collection of all of the forms and all the data under timeframes deemed reasonable by the OPTN.

The EC Chair recognized the hard work of the community to complete the retrospective data submission, as well as the fact that there will be some data, such as lab results not done, that will not be retrospectively submitted. There will likely be some gaps in what is traditionally collected on the TRFs. LDF and PTM forms collect important data, but are elective, lower-risk forms. Even pre-COVID, there was always a percentage of follow-up forms that were in "not seen," when a center was unable to see a patient. Even if the OPTN requires centers to go back and validate all of the forms that are in amnesty, there will likely be a higher percentage of "not seen" during this time period than normal.

One Committee member shared comments from TAC. The TAC preferred at least a 60-day notice before ending the Amnesty Policy, which they understand must be ended. One challenge with completing forms was that the forms were disappearing from expected lists when they went into amnesty, so they could not see that they still needed completion. In addition, there are still some patients declining to come into clinic, particularly if they have not been vaccinated yet.

The potential end date to the policy is 4/1/2021, 30 days from this meeting. This would allow enough time to notify all centers and provide resources to the centers that have a large number of forms in

amnesty. Once all centers have been notified of the policy end date, they would be given a reasonable timeline to complete submission of the retrospective data, which would be a separate timeline. The EC discussed two options for retrospective data submission requirements: Option 1, require members to fully complete all past forms, and Option 2, require partial completion (data needed for SRTR program-specific reports) of all TRF forms.

One Committee member suggested focusing on requiring critical data needed to validate the TRF forms, rather than have centers spend too much time trying to fully complete the forms and ultimately not obtain all the critical data needed. This perspective is closely aligned with option 2. UNOS staff noted that 88% of the forms in amnesty were able to be validated per the usual validation requirements, meaning transplant programs are providing the patient status and graft status, which then allows them to put "unknown" for some fields and "not available" for some lab values. The form does allow centers to enter that the patient was not seen. About 1% to 2% of the forms included only patient status and graft status, so some information was entered, but not enough to validate the form completely. There was additional support from the Committee for obtaining enough information to validate the forms. Transplant programs are aware of what information is needed to validate the forms, so that would be a straightforward process for centers.

Different possibilities for final deadlines to submit the retrospective data were then reviewed. DAC supported a date of 4/30/2021, with a milestone deadline for 6 months, 1-, 2-, and 3-year TRF forms with other forms due later. TCC supported a final submission deadline of 7/1/2021, 90 days from end of amnesty. DAC and TAC supported a deadline of 8/30/2021, 6 months from end of amnesty. MPSC supported a final submission deadline of 10/31/2021, 8 months from end of amnesty. A final possibility for a deadline is 4/1/2022, one year after the Amnesty Policy ends.

The group noted that the April 30th deadline is impractical given the number of forms in amnesty. One Committee member noted that much work has been done with tools to enhance data analysis. Perhaps tools or technology, such as APIs that are not in place or not being used, could help make it possible for centers with a smaller staff to be able to enter all the data in amnesty. However, it was pointed out that if the centers are not already using it, it may not come into place fast enough to help meet the deadlines. Many things on the TRFs are not discrete elements and require more judgment.

UNOS staff will ensure PTM and LDF forms get pulled back into expected reports once a path forward has been determined. The amnesty report that has been provided to transplant coordinators and will continue to go out and provide updates on forms not completed. Once a decision is made, they will put together a toolkit to make the community aware of available resources. One Committee member noted that there seems to be consensus for ending amnesty on April 1st. After this date, centers will be expected to complete the forms as was done pre-COVID.

The Executive Committee agreed on a deadline of 90 days after the end of amnesty to require retrospective data submission. One Committee members noted that this date will also help the SRTR to develop important data reports. Forms can be validated by entering all required fields or if all details are not available because the patient was not seen or only seen through telehealth and labs were not done, centers could enter critical elements and then select "not seen" or "unavailable" and validate the form with nothing else on the form. The EC will reassess this at 60 days after Amnesty Policy end.

The HRSA representative asked for clarity on the data elements, and UNOS staff explained that centers can either complete the form with data or note that patient was not seen. HRSA felt this was reasonable and in alignment with their desired outcome. The key elements are graft function, patient survival, and cause of death, but there are other variables that are collected that are used in outcomes reporting and other research. If any of those data are available, such as EGFR, acute rejection, and post-transplant

diabetes, they should be collected to be included in longer-term outcome measures. The Committee agreed that the expectation is that centers complete everything they can with the option to mark as not seen. The group clarified that they are in favor of Option 1, repealing the policy on April 1 and requiring retrospective submission of forms by July 1.

A motion was made and seconded for the Executive Committee to repeal COVID-19 Policy 2: Relax Data Submission Requirements for Follow-up Forms (Amnesty Policy) on April 1, 2021, with a deadline of July 1, 2021, to validate forms in amnesty with as much retrospective data that are available for each patient (Option 1).

A vote was taken and results were as follows: 100% yes; 0% no; 0% abstained.

Next steps:

Communication will be send out immediately to notify the centers of the repeal and associated dates.

5. Adjourn

The EC Chair thanked the Committee for their work. The meeting was adjourned.

Upcoming Meetings

- April 26, 2021
- June 14, 2021

Attendance

- **Committee Members**
  - David Mulligan
  - Matthew Cooper
  - Maryl Johnson
  - Mindy Dison
  - Robert Goodman
  - Timothy Snyder
  - Lisa Stocks
  - Denise Alveranga
  - Jeff Orlowski
  - Valinda Jones
  - Atsushi Yoshida
  - Medhat Askar
  - Christopher McLaughlin, HRSA (Ex-officio, non-voting)
  - Brian Shepard, UNOS (Ex-officio, non-voting)
- **SRTR Staff**
  - Jon Snyder
  - Ajay Israni
- **UNOS Staff**
  - Chelsea Haynes
  - Laura Cartwright
  - Sarah Taranto
  - Elizabeth Miller
- **Other Attendees**
  - Alexandra Glazier