

**OPTN Transplant Administrators Committee
Meeting Summary
July 22, 2020
Conference Call**

**Nancy Metzler, Chair
Susan Zylicz, MHA, BSN, RN, CCTC, Vice Chair**

Introduction

The Committee met via Citrix GoToTraining teleconference 07/22/2020 to discuss the following agenda items:

1. Welcome and Leadership Introductions
2. Welcome New TAC Members and Introductions
3. Minority Affairs Committee (MAC) Update
4. COVID-19 Emergency Policies and Data Collection
5. Vascular Composite Allograft (VCA) Committee Project Updates
6. Modify Living Donation Policy to include Living VCA
7. Transplant Coordinator Committee (TCC) Volunteer Opportunity
8. Other Business

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

1. Welcome and Leadership Introductions

The Chair thanked everyone for attending and introduced leadership.

Summary of discussion:

The Chair introduced themselves and shared that they have participated on the Transplant Administrator Committee (TAC) for about eight years. They noted that one of the benefits of committee work is staying informed about OPTN policies. They said that they appreciate the attendees for volunteering their time to contribute to the Committee.

2. Welcome New TAC Members and Introductions

All members and support staff introduced themselves.

Summary of discussion:

Each attendee introduced themselves by stating their title and role on the Committee. The new members were welcomed.

3. Minority Affairs Committee (MAC) Update

The Vice Chair of the Minority Affairs Committee (MAC) provided an overview of the Data Collection to Assess Socioeconomic Status and Access to Transplant proposal, answered questions, and solicited feedback from TAC members.

Summary of discussion:

The Vice Chair of MAC has been with MAC the last 3 years. Last year, MAC proposed a policy that includes additional data collection around Socioeconomic Status (SES) data. The proposal is intended to go back out for public comment this January. The Vice Chair asked for feedback from TAC on the proposal's current state.

The Vice Chair of MAC shared that OPTN only gathers highest level of education, whether they are working for income, and primary source of payment. No income data is collected. MAC has discussed this proposal and received input from the Data Advisory Committee (DAC). From these discussions, it was recommended to collect household income and household size. These datapoints are commonly collected by government agencies and for research purposes. The proposal requests these two data fields be added to the Transplant Candidate Registration (TCR) form.

The Vice Chair of MAC said that the purpose for collecting this data is to help monitor allocation policy changes and its impact to vulnerable populations as well as identify inequities that exist. The collected information would help refine current transplant equity models and allow transplant programs to create interventions for high-risk patients by providing support for immunosuppression extension coverage or transportation assistance.

The Vice Chair of MAC presented sentiment data from when the proposal was previously presented at regional meetings. They noted that overall the proposal was accepted favorably but there were also some negative responses including concerns around the invasiveness of the question. The key themes from public comment included that proposal is timely, there was acknowledgement that SES factors impact transplantation, and that more data is needed. Some negative feedback included concerns regarding data quality, fear of misuse of data, and data entry burden. In response to data entry burden, the Vice Chair of MAC noted that the additional data entry only consists of two additional questions which are commonly collected during the psychosocial evaluation. There were also criticism about patient confidentiality and intrusiveness. To address the concern around intrusiveness, the proposal was updated to collect income ranges rather than exact dollar amounts. This is to increase the patients' trust and comfort. Patients can also opt out of answering the question.

The Vice Chair of MAC emphasized the necessity of collecting this data and stated that if it is not collected by UNOS, it will be collected by the government. COVID-19 has further highlighted inequity in access to care. National Institute of Health and government representatives are working to gather these data to improve equity.

The Vice Chair of MAC requested feedback to share with MAC and DAC. The Chair invited members to ask questions.

A member asked why household income and household size were chosen to measure SES. The Vice Chair of MAC responded that there is no single parameter is ideal but the ones chosen were based on what would provide the most gain with the minimal amount of data entry required in order to lessen the entry burden. Ideally, there would be more questions asked to better reflect what is going on at an individual level. The selected parameters are used commonly and were suggested by DAC.

A member commented that unless income documentation is provided, the SES data will be self reported and we will need to rely on that data. The Vice Chair of MAC responded that when these questions are asked, it will need to be stated why this data is collected and remind them that it will not affect their ability to be transplanted as well as inform them of who will have access to this data. They emphasized that hospitals already collect this information and acknowledged that some patients will be uncomfortable.

A member questioned whether hospitals collect this information for fully insured patients. The member also asked what action this data will inform. The Vice Chair of MAC responded by reviewing the purpose of the data being collected presented previously. The member raised a concern about patients' access to care before they are listed. The Vice Chair of MAC agreed that this is an area of concern but noted that the OPTN does not have jurisdiction to collect data on patients before they are listed. A member agreed that financial information is not currently collected for fully insured patients and raised a concern that the patient may perceive that the data may be used to limit their ability to be listed.

A member asked if education for how to sensitively collect this information has been considered when developing this proposal. The Vice Chair commented that an educational component will be emphasized during public comment.

UNOS Staff asked the Committee to respond to the feedback questions presented. The Chair commented that they will check what financial data is collected by their program's financial counselor and where this data is stored. A member raised a concern about making sure that this proposal is addressing access to transplant, commenting that there are other factors that may create barriers to care beyond SES. The Chair commented that outcomes can be tied to SES factors due to transportation and medication access issues. The member responded that they can assess SES by zip code. The Vice Chair of MAC commented that zip codes act as a surrogate for SES data and is not individualized to the patient. Zip codes can encompass various affluent and not affluent areas.

UNOS Staff asked the Committee to comment on changes that would garner more support of the proposal. A member responded that they are concerned about making patients uncomfortable by asking income questions and does not want to add burden to staff who need to be educated in how to communicate the data use to patients, especially when there is already strain on resources due to COVID-19. The Chair commented that there needs to be a concrete plan for why this data needs to be collected and how it will be used that can be shared with the staff collecting it. The Vice Chair of MAC responded that MAC cannot determine what is done with the data. They commented that SES affects the ability to be transplanted, even when listed. Many patients will not care to share this information but they predict that there will be external pressures to collect this data in the near future. The data has the potential to create a more equitable and socially just access to transplant.

UNOS Staff asked the new TAC members for comments. A member reported that their program collects household income on all kidney candidates unless fully insured. They commented that they appreciate the Vice Chair of MAC's passion and they want to ensure the data is meaningful and accurate. They also shared that they would prefer to manage this request rather than have it be mandated.

The Vice Chair of MAC thanked the Committee.

A member suggested assessing equity by comparing financial data from all patients that are referred to the transplant hospital to those that are listed. The Vice Chair of MAC agreed that would be ideal but this type of data collection is not currently in the purview of the OPTN.

Next steps:

Members should send Pete Sokol the financial data already being collected by their programs. This information will be blinded, summarized, and combined with the discussion captured in the meeting summary. This summary will be shared with the Committee for approval and then sent to MAC.

4. Update COVID-19 Emergency Policies and Data Collection

UNOS Staff gave overview of COVID-19 Emergencies Policies and Data Collection.

Summary of discussion:

This policy was created in response to the challenges being experienced by transplant hospitals due to COVID-19. These policies have already been passed by the Executive Committee. Retrospective public comment is being requested to discuss whether the following actions taken were appropriate and to request feedback. The primary goals of the policies were to promote patient safety and assist the transplant community.

Action 1: Allow for most recent candidate lab results to be carried forward for medical urgent statuses

Action 2: Relax data submission requirements for follow-up forms (recipient and living donor)

Action 3: Modify wait time initiation for non-dialysis kidney candidates

Action 4: Incorporate COVID-19 infectious disease testing into DonorNet®

The rationale is to reduce candidate and living donor exposure to COVID-19, reduce hospital burden, avoid disadvantage for candidates who are unable to safely access the hospital for pre-transplant lab testing, and provide organ procurement organizations (OPOs) and transplant programs efficient communication of COVID-19 testing status and results.

The members were asked to provide feedback on how long the policies should remain in effect. They were asked to respond to whether the COVID-19 infectious disease testing should remain in DonorNet® past September 30, 2020 and be mandatory. The members were also asked to comment on whether the emergency policy process used by the OPTN was the most appropriate way to respond to an emerging health crisis.

A member commented that there is still a resurgence of COVID in their area and commented that the question should not be how long the policies should remain in effect but what the trigger should be to discontinue these policies. The Chair asked if the policy could be discontinued in a tiered approach, keeping the loosened requirements for the older forms such as three years and out which take more time for data collection. UNOS Staff will share this suggestion with the Executive Committee.

A member commented that everyone is still in the learning phase of this disease and agreed with the sentiment to continue with keeping the policies in place until a triggering event is determined on when to discontinue.

A member representing OPOs commented that they are testing all donors for COVID-19 and shared that it is not a burden to enter COVID-19 data.

A member shared that there is a need to continue collecting COVID-19 data. The Vice Chair agreed, noting that we do not know how long COVID-19 will continue to be an issue and collecting the data is appropriate. The Chair commented that COVID-19 testing may always be a required test for OPOs and may become a permanent field in DonorNet®. They support this data collection being mandatory. A member agreed that the emergency policies should remain and the COVID-19 test data should be mandatory. Additional members agreed.

UNOS Staff asked if the OPTN acted appropriately with these policies and issued communications in a timely manner. A member commented that the data entry changes were good. The main challenge they said they experienced initially was finding surgeons to do procurements and is unsure if this could be addressed with policy or is the role of the OPTN. The Chair agreed that this was a challenge and asked if there should be a centralized database of local recovery surgeons. They commented that some hospitals did not allow surgeons to travel from COVID-19 hot spots to recover organs. The member agreed that they had similar experiences and noted that there could have been communications from the OPTN about using local recovery. There were inconsistencies in processes across the country. A member agreed that there were challenges relating to travel and COVID-19 safety.

The Chair said that the communications from UNOS and policies implemented were useful and timely.

5. Vascular Composite Allograft (VCA) Committee Project Updates

UNOS Staff gave an update on the VCA projects going to public comment and an overview of project ideas being addressed by the VCA Committee.

Summary of discussion:

Programming VCA Allocation in UNetSM

VCA is currently managed outside of UNetSM. The purpose of the proposal is to align how VCA allocation is coordinated and data is collected with the rest of solid organs. The proposal outlines policy changes required to program deceased donor VCA allocation and data collected in UNetSM. The target implementation date is December 2021.

Modify Data Collection on VCA Living Donors

Currently, transplant programs submit data on living donors through the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms. The proposal requires data collection on VCA living donors and adds VCA specific data element to the LDR and LDF. The proposal also includes policy changes associated with programming living VCA donor data collection in UNetSM including Living Donor Feedback, LDR, LDF, and Donor Histocompatibility. The target implementation date is June 2022, following the VCA allocation programming into UNetSM.

UNOS Staff offered to present more information on these proposals during public comment if TAC is interested.

UNOS Staff gave an overview of other following project ideas the VCA Committee is discussing.

- Membership requirements for uterus or genitourinary transplant programs
- Policies or guidance related to uterus or genitourinary transplantation
- VCA graft failure definition
- Increase awareness of VCA donation and transplantation
- Membership requirements for living VCA donor programs
- Modify Deceased Donor Registration (DDR) for VCA
- Data collection on children born to uterus recipients
- Updates to VCA allocation/addressing geographic disparities

The Chair commented that their program does not currently do VCA transplants but asked what the membership requirements are if they were to start to offer VCA transplants. UNOS Staff responded that a program is required to submit a letter of notification that includes the type of VCA transplant their program intends to perform. Another member commented that they also do not offer VCA transplants.

UNOS Staff commented that the Fiscal Impact Group (FIG) had a good discussion on the VCA proposals going to public comment that included some VCA experts. These experts and the FIG members were all supportive of VCA data collection and creating a consistent system and process as the other solid organs. A member commented that having the VCA experts participate was an important part of FIG's review process.

Next steps:

6. Modify Living Donation Policy to include Living VCA

A member of the OPTN Living Donor Committee gave an overview of the Modify Living Donation Policy to include Living VCA policy proposal sponsored by the OPTN Living Donor Committee

Summary of discussion:

Current OPTN living donor policy does not address living VCA donors. This purpose of the proposal is to expand current policy to address all living donors including VCA living donors, and establish compliance standards for VCA programs. The proposal also includes requirements specific to VCA for informed consent and medical evaluation requirements. There has been a significant increase in VCA donations, specifically for uterus transplants. VCA is unique because of psychosocial concerns.

The proposal was informed by member expertise, literature, and Institutional Review Board (IRB) protocols of existing uterus programs as well as input from the Disease Transmission Advisory Committee (DTAC).

VCA programs will need to become familiar with new requirements and incorporate these requirements into their current protocols. Staff training will be required.

7. Update Transplant Coordinator Committee (TCC) Volunteer Opportunity

UNOS Staff invited TAC members to join a new workgroup sponsored by the Transplant Coordinator Committee (TCC).

Summary of discussion:

TCC is starting a new workgroup on revising temporarily inactive codes, and is looking for one member of TAC to join. The commitment involves attending an hour-long meeting in August, November, December, and January. The focus of the workgroup is to provide more granular codes for the top two reasons candidates are temporarily inactivated. Currently, 62% of inactivated candidates are coded “temporarily too sick” or “candidate workup incomplete.”

The Chair commented that TAC is different in the way that they do not propose their own policies. This volunteer opportunity is a great way for someone who is interested to dive into other committee work and report out at TAC.

A member asked if this group is tasked with revising the codes or addressing inactive status at large. UNOS Staff responded that the workgroup is reviewing the temporarily inactive codes. Nearly 65% of all patients fall into “temporarily too sick” or “candidate workup incomplete.” Additional granularity of data on those listed as temporarily inactive is requested as those candidates are more likely to experience waiting list mortality.

Next steps:

If interested in volunteering on this workgroup, email Pete Sokol.

8. Update Other Business

UNOS Staff provided additional updates to the Committee.

Summary of discussion:

The public comment documents reviewed previously in this meeting still need approval from the Policy Oversight Committee and the Executive Committee. The goal of sharing these proposals was to loop TAC in prior to public comment.

The Chair invited the members to share any additional news or concerns. No members responded.

The Chair thanked the members for their time and work.

Upcoming Meetings

- August 26, 2020
- September 23, 2020