

**OPTN Patient Affairs Committee
Meeting Summary
March 26, 2024
Teleconference**

**Garrett Erdle, MBA, Chair
Molly McCarthy, Vice Chair**

Introduction

The Patient Affairs Committee (the Committee) met via teleconference on 3/26/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Directors & Officers Information
3. In Person Debrief
4. Inactive Status Data Conversation
5. Open Forum
6. Adjourn

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

1. Welcome and Announcements

Committee Leadership welcomed the Committee members and thanked them for their continued participation. The Chair noted that a member was not in attendance today due to a concurrent Board of Directors meeting.

A Committee staffing change was shared with the group.

Summary of discussion:

The Committee did not make any decisions.

OPTN Contractor staff liaison announced his departure and introduced the new staff liaison. Mr. Carmack shared his appreciation to Committee members, recognizing their hard work and preparedness.

2. Directors & Officers Protections Information

Committee members received a brief update on the current status of Directors & Officers (D&O) protections amidst contract discussions and the separation of the OPTN and UNOS Boards.

Summary of discussion:

The Committee did not make any decisions.

OPTN Contractor staff noted that discussion between the OPTN Contractor and HRSA is ongoing regarding the separation of the OPTN and Contractor boards, which includes the D&O coverage. Additional information will be shared as soon as it becomes available.

The Vice Chair asked if D&O coverage will be ending at the end of March, noting that she initially thought this applied only to Board of Directors members. OPTN Contractor staff noted that the Board is meeting currently, and this may be part of those discussions, but reinforced that UNOS and HRSA are actively working together to address this in real time.

A Committee member shared concerns that without this D&O coverage, individual Committee members could be subject to liability. It was noted that all OPTN volunteers should be made aware of this. The Committee member continued, noting that if coverage is no longer present after March 29 that his participation in the Committee will end. A formal response was requested before March 29, noting that volunteers deserve to know whether they have this liability with committee or Board service.

OPTN Contractor staff recognized the concerns and noted that they were shared with leadership, and this discussion is ongoing. HRSA had nothing to add other than confirming that they are actively working on this negotiation.

Next Steps:

OPTN Contractor staff will update Committee members regarding the status of D&O coverage as soon as new information is available.

3. In Person Debrief

OPTN Contractor staff requested Committee member feedback on the February 16, 2024, meeting in Houston.

Summary of Discussion:

The Committee did not make any decisions.

OPTN Contractor staff recognized feedback from the September 23, 2023, meeting in Detroit and the focus to make agenda adjustments for this most recent in person meeting based on the thoughts shared. Committee members requested fewer agenda topics and shorter presentations to allow for more discussion time and incorporate more breaks. Feedback was requested on whether this most recent meeting met these requests, seeking responses from both in person and online participants.

A Committee member noted that, while this was her first meeting, she appreciated the balance of information and preparedness for discussion.

Committee members voiced general approval of the updated format, noting that the limited agenda allowed for more discussion and participation.

A Committee member who participated online for the meeting. It was noted that virtual is never perfect, but there were no specific issues outside of challenges identifying speakers in the room. If Committee members do not have their cameras on, it would be helpful to identify yourself before speaking.

A Committee member shared feedback regarding the public comment process. Individual Committee member feedback was requested prior to the meeting. This pre-meeting request resulted in robust conversation at the in-person meeting, as Committee members discussed their thoughts as a group. OPTN Contractor staff shared that it is common practice across committees to draft the formal Committee response after the meeting and seek Committee leadership approval before final submission. Contractor staff submits all written comments offered by committee members as

attachments to the formal public comment so that sponsoring committees have full patient feedback. This information is also included in the meeting summary.

The Committee member asked that any modifications made to the draft response included in the meeting materials be shared with the Committee after approval by Committee leadership, highlighting changes as appropriate. The Committee member continued, noting that conversation during the meeting differed from what was submitted by individuals. OPTN Contractor staff encouraged members to submit their individual comments during the public comment period, especially in cases where individuals may have something to add or a differing opinion. Contractor staff noted the members' recommendations and will discuss incorporating them with Committee leadership for the next PC cycle.

Another Committee member shared some confusion regarding whether he should be representing PAC feedback or his personal thoughts at regional meetings.

The Vice Chair questioned whether any feedback on the Committee's responses had been received from the two committees who presented in February. OPTN Contractor staff shared positive feedback from Minority Affairs and Histocompatibility Committee members, noting that both appreciated the opportunity to speak to the Committee and recognized the members' preparedness for discussion and feedback.

Next Steps:

OPTN Contractor staff will share final public comment responses with the Committee via email and/or SharePoint once Committee leadership has approved language. This will include highlighting any modifications to what was included in the meeting materials based on discussion during the meeting.

OPTN staff will work to implement this change and education regarding regional representative guidance into public comment education before the next comment cycle in July.

Inactive Status Data Conversation

The Committee continued its exploration of data on candidates set to inactive status. SRTR Contractor staff shared perspectives on potential inferential data that may help address the Committee's continued questions on this topic.

Summary of Discussion:

The Committee did not make any decisions.

SRTR Contractor staff provided introductory background to explain the differences between the Scientific Registry of Transplant Recipients (SRTR) and the OPTN contracts. These two roles are meant to be complimentary, with SRTR focused on data related to inferential analyses and simulations and the OPTN completing descriptive data analyses. Rather than describing a population (as was seen on the previous data report during the in-person meeting), inferential data predicts or infers what might happen or what might be expected. The SRTR Contractor staff noted that some questions posed by the Committee during its October 2023 meeting cannot be addressed using the OPTN data set because that information is not collected by the OPTN.

SRTR Contractor staff confirmed a question from a Committee member, noting that there are specific codes to denote a candidate's inactive status. This information was shared previously with the Committee during its April 18, 2023 meeting as part of an OPTN data report. A Committee member questioned whether there was a code to denote center error in marking a candidate as inactive. An anecdotal story was shared where a center error was an issue for a patient. SRTR Contractor staff noted

there is no specific code or way to analyze the OPTN data and determine the number of candidates marked inactive due to center error.

SRTR Contractor staff reviewed the Committee's OPTN data request from the November 14, 2023 meeting and recognized the Committee's desire to expand on that information. In relation to questions related to race and education, SRTR Contractor staff suggested that inferential data may be useful to determine the likelihood of inactive status based on given characteristics of patients on the wait list over time. This could include characteristics such as comorbidities, blood type, race, gender, insurance type, and educational attainment associated with a higher probability of inactive status or lower probability of converting from inactive to active status.

SRTR Contractor staff did offer caution that this will still not answer the Committee's questions about patient notification of inactive status. The Committee still desires information on the number of candidates who may be marked as inactive and are unaware of this information. SRTR Contractor staff noted that a survey may be the only vehicle to potentially provide this type of information.

A Committee member reflected on the initial data request being broad and including the term "at minimum" to seek answers to their questions. The Committee member noted a desire to see the inactive codes included in the final report in order to continue discussion and look for potential trends.

The Vice Chair sought direction on next steps to address this issue, recognizing that Committee members were stunned by the total number of inactive candidates and the inability to determine whether these candidates are aware of this inactive status. Because of this, the Vice Chair noted, the Committee opted to cast a wide net regarding its data request and noted that they felt pushed towards a potential ethnicity bias related to these questions.

Rather than continuing to pose questions that are not easily answered with existing data, the SRTR Contractor staff suggested potentially surveying centers to learn more about their practice for informing patients or survey the patients themselves. Alternately, SRTR Contractor staff noted that the process is known not to be standardized, so there is opportunity here to move toward a policy proposal to require patient notification, as this is important to the Committee and impacts a large number of patients awaiting transplantation. This project could also include patient education so they know what their options are upon receiving this information. Committee members noted that it is important to provide this information in an easy to access and easily understood format. The Committee member continued, noting that it is not reasonable to expect sick people to know what is going on and to have to search for it. This cannot be forgotten as part of the development process.

A Committee member noted that they thought notifications were required when status changes were made. OPTN Contractor staff acknowledged that there is no OPTN policy to require notification of candidates who are put on inactive status and wait time accrual during inactive status varies by organ.^{1,2} Centers for Medicare and Medicaid Services (CMS) and the OPTN do have requirements in place requiring patient notification of transplant status, including placement on the waitlist, decision not to

¹ OPTN Policy 3.4.E Inactive Status. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (accessed 3/27/2024)

² OPTN Policy 3.6.A Waiting Time for Inactive Candidates. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (accessed 3/27/2024)

place the patient on the waitlist and/or waitlist removal.^{3,4} Some transplant centers interpret this to mean that they should notify patients of inactive status (though the patient remains on the waitlist, they do not appear on match runs). For this reason, there is no conformity on if, how, and when notifications are made.

The Vice Chair suggested bringing the original work group back together to revisit what has been learned, determine if inferential data request will be beneficial, and make recommendations to the full Committee on this and whether a policy proposal project should be developed for Policy Oversight Committee consideration. Current members of that group were listed and other Committee members were invited to participate if they are interested.

Next Steps:

OPTN Contractor staff will re-circulate the inactive status codes to the Committee for review.

SRTR Contractor staff will circulate bullet points for further discussion related to a potential SRTR data request.

Original work group will reconvene to determine what has been learned and make a recommendation to the full committee on:

- whether an SRTR data request will be pursued, and if so, finalize this during the April 16, 2024 teleconference; and
- whether a policy proposal project and a complementary patient education resource should be developed to require notification to candidates moved to inactive status.

5. Open Forum

The Chair congratulated a second committee member on her recent election to the Board of Directors as an At-Large Patient and Donor Affairs representative. He reflected on a longstanding desire for Committee members to graduate to higher positions within the organization and thanked her for her commitment.

OPTN Contractor staff reminded Committee members of their next meeting, an April 16, 2024 teleconference.

6. Adjourn

The meeting was adjourned at 3:57 PM ET.

Upcoming Meetings

- April 16, 2024 conference call
- May 21, 2024 conference call
- June 18, 2024 conference call

³ 42 CFR § 482.94 Condition of participation: Patient and living donor management.

<https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-E/subject-group-ECFRc4be2badf376a95/section-482.94> (accessed on March 28, 2024)

⁴ OPTN Policy 3.4 Patient Notification. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (accessed on 4/4/2024)

Attendance

- **Committee Members**
 - Garrett Erdle
 - Molly McCarthy
 - Lorrinda Gray-Davis
 - John Sperzel
 - Denise Abbey
 - Steve Weitzen
 - Calvin Henry
 - Jenny Templeton
 - Andreas Price
 - Kristen Ramsay
 - Justin Wilkerson
- **HRSA Representatives**
 - Mesmin Germain
 - Robert Johnson
 - Arjun Naik
- **SRTR Staff**
 - Allyson Hart
 - Katie Audette
- **UNOS Staff**
 - Alex Carmack
 - Shandie Covington
 - Desiree Tenenbaum
 - Kimberly Uccellini
 - Jenna Reformina
 - Jesse Howell
- **Other**