

**OPTN Patient Affairs Committee
Meeting Summary
January 16, 2024
Conference Call**

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

Introduction

The OPTN Patient Affairs Committee (PAC), the Committee, met via WebEx teleconference on 1/16/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Expeditious: Organ Usage Through Placement Efficiency
3. Public Comment: Expedited Placement Variance

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

1. Welcome and Announcements

The Chair of the Committee opened the meeting and welcomed those who were on the call. OPTN contractor staff reminded Committee members that the booking for the in-person meeting was open. In addition, he asked that members notify leadership if they will be attending the next meeting in a virtual or in-person capacity. OPTN contractor staff also noted that they have added an agenda item to the in-person meeting to revisit previous conversations regarding Calculated Panel Reactive Antibody (CPRA).

The Committee was notified that the proposal *Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection* will be undergoing revisions and will not be going out for public comment this cycle. Due to these changes, leadership will be re-evaluating potential ideas and will update the Committee before moving forward.

Summary of discussion:

The Committee did not make any decisions.

The Chair of the Committee added that the leadership team will make a quick decision regarding the new ideas to be sure that their time at the in-person meeting is meaningful.

Next steps:

Committee leadership and OPTN contractor staff will notify the Committee when a decision regarding items that will be discussed for public comment is made.

2. Expeditious: Organ Use Through Placement Efficiency

OPTN contractor staff provided the Committee with a background and progress update related to the Expeditious Task Force.

Presentation summary:

- OPTN Board of Directors approved the creation of a task force to study and improve the efficiency of organ usage and placement.

Key Responsibilities:

- Evaluate existing data and recommendations regarding system challenges and improvements.
- Engage directly and frequently with the community to obtain data, feedback, and suggestions.
- Prioritize issues to address. Recommend both short-term improvements and long-term strategies to address larger challenges.
- Frequently update the Executive Committee and Board of Directors.

Implications on OPTN Committee Work:

- OPTN governance structure remains unchanged: OPTN committees sponsor requests for new OPTN policies.
- The task force is a new entity and new relationships will be formed between the task force and existing OPTN committees.
- Task force will lead the OPTN's effort to improve efficiency/reduce non-use and AOOS will require significant input from committees.
- Some solutions may fall within the committees' purview (policy and data collection efforts)
- Goal is for committees to work within its scope and support the task force through review of relevant policy and data collection projects and providing input and suggestions to the task force.

Summary of discussion:

The Committee did not make any decisions.

A member of the Committee emphasized the significance of not only generating innovative ideas for enhancing transplantation efficiency but also formulating effective strategies for their implementation. While acknowledging the commendable efforts of the task force in brainstorming ideas, the member underscored the equal importance of developing practical approaches to execute these proposals. The member cautioned against progressing too far along the conceptual path without a clear plan for execution.

A member expressed her curiosity regarding the creation of the task force, especially considering the existing strategic goals are already aimed at improving process and efficiency. Elaborating further, she pointed out that the OPTN should already be executing tasks outlined in its strategic plan. She questioned the task force's differentiation and its approach to deviating from standard work that should be integral to the OPTN's existing strategic plan.

In response, an OPTN contractor clarified that the task force was conceptualized to consolidate efforts from various committees and entities to enhance efficiency and utilization, consolidating work that was previously dispersed across different committees. The OPTN contractor emphasized the task force's broader perspective aimed at challenging assumptions about member capabilities and OPTN operations to inspire innovative problem-solving. The member raised a concern about the task force's composition, suggesting a need for more patient representation if it is meant to encompass different committees.

A Committee member raised a concern about the escalating instances of allocation out of sequence, questioning whether it indicates that OPTN policies may be falling short in capturing all relevant variables. He proposed that the operational procedures of the OPTN might be inadvertently leading to these workarounds due to inadequate consideration or capture of pertinent factors.

In response, an OPTN contractor staff member acknowledged the absence of a definitive answer regarding whether instances of allocation out of sequence signal policy inadequacies. However, they acknowledged the growing concern over the increasing metric and expressed the intent to delve deeper into understanding the root causes. The OPTN contractor highlighted the importance of the newly formed task force, emphasizing its role in bringing together diverse expertise from different committees and organs. The objective is to collectively analyze and comprehend the various issues in allocation, enabling the development of appropriate responses to address these concerns effectively.

A group member also highlighted that three to four Organ Procurement Organizations (OPOs) in the South, or the Atlantic region were responsible for the majority of allocation out of sequence cases. He expressed an assumption that these OPOs might be operating under some form of a variance. The member inquired if there have been discussions on whether existing variances could be contributing to these instances of allocation out of sequence.

In response, an OPTN contractor staff member acknowledged the existence of a couple of different variances currently in place. However, he clarified that the protocols or variances the member referred to are not approved by the OPTN; instead, they are individual OPO protocols for handling challenging organ placements. The OPTN contractor stated that there are only a few limited variances approved at present, and he does not believe these are contributing to the observed increase in allocation out of sequence instances.

3. Public Comment: Expedited Placement Variance

OPTN contractor staff introduced the special public comment item that focuses on expedited placement variance.

Presentation summary:

The *Expedited Placement Variance*, originating from the Expeditious Task Force and sponsored by the Executive Committee, is currently open for public comment. The purpose of the proposal is to create a variance to test expedited placement protocols.

Structure of Pilot:

- Structure as a variance
 - Board/ExCom approves an open variance
 - Special public comment
 - Time limited study
 - Members opt in
- Protocols
 - Collect protocols from community
 - Task force will develop framework to select protocols to test
 - The protocols would live outside of policy but be accessible to the community
- Test protocols to assess most effective protocols
 - Evaluation plan with objective criteria to measure the variance's success
 - Members submit information required by variance

Requirements for Protocols:

- Each protocol must include criteria for organs eligible for expedited placement, criteria for candidates eligible to receive expedited placement offer, conditions for the use of expedited placement, and OPO and transplant hospital responsibilities
- Protocols must comply with NOTA and the OPTN Final Rule

Proposed Changes to Variance Governance:

- Clarification regarding the creation of variances
- Remove requirement to solicit agreement prior to public comment
- Change frequency of reporting requirements. Important for short, iterative variances.

Summary of discussion:

The Committee submitted the following commentary into the official public comment for this proposal.

The OPTN Patient Affairs Committee appreciates the opportunity to comment on this proposal. The Committee supports efforts to increase the number of transplants and reduce organ non-use and supports iterating on potential solutions to address problems rapidly. However, the Committee has some concerns regarding this proposal. A member noted that there is no requirement for transplant hospitals or OPOs to participate in the variance or protocols and expressed concern that transplant hospitals and OPOs may not actually be interested in participating. Members noted that 18 months does not seem like an expedited timeline and recommended shortening the variance to 30, 60, or 90 days to create a greater sense of urgency, and recommended working with OPOs who are already doing expedited placement effectively to implement their processes into the system faster. Additionally, while there are patient representatives on the task force, the Committee is concerned that the patient representation is not sufficient and that members of the Committee were not included in the task force. The Committee requests to be more involved as proposals and protocols are developed and recommends including additional people on the task force who have not previously had leadership roles in the OPTN.

Upcoming Meeting

- February 16, 2024; Houston, Texas

Attendance

- **Committee Members**
 - Garrett Erdle
 - Molly McCarthy
 - Julie Spear
 - Tonya Gomez
 - Jenny Templeton
 - Cathy Ramage
 - Justin Wilkerson
 - John Sperzel
 - Steve Weitzen
 - Andreas Price
 - Lorrinda Gray-Davis
 - Kristen Ramsay
 - Cheri Coleman
 - Calvin Henry
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
 - Mesmin Germain
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Alex Carmack
 - Kaitlin Swanner
 - Desiree Tenenbaum
 - James Alcorn
 - Kim Uccellini
 - Houlder Hudgins