OPTN Histocompatibility Committee Meeting Summary February 13, 2024 Conference Call

John Lunz, Ph.D., F(ACHI), Chair Gerald Morris, MD, Ph.D., Vice Chair

Introduction

The Histocompatibility Committee, the Committee, met via WebEx teleconference on 2/13/2024 to discuss the following agenda items:

- 1. OPTN Strategic Plan 2024-2027
- 2. Prevalence of Sensitization in Adult Heart Candidates
- 3. Update on Continuous Distribution of Hearts

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

1. OPTN Strategic Plan 2024-2027

The Vice President (VP) of the OPTN provided an overview of the OPTN Strategic Plan for 2024 to 2027.

Presentation Summary:

- This strategic plan is not an exhaustive list of the OPTN's work, but rather serves as a high-level framework to guide the OPTN's strategic focus.
- The Committee intentionally selected goals with greater specificity to allow for a focusing of resources on key opportunities, driving action to ultimately benefit patients.
- Proposed Goals:
 - **Improve Offer Acceptance Rate**: Increase opportunities for transplants for patients in need by enhancing offer acceptance.
 - **Optimize Organ Use**: Maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains.
 - **Enhance OPTN Efficiency**: Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.

Summary of discussion:

The Committee did not make any decisions.

A member raised concerns about the potential impact that the reprioritization of the strategic plan has on ongoing projects. Specifically, he questioned whether there was room to justify the continuation of projects that may not align perfectly with the strategic plan. In response, the Vice President of the OPTN acknowledged the finite nature of resources available, indicating that accommodating all projects might prove challenging. He emphasized the necessity for the organization to operate within these constraints, highlighting the reality of working in a resource-limited environment. Additionally, the VP expressed confidence in the ability of the Histocompatibility Committee to identify and pursue projects that align with the strategic plan seamlessly. The Chair raised a concern regarding how future policies, guidance documents, or proposals related to regulatory changes for laboratories would fit within the framework of the strategic plan, especially if they fell outside its scope. In response, the VP of the OPTN acknowledged the potential necessity of undertaking such projects regardless of their alignment with the strategic plan. He emphasized the importance of ensuring the proper functioning of all stakeholders within the OPTN, suggesting that these projects may be foundational to its operations.

A member proposed the collaboration of entities like the OPTN and ASHI to develop a unified white paper on virtual cross matching, citing potential benefits for patients and the need for a cohesive message for laboratories. The member sought the presenter's opinion on the matter. In response, the presenter refrained from commenting from a policy and project standpoint, citing that it would be inappropriate for the VP of the OPTN to comment on individual projects. Instead, he advised the Committee to assess the proposal and determine its alignment with the strategic plan goals.

The presenter urged the Committee to offer public comments on the strategic plan to ensure their perspectives are considered as the Board progresses.

2. Prevalence of Sensitization in Adult Heart Candidates

OPTN contractor staff provided an overview into pertinent data as it relates to sensitization in heart candidates.

Presentation Summary:

Sensitization in the Heart Context:

- Unacceptable antigen entry and screening works the same for heart as it does for kidney
- However, CPRA was only calculated from UAs for heart registrations beginning January 2023
- < 20% of heart registrations have any UAs entered
- <u>This analysis</u>: most recent CPRA for heart registrations ever waiting January 31st, 2023 July 31st, 2023

Key Takeaways:

- Sensitization is likely underreported in heart candidates
 - ~20% of adult heart registrations with unacceptable antigens
 - o Likely to increase if CPRA incorporated into CD
- Current data do not suggest large differences from lung or kidney sensitization
 - o May have more highly sensitized heart candidates

Summary of discussion:

The Committee did not make any decisions.

A member raised a question about potential regional disparities in transplant rates for highly sensitized patients. The presenter acknowledged that she had not yet examined this aspect but expressed that she would delve deeper into it. The member suggested that obtaining such information could be beneficial, considering the potential for variations in transplant rates between densely populated regions and more central areas of the country.

3. Update on Continuous Distribution of Hearts

The Chair of the Heart Committee provided a broad overview of the request for feedback document put out by the Heart Committee for the current public comment period.

Presentation Summary:

Purpose:

- Share proposed attributes and rating scales
- Seek community feedback regarding:
 - Proposed attributes and rating scales
 - Priority to assign each attribute in the continuous distribution of hearts framework
 - o Values-based decision-making for weighing attributes against each other
 - Project plan and approach

Additional Information:

- The request for feedback outlines a mixture of identified attributes that are new or currently written in policy
- The Committee intends to use rating scale and weighting to define the different attributes
- The request for feedback asks that members of the community participate in a Values Prioritization Exercise (VPE) to better understand their sentiment on how certain aspects of heart allocation should be prioritized against each other

Summary of discussion:

The Committee did not make any decisions.

The Chair made a remark indicating that the Committee has typically been in favor of incorporating sensitization points for highly sensitized patients, recognizing the challenges in finding them suitable matches.

The Vice Chair expressed concerns regarding the validity of using the Value Prioritization Exercise (VPE) to gauge sentiment, noting that while the VPE offers a binary decision, the ultimate decision-making process is not strictly binary. He emphasized that the VPE oversimplifies complex decisions, as implementation and implications are multifaceted. In response, the presenter clarified that the VPE incorporates a magnitude scale alongside the binary choice, indicating the relative importance of the attributes being compared. He defended the use of the VPE as the best method to gather feedback from the community regarding their preferences. The presenter suggested proceeding with input gathering and adjusting as necessary, acknowledging that the process may not be perfect initially.

A member voiced support for the direction of continuous distribution of hearts. He proposed that as the Heart Committee further develops this approach, it could be beneficial to involve both the heart surgeon or physician and the HLA director in approving sensitization categorization, particularly because the categorization awards a significant number of points. In response, the presenter indicated that the responsibility for determining sensitization and what is deemed acceptable rests with the individual program. The member reiterated the importance of a coordinated effort in this process.

Upcoming Meeting(s)

- March 12, 2024
- April 12, 2024

Attendance

• Committee Members

- o John Lunz
- Gerald Morris
- Caroline Alquist
- o Laurine Bow
- o Amber Carriker
- o Manish Gandhi
- o Lenore Hicks
- o Julie Houp
- o Andres Jaramillo
- o Helene McMurray
- o Darryl Nethercot
- o Hemant Parekh
- o Crystal Usenko
- o Qingyong Xu
- o Hua Zhu
- HRSA Representatives
 - o Jim Bowman
- SRTR Staff
 - o Katie Audette
 - o Rocky Daly
 - o Jon Miller
- UNOS Staff
 - o Courtney Jett
 - o Thomas Dolan
 - o Betsy Gans
 - o Kelsi Lindblad
 - o Eric Messick
 - o Laura Schmitt
 - Kaitlin Swanner
 - o Susan Tlusty
- Other Attendees
 - o Rich Formica