

**OPTN Histocompatibility Committee  
Meeting Summary  
September 12, 2023  
Conference Call**

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

## **Introduction**

The Histocompatibility Committee (“Committee”) met via WebEx Teleconference on 09/12/2023 to discuss the following agenda items:

1. Public Comment Presentation: Heart Continuous Distribution
2. Public Comment Presentation: Membership and Professional Standards Committee (MPSC) Require Reporting of Patient Safety Events
3. Discussion: Reporting of lab status in a local area emergency

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

### **1. Public Comment Presentation: Heart Continuous Distribution**

Dr. J.D. Menteer, vice chair of the OPTN Heart Transplantation Committee, provided the group with an overview of the Heart Committee’s *Continuous Distribution of Hearts Concept Paper*<sup>1</sup>.

#### Presentation summary:

- Concept paper provides overview of continuous distribution and policy development approach, summarizes attributes being considered by Heart Committee, outlines how attributes align with NOTA and Final Rule, and seeks community feedback on progress and path forward
- Continuous distribution will rank candidates based on a composite allocation score (CAS) that aligns with requirements found in NOTA and the OPTN Final Rule such as medical urgency, post-transplant survival, candidate biology, patient access, and placement efficiency
- About 80 to 85% of all heart recipients are listed as not pre-sensitized
- Most recipients who are sensitized are sensitized at a Calculated Panel-Reactive Antibody (CPRA) less than 25% with smaller percentages sensitized up to 100%
- There is a lower level of access to transplantation for highly sensitized patients

#### Summary of discussion:

**Decision #1: The Committee recommended and approved of sensitization status being included as an allocation criterion in heart continuous distribution.**

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<sup>1</sup> *Continuous Distribution of Hearts Concept Paper*. Richmond, VA: Organ Procurement and Transplantation Network, 2023.

The Chair acknowledged that as it stands, highly sensitized patients do not receive any allocation benefit for their sensitization status. Therefore, he mentions that the Committee is generally favorable toward the inclusion of points for an elevated CPRA for sensitized patients depending on how individual transplant centers define it. A member added that the percentage of patients that have no unacceptable antigens reported is most likely underestimated since there are currently no points awarded for listing unacceptable antigens. Allowing points for these situations is likely to increase efficiency as well.

Dr. Menteer responded and explained that since different programs use different MFI levels, the Heart Committee's proposal is to use the CPRA based on unacceptable antigens that are entered into the database to award such points. Dr. Menteer also mentions how the next aspect to consider would be regarding whether to allocate points to sensitized patients in a linear or geometric fashion. For example, he offers that points may be allocated linearly and based on the percentage of sensitization. With this option, a patient with a ten percent unacceptable antigen burden would be awarded ten percent of the points.

A committee member responded and offered that the geometric sliding scale of points would be the best option for heart allocation. A different member agreed that this would be an appropriate option especially considering that the Lung Committee has used this method to incorporate unacceptable antigens and CPRA into their live algorithm.

## **2. Public Comment Presentation: Membership and Professional Standards Committee (MPSC) Require Reporting of Patient Safety Events**

Dr. Zoe Stewart Lewis, chair of the OPTN MPSC, provided the group with an overview of their *Require Reporting of Patient Safety Events*<sup>2</sup> public comment proposal.

### Presentation Summary:

- The proposal aims to add specific patient safety reporting requirements to OPTN Policy 18.5: *Reporting of Living Donor Events*, and update OPTN Improving Patient Safety Portal Safety Situation and Living Donor Event form instructions
- Proposal requires transplant hospitals to report specified events through the Patient Safety Portal within 24 hours of becoming aware of the incident
- This proposal will broaden the current living donor requirement to report a liver living donor listed on the liver wait list or a kidney living donor listed on the kidney wait list within two years after donation.
- Recovery hospitals will now be required to report when a living donor is listed on the wait list within two years after donation.
- Requires Organ Procurement Organizations (OPO) to report the event through the Patient Safety Portal within 24 hours of becoming aware of the incident
- The proposal requires all OPTN members to report specified events through the Patient Safety Portal within 24 hours of becoming aware of the incident
- This change should not result in a significant increase in member burden
- Member actions include becoming familiar with the proposed patient safety reporting requirements, and reporting these events within 24 hours after becoming aware of the incident through the OPTN Improving Patient Safety Portal

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<sup>2</sup> *Require Reporting of Patient Safety Events*. Richmond, VA: Organ Procurement and Transplantation Network, 2023.

Summary of discussion:

**The committee discussed the public comment proposal from the MPSC; however, they did not make any formal recommendations or decisions.**

A committee member commented that the MPSC should consider HLA typing discrepancies similar to ABO typing errors. Dr. Stewart Lewis responded that this was something that had been discussed in the past, and that it could be added as a required element in the future.

Another committee member added that the term “sanction” may need to be more clearly defined to point out whether it restricts provider’s ability to practice safely. A member added that it could be helpful to share the Histocompatibility Committee’s definition of a critical discrepancy with the MPSC so that they may delineate and include these situations as required elements.

**3. Discussion: Reporting of lab status in a local area emergency**

The chair led the committee in discussion regarding the requirement of laboratories to report lab status to HRSA during local area emergencies.

Presentation Summary:

- HRSA has asked that lab statuses be reported to them in local area emergencies
  - Requires OPTN Contractor staff to contact labs to ascertain status
  - Status has historically only been assessed for transplant hospitals and OPOs
- This is intended as an assessment of transplant activity/ability during local area emergencies
- Should this be communicated to labs, so they are aware that these inquiries may occur and so they know what the purpose is?

Summary of discussion:

**Decision #2: The Committee decided that it was appropriate to provide communication to laboratories regarding required reporting of lab status in a local area emergency.**

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The group believed that this added communication to laboratories is important because it will allow them to be aware and alert of any future contact made by the OPTN. Laboratories can ensure that they are responding to the OPTN in a timely matter, so they are able to provide their lab status within these local area emergencies.

Next steps:

The committee will draft communication that makes laboratories aware of the requirement to report lab status in local area emergencies.

**Upcoming Meeting(s)**

- September 27, 2023
- October 10, 2023

## Attendance

- **Committee Members**
  - John Lunz
  - Gerald Morris
  - Caroline Alquist
  - Laurine Bow
  - Amber Carriker
  - Manish Gandhi
  - Lenore Hicks
  - Julie Houp
  - Helene McMurray
  - Omar Moussa
  - Darryl Nethercot
  - Qingyong Xu
  - Hua Zhu
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Courtney Jett
  - Jenna Reformina
  - Rebecca Brookman
  - Thomas Dolan
  - Cole Fox
  - Jon Miller
  - Eric Messick
  - Laura Schmitt
- **Other Attendees**
  - Jondavid Menteer
  - Zoe Stewart Lewis