

**OPTN Histocompatibility Committee
Meeting Summary
January 14, 2024
Webex Meeting**

**Gerald Morris, MD, Chair
Kelley Hitchman, PhD, MS, Vice Chair**

Introduction

The Histocompatibility Committee (“Committee”) met via WebEx teleconference on 1/14/2025 to discuss the following agenda items:

- 1. Referral Process Overview**
- 2. Center for Medicare and Medicaid Policy – Guidance Update Discussion**

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

1. Referral Process Overview

No decisions were made.

Summary of Presentation:

An OPTN Implementation and Evaluation Analyst presented on the Membership and Professional Standards Committee’s referral process. She discussed recent examples of such referrals.

OPTN policy staff continued that the referral asks for the creation of policy that requires that molecular testing be utilized when blood typing discrepancies occur, especially after mass transfusions.

Summary of Discussion:

The Committee discussed how OPTN Policy 2.6 could be updated to ensure protocols for safety and utilization. A committee member who works in the Organ Procurement Organization field stated that this would be a great project to take on, given that there is no current standard definition for mass transfusion. A member added that ABO typing may be out of the scope of the Histocompatibility Committee, stating that the OPO Committee would be a better fit for this project.

The Chair responded that the OPO Committee does not have adequate experience with laboratory testing for this project. The member replied that OPOs are currently relying on whole blood for transfusions. The Chair said that he has experienced mass transfusions potentially causing acute rejection because of lack of clarity on blood type, supporting the intent behind this referral.

A member asked if OPOs have the capacity to do mass transfusion testing, as well as what should be included in the definitions included in the guidance, such as “mass transfusion” and number of specimens.

Members agreed that this project is important to create clarifying policy around current, ambiguous guidance and preventing future patient safety risks. A member asked if the Committee had time for this project given their current project discussions. The Chair replied that this project could take priority because of its patient safety concerns.

The Chair considered bringing in members from other committees to gain perspectives on the definition of mass transfusion. The Ex-Officio member stated that molecular typing could open the donor pool, along with getting accurate blood types. The Chair continued that this project work could include discussions of requirements for A subtyping.

The Committee took an informal vote to move ahead with sponsoring this project. The Committee will continue discussing this project work.

The Committee discussed research and data access for the molecular typing project. The Chair asked to see a distribution of donors by how many units of blood they've received prior to recovery. The Ex-Officio asked to see data regarding scope of the issue to gauge how many donors may be affected by this project. Members also asked to see subtype assignments for donors.

2. CMS Policy – Guidance Document Discussion

No decisions were made.

Summary of Presentation:

The Chair presented background on the CMS guidance updates and how it could fit into an update for the 2017 Histocompatibility Guidance Document. New CMS guidance states that “the laboratory must make a reasonable effort to have available monthly serum specimens,” a change from their prior policy which stated that labs “must make a reasonable attempt.” Prior OPTN guidance from the Committee states that laboratories should collect samples “at regular intervals.”

Summary of Discussion:

Members said that OPTN guidance should be updated to match CMS guidance. A member said that the American Society for Histocompatibility and Immunogenics standards interpret “should” as “must.” The Chair said the definition of current serum acceptable for testing is left to the transplant programs, therefore, programs can flexibly meet CMS requirements.

Staff and the Committee discussed pathways for changes. The Committee will continue discussing the guidance document language.

Upcoming Meeting

- February 11, 2025

Attendance

- **Committee Members**
 - Helene McMurray
 - Julie Houp
 - Michael Gautreaux
 - Dave Pinelli
 - John Lunz
 - Mike Hurtik
 - Qingyong Xu
 - Ryan Pena
 - Andres Jaramillo
 - Darryl Nethercot
 - Bobbie Rhodes-Clark
 - Crystal Usenko
 - Kelley Hitchman
 - Hemant Parekh
 - Jerome Saltarelli
 - Laurine Bow
 - Jerry Morris
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Rajalingam Raja
- **UNOS Staff**
 - Jamie Panko
 - Betsy Gans
 - Kaitlin Swanner
 - Thomas Dolan
 - Laura Schmitt
 - Susan Tlusty