

Meeting Summary

OPTN Histocompatibility Committee
Meeting Summary
May 10, 2022
Conference Call

Peter Lalli, PhD, F(ACHI), Chair John Lunz, PhD, D(ABHI), Vice Chair

Introduction

The Histocompatibility Committee (the Committee) met via Citrix GoToMeeting teleconference on 05/10/2022 to discuss the following agenda items:

- Agenda/Updates
- 2. Policy Language Review/Vote: Change Calculated Panel Reactive Antibody (CPRA) Calculation
- 3. Update Histocompatibility Policies/Guidance

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

1. Agenda/Updates

The Chair provided updates regarding:

- Recent member concerns about lack of clarity around laboratory key personnel approval process for OPTN histocompatibility laboratory members
- Request received for increased information to help members navigate OPTN processes- staff will assist Histo/MPSC Leadership in developing materials

Summary of discussion:

Attendees had no questions or concerns regarding the agenda/updates.

2. Policy Language Review/Vote: Change Calculated Panel Reactive Antibody (CPRA) Calculation

Staff reviewed the policy language for the Committee's proposal to <u>Change Calculated Panel Reactive</u> <u>Antibody (CPRA) Calculation</u>, including all recommended changes, with the Committee. The full policy language is available in the meeting materials. Attendees had no questions and expressed no concerns. The Chair called for a verbal vote and no members abstained of voted against the proposal.

3. Update Histocompatibility Policies/Guidance

The committee discussed updating histocompatibility-related policies and guidance documents to be more consistent with current practice.

Summary of discussion:

The Committee discussed the current OPTN *Policy 4.1: Requirements for Laboratory Review of Reports*. The policy currently relays that all deceased donor HLA typing and crossmatch reports must be reviewed during the next day of regular laboratory operation. A committee member noted most people do not chart or create a final report on-call or next business day. Another member stated the donor typing is

not in any type of electronic health record, so there is a question of whether this review applies to a finalized report, or any report/preliminary data sent out/added to the OPTN Donor Data and Matching System. The presenting member suggested changing the wording to, "All deceased donor HLA typing and crossmatching results communicated [while] on call must be reviewed during the next day of regular lab operation." The committee members agreed and will clarify in the guidance document what is meant by results/reports. The members agree this will not change existing lab practice. Members agreed that documentation for this policy does not need to be extensive since labs already follow these requirements due to Clinical Laboratory Improvement Amendments (CLIA).

UNOS Staff noted the HLA audit log tracks activity in the OPTN Computer System. The system allows tracking of view and edit of HLA typing for deceased donors, as well as a view and edit of HLA data for candidates. Committee members asked if this could be made available to members. Lab member access to a report of which members viewed and edited HLA data for donors and candidates would be beneficial to assist in the verification that HLA data was reviewed.

Committee members agree that OPTN Policy 4.2 language needs to be updated to verify the waiting list histo data for every patient the laboratory enters into Waitlist. Additional verbiage needs to expand upon this to reflect that a program that does not utilize the laboratory to update Waitlist for histocompatibility data is responsible for managing that. A committee member suggested changing the word 'review' in the policy language. Committee members then discussed the challenges of verifying the waiting list data for every test result lab is complete. UNOS staff noted verifying this data may be able to be tracked in multiple ways and this additional information will be provided to labs. A committee member suggested that maybe spot checking the data and not verifying every single patient will ensure fidelity of API. If this is not possible, a different process will need to be put in place to verify the data. A committee member argued that doing so is not an accurate review of waiting list data, but rather an artifact for how the computer system is set up. A distinction needs to be made between a one patient at a time update and a batch update. UNOS staff reminded the committee that the way the policy is written it only requires a single verification. The committee will need to clarify which HLA data is needed to be reviewed for patient safety and see how this works within different laboratory informatic systems. A committee member voiced concern regarding running an antibody screening for a patient because it needs to be updated right away into the OPTN Computer System. For patients with no unacceptables listed, does this need to be updated every time there is an antibody screening? The committee members ended the discussion by concluding that they need to figure out what is needed to protect patient safety in a way to not be a burden on labs or drastically change practice.

Upcoming Meeting

June 14, 2022, 12PM ET, Teleconference

Attendance

Committee members:

- Amber Carriker
- Andres Jaramillo
- Bill Goggins
- Caroline Alquist
- Evan Kransdorf
- Gerald Morris
- Idoia Gimferrer
- Jennifer Schiller
- John Lunz
- Manu Varma
- Marcelo Pando
- Omar Moussa
- Peter Lalli
- Qingyoung Xu
- Reut Hod Dvorai
- Valia Bravo-Egana
- Vikram Pattanayak
- Yvette Chapman

SRTR Staff

• Katherine Audette

HRSA Representatives

- Jim Bowman
- Marilyn Levi
- Raelene Skerda

UNOS Staff

- Amelia Devereaux
- Courtney Jett
- Lauren Mauk
- Marta Waris
- Sandy Miller
- Sarah Scott
- Tamika Watkins
- Teresa Cullen
- Rebecca Brookman