OPTN Histocompatibility Committee
Meeting Summary
September 10, 2024
Webex Meeting

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

Introduction

The Histocompatibility Committee ("Committee") met via WebEx teleconference on 09/10/2024 to discuss the following agenda items:

1. **Regional Meeting Recaps**
2. **HLA Language Update**

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

1. Regional Meeting Recaps

No decisions were made.

Summary of presentation:

For Region 1, HLA comments included:

- Discussion around the 24-hour timeframe for critical discrepancy reporting, with both positive and negative feedback
- Suggestion that OPOs have a designated person to receive reports
- Request for clarification around what counts as a "wrong antibody"
- Discussion around including split antigens
- Request for a single reporting mechanism

For Region 6, HLA comments included:

- Discussion around 24-hour timeframe

For Region 8, Bylaws comments included:

- Burden of laboratory director case portfolio submissions
- Laboratory personnel should align with CLIA
- Testing turn-around time should be left to the parties involved
- MPSC should only require a minimum number of cases reviewed for laboratory directors if the laboratory demonstrates repeated performance issues

For Region 8, Bylaws comments included:

- Agreement on critical discrepancy definition
- Both discovering and original lab should be involved in reporting discrepancies
- Suggestion for 48, which could also include root cause analysis

- Incorrect donor or recipient samples used for crossmatch should be included in required reporting

For Region 9, Bylaws comments included:

- Concern that new regulations may reduce number of laboratory directors
- Support for multiple laboratory directors
- Increased burden for tracking cases

Summary of Discussion:

The Region 1 representative mentioned further comments she received around what counts as a critical discrepancy, including questions about using virtual crossmatch on an immunodiffusion assay versus a single antigen assay. The Chair confirmed that the Committee should make it clear that the proposal refers to critical discrepancy reporting. A member raised concerns about confusion found in some of the public comments, and the Chair responded that clarification in language can help clear up concerns in the proposal as well as meet the goals of the Committee.

For Region 6, a member asked about aligning laboratory personnel with CLIA. The Chair talked about overlapping definitions of laboratory directors, technical supervisors, and clinical consultants. He mentioned that proposal language should be changed to clarify that the proposal is referring to histocompatibility directors serving in the role of technical supervisor and/or clinical consultant.

For Region 8, a member discussed including near-misses in the new definition, and the Chair responded that near-misses are included in the overall process recordings.

For Region 9, the presenting member discussed that they also received comments concerning the 24-hour reporting time, suggesting this be changed to 72-hours. A staff member mentioned MPSC's reporting requirement of 72-hours.

Following the presentation, the Chairs discussed purview concerns around critical discrepancy typing. The Vice Chair mentioned that there are OPO laboratories that are using and entering two-field typing (high-resolution sequencing) data for donors. She stated that she heard concern that patient safety information in this case would need to be disseminated.

The Chair also suggested aligning with MPSC's 72-hour reporting time for consistency.

2. HLA Typing Language

No decisions were made.

Summary of presentation:

Staff presented on a possible critical discrepancy definition change post-public comment that would include p-group language given that proposed policy language does not align with HLA equivalency tables. New language would include "within the same P group according to IMGT/HLA are considered equivalent." Staff stated that this addition would allow for interpretation of either the same serologic split antigen group or within the same p-group, with anything outside of this being reportable.

Summary of discussion:

The Chair stated that this new definition helps with alleles that don't have WHO-defined serologic antigens. A member suggested that language be simplified in the language in the critical discrepancy definition to allow other medical personnel to understand. Another member added that with continuing alignment with WHO, that HLA tables may not need to be updated every year.

Next steps:

This conversation will be continued post-public comment.

Upcoming Meeting

- October 1, 2024

Attendance

- **Committee Members**
  - Bobbie Rhodes-Clark
  - Crystal Usenko
  - Darryl Nethercot
  - Gerald Morris
  - Helene McMurray
  - Hemant Parekh
  - Kelley Hitchman
  - Stephanie Osier
  - John Lunz
  - Andres Jaramillo
  - Mike Hurtik
  - Julie Houp
  - Laurine Bow
  - Michael Gautreaux
  - Ryan Pena
  - Tiffany Bratton
  - Qingyong Xu
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Rajalingam Raja
- **UNOS Staff**
  - Thomas Dolan
  - Amelia Deveraux
  - Jamie Panko
  - Joann White
  - Susan Tlusty