OPTN Histocompatibility Committee
Meeting Summary
October 14, 2025
Conference Call

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

Introduction

The Histocompatibility Committee ("Committee") met via teleconference on 10/14/2025 to discuss the following agenda items:

1. Public Comment Review and Discussion: Histocompatibility Human Leukocyte Antigen (HLA) Table Update 2025
2. Open Forum

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

1. Public Comment Review and Discussion: Histocompatibility HLA Table Update 2025

The Committee voted to approve the *Histocompatibility HLA Table Update 2025* proposal to be implemented per the expedited action policy.

12 members voted in approval; 2 abstained.

The Chair presented a summary of the *Histocompatibility HLA Table Update 2025* proposal and a brief public comment analysis. The Committee discussed the proposal and expedited action, and voted to approve the proposal and implement per the expedited action policy.

Presentation Summary:

Purpose: *Histocompatibility HLA Table Update 2025* proposes additional higher-resolution HLA typing options for more precise immunologic screening. The proposal also aligns HLA tables with the International Immunogenetics (IMGT) database, which serves as a comprehensive resource for histocompatibility. This proposal also ensures that the unacceptable antigen screening for candidates will appropriately exclude incompatible donors based on current p-group equivalencies and epitopes. P-groups, or protein groups, join HLA alleles with the same protein sequence.

Specifically, this proposal will:

- Add necessary p-values to *Table 4-16: Epitope based Unacceptable Antigen Assignment for DPB1*
- Add C*04:09L to *Table 4-7: HLA C Unacceptable Antigen Equivalences*
    - Aligns with allele status changes from null to low-expression
- Does not change requirements for candidate, donor, or recipient HLA typing
- Updates the equivalency tables via *E.8 Expedited Actions* of the OPTN Management and Membership Policies pathway

The proposal was released for Public Comment between August 27 and October 1, 2025, and received 263 comments through virtual regional meetings, committee meetings, and the OPTN website.

Participation was highest for transplant hospital members. Across regions, participation was highest in regions 5 and 11. Average sentiment on the Likert scale was 4.0, with most commenters expressing support, strong support, or neutrality.

There was general support for the proposal, with supportive comments received from patients, individual commenters, individual OPTN members, regional representatives, and stakeholder organizations. Support was received from the Association of Organ Procurement Organizations, American Society for Transplantation, American Society for Histocompatibility and Immunogenetics, and the American Nephrology Nurses Association.

The proposal asked if "[there are] recommendations for changes to instructions in unacceptable antigen listing or donor HLA typing that would improve the efficacy and equity of allocation in the OPTN Computer System?"

- One member in region 5 recommended that additional HLA table updates be included
- One member in region 1 requested that the OPTN should ensure that policy requirements for OPO contract laboratories performing HLA typing of deceased donors clarify whether labs are required to resolve to the P-group and null/low expressing allele level
- One commenter wrote, "I support with these changes, but there should be a more expansive effort by OPTN to support full WHO HLA nomenclature and enable the capability for all HLA alleles and typing ambiguities to be entered into the allocation system..."

Since the table updates are performed regularly, the Committee may consider additional changes or tables in their next policy language review.

One sentiment response of "strongly oppose" was received during public comment at a regional meeting (Region 6). There was no oppose sentiment on the proposal, and there were 197 sentiment scores for either "support" or "strongly support." There was no written comment accompanying the "strongly oppose" sentiment.

This update was approved for expedited action by the OPTN Board. OPTN *Policy 4.10: HLA Value Updates* states, "change to the equivalency tables in *Policy 4.11* and proportions of donors (Di) are eligible for future expedited updates pursuant to OPTN Management and Membership *Policy E.8: Expedited Actions."*

Summary of Discussion:

The Chair asked the Committee if they are in agreement to approve the proposal, or if this warrants additional consideration by the OPTN Board of Directors (the Board) beyond the expedited action pathway.

One member asked if there were specific comments as to why the participant submitted a "strongly opposed" sentiment, and if there was reasoning provided. The Chair explained no comment or explanation was provided. The member responded that it could have been submitted in error. The Chair agreed, but noted that there is no way to know that without comment. The Chair noted there is nothing in that opposition to address. Another member agreed, noting that this could have been a misunderstanding or an error, but without comment, it's impossible to tell. The member remarked that there is nothing to address, and expressed support for continuing with the expedited action pathway, particularly given the significant support for this proposal expressed by other public comment participants. The member expressed support for the expedited action pathway over referring to the Board.

One member also expressed support for the policy as proposed. The member noted that not all the common alleles from IMGT will be included in the proposal. The Chair noted that the original version of including the p-groups was to enable the table update to include all the common and well documented alleles without having an unnecessarily long table. The Chair added that the table has historically been limited to common alleles but does not have all of them, noting that is an ever-changing target. The Chair explained that as more labs more towards Modified Giemsa Stain (MGS), it becomes more free range for how typing is entered and there will be more things that don't crosswalk with the tables. The Chair added that the idea was to use the p-groups in those cases. The Chair noted that it was easier when utilization of bead sets provided a more narrow focus for typing, but as labs have the ability to type for more things, the question becomes how broad the table needs to be to include those options. The member thanked the Chair, and noted that not all the common intermediate well documented alleles within IMGT will be included. The Chair confirmed this, noting that not all have a serological equivalent assigned, so there are issues with how they are input in the table. The Chair explained that the sentiment was that p-groups provided a workaround for that issue. The Chair added that at a Committee level, at some point, there is likely a larger table update coming if serotypes are ready to be implemented to include these other options. The member agreed, noting that could be a better time to address a more inclusive common intermediate well documented list. With that clarified, the member expressed support for moving forward with the proposal as proposed.

The Committee voted to approve the *2025 Histocompatibility HLA Table Update* to be implemented per the expedited action policy:

- 12 approved
- 0 opposed
- 2 abstained

2. Open Forum

The Committee discussed the implementation status of the *Update Histocompatibility Bylaws* project.

Summary of discussion:

One member asked about HLA written agreements with transplant programs and OPOs, and asked if there was official policy regarding this, noting it was reorganized. The Chair responded that those modifications may have been related to the bylaws update to align OPTN bylaws with the Clinical Laboratory Improvement Amendments (CLIA). Another member agreed, noting that should be official.

One member remarked that there are a lot of moving parts, and did not recall when that was made official. The Chair explained that was included in the bylaws update from 2024 which has not yet been implemented into the OPTN Bylaws. OPTN Contractor staff clarified that the *Update Histocompatibility Membership Requirements* proposal has been approved by the Board but is still pending approval from the Office of Management and Budget. OPTN Contractor staff noted that membership policies have been separated from the OPTN Bylaws into the OPTN Management and Membership Policy. The member remarked that he has only been able to find the guidance document with the bylaw sections and subsections, but could not find the approval. OPTN Contractor Staff noted that the policy notice shows the Board approval, and the implementation status on the OPTN site shows pending OMB approval before it can be implemented into the OPTN Management and Membership Policy. The member shared that he has been waiting for the final form to ensure all lab agreements address all the requirements.

One member remarked that the changes to be implemented look more like reorganization, as opposed to substantive changes to the requirements themselves. The member agreed. Another member noted

that all the changes are defined in the Policy Notice on the *Update Histocompatibility Bylaws* page, and that the proposal incorporated a number of changes, including removal of non-relevant requirements. The member added that it is Board-approved pending implementation. The member shared that their laboratory changed their agreements to align with these incoming requirements, and noted that those changes to practice can be made in advance of implementation. The Chair added that there is nothing in that proposal that is out of alignment with American Society for Histocompatibility and Immunogenetics (ASHI) or other standards, so there are not substantive changes.

One member shared that the *Update Histocompatibility Bylaws* reorganized a number of things, eliminated non-contemporary terms for histocompatibility labs, and noted that it's now in sections of requirements, instead of numbered points. The member continued that it may make sense to reorganize agreements based on the reorganized requirements, as opposed to the points, but that is up to clinical discretion at each lab.

A representative from the Scientific Registry of Transplant Recipients (SRTR) asked if the member's question related to new requirements from the Center for Medicare and Medicaid Services (CMS) regarding collection of sera. The member explained that they were just seeking clarity on what was required. The Chair shared that their agreements consider the standards for collection of serum as recommended, but testing is determined by the program, as there are patients who may not need monthly serum collection. The Chair explained that CLIA recommends monthly serum collection. The Chair explained those are the new requirements of the program agreement, and the rest of the changes were reorganization. The Chair explained that the updates are in alignment with the accrediting agencies.

One member explained that CMS released a guidance document for CLIA in September, and recommended that the Committee circle back to this. The Chair agreed, and recommended the Committee review that document.

Upcoming Meeting

- TBD

Attendance

- **Committee Members**
    - Gerald Morris
    - Jerome Saltarrelli
    - John G. Lunz
    - David Pineli
    - Lakshmi Samidurai
    - Kelley Hitchman
    - Tim Wellerritter
    - Darryl Nethercot
    - Laurine Bow
    - Crystal Usenko
    - Bobbie Rhodes-Clark
    - Ryan J. Pena
    - Michael Gautreaux
    - Xu Qingyong
- **SRTR Staff**
    - Rajalingam Raja
- **UNOS Staff**
    - Lindsay Larkin
    - Rebecca Murdock
    - Kayla Temple