

**OPTN/UNOS Histocompatibility Committee
Meeting Summary
May 2, 2016
Chicago, IL O'Hare Hilton**

**Dolly Tyan, PhD, D(ABHI), Chair
Robert Bray, PhD, D(ABHI), Vice Chair**

Discussions of the full committee on May 2, 2016 are summarized below. All committee meeting summaries are available at <https://optn.transplant.hrsa.gov>.

Committee Projects

1. Removing HLA Equivalency Tables From Policy

The committee discussed removing the Human Leukocyte Antigen (HLA) tables from OPTN policy, noting the following frustrations with changing/updating the tables through the UNOS process:

- A frustratingly slow and difficult process due to public comment, board adoption, and long implementation times
- Tables don't reflect up-to-date HLA knowledge
- The HLA community would benefit from quicker changes to tables.
- HLA tables are specific to the HLA community and the rest of the transplant community is not concerned about them or maintaining them.

The Policy Liaison and the Policy Manager explained that the tables need to remain in policy since they directly impact allocation and UNOs needs to be open and transparent about allocation decisions, that the process is slow on purpose to build robust policies, that because the HLA system requires some modicum of judgment and interpretation we need to show how UNOS interprets the HLA system, that costs of changing the processes needs to be captured through the process, and that policy only requires the Histocompatibility Committee to review the tables annually, but does not necessarily require a change.

The Policy Liaison and Policy Manager discussed several alternatives with the committee that included:

- Referencing outside equivalency tables or unacceptable antigen databases – the committee determined that there were no other sources of this kind that could be referenced in the policies.
- Alternative transplant systems using unacceptable antigens such as those in Canada or Europe – the committee determined that those systems would not be applicable to the OPTN or serve the needs of the US community.
- The Expedited Policy Pathway – The committee discussed this option in depth noting that it provided an advantage of time, and wondered whether this process could be synced to coincide with regional meetings and annual UNOS programming.

The committee resolved to consider adding language for using the expedited pathway to make changes to the HLA tables in future Histocompatibility Committee projects.

2. Adding HLA-DPB1 Equivalency Tables to Policy

The committee discussed how to appropriately add an unacceptable antigen table for HLA-DPB1 to OPTN policy. Two committee members displayed alternate methods their labs use in order to make a determination of compatibility between candidates and donors for DPB1. The committee discussion focused on the difficulties and practicalities of using epitopes as a candidate/donor and the limitations of testing for DPB1 using single antigen bead assays. Additionally, some committee members discussed the need to develop a table and a system that OPO coordinators, physicians, and transplant surgeons could use and understand.

3. Addressing HLA Typing Errors

The committee was re-presented with data on the general trends in the HLA typing discrepancy report. The committee discussed possible root causes of the typing discrepancies and how they varied across a wide range of causes from simple transcription errors to completely wrong donor HLA typings. The committee also discussed the error rate among individual labs, noting that a small number of labs were responsible for a high percentage of the most concerning HLA typing discrepancies. The committee discussed possible paths forward to solving this problem. The committee resolved that they would begin communicating with HLA member labs both en masse and through individual outreach to labs with the highest percentage of errors in order to educate and continue looking for possible policy solutions.

The Committee also considered possible changes to the UNet system that could help reduce the errors they are seeing due to simple user experience errors. The committee viewed a demonstration from the UNOS IT department showing what a double entry system for HLA data in DonorNet would look like. The committee resolved to adopt the changes seen in the mockup and to explore other system enhancements that would help reduce HLA typing discrepancies.

4. New Project Ideas and Committee Prioritization

The Committee discussed new project ideas that were submitted since the last full committee meeting. The committee took a pre-meeting survey to rank the ideas in order of preference and discussed the project ideas in order. The committee decided that their prioritization for upcoming projects was in the following order:

1. The committee will pursue a project that adds DPB1, DQA1, and DPA to the CPRA calculator and adds a field for DPA in UNet. This project was originally two different projects and the committee decided to combine them as they are all related and of the same importance.
2. Enhancing Priority for DR Matching in Kidney Allocation
3. Programming Allele Level Typing in UNet
4. Aligning UNOS Policies/Bylaws with ASHI & CAP
5. Add a CPRA calculation view for all patients in Waitlist
6. Develop guidelines for Deceased Donor Materials Used in Crossmatches.

The committee decided not to consider pursuing two projects and determined that a third project could be included in the scope of the data requests for a KAS: Desensitization and Priority Points for Candidates Undergoing Desensitization.

5. Supplemental Discussion Topics

Two topics not on the agenda were discussed by the Committee briefly

Lab Coverage Plans in the Absence of a Director When There is No Second Director

A committee member described an issue regarding lab coverage related to an application that was recently denied by the UNOS Membership and Professional Standards Committee. The Committee discussed this situation and the need for coverage, and the importance of defining and determining availability. Several scenarios regarding when someone is or is not available was discussed and the Committee noted that there could be possible legal implications if a backup Lab Director is used who is unfamiliar with a lab's policies and procedures. The Committee decided this topic could be a future project.

Fiscal Impact Analysis

The Policy Liaison and Policy Manager described a proposal to the OPTN Board of Directors that had the potential to impact the work of the Histocompatibility Committee. The proposal would require Committee members to provide a fiscal impact analysis of policies on labs. The Committee questioned what the purpose of the analysis was and what the Board of Directors hoped to determine by having the knowledge. The Committee expressed concern about the amount of time completing an analysis would take, and, using the KAS implementation as an example, illustrated that the costs of a policy implementation for labs is not always obvious up front – calling into the question the accuracy and usefulness of a fiscal impact analysis. The Policy Manager encouraged the Committee Chair to share the committee's feedback with the OPTN Board of Directors during the next meeting.

6. KAS 1-Year Data Report

With the remaining time of the meeting, the UNOS Research Department presented the Committee with the results of the KAS 1-Year Data Report. The Committee discussed the results related to the impact on pediatric patients, how the increase in donors impacted the KAS data, and the difference between the projected SRTR modeled impact and the actual impact. Time constraints forced the Committee to table the entirety of the presentation to the May 10 conference call.

Upcoming Meeting

- The committee will meet via teleconference on June 21, 2016