

OPTN/UNOS Histocompatibility Committee
Meeting Summary
March 30, 2015
Chicago, Illinois

Dolly Tyan, Ph.D., Chair
Robert Bray Ph.D., Vice Chair

Discussions of the full committee on March 30, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Histocompatibility Bylaws Rewrite Phase II

The second phase of the Bylaws rewrite contains changes dealing with education, certification, and experience requirements for laboratory key personnel and performance indicators that will trigger a mandatory performance review of a laboratory.

Several post-public comment amendments were made to the proposal. The Histocompatibility Committee (the "Committee") agreed there should be a pathway for laboratory directors who were approved and served as directors prior to the 2003 requirement for their board certification to have that requirement waived. This is a CLIA based clause and requires waiving board certification for individuals already operating as a laboratory director prior to 2003. The Committee approved an amendment to include this group of individuals as qualified laboratory directors.

Some commenters were concerned that the requirement that laboratory directors have publications in (greater than one) peer-reviewed journal is too stringent. The Committee came to a compromise on this language. The amendment allows for either demonstrated participation in laboratory professional conferences *or* publications in peer-reviewed journals.

In addition, there was concern that the proficiency testing performance review criteria is too excessive since the words "satisfactory" and "unsatisfactory" apply to individual send-outs. The Committee was divided on this issue and came to a compromise on the following amendment:

1. For programs other than ABO, a less than 80% ~~successful~~ satisfactory performance on more than one in an external histocompatibility proficiency testing program within a year ~~the previous twelve months~~.

Notably, the Committee also agreed to delete *C. Submission Requirements for Laboratories Using New Techniques*. The Committee reasoned that this section is more appropriate for the histocompatibility laboratory accrediting agencies to monitor.

The Committee voted unanimously to send the entire proposal with the post-public comment amendments to the Board of Directors for consideration.

2. Histocompatibility Guidance Document

The OPTN/UNOS Histocompatibility Committee continuously reviews and monitors bylaws and policies that govern histocompatibility testing for solid organ transplantation. New requirements and changes to OPTN/UNOS policy are sponsored by an OPTN/UNOS committee, submitted for public comment, and revised accordingly before being submitted to the OPTN/UNOS Board of Directors for a vote. In many instances, a bylaw or policy may have several different interpretations depending upon the situation or may require additional information for interpretation. To address this issue, a guidance document is being developed to address aspects of the bylaws and policies that need additional clarification. Laboratories may also use this document to assist in ensuring they are compliant with all OPTN/UNOS bylaws and policies. This guidance document is designed to provide additional information or clarification, where needed, to both the bylaws and policies of the OPTN/UNOS.

Other Significant Items

3. Discrepant HLA Typing Subcommittee Update

OPTN/UNOS policy requires the Committee to review, at least every three months, any outstanding discrepant typing in Discrepant Donor and Recipient HLA Typing reports in UNetSM. This past fall, the subcommittee reviewed the first quarter report. Following that call, the subcommittee chair created a list categorizing discrepancies which was agreed upon by the other subcommittee members. Afterwards, the Committee directed the subcommittee to perform two tasks: (1) prioritize the categories by seriousness of their implications and provide examples for each; (2) determine how many discrepancies fall into each category. The subcommittee chair explained that members began to form the following problem statement: "Donor match-runs in quarterly reports contain donor HLA discrepancies that could affect organ allocation or safety in transplantation." It was noted that members believe most of these errors are at the donor and recipient histocompatibility forms and not on the match-run. Members are unsure as to how and where these errors are occurring; therefore, the subcommittee will work to track the source of these errors by determining who entered the discrepant data. The Committee requested that UNOS staff provide information on the position of those individuals and whether they are affiliated with a transplant program, OPO, or histocompatibility laboratory.

4. HLA Equivalency Table Update Subcommittee

OPTN/UNOS policy requires the Committee to review and recommend any changes needed to the equivalency tables on an annual basis. In February, the HLA Equivalency Table Update Subcommittee provided a status report on updating the equivalency tables. The Committee believes there will need to be a corresponding educational effort with any update to the tables. In particular, the Committee discussed updating the equivalency tables for DPB/DQA reporting and future equivalencies. The Committee reviewed the subcommittee's draft of the equivalency tables and directed the subcommittee to continue its update of the tables.

5. Policy Oversight Committee (term limit vote)

Currently, committee members have terms of two years, except for Patient Affairs, Ethics, and Transplant Administrators Committees who serve three year terms. Committee members often comment that a two-year term is not enough time to allow follow-through on large projects that may take longer to complete. Two-year terms also often mean that roughly half of the committee needs to be educated and brought up to

speed every two years which is inefficient and may cause the committee to lose important expertise or historical knowledge. The Committee voted unanimously on three-year committee member terms and two-year leadership terms.

6. Virtual Crossmatch Workgroup Report

The Committee received an update from the Virtual Crossmatch Workgroup (“the Workgroup”) which presented to the Clinical Laboratory Improvement Advisory Committee (CLIAC). In November, the Workgroup presented to CLIAC the transplant community’s issues and concerns regarding organ and tissue transplantation and the need to obtain the results of the crossmatch prior to transplantation. There are two primary concerns of the transplant community: (1) current standards are not reflective of evolving clinical practice (i.e. desensitization protocols and use of a virtual crossmatch) and (2) this standard puts laboratories at odds with clinicians by dictating clinical practice. The Workgroup was charged with providing input to CLIAC regarding the acceptability and application of virtual crossmatching in lieu of serological crossmatching for transplantation by providing suggestions for criteria for determining when a virtual crossmatch is appropriate and guidelines for laboratories performing virtual crossmatching.

7. KAS Update

The Committee received a presentation on early KAS data. The purpose was to provide an early look at high-level metrics revealing performance of the system, and detect unanticipated patterns that suggest early, severe unintended consequences that may warrant near-term course corrections. The goal of the “Out-of-the-Gate” Monitoring Report was to provide information for the transplant community in the wake of KAS implementation on December 4, 2014. The report serves as a complement to the more extensive analyses that will be performed for the Kidney Committee at 6 months, 1 year, and 2 year post implementation. The report was aimed at addressing questions from the following categories: waitlist, transplants, and kidney utilization.

8. UNOS Strategic Plan

UNOS staff presented to the Committee the organization’s new strategic plan. This new plan will be in effect from 2015-2018. The 2015 strategic plan includes the following goals: increase the number of transplants; improve equity in access to transplants; improve waitlisted patient, living donor, and transplant recipient outcomes; promote living donor and transplant recipient safety; and promote the efficient management of the OPTN website.

9. Data Advisory Committee Presentation

The Data Advisory Committee (DAC) gave a presentation on the goals of the committee and explanation of their projects. The goal of the Committee’s work is to develop specifications for and advise the OPTN Board of Directors on collecting data pertinent to the operation of the OPTN and SRTR, including continuous quality and patient safety improvements. Ongoing work of the committee may include maintenance of principles of data collection and development of policy requirements for OPTN data collection. Currently the DAC’s portfolio consists of four projects: Modify OPTN/UNOS Data Release Policy; Evaluate Current and New Data Elements for OPTN Database; Improve OPO and Tx Ctr Metrics and Measures; and Secure Enterprise Solutions for OPTN Database.

Upcoming Meetings

- May 20, 2015 2:00pm-3:00pm ET (Conference Call)