Summary
Histocompatibility Committee Meeting
January 3, 2013
2:00-4:00pm ET
Conference Call

Participants:

- Committee: Lee Ann Baxter-Lowe PhD,D (ABHI), Dolly Tyan PhD, D(ABHI), Nancy Reinsmoen PhD, D(ABHI), Julie Houp, Neng Yu MD, Robert Bray PhD, D (ABHI), Cathi Murphey PhD, Ellen Klohe PhD, Sara Dionne, PhD, A. Bradley Eisenbrey MD PhD, David Kiger CHS CHT, Luis Campos MD
- OPTN: Gena Boyle, Anna Kucheryavaya, Cheryl Hall, James Alcorn, Elizabeth Miller, Sally Aungier
- SRTR: Howard Gebel, PhD

Summary:

The OPTN/UNOS Histocompatibility Committee ('the committee') met via Live Meeting on January 3, 2013 to review and vote on final recommendations from the committee's Bylaws Rewrite Subcommittee ('the subcommittee) to be released for public comment in Spring 2013.

The committee voted 0-Support, 10-Support as Amended, 0-Oppose, 0-Abstain to send the following changes to Appendix C: *Membership Requirements for Histocompatibility Laboratories* out for public comment in Spring 2013:

- Article 1.4 *Histocompatibility Laboratory Members* and Appendix M: *Definitions*
  The committee adopted an amended definition for an OPTN histocompatibility laboratory. The amended definition includes laboratories that serve only an OPO and removes the requirement that any OPO or transplant hospital member served by the laboratory be located within the Donation Service Area (DSA). Members of the subcommittee reasoned that written agreements between these two entities cross DSA boundaries. The new definition also describes the tests that laboratories routinely perform (HLA typing, antibody screening, compatibility testing, and crossmatching).

- Section C.1: *Histocompatibility Laboratory Compliance*
  The committee adopted new language requiring histocompatibility laboratories to comply with the Clinical Laboratory Improvement Amendments (CLIA), unless specifically exempt from these regulations under federal law (i.e. laboratories that are located within veterans hospitals). In addition, the committee adopted language requiring laboratories to meet the ASHI standards or CAP checklists as of a date certain, as they apply to solid organ and islet transplantation. In the presentation to the committee, members of the subcommittee explained that they originally considered the alternative of mandating accreditation by ASHI or CAP as a condition of membership in the OPTN. However, UNOS policy staff was concerned that a change in ASHI or CAP requirements would automatically amend OPTN standards without an opportunity for the public to comment or approval by the OPTN Board of Directors. In addition, the subcommittee wanted to

ensure that these requirements are transparent and accessible to OPTN members and the general public.

One committee member asked whether the committee will now regularly review the ASHI and CAP accreditation documents to monitor changes. Members of the subcommittee responded that the intention is for the committee to annually review any changes to these documents and, if there is a desire to adopt the new standards or requirements, release those changes for public comment and proceed with the Board of Directors approval process.

The committee also adopted new language to clarify that no OPTN member is required to pay a membership or accreditation fee to ASHI or CAP in order to be eligible for membership in the OPTN. One committee member asked for an explanation of this language and how compliance would be monitored without requiring accreditation. UNOS policy staff responded that a monitoring plan will be released with the implementation of these changes (if approved) and that this question will ultimately be left to the OPTN Contractor, but the OPTN does want to maintain its own standards for solid organ transplantation.

- Section C.2 *Facilities and Resources*
  The committee opted to eliminate several OPTN standards for facilities and resources because detailed requirements are already specified by ASHI and CAP in the documents referenced in C.1. These include detailed standards for refrigeration, liquid nitrogen storage, equipment maintenance, health and safety compliance, and software validation. However, the committee decided to retain standards specifying that laboratories must have the adequate facilities, equipment, and resources needed to perform accurate and efficient testing and has added language to specify that records for active candidates must be immediately accessible onsite (includes electronic access).

  The committee adopted language requiring that laboratories have written agreements with every transplant program or OPO the laboratory serves. Current OPTN policy (Appendix 3D) lists recommended elements for agreements between transplant programs and histocompatibility laboratories. Recognizing that histocompatibility laboratories serve both transplant programs and OPOs, the subcommittee proposed to require written agreements with every OPO the laboratory serves as well and the committee agreed.

  The committee adopted the recommendation that this section be moved from Appendix 3D to the Bylaws to be consistent among all OPTN members (written agreements are a condition of membership in the bylaws governing OPOs and transplant hospitals). The subcommittee explained that the required elements chosen were determined to be critical for patient safety and written with the recognition that clinical practice varies among OPTN members.

- Section C.3 *Histocompatibility Laboratory Key Personnel*
  The committee adopted the subcommittee recommendation to add the General Supervisor as a member of the laboratory key personnel, because this is an essential personnel position required by CLIA. The committee also agreed with the subcommittee recommendation to move the language regarding delegation of the laboratory director and technical supervisor's duties to the new section C.4 *Laboratory Coverage Plan*.

- C.4 *Laboratory Coverage Plan*
  The committee adopted the subcommittee's recommendation to add a new section in the bylaws to require histocompatibility laboratories to submit a Laboratory Coverage Plan to the OPTN Contractor. Members of the subcommittee explained that this change is intended to address problems that the MPSC has experienced with monitoring key personnel and testing staff coverage at laboratories. Members of the subcommittee explained that D.5.B *Surgeon and Physician Coverage (Program Coverage Plan)* was used as a model in drafting this new requirement in order to try to provide some consistency among OPTN members. Under the new proposal, the Laboratory Coverage Plan must include the following details:

  - Documentation that the clinical consultant and technical supervisor are available to provide onsite, telephone, or electronic consultation to facilitate organ acceptance and transplantation.

  - A list of any responsibilities designated to the laboratory director, technical supervisor, clinical consultant, or general supervisor that will be performed by other laboratory staff. In addition, the laboratory must document the times when the duties will be delegated, the qualifications of the staff performing the duties, and the quality systems in place to ensure the duties are correctly performed.

  - Documentation that the laboratory has qualified key personnel coverage at all times, including during the application process for changes in key personnel.

  - For laboratories engaged in histocompatibility testing for deceased donor transplants, documentation that the laboratory has key personnel and qualified testing personnel available 24 hours day, 7 days a week unless a written explanation for coverage is provided to the Membership and Professional Standards Committee (MPSC).

  - For laboratories with key personnel who serve more than one laboratory, documentation of how continuous coverage will be provided at each laboratory served.

The Committee adjourned at 4:00pm ET. The next meeting will be held by conference call on January 8, 2013 from 12:00-1:00pm ET.