

## **OPTN Histocompatibility Committee**

### **Meeting Summary**

**August 9, 2022**

**Conference Call**

**John Lunz, PhD, D(ABHI), Chair**

**Gerald Morris, MD, PhD, Vice Chair**

### **Introduction**

The Histocompatibility Committee (the Committee) met via Citrix GoToMeeting teleconference on 07/12/2022 to discuss the following agenda items:

1. HLA Confirmatory Typing Feedback
2. Post-implementation monitoring report: Dual Entry
3. Updates to Histocompatibility Policies/Guidance
  - Preservation of Excess Specimens
4. CMS Proposed Rule Updates

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

#### **1. HLA Confirmatory Typing Feedback**

The Committee discussed feedback they have received from other OPTN Committees on their Deceased Donor Confirmatory HLA Typing project. The Committee received feedback from the OPTN Organ Procurement Organization Committee and the OPTN Kidney Transplantation Committee that voiced concern over the potential policy causing a delay to allocation. The OPTN Organ Procurement Organization Committee also voiced concerns regarding the project's potential to increase cost. The OPTN Organ Procurement Organization Committee also questioned how this potential policy would be operationalized, how discrepancies would be resolved by organ procurement organizations, and how finalized typing would be submitted based on the two results.

The Chair and Past Chair asked if there was anyone on the Committee not in favor of this proposal or who had questions or concerns regarding this proposal.

#### Summary of discussion:

A Committee member asked if this second typing of the deceased donor will need to occur before acceptance. The Chair explained that this would need to be completed at the initial workup of the donor. The member then asked if this would be performed by the same lab, on the same sample, and by the same method because there is then concern on how the discrepancy would be resolved. The Chair stated there would be two separate samples drawn five minutes apart. The Chair explained the Committee cannot mandate methodology, but in guidance the Committee may recommend two different test kits. The Chair explained the proposal requires two typings performed for all loci that could be ran in parallel, which would not cause significant delay. No Committee members expressed that they are opposed to the project.

#### Next steps:

- The Committee will present to the OPTN Operations and Safety Committee

- The project will be discussed at the in-person meeting
- The finalized language will be presented and voted on in the November 2022 meeting
- The proposal will go out to January 2023 Public Comment

## 2. Post-implementation monitoring report: Dual Entry

UNOS Staff gave a post-implementation monitoring report on the dual entry of HLA typing data. The Addressing HLA Typing Errors Project introduced three new requirements: the upload of raw donor data, the mandate of a process for verifying HLA, and the dual manual entry of HLA into the OPTN Computer System. The report examined data from quarterly donor discrepancy reports using February 27, 2020, as the implementation date.

### Data summary:

The data does not distinguish between actual discrepancies and differences in typing resolutions or in equivalent values. The data shows there was a spike in discrepancies in quarter four of 2020. There was a drop in the median number of critical discrepancies from 12 to 7 after the dual entry was implemented. The Past Chair sorted the discrepancies into typing errors, split vs. parent errors, and sample integrity. Typing errors declined the most since implementation, and donor HLA typing errors have declined as well.

### Summary of discussion:

The Chair noted this data reflects that typing errors do occur, but the more the Committee implements to make HLA typing as solid as possible is essential for the entire transplant process to occur.

## 3. Updates to Histocompatibility Policies/Guidance

- Preservation of Excess Specimens

The Committee discussed revisions to [OPTN Policy 4.8: Preservation of Excess Specimens](#) and [OPTN Guidance](#) (2017).

- [OPTN Policy 4.8: Preservation of Excess Specimens](#)
  - Recommendation: If a laboratory performs testing to determine histocompatibility between a donor and recipient, then the laboratory must preserve enough specimen from the ~~deceased~~ donor to perform subsequent testing ~~for at least five years after transplant.~~ The type and amount of donor specimens preserved, and the period of storage shall be defined in the agreement with the transplant program.
- [4.8: Preservation of Excess Specimens](#)
  - Recommendation: The type, and amount, and storage time of donor specimens preserved should correspond to any potential testing that may be requested by the clinicians for the purpose of patient care (e.g. crossmatch, additional HLA typing, and other genotyping). are at the discretion of transplant clinicians and the histocompatibility lab.
    - The donor may be a deceased and/or living donor;
    - The donor specimens may be cells and/or DNA or others, depending on the need for post-transplant testing, such as crossmatch, additional HLA typing, etc.
  - Recommendation: Remove, “The handling and storage methods of preserved specimens should ensure that specimen integrity can be appropriately maintained for generating reliable test results for that type of specimen.”

### Summary of discussion:

- [OPTN Policy 4.8: Preservation of Excess Specimens](#)

The Chair explained the policy recommendation was left vague to not be prescriptive of all different circumstance. The Vice Chair vocalized concern by stating that this seems as if we are not needing to have a policy at all, so we should instead set a minimum standard. Committee members agreed. The Chair countered that the preservation of specimens standards would be in the testing agreement between the histocompatibility lab and the OPO. The Vice Chair stated if there is no need to produce a minimum standard in policy, then there should not be a policy at all. The Committee agreed on having a minimum standard.

The Vice Chair suggested the minimum standard should be set at the preservation of DNA, since that is the easiest to process and store. He suggested shying away from the storage of viable cells because it is usually not done well and OPOs who do not have an in-house lab would be forced to contract out. Committee members agreed and vocalized ten years is a reasonable ask for storage timeframe.

Members suggested a quantity of DNA to store at 10 micrograms, but the Chair believes this in policy is too specific. UNOS staff noted that 10 years lines up with infectious disease plasma and serum, while members agreed this would be the standard for living donors as well. The members agreed to require the storage of DNA for ten years for all donors.

The Committee members did not discuss [OPTN Guidance](#) (2017) due to limited time after this discussion.

### Next steps:

The Committee will discuss [OPTN Guidance](#) (2017) in their in-person meeting in October.

## **4. CMS Proposed Rule Updates**

The Chair provided an update on CMS Proposed Rule 3326-P: Updates to CLIA. The Chair explained the Committee will draft a response to the proposed rule. The Chair noted the Committee will not respond to all portions of the proposed rule but will focus on crossmatching. The Chair highlighted the proposed rule allows virtual crossmatching to replace physical crossmatching prior to transplant and requires recipient specimen for crossmatch collected on the day of transplant.

### Summary of discussion:

The Vice Chair suggested a timeline for submitting comments to the OPTN response. UNOS Staff asked for Committee comments to be sent by 8/12/22.

### Next steps:

The Committee will develop a response for approval by the OPTN Executive Committee. Members may submit individual responses, or responses on behalf of their institution.

## **Upcoming Meetings**

- September 13, 2022, 12 PM EST, teleconference
- October 7, 2022, in-person

## **Attendance**

### Committee members:

- Amber Carriker
- Andres Jaramillo
- Bill Goggins
- Caroline Alquist
- Gerald Morris
- Hua Zhu
- John Lunz
- Kelley Hitchman
- Laurine Bow
- Manu Varma
- Marcelo Pando
- Omar Moussa
- Peter Lalli
- Phyllis Weech
- Qingyoung Xu
- Reut Hod Dvorai
- Valia Bravo-Egana
- Yvette Chapman

### SRTR Staff

- Katherine Audette

### HRSA Representatives

- Jim Bowman
- Raelene Skerda
- Megan Hayden

### UNOS Staff

- Amelia Devereaux
- Courtney Jett
- Kelsi Lindblad
- Krissy Laurie
- Lauren Mauk
- Sarah Scott
- Taylor Livelli
- Thomas Dolan