

**OPTN Histocompatibility Committee
Discrepant HLA Typings Notification Workgroup
Meeting Summary
November 19, 2020
Conference Call**

**Peter Lalli, Ph.D., D (ABHI), Chair
John Lunz, Ph.D., D(ABHI), Vice Chair**

Introduction

The Discrepant HLA Typings Notification workgroup met via Citrix GoToMeeting teleconference on 11/19/2020 to discuss the following agenda items:

1. Timing and Form of Required Notifications
2. Notification Triggers
3. Discrepancy Documentation
4. Draft Policy Language Review

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

1. Timing and Form of Required Notifications

The Histocompatibility Committee Chair asked what timing the workgroup felt was appropriate for histocompatibility labs to notify OPOs/transplant programs, and for OPOs to notify transplant programs.

Summary of discussion:

Committee members were concerned about what constitutes "discovery" of a discrepancy.

Committee members would like to emphasize that this timing should be as quickly as possible to ensure patient safety. UNOS Member Quality staff explained that if a member is non-compliant, there would be no way to enforce this policy if there is no maximum time in policy. In addition, when MPSC reviews cases, the full conditions of the incident are taken into account.

The workgroup's OPO representative explained that 24 hours was too long of a timeframe to allow for OPOs to notify accepting transplant programs of donor HLA typing changes pre-recovery, and that 1 hour was too short.

One member brought up that there's more urgency that there's the most urgency post-procurement and pre-transplant.

Next steps:

Committee liaison will draft policy language regarding these specifications for the workgroup to review.

2. Notification Triggers

The Histocompatibility Committee Chair asked what the workgroup felt was appropriate from a UNet systems perspective.

Summary of discussion:

One member discussed the potential for a systems update using the trigger from the HLA audit log, or adding a note to the HLA page when a discrepancy is discovered.

One committee member mentioned that adding additional steps for histocompatibility labs after discovery of a discrepancy would likely not be a help, since they happen so rarely a member is unlikely to be familiar with the policy. They feel that labs will understand the urgency and reach out to the transplant program or OPO directly.

Workgroup members mentioned that pre-recovery, an electronic notification would likely be lost. In addition, one member recommended this be evaluated in the post-implementation monitoring of the policy. If the notification system used is not effective, the committee could always recommend an alternative route. Multiple members agreed that while a notification would be good for evaluation and tracking of this policy use, they would be uncomfortable as a lab director if they did not also call to confirm receipt of the typing change from the OPO. However, they felt that for OPOs, calling all of the provisional yes potential recipients may be better handled in an electronic notification.

The HRSA representative to the project mentioned the post-recovery culture reporting platform and how it could potentially be helpful in this case. Members brought up the objection that while it is extremely helpful, it's not intended for the reporting of critical information changes, because a patient safety contact likely will not be available 24/7.

One workgroup member proposed that there could be a notification on the HLA typing page, based on the audit log, that HLA typing has changed since the initial entry. Programs may not know to go back to look at it, but at the end of the double entry it there could be a note that there is a typing discrepancy between the previous entry with language that mentions that the user should contact the OPO or transplant program. One member mentioned that if this change happens post-recovery and post-transplant the typing may not be changed within DonorNet, only within the Donor or Recipient Histocompatibility Forms, and new source documentation would be uploaded. Histocompatibility lab members were concerned, as they do reference the HLA typings within Waitlist and DonorNet.

Another member brought up the Policy Oversight Committee (POC) dynamic match run idea, and how this would be more easily incorporated within that system. Members agreed that it would be the ideal outcome for this policy, but it is likely quite a time away.

Next steps:

Committee liaison will draft policy language regarding these specifications for the workgroup to review.

3. Discrepancy Documentation

The Histocompatibility Committee Chair asked what documentation the workgroup felt was appropriate for monitoring the use of this policy.

Summary of discussion:

Workgroup members discussed how to document notifications, and whether or not this documentation would need to be within DonorNet or a member's EMR. They discussed that an auditor would look for documentation within the donor chart, and that programming within DonorNet would be excessive.

Next steps:

Committee liaison will draft policy language regarding these specifications for the workgroup to review.

4. Draft Policy Language Review

The Histocompatibility Committee Chair reviewed the drafted policy language and requested workgroup input.

Data summary:

Draft policy language attached.

Summary of discussion:

Members agreed on the definition of a critical discrepancy. Members also agreed that a candidate or recipient's typing does not have the same urgency as that of a donor, and that notification should not be required within an hour as it would affect post-transplant monitoring and potentially the order a candidate would appear on a match run, but would not cause a patient safety concern. Members agreed on the wording "as quickly as possible to ensure patient safety", as it better encompassed potential situations.

One member brought up the fact that some transplant programs may have declined an organ offer with the prior HLA typing, but may have accepted it with the current typing. The OPO representative mentioned that if allocation has not started yet, executing a new match run would make the most sense. If allocation has already started, calling all programs who documented a refusal would be very burdensome. Members agree that it's unfortunate, but happens so rarely that it's difficult to write into policy what should happen in those very few cases.

Next steps:

Committee liaison will draft policy language regarding these specifications for the workgroup to review.

Upcoming Meetings

- December 4, 2020, Teleconference

Attendance

- **Workgroup Members**
 - Alejandro Diez
 - Cathi Murphey
 - Jennifer Schiller
 - John Lunz
 - Karl Schillinger
 - Larry Suplee
 - Peter Lalli
 - Phyllis Weech
 - Reut Hod Dvorai
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **UNOS Staff**
 - Adel Husayni
 - Kelsi Lindblad
 - Leah Slife