OPTN Histocompatibility
Meeting Summary
May 9th, 2023
Conference Call

John Lunz, Ph.D., F(ACHI), Chair

Gerald Morris, MD, Ph.D., Vice-chair

Introduction

The Histocompatibility Committee ("Committee") met via Citrix GoToMeeting teleconference on 05/09/2023 to discuss the following agenda items:

1. OPTN Improving Patient Safety Portal: Root Cause Analyses of Critical HLA Discrepancies
2. HLA Equivalency Tables Update 2023

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

1. OPTN Improving Patient Safety Portal: Root Cause Analyses of Critical HLA Discrepancies

Staff presented root cause analyses of HLA discrepancies reported in the OPTN Patient Safety Portal.

Data summary:

Public Comment feedback on the Committee's proposal "Require HLA Confirmatory Typing for Deceased Donors" suggested that the Committee perform root cause analyses on the discrepancies reported.

Reporting on critical discrepancies is entirely voluntary and is informed by members' own internal investigation.

The Committee reviewed all critical discrepancies reported in the portal (91 total cases; January 1, 2015 – March 1, 2023)

Summary of discussion:

A member inquired if there were a denominator for the number of sample swaps that occurred; it would demonstrate how likely this was among all samples. They added that 11 sample swaps out of 91 critical discrepancies would be approximately 10%, which was not an insignificant amount. The Chair supported trying to identify denominators – not just amongst the total of samples tested, but also of discrepancies. They wondered if members could use their own institutions' reporting on critical discrepancies to determine a plausible denominator.

A second member wondered how many labs were involved in the 11 sample switches. Member Quality Staff reported that there were no standout labs that were significantly higher than others.

The Chair felt that this root cause analysis supported API development and use in the community, as many of the critical discrepancies reported in the portal were data entry errors.

A member asked if critical discrepancies were not tracked prior to 2015. Staff responded that root cause analyses were not available to be submitted prior to the 2015 patient safety portal update, so any critical discrepancy reports would be difficult to assign cause.

A member also suggested that there be a mandatory reporting requirement for critical discrepancies, noting that the exact details of what, when, and how reporting should be done could be informed by conversations with accrediting stakeholder organizations. Root cause analyses could still be performed on the OPTN data reported, but the regulatory bodies should develop policies to require that information be shared. They felt that the OPTN lacked punitive ability should any significant or consistent trends be identified in a lab.

It was suggested that, outside of requiring reporting, it could also be beneficial to collect data on existing retyping practices at programs. Currently retyping is assumed when two different uploads exist for donor HLA, but a member proposed having a binary response field that assessed if confirmatory typing was performed. Staff noted that, even with that current data collection, it seems that confirmatory typing is performed 82% of the time.

A member asked what fields were available to members when reporting critical discrepancies. Staff replied that a subcommittee of the Committee is currently evaluating the donor and recipient histocompatibility forms to determine field relevancy, and one of those forms is the discrepancy report. The member suggested that, as an update to the discrepancy report, an area should be included to input why the discrepancy occurred. Staff clarified that a separate form in the Data System of the OPTN captured that information, but the subcommittee is proposing to have that automatically be triggered for every discrepancy that occurs.

Another member inquired if the self-reporting on discrepancies captured in the Data System of the OPTN was reviewed by the OPTN Membership and Professional Standards Committee (MPSC). Staff answered that only the discrepancies reported in the patient safety portal were reviewed by the MPSC. The forms submitted through the Data System of the OPTN were not. The Chair proposed first, potentially exploring policy opportunities to require reporting of discrepancies, and second, to aggregate the two methods of reporting discrepancies such that one does not receive a different review than the other. Two members agreed with this analysis, with one noting that feedback from the community on the confirmatory typing proposal was that the data on discrepancies needs to be more complete. The Chair added that this would not only ensure data quality when assessing discrepancies, but also drive labs to provide the best typing possible knowing that discrepancies are captured and evaluated.

A member wondered if a lab was required to submit information twice for each discrepancy; first through the patient safety portal and second through Data System of the OPTN. Staff clarified that neither were required, but the Committee could endorse reporting through one avenue or another. They added that a potential downside of using the patient safety portal was that it could not be automatically triggered when a discrepant typing is reported. The member suggested using the Data System of the OPTN, then, to have the discrepancy report form automatically trigger.

In reviewing the proposed update to the discrepancy cause list, a member suggested including an option for “typing error” which provided a subset of options to clarify the cause of the typing error. Another member suggested the terminology “reagent/technical error”.

The Chair asked whether members will be able to input multiple options for the source of error or if they will have to choose only one. Staff replied that, in the field’s current format, it was a single-select option. The Chair tentatively suggested allowing multiple options to be selected to provide more clarity into the discrepancy.

Next steps:

2. HLA Equivalency Tables Update 2023

The Chair provided an update on their project to update the HLA equivalency tables.

Data summary:

The Chair discussed:

- P-group vs. Individual allele unacceptable antigens
- A crosswalk of Bw4/Bw6 epitopes within policy

Summary of discussion:

The Chair asked if unacceptable antigen equivalencies should be rolled into P-groups or if they should remain as individual alleles. A member supported rolling them into P-groups for simplicity's sake. A second member agreed, but wondered if that could impact the efficiency of HLA APIs. The Chair also added that there could be scenarios where a P-group does not accurately reflect a candidate's true unacceptable antigens. It was suggested and endorsed by three members that both could be reported such that candidates can retain granularity in which alleles are unacceptable but there is simplicity in reporting if the P-group is accurate.

Next steps:

The Committee will continue their discussion at their following meeting.

Upcoming Meeting

- June 13, 2023

Attendance

- **Committee Members**
  - John Lunz
  - Gerald Morris
  - Andres Jamarillo
  - Kelley Hitchman
  - Lenore Hicks
  - Qingyong Xu
  - Hemant Parekh
  - William Goggins
  - Laurine Bow
  - Manish Gandhi
  - Helene McMurray
  - Hua Zhu
  - Rajalingam Raja
  - Manu Varma
  - Peter Lalli
  - Reut Hod Dvorai
  - Yvette Chapman
  - Crystal Usenko
  - Roshini Abraham
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Debra Vicars
  - Courtney Jett
  - Isaac Hager
  - Krissy Laurie
  - Sarah Scott
  - Thomas Dolan
  - Susan Tlusty