OPTN Histocompatibility Committee Discrepant HLA Typings Subcommittee Meeting Summary February 1, 2023 Conference Call

Laurine Bow, PhD, Chair

Introduction

The Discrepant HLA Typings Subcommittee ("Subcommittee") met via Citrix GoToMeeting teleconference 02/01/2023 to discuss the following agenda items:

- 1. Discrepancy Review Process
- 2. Patient Safety Review Process

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

1. Discrepancy Review Process

Staff provided a brief overview of the discrepant human leukocyte antigen (HLA) review process when reported to the OPTN.

Data summary:

With the latest update to the discrepant typing report, equivalent typings will no longer show up as discrepant. Committee members are asked to report any equivalencies that are reported as discrepant.

Data request:

- 72.4% of all deceased kidney donors were retyped by recipient centers. On average, deceased kidney donors were retyped 1.05 times per donor
- When considering only deceased kidney donors whose kidneys were retyped at least once, this average increases to 1.45 times per donor.

Discrepancy review process:

- The function of the spreadsheet is to identify the discrepant typings where there was potential concern for safety
- Any initial typing is included on the spreadsheet, as well as any subsequent typings
- The spreadsheet compares different sources of HLA information (Recipient Histocompatibility form, Donor Histocompatibility form, Match Run) and checks to see if they are equal
 - E.g. Kidney match run indicates Bw6 positive, while Liver match run indicates Bw6 negative; this would flag as discrepant
- In documenting this, three general classifications of discrepancies were identified:
 - Sample integrity issues (Incorrect overall)
 - Typing reporting errors (Individual switches, clerical errors)
 - Split vs Parent (Reporting equivalencies at a higher resolution)
- The Subcommittee is primarily concerned with discrepant typings stemming from the match run, and less concerned with discrepant typings stemming from two forms both are important, but one indicates a potential safety event

Summary of discussion:

A member requested that the data from the request be incorporated into the slides for regional meetings to demonstrate that the proposed policy mirrors existing practice.

A second member asked if there was data on how many of the deceased donors were retyped in real time during allocation. Staff replied that they did not, and the Chair speculated that it was unlikely most were retyped during allocation. The Chair asked if retyping was required by policy. Staff responded that it was not currently required; the ex officio added that there was a guidance document that noted best practice was to retype donors.

The ex officio noted that, prior to double entry for HLA, clerical errors were the primary source of discrepancies – this did not resolve the issue but diminished the number of occurrences.

A member suggested that requiring double entry would still not catch issues in which the entire sample was switched. The ex officio replied that there were many areas an error could occur along the way, and there were separate checks put in at different points to try to address them. They noted that, in the future, the best-case scenario would be for an API to exist between EMRs and the OPTN Donor Data and Matching system to ensure an errorless transcription. The impetus behind the confirmatory typing proposal, as well, was to ensure that sample switches are more difficult.

The Chair wondered if requiring confirmatory typing would resolve sample swap issues in cases when the samples are drawn in the same small time frame. The ex officio replied that a limitation in the analysis of the confirmatory typing proposal was using blinded data; each instance of a discrepancy occurs in its own situation, which is sometimes masked by the blinded data. The Chair agreed that the blinded nature of the data limited the Subcommittee's understanding of error reports.

Staff clarified that, in instances when there are larger discrepancy reports, they can follow up with Member Quality to determine if a patient safety event has also been reported. This would allow a further investigation of the circumstances leading up to the event. While the details of the case cannot be reported to the committee, a larger aggregate analysis can be reported back on whether these were instances of sample switches or other errors.

The Chair asked if there was any information on sample integrity errors. Staff replied they would follow up on that request.

Next steps:

The Chair will delegate roles and responsibilities to members of the Subcommittee.

2. Patient Safety Review Process

Staff provided a summary of the patient safety review process for incidents reported through the OPTN patient safety portal.

Data summary:

- Any OPTN member can report a potential safety event for investigation to the OPTN Improving Patient Safety Portal
 - All safety incident reports are voluntary (disease transmission reports are required)
- All incidents have been historically investigated by patient safety
 - This includes requests for information for all members involved

 This includes when the discrepancies are only differences in resolution of typing, reported by an OPO or transplant hospital

Summary of discussion:

This item was not discussed.

Next steps:

The Subcommittee will discuss this item at a future meeting.

Upcoming Meeting

• TBD

Attendance

• Subcommittee Members

- o Laurine Bow
- o Andres Jaramillo
- o John Lunz
- o Peter Lalli
- Reut Hod Dvorai
- o Qingyong Xu
- HRSA Representatives
 - o Jim Bowman
 - o Marilyn Levi
- UNOS Staff
 - Amelia Devereaux
 - o Courtney Jett
 - o Eric Messick
 - o Isaac Hager
 - o Thomas Dolan