OPTN Histocompatibility Committee
Donor and Recipient Histocompatibility Forms Review Workgroup
Meeting Summary
March 21, 2023
Conference Call

Introduction

The Donor and Recipient Histocompatibility Forms Review Workgroup ("Workgroup") met via Citrix GoToMeeting teleconference on 04/18/2023 to discuss the following agenda items:

1. Timeline, Feedback
2. HLA Typing Data
3. HLA Antibody Screening Data

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

1. Timeline, Feedback

The Workgroup reviewed the proposed timeline for the project and the sections that will be updated within the project.

Data summary:

The Workgroup proposes changes to the donor and recipient histocompatibility forms (DHF/RHF) based on the following aspects of their data:

- Utility
- Clarity
- Reliability
- Usability
- Interoperability
- Standardization

Summary of discussion:

There was no discussion surrounding this item.

Next steps:

Staff will share any updates to the proposed timeline in the event of changes.

2. HLA Typing Data

The Workgroup discussed specific data elements and reviewed their continued relevancy.

Summary of discussion:

Elements: Date Typing Completed Class I, Date Typing Completed Class II

A member strongly endorsed that these date fields be merged into one date, given the extremely high likelihood these are performed at the same time. A second member also supported this change, noting

that the split may have existed because of constraints with serological typing. The rest of the Workgroup agreed with these assessments.

Element: Typing Method

Staff asked if there was utility to maintain this field on the DHF given the policy requirement for molecular typing on deceased donors. A member proposed removing it altogether because of the policy requirement. Staff noted that there was no requirement of molecular typing for retyping or recipients. Members of the workgroup felt that there was no need to gather this information on the DHF or RHF, as the insight it provided in those cases was not large. A member suggested that a possible question for public comment could be to ask if any program is performing serological typing on recipients or for retyping. They also inquired if data were available to see how programs respond to the question. Staff replied that it was, and they could follow up on that request for a subsequent meeting.

Element: Donor Retyped at Your Center?, Donor Retyped Class I, Donor Retyped Class II

Three members felt there was no need to separate the class I and class II typing questions.

Element: Target Source for Class I, Target Source for Class II

A member felt that there may be small benefit to maintaining separate fields if a program ran out of typing material after evaluating class I. However, they also noted that the value these data add does not seem to be high, so it may be beneficial to remove it altogether. Another member agreed that these values, in their experience, are rarely, if ever, reviewed in the clinical setting. They felt that this field could also be a product of former typing constraints. Members agreed that there was low clinical relevance to gathering these data.

Next steps:

Staff will incorporate feedback from the Workgroup into their modifications to the form.

3. HLA Antibody Screening Data

Staff presented elements from the HLA Antibody Screening sections of the RHF and DHF.

Summary of discussion:

Element: Antibody detection by Cytotoxicity and Solid-Phase

A member felt that this level of detail was unnecessary, and the response options were outdated. They suggested that the entire field should be removed. A second member noted that the lack of antibody testing may be important to capture, if, for example, a liver segment is transplanted without antibody testing. They proposed that the field should become “Were any HLA antibodies detected pre-transplant?”, and the response options would be yes, no, or not done.

Elements: Were there current donor-specific HLA antibodies, Were there historical donor-specific HLA antibodies

A member felt that the definition of “current” could vary between programs. A second member noted that the question really should be trying to capture whether there were any donor-specific antibodies captured pre-transplant and post-transplant. They wondered if the question could be reduced to simply “Were there any pre-transplant donor-specific antibodies detected?”. This would reduce the disparities in data quality caused by different definitions of “current”. A member resisted this rephrasing, suggesting that the function of these two questions were to understand if there were immediately detectable antibodies that were found as the patient was going into transplant, or if there were antibodies that had been present, but were not detectable when the patient went into transplant.

A member suggested that retaining this information as separate could be helpful to inform post-transplant outcome monitoring. A member felt that this may not be beneficial, as, in the presence of many other factors post-transplant, including immunosuppression plans, it would be hard to attribute significance to the data. The first member rebutted, stating that they felt there could be benefit to knowing whether a transplant was performed in the presence of specific antibodies. They proposed maintaining the two questions as separate but removing “current” and adding a timespan for how long “historical” meant. A member endorsed this suggestion, proposing 24 months as the timeframe for “historical”.

Another member wondered how different values of mean florescent intensity (MFI) should be reported when considering positive results, as some programs will report a positive test whereas others will report a negative based on what MFI they are using. If these data are being collected for retrospective analyses, there should be some standardization on MFI values to ensure data quality. A member suggested including acceptable ranges of MFI values to return positive tests. A second member noted that may be outside the scope of this current project, but that they agreed there should be more standardization if the data from the question would be used. A third member noted that MFI values also depend on the resources available at the testing location, which could make standardization efforts difficult. They supported having MFI ranges that are reported alongside the test result.

It was suggested that the data's point may be to determine if there were donor-specific antibodies available pre-transplant and not bring up the question of MFI during this evaluation. A member pointed out that by not changing it during this evaluation, the Histocompatibility Committee would be unlikely to change it again soon.

Staff asked what the Workgroup felt for the final state of the question(s). Members supported removing the question that asked about historical donor-specific antibodies, as data collected was not as useful as current donor-specific antibodies and the definition of “historical” was too vague.

Next steps:

Staff will introduce the following meeting with a discussion of what current donor-specific antibodies entail.

Upcoming Meeting

- April 18, 2023

Attendance

- **Workgroup Members**
  - John Lunz
  - Andres Jamarillo
  - Kelley Hitchman
  - Laurine Bow
  - Omar Moussa
  - Valia Bravo-Egana
  - Rajalingam Raja
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Courtney Jett
  - Thomas Dolan
  - Debra Vicars