OPTN Histocompatibility Committee
Donor and Recipient Histocompatibility Forms Review Workgroup
Meeting Summary
July 18, 2023
Conference Call

Introduction

The Donor and Recipient Histocompatibility Forms Review Workgroup ("Workgroup") met via Citrix GoToMeeting teleconference on 07/18/2023 to discuss the following agenda items:

1. Review of Recommended Data Collection Changes

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

1. Review of Recommended Data Collection Changes

The Workgroup reviewed the previously recommended data collection changes for the Donor Histocompatibility Form, Recipient Histocompatibility Form, and TIEDI Discrepancy Form.

Summary of discussion:

Decision #1: The Workgroup reviewed the Donor Histocompatibility Form and agreed with previously recommended changes to the Date Typing Completed, Target Source, and Typing Method fields.

Decision #2: The Workgroup discussed potential changes to the Physical Crossmatch Done and Virtual Crossmatch Done questions on the Test Information section of the Recipient Histocompatibility Form.

Decision #3: The Workgroup approved of the previously recommended changes to Section I: Recipient HLA Typing of the Recipient Histocompatibility Form and agreed that using autofill for information provided on the OPTN Waiting List would be beneficial.

Decision #4: The Workgroup did not finish reviewing Section II: HLA Antibody Screening of the Recipient Histocompatibility Form but did discuss potential data collection changes to the pre-transplant donor specific HLA antibodies (DSA) field.

Decision #1: The Workgroup reviewed the Donor Histocompatibility Form and agreed with previously recommended changes to the Date Typing Completed, Target Source, and Typing Method fields.

The Workgroup did not have any further discussion regarding changes to the Donor Histocompatibility Form.

Decision #2: The Workgroup discussed potential changes to the Physical Crossmatch Done and Virtual Crossmatch Done questions on the Test Information section of the Recipient Histocompatibility Form.

The previously recommended changes to the Test Information section of the Recipient Histocompatibility Form proposed specific data collection fields for physical and virtual crossmatches done. The group reviewed the previously proposed change and offered three other potential options for the crossmatch fields.

Option #1 (previously proposed):

- Physical Crossmatch Done
    - Response options: Yes, No (Triggers Section III: Crossmatch)
    - If yes, was the crossmatch prospective to transplant?
        - Response options: Yes, No, Unknown
- Virtual Crossmatch Done
    - Response options: Yes, No
    - If yes, was the crossmatch prospective to transplant?
        - Response options: Yes, No, Unknown

Upon further discussion, a Workgroup member stated that the questions posed allowed individuals to answer that they had done, both, a physical and virtual crossmatch prospectively. The member shared that even though a physical and virtual crossmatch may be done prospectively, there should only be one identified. In response, a few members expressed that some transplant centers do complete a physical and virtual crossmatch in a prospective manner, especially for candidates that are highly sensitized.

Option #2 (newly proposed):

- Option #2 would eliminate the physical and virtual crossmatch fields and would replace it with a final crossmatch question
- Final Crossmatch
    - Response options: Physical Crossmatch, Virtual Crossmatch
    - If yes for physical crossmatch, was the crossmatch prospective to transplant?
        - Response options: Yes, No, Unknown

Option #3 (newly proposed):

- Physical Crossmatch Done
    - Response options: Yes, No (Triggers Section III: Crossmatch)
    - If yes, was the crossmatch prospective to transplant?
        - Response options: Yes, No, Unknown
- Final Prospective Crossmatch
    - Response options: Physical Crossmatch, Virtual Crossmatch, None

Option #4 (newly proposed):

- Physical Crossmatch Done
    - Response options: Yes, No (Triggers Section III: Crossmatch)
    - If yes, response options: Prospective, Retrospective
- Prospective Virtual Crossmatch Done
    - Response options: Yes, No
    - If yes, response options: Prospective, Retrospective

Following review of the original proposal and the three new proposals, the Workgroup discussed which option might be best. A member highly recommended that Option #1 (previously proposed) might be the best as practices often vary between transplant centers across the United States. However, Option #1 may still influence individuals to categorize both the physical crossmatch and virtual crossmatch as prospective.

The group discussed that Option #4 might be the most beneficial as it would cover every scenario related to physical and virtual crossmatches done and those completed in a prospective manner. The group believed that this was an option that was clear and covered most possibilities. In addition, the

data collected from Option #4 would allow the group to get a glimpse into the practices across the United States.

Decision #3: The Workgroup approved of the previously recommended changes to Section I: Recipient HLA Typing of the Recipient Histocompatibility Form and agreed that using autofill for information provided on the OPTN Waiting List would be beneficial.

The Workgroup briefly discussed whether it would be beneficial to have information from the OPTN Waiting List autofill for the recipient on their Recipient Histocompatibility Form. The group decided that having that information would be beneficial because it would minimize transcriptional errors that may occur.

Other than their brief discussion regarding autofill information, the Workgroup had agreed on the previously recommended changes to the Date HLA Typing Completed, and Typing Method Class fields to the Recipient Histocompatibility Form.

Decision #4: The Workgroup did not finish reviewing Section II: HLA Antibody Screening of the Recipient Histocompatibility Form but did discuss potential data collection changes to the pre-transplant donor specific HLA antibodies (DSA) field.

<u>Option #1 (previously proposed):</u>

- Were there current donor specific HLA antibodies?
    - Response options: Yes, No, Unknown

After reviewing this section of the Recipient Histocompatibility Form, a Workgroup member mentioned that it would be important to capture further DSA and MFI information as the data can be valuable for answering certain questions, identifying trends, and analyzing data. An OPTN contractor staff explained that the Workgroup had initially decided against collecting additional DSA and MFI information because there was a lack in standardization that would not fit with OPTN data collection principles. In addition, the individual had mentioned that the DSA information could potentially be a lot of data collection.

Other Workgroup members shared their support for collecting additional data related to DSA and MFI because it will allow them to see different practices across the United States. Members believe the lack of data collection now will be a missed opportunity that may not change for years to come.

In discussing the matter further, a member stated that it may be difficult to connect DSA and MFI data with transplant outcomes. To make the data useful and useable, the group would need to identify a mechanism that would be able to connect this information. In addition, there would need to be an innovative and complex way to account for all center specific variabilities. Since MFI thresholds vary between transplant centers, the form would need to be complex. This is incredibly important, as false information collected or derived from this data can have significant implications.

The Workgroup worked through the challenges that the lack of MFI standardization poses. Members suggested that collecting DSA information, the transplant center's MFI Cutoff, or the Range of MFI Cutoff may be helpful. It was suggested that the range of MFI could be recorded through whole number free text.

<u>Option #2 (newly proposed):</u>

- Minimum of range of MFI you consider positive for donor specific HLA antibodies
    - Response option: whole number free text
- At which loci did you detect donor specific HLA antibodies?
    - Response options: All HLA loci

Option #3 (newly proposed):

- Were there pre-transplant donor specific HLA antibodies?
    - Response options: Yes, No, Unknown
- (If DSA is a yes) At which loci did you detect donor specific HLA antibodies?
    - Response option: All HLA loci, or free text the particular DSA
        - (If yes for locus, per locus) What is the MFI?
            - Response options: Whole number free text for the identified DSA

Since there are only around 10-15% of people with pre-transplant DSA and only have one or two pre-transplant DSA, a member suggested that Option #3 might be the best option. The Workgroup discussed how one of the downsides to reporting whole number free text would be that it is difficult to parse the data in the future.

Since the group did not complete their discussion on this matter, OPTN contractor staff requested that the members brainstorm potential options to address DSA and MFI data collection in a future meeting.

Next steps:

The Workgroup did not complete their review of the Recipient Histocompatibility Form and Discrepant HLA Typings Form and will continue this discussion in a future meeting. In addition, the Workgroup will brainstorm a few ideas regarding how to collect useable DSA data so that they may further discuss this topic in future meetings as well.

Upcoming Meeting

- August 15, 2023, 1PM EST

Attendance

- **Workgroup Members**
  - Roshini Abraham
  - Laurine Bow
  - Andres Jaramillo
  - Helene McMurray
  - Omar Moussa
  - Hemant Parekh
  - Rajalingam Raja
  - Jerome Saltarrelli
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Courtney Jett
  - Jenna Reformina
  - Amelia Devereaux
  - Thomas Dolan
  - Susan Tlusty