

**OPTN Histocompatibility Committee
Donor and Recipient Histocompatibility Forms Review Workgroup
Meeting Summary
August 15, 2023
Conference Call**

Introduction

The Histocompatibility Workgroup (the Workgroup) met via WebEx teleconference on 08/15/2023 to discuss the following agenda items:

1. Review of Recommended Data Collection Changes, Vote on Sending to Full Committee

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

1. Review of Recommended Data Collection Changes, Vote on Sending to Full Committee

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 decided that Option #2, to consolidate physical and final prospective crossmatch questions in the Test Information section of the Recipient Histocompatibility Form, was the best choice.

Decisions #2: The Workgroup decided to add the question “(If answer “Virtual” for prospective) Was physical crossmatch considered concordant with virtual crossmatch/antibody analysis” to Section III: Crossmatch of the Recipient Histocompatibility Form.

Decision #3: The Workgroup discussed potential data collection changes to the pre-transplant donor specific HLA antibodies (DSA) field on the Recipient Histocompatibility Form and decided to send the matter to the full committee for further consideration.

Decision #4: The Workgroup decided that they would add the “Original Typing Confirmed Correct” option to the Resolved Reason for Discrepancy field in the Discrepant HLA Typings Form.

Decision #5: The Workgroup decided to add “Reagent/Assay Issue” as an answer for the Resolved Reason for Discrepancy field in the Discrepant HLA Typings Form.

Decision #6: The Workgroup decided to change “Incorrect Split” to “Incorrect Allele Assignment” for the Resolved Reason for Discrepancy field in the Discrepant HLA Typings Form.

Vote to send to full committee:

Yes: 7, Abstain: 0, No: 0

Decision #1: The Workgroup decided that Option #2, to consolidate physical and final prospective crossmatch questions in the Test Information section of the Recipient Histocompatibility Form, was the best choice.

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
- Final Prospective Crossmatch
 - Response options: Prospective, Retrospective

Option #2 (newly proposed):

- Final Crossmatch performed?
 - Response: Physical, Virtual, Not Done
 - If virtual, question: Was a retrospective physical crossmatch done?
 - Response: Yes, No
 - Triggers Section III: Crossmatch for physical crossmatch, prospective or retrospective

A member had mentioned that Option #1 would be too confusing due to the multiple questions. Additionally, they stated that the first option would produce too much meaningless data and, therefore, proposed Option #2. The group discussed that what is important is to understand whether the final crossmatch was physical or virtual, as that is what really determines if transplant takes place. While this information would still theoretically be available through Option #1, the Workgroup determined and decided that Option #2 would be the more straightforward choice. In addition, the group decided to add that physical crossmatch, prospective or retrospective could trigger Section III. This will allow the OPTN to understand whether there were donor specific HLA antibodies or whether the physical crossmatch was positive.

Decisions #2: The Workgroup decided to add the question “(If answer “Virtual” for prospective) Was physical crossmatch considered concordant with virtual crossmatch/antibody analysis” to Section III: Crossmatch of the Recipient Histocompatibility Form.

Version #1:

- (If answer “Virtual” for prospective) Was physical crossmatch concordant with virtual crossmatch/antibody analysis?
 - Response options: Yes, No

Version #2:

- (If answer “Virtual” for prospective) Was physical crossmatch considered concordant with virtual crossmatch/antibody analysis?
 - Response options: Yes, No

When Version #1 had been proposed, a member expressed concern that interpretation of the question could be skewed since practices vary from transplant center to transplant center across the United States. A member then suggested Version #2 where they add the word “considered” in front of concordant. This change would allow the user to interpret it in their own way and according to the circumstances of their transplant center.

Decision #3: The Workgroup discussed potential data collection changes to the pre-transplant donor specific HLA antibodies (DSA) field on the Recipient Histocompatibility Form and decided to send the matter to the full committee for further consideration.

The Workgroup determined that if they were worried about inter-lab variability and about how the crossmatch may be interpreted, adding MFI and DSA fields are not the best option. Since labs are vastly different, there would be no threshold for positive or negative. DSA may work in some form, however,

getting into the weeds of how a lab evaluates the strength of an antibody is problematic. The Chair agreed that MFI would be too problematic to include due to the variability between labs.

A few members of the Workgroup thought that information about MFI would be important to collect. They stated that not collecting the information would prevent further analysis in the future. He suggested that if they can at least collect the information, they could refine it later. While another member agreed and offered a potential solution that would utilize a threshold for MFI, other members cautioned against it.

The Chair and a few other members expressed serious concern for collecting MFI data. They cited that once they have such data, it becomes available for anyone to use. Once it becomes available, they are unable to control how the data is being used or interpreted. If an individual does not understand the variability of the data, they can misuse it to make erroneous conclusions. Since the Workgroup could not come to consensus, they decided to send this matter to the full committee for further consideration.

Decision #4: The Workgroup decided that they would add the “Original Typing Confirmed Correct” option to the Resolved Reason for Discrepancy field in the Discrepant HLA Typings Form.

The group had discussed whether to add back “Correct Typing” as an option for the Resolved Reason for Discrepancy question. An OPTN contractor staff stated that “Correct Typing” is used frequently in situations where cases are pulled for being discrepant, even if they are not, because they are tied to other true discrepant cases. A member suggested that rephrasing this option to “Original Typing Confirmed Correct” would be a better choice as it would allude to a process being followed to be able to determine what was correct. With the previous option, an individual could answer “Correct Typing” simply because they think it is correct. Therefore, the Workgroup agreed to make this change.

Decision #5: The Workgroup decided to add “Reagent/Assay Issue” as an answer for the Resolved Reason for Discrepancy field in the Discrepant HLA Typings Form.

The Workgroup decided that this was a good choice because it would provide the option to report a true technical error.

Decision #6: The Workgroup decided to change “Incorrect Split” to “Incorrect Allele Assignment” for the Resolved Reason for Discrepancy field in the Discrepant HLA Typings Form.

A member stated that sometimes individuals make allele specific calls when they really do not have enough information to do it, therefore, “Incorrect Split” may not be appropriate. This is an issue that has come up in the past which motivated the group to make the change to “Incorrect Allele Assignment.”

Vote to send to full committee:

Yes: 7, Abstain: 0, No: 0

Next steps:

OPTN contractor staff will be sending these recommendations to the full committee for their consideration.

Upcoming Meeting(s)

- September 12, 12 PM ET

Attendance

- **Workgroup Members**
 - John Lunz
 - Laurine Bow
 - Jim Bowman
 - Andres Jaramillo
 - Marilyn Levi
 - Gerald Morris
 - Jerome Saltarrelli
- **UNOS Staff**
 - Courtney Jett
 - Jenna Reformina
 - Amelia Devereaux
 - Thomas Dolan
 - Krissy Laurie
 - Susan Tlusty