

OPTN Histocompatibility Committee

Meeting Summary

March 12, 2024

Conference Call

John Lutz, Ph.D., F(ACHI), Chair
Gerald Morris, MD, Ph.D., Vice Chair

Introduction

The Histocompatibility Committee, the Committee, met via WebEx teleconference on 3/12/2024 to discuss the following agenda items:

1. Update Histocompatibility Policies, Guidelines, and Bylaws
2. Referral from Expeditious Task Force: Increasing Utilization of Virtual Crossmatching

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

1. Update Histocompatibility Policies, Guidelines, and Bylaws

The Chair provided the Committee with an update and overview regarding two projects previously put on hold that focused on updating histocompatibility policies, guidelines, and bylaws.

Presentation Summary:

Background:

- The Committee began a project to update policies/guidance in 2022, put on hold to ensure alignment with CLIA regulations
- The MPSC had a project to update histocompatibility bylaws in 2020, put on hold due to HRSA concerns on pending litigation
- Both projects have drafted language in line with CLIA regulations, and can be combined to be released as a package

Goals of Project:

- Update histocompatibility-related policies, guidelines, and bylaws to ensure they reflect current practices

Summary of discussion:

The Committee did not make any decisions.

Next steps:

The Committee will have draft policy, bylaws, or guidance language to review prior to the next meeting, during which the group will discuss necessary revisions.

2. Referral from Expeditious Task Force: Increasing Utilization of Virtual Crossmatching

The Chair of the Committee led the group in discussion regarding a referral from the Expeditious Task Force to increase virtual crossmatching.

Presentation Summary:

Task Force Referral to the Histocompatibility Committee:

- Recommendation: Develop guidance on virtual crossmatching
- Goal: Increase utilization of virtual crossmatching and spread best practices to increase overall efficiency of transplantation system

Potential Opportunities for Action:

- The Committee could choose to pursue creating an OPTN guidance document that would provide evidence-based recommendation to the community
 - OPTN guidance requires project approval through the Policy Oversight Committee and Executive Committee, as well as public comment and Board approval
- A quicker alternative to spread awareness and gather feedback could be a webinar or educational offering on best practices to increase utilization/efficiency of virtual crossmatching
 - A webinar may include information related to the introduction of virtual crossmatching, data on benefits of virtual crossmatching, waitlist management best practices and scenarios, communications between labs/transplant hospitals, and laboratory tools to utilize

Goals for Discussion:

- Discuss referral from expeditious task force, potential structure of community outreach, and begin outlining/brainstorming content for outreach
- Next steps: begin drafting content for committee review

Summary of discussion:

The Committee did not make any decisions.

During discussions about the incorporating aspects of the current guidance document into a webinar, a member emphasized the necessity of explicitly stating in the presentation that virtual crossmatching does not require involvement from a clinical consultant or technical supervisor. As the intention for the webinar is to offer guidance, the Chair affirmed that while they would share best practices, none of the recommendations would be obligatory for laboratories. Another member echoed the sentiment, underscoring the importance of conveying that the guidance proposed is not a mandatory requirement but rather a collection of recommended best practices.

A member raised the question of whether there was any inclination within the community to eliminate the necessity for a final crossmatch before kidney transplantation, noting the advancements made by laboratories and the community since the inception of this requirement. In response, the Chair pointed out that according to CLIA regulations, this requirement still stands. However, the Chair clarified that despite the current CLIA regulations mandating a final crossmatch, policy language is flexible enough to permit virtual crossmatching as an alternative approach to a physical crossmatch.

A member expressed concerns regarding the shortage of directors available to facilitate virtual crossmatching and inquired if there were any initiatives the OPTN could undertake to address this scarcity. In response, the Chair indicated that such efforts would likely fall beyond the scope of the OPTN's purview. The decision to recruit additional directors would remain within the scope of individual laboratories. He added that since the OPTN wants to advocate for virtual crossmatching and its positive impact on the community, there might be an opportunity to mention how staffing availability could play into virtual crossmatching and allocation.

In the context of a webinar, a participant proposed the inclusion of a segment addressing the challenges associated with physical crossmatching. She highlighted the prevalence of false-positive results in physical crossmatching procedures, emphasizing the significance of this issue.

A participant expressed surprise at the relatively low utilization rate of virtual crossmatching in kidney transplants, noting that only about 38% of transplants utilized this method. He suggested sending a survey to centers to gather more data on their practices and attitudes toward virtual crossmatching. The Chair cautioned against this approach, explaining that surveys involving more than ten respondents require approval from the Office of Management and Budget (OMB), a process that can be lengthy, taking up to a year. However, members pointed out that if the American Society for Histocompatibility and Immunogenetics (ASHI) were to initiate the survey, it would not require OMB approval. The original commenter suggested consulting the ASHI Board of Directors, emphasizing the timeliness of virtual crossmatching and the potential importance of the survey's findings in shaping current practices.

A member brought attention to the positive outcomes associated with virtual crossmatching in transplantation, particularly its role in reducing delayed graft function. He suggested including a question in any potential survey sent to transplant centers, querying whether virtual crossmatching is the default method and if there are preferences for physical crossmatching in certain cases. The member indicated that such information may reveal why some entities do not perform virtual crossmatching.

A member expressed skepticism about the necessity and relevance of conducting a survey, pointing out the considerable variation in practices among different transplant centers and laboratories. She highlighted the diversity of approaches and procedures, suggesting that reaching a consensus within the community on when to utilize virtual crossmatching might be challenging due to these discrepancies. She also pointed out that a survey was not necessary for a webinar, as there is already data supporting the fact that virtual crossmatching increases allocation efficiency.

A group member emphasized the importance of encouraging laboratories to adopt high-resolution donor typing in order to better facilitate virtual crossmatching. While recognizing that the OPTN lacked the ability to mandate such a requirement at this time due to limited testing capabilities at many donor typing labs, the member suggested that promoting this practice could significantly enhance the utilization of virtual crossmatching.

Next steps:

Committee leadership will use the information and input from this meeting's brainstorm to organize a webinar on virtual crossmatching.

Upcoming Meetings

- April 12, 2024
- May 14, 2024

Attendance

- **Committee Members**
 - John Lunz
 - Gerald Morris
 - Caroline Alquist
 - Laurine Bow
 - Amber Carriker
 - Manish Gandhi
 - Andres Jaramillo
 - Marilyn Levi
 - Omar Moussa
 - Darryl Nethercot
 - Heman Parekh
 - Jerome Saltarrelli
 - Crystal Usenko
 - Qingyong Xu
 - Hua Zhu
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
 - Jon Miller
- **UNOS Staff**
 - Courtney Jett
 - Alex Carmack
 - Amelia Devereaux
 - Thomas Dolan
 - Laura Schmitt
 - Susan Tlusty
 - Tamika Watkins