

OPTN Histocompatibility Committee

Meeting Summary

July 11, 2023

Conference Call

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

Introduction

The Histocompatibility Committee (“Committee”) met via Citrix GoToMeeting Teleconference on 07/11/2023 to discuss the following agenda items:

1. CPRA 99-100% Form Data Request
2. Data Related to Critical Discrepancies
3. Remove DSA and Region from Kidney Allocation 2-Year Data Report
4. Reducing HLA Critical Discrepancies Guidance Discussion

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

1. CPRA 99-100% Form Data Request

OPTN contractor staff reviewed the data request that looked at the removal of the form for candidates with a Calculated Panel Reactive Antibody (CPRA) greater than 98%. The data observed all kidney alone registrations added to the OPTN Waiting List between March 15, 2021, and February 28, 2023. Considering implementation of the removal of this form may take about twelve months, the Committee considered whether reminders about un-signed forms needed to be sent out and they discussed what the appropriate timing for such action would be.

Data summary:

Table 1: Time in Days from CPRA >98% to Signatures Received

Number of Registrations	Min	25th %-tile	Median	Mean	75th %-tile	Max
4,070	0	2.07	6.83	20.09	18.92	608.18

Note: This analysis does not account for inactive time.

- About 75% of cases are receiving their signatures within a matter of 20 days
- There are outliers identified beyond the 90-day mark
- Out of the 4,070 registrants, 195 candidates waited, or are waiting, >90 days for these signatures to be completed
- 66 different hospitals had at least one candidate who waited, or are waiting, >90 days for these signatures to be completed

Summary of discussion:

Decision #1: The Committee agreed that it would be beneficial to provide reminders to transplant programs that have outstanding forms past the recommended timeframe.

Decision #2: The Committee did not come to a consensus about a specific timeframe to notify transplant programs but discussed how the 20 to 30-day window may be appropriate.

Decision #3: The Committee did not come to a consensus about referring such cases to the Membership & Professional Standards Committee (MPSC), but they did discuss the possible implications of such action.

Decision #1: The Committee agreed that it would be beneficial to provide reminders to transplant programs that have outstanding forms past the recommended timeframe.

The removal of the CPRA >98% form would require a year-long implementation period. During this time, however, there may be candidates that have incomplete forms for an extensive period, and as a result, a decrease in access to transplant. Therefore, the Committee considered if they should provide outreach to those transplant programs that have outstanding forms. The Committee agreed that it would be beneficial to notify these programs so that they may get their patients up to date.

Even though the OPTN Computer System provides pop-ups that notify users that they have outstanding forms to be completed, individuals may not be looking often enough to see them. Members questioned if OPTN contractor staff had the capacity to provide such outreach. Staff replied that this plan would require a little bit of effort, however, they feel that they have the bandwidth to move forward with it. A Committee member also shared that it may be a good idea to consider an automated system that would automatically ping a program once a set number of days has passed. OPTN contractor staff stated that this is something into which they could look.

Decision #2: The Committee did not come to a consensus about a specific timeframe to notify transplant programs but discussed how the 20 to 30-day window may be appropriate.

Upon discussing the benefits of providing outreach to transplant programs with incomplete forms, the Committee was asked to consider at what time this communication would be appropriate. The Chair had mentioned that, according to the presented data, the median time for the form to be completed was 20 days. He then added that the appropriate timeframe for notification might be between the 20 to 30-day window.

The Committee wants to ensure that candidates have as much access to transplants as possible. Those who are waiting prolonged periods of time to obtain these signatures may be disadvantaged since they will have to wait longer to receive their points. Therefore, a few members suggested that it was important to notify these programs sooner rather than later since potential donors may come between that time period.

Decision #3: The Committee did not come to a consensus about referring such cases to the Membership & Professional Standards Committee (MPSC), but they did discuss the possible implications of such action.

The Committee also discussed whether cases should be referred to the MPSC and when that would happen. The Chair suggested that if the initial outreach to transplant programs remained unaddressed, then a subsequent outreach to the MPSC for further evaluation or action may be meaningful. A Committee member stated that this may be a hard rule to enforce considering that there is no policy that explicitly states a timeline by which transplant programs must complete the forms. This member

adds that the lack of policy to address this would technically mean that transplant programs are not in violation.

2. Data Related to Critical Discrepancies

The Committee reviewed previous data requests about critical discrepancies and considered whether it is appropriate to reach out to labs with high rates of discrepancies to notify them of their cases, if it is appropriate to refer these labs to the MPSC for further review, and at what threshold either of these actions would take place.

Data summary:

- **Counts of Discrepancies**
 - Range: 1-8
 - Mean: 1.9
 - Median: 1
- **Percentages of Discrepancies**
 - Range: 0.1-3.8%
 - Mean: 0.95%
 - Median: 0.55%

Labs with more than 1 discrepancy

Total N donors typed by lab 2022	Total N discrepancies 2022	Percent Total Discrepancies 2022
280	8	2.857142857
487	4	0.821355236
668	4	0.598802395
124	4	3.225806452
344	3	0.872093023
254	3	1.181102362
170	3	1.764705882
140	3	2.142857143
162	3	1.851851852
442	3	0.678733032
353	2	0.566572238
267	2	0.74906367
253	2	0.790513834
278	2	0.71942446
328	2	0.609756098
52	2	3.846153846

Summary of discussion:

Decision #4: The Committee did not come to a consensus regarding what the threshold of critical discrepancies should be to trigger a referral to the MPSC.

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Considering that labs with a high number of discrepancies pose a potential threat to patient safety, the Committee offered ideas regarding a threshold of critical discrepancies that would warrant a referral to the MPSC. The Chair of the Committee shared that he thought that labs with higher typing discrepancies should be passed on to the MPSC or even the MPSC Histocompatibility Subcommittee. In addition, a Committee member stated that it would be important to involve the MPSC in the current conversations to understand what is possible in the context of the OPTN bylaws and rules.

The Committee further discussed whether this threshold should be based on the mean count and mean percentages identified through the data. For example, the group proposed that they could gauge and set their thresholds in line with the mean count of two discrepancies and/or the mean percentage of

about one percent. Some members agree that this approach may work but emphasize that if the threshold is based on frequency or percentage, it would need to be set lower. Critical discrepancies may impact match runs and alter access to certain candidates, so it is important that the threshold be at a lower level.

A Committee member suggested that instead of looking directly at the number of discrepancies, they could review the outcomes of critical discrepancies. These outcomes might include adverse effects on patients or changes in allocation. However, this data is not collected because it is not required to be reported and is therefore not available to the Committee. Another Committee member stated that it may be best to use the word “near miss” instead of “critical discrepancy.” They suggested that changing the wording may encourage a better working relationship between labs and the MPSC. For example, it would encourage proactive monitoring by the MPSC, which may be more effective than retroactive, punitive action.

Finally, the Committee discussed the importance of understanding where these critical discrepancies are taking place. Members share that the group has assumed that the discrepancy has happened at the original typing lab, however, that may not be the case. Therefore, to know where the issues are occurring, it would be important to identify if a typing discrepancy has taken place in the original lab or the confirmatory typing lab.

3. Remove DSA and Region from Kidney Allocation 2-Year Data Report

OPTN contractor staff reviewed the two-year monitoring report for the removal of the Designated Service Area (DSA) and region.

Data summary (as applicable):

Information presented to the Committee reviews the final data report, *Eliminate Use of DSA and Region*.

Main Points:

- There were notable increases in the transplant rate for several subpopulations including:
 - Pediatric candidates
 - Black, Hispanic, and Asian candidates
 - Candidates with a CPRA between 80% and 97%
- Deceased donor kidneys are traveling further, although a majority are staying within 250 NM
- Non-use of kidneys has increased by 4.9% overall
- There has been a notable increase in the median cold ischemic time
- There has been a notable increase in the rate of delayed graft function

Summary of discussion:

Decision #5: The Committee did not have any further discussion and did not make any decisions related to the data review.

4. Reducing HLA Critical Discrepancies Guidance Document

The Chair of the Committee asked members to continue thinking about a proposed Guidance document in which they might be able to incorporate best or better practices to help with reducing critical HLA discrepancies.

The Chair shared that they should consider something that they could submit to the community that would highlight the Committee’s recommendations for better practices. He also said that they would continue discussing this matter in the August meeting.

Summary of discussion:

Decision #6: The Committee did not make any decisions about writing a guidance document but agreed to continue this conversation in future meetings.

Upcoming Meeting(s)

- August 8, 2023, 12 PM ET

Attendance

- **Committee Members**
 - John Lunz
 - Gerald Morris
 - Roshini Abraham
 - Caroline Alquist
 - Laurine Bow
 - Manish Gandhi
 - Lenore Hicks
 - Andres Jaramillo
 - Helene McMurray
 - Omar Moussa
 - Darryl Nethercot
 - Hemant Parekh
 - Crystal Usenko
 - Qingyong Xu
 - Hua Zhu
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Courtney Jett
 - Jenna Reformina
 - Thomas Dolan
 - Krissy Laurie