**OPTN Histocompatibility Committee**
**Donor and Recipient Histocompatibility Forms Review Workgroup**
**Meeting Summary**
**May 16, 2023**
**Conference Call**

## Introduction

The Donor and Recipient Histocompatibility Forms Review Workgroup ("Workgroup") met via Citrix GoToMeeting teleconference on 05/16/2023 to discuss the following agenda items:

1. TIEDI Discrepancy Report

The following is a summary of the Workgroup discussions.

## 1. TIEDI Discrepancy Report

The Workgroup continued their review of the TIEDI discrepancy form from the previous meeting.

Data summary:

Feedback on the forms should be informed by:

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

The current information contained is:

- Donor ID
- Record for HLA typing
- HLA typing result
- Lab Code
- Class I/II test dates
- Reason for discrepancy
- "Discrepancy not resolvable" option (will be removed)
- Due date

Additional information to consider collecting could be:

- Root cause analysis performed?
- Correct action plan implemented?
- Adverse patient safety event?
- Organ allocation impact?

Summary of discussion:

The Chair asked if there were any more information shareable that would not infringe on confidentiality. For example, is there any possibility that it could be mined later and deidentified. Staff clarified that the information gathered would not be provided in the OPTN shared data.

A member wondered if it would be too early to determine any adverse patient effects at the time of reporting. Similarly, the lab completing the form may not have any perspective if the discrepancy impacted allocation. They felt that the lab should know, but in some cases they may not be aware. A second member felt it could be difficult to tie together lab information about discrepancies and transplant program information about outcomes. It was suggested that the question could be rephased to "Rerun match due to discrepancy?" to give the lab clear causality about the result of the discrepancy identification.

A member suggested that the form carry the same information regardless of when it was being completed. If a program discovers the discrepancy during allocation, for example, they may rerun the match, an action only possible if the discrepancy is found during allocation. However, if the same discrepancy is found after allocation, rerunning the match is not possible. One member suggested that the questions could be "was organ allocation impacted at your center?" or "were there adverse patient safety events occurring at your center?". Another member agreed with the point and suggested that they add a question for if another lab contacted them with the discovery of the discrepant typing, since the majority of the times labs discover a discrepant typing when contacted by another lab. The member also suggested asking what the related resolution or corrective actions were.

Staff clarified that the discrepant typings form shows up for every lab involved, and asked if it's a recipient lab if it should ask if there was an adverse patient safety event with the recipient, and if it's a donor typing lab it should ask if there was an organ allocation impact. That way the question would only display for certain labs, specific to what their role in the allocation was. A member clarified that if these questions are in the post-transplant forms, the questions would only be asked if the patient was transplanted. The SRTR representative stated that most of the time the labs aren't aware of errors in HLA typing until a later time, normally from retyping. A member stated that OPTN members are only going to answer these questions after allocation and after transplant if they are in the post-transplant forms, and that they thought we were discussing questions for the OPTN Improving Patient Safety Portal. Staff clarified that these are the questions that are being asked for patient safety after a report through the portal, but it's a manual process right now and the questions are being asked after an event is reported.

A member stated that it can be hard to measure organ allocation impacts in many of these cases, since it will impact who shows up on a match run, and it's not possible for labs to know the full scope of allocation impacts. Staff asked if labs would know if a match run was re-executed due to discrepant typings. A member stated that they wouldn't be aware unless a different patient came up for an offer from that donor, and even then they could assume the center is just dipping further into the list. They stated that they would likely not know if a match run was re-executed, and another two members agreed. Another member stated that if the first patients on a match run are not sensitized there is no direct measure of the impact to a match run. Staff clarified that it sounded like the committee agreed that "impact to allocation" would not be something to consider adding to any forms for labs, since it's not something they would necessarily know.

A member stated that they did like including adverse patient safety event on the forms, and that it's critical information.

One member suggested the inclusion of data on communication to receiving centers. Staff asked if he was suggesting data on communication to transplant hospitals or OPOs? The member clarified that he meant both, and that the lab needs to contact them both quickly. Another member agreed, and added that when the discrepancy was discovered would be important, prior to allocation, after allocation, or after transplant. Staff clarified that right now the only required reporting to the OPTN today is filling out the post-transplant forms. Staff asked if the Committee would want a standardized reporting form that automatically triggers for member reporting, or have people able to create their own if necessary. Staff also clarified that currently the form doesn't trigger for errors corrected between match runs and asked if there was a benefit in having a form for errors that have been corrected before a second match run. A member stated that most of the time for donor discrepancies they find out post-transplant, sometimes as much as a year later when re-typing.

One member asked how other members felt about donor HLA typings uploaded to a donor ID they didn't belong to, stating they felt it would be great for people to know about that. They stated it is a change in the system that you might not see but it's still worth knowing about. They asked if other members felt this applied as a discrepancy.

One member asked for clarification if a lab identifies a discrepancy if they're required to notify the OPO. Staff agreed that this is a policy requirement. The member then asked why people were stating that we don't know about the discrepancy until we receive the recipient post-transplant forms. Staff then clarified that the reporting isn't happening to the OPTN until then. The member said that their techs are immediately reporting the discrepancy to the OPO within an hour of discovery. Staff stated that the forms aren't triggering then, and that the quarterly HLA discrepant typings subcommittee is reviewing the information but not receiving additional data collection on the reasons for the discrepancy, or additional information under discussion, unless the reporting is required through additional system logic or required reporting through the OPTN Improving Patient Safety Portal. The member then asked if the Committee was discussing immediate data collection after the retyping or data collection after the recipient histocompatibility form is submitted. Staff stated that we could update the system logic to trigger a discrepancy form whenever a discrepancy occurs within the system, and that the question to the Committee is if there is a benefit to having a trigger within the system for whenever a discrepancy is detected within the system. The member stated that it's important to have a system where information is disseminated quicky, but that the errors aren't often being detected in the moment of allocation. Another member stated that the post-transplant forms aren't useful for real-time notification and monitoring. Another member asked if there's a redundancy between the different forms, with the patient safety and discrepant HLA typings form. Another member stated that if the data collection is equal then it's just a matter of putting the data in two places, but if it's not you may have a partial story in one and more complete story in another, or two different stories entirely, and asked in that case which one do you believe. He then stated that it might be replication of the data collection. Another member agreed that it seemed duplicative. The SRTR representative stated he didn't think that capturing errors that are corrected before transplant are very useful and would add more complexity. A member stated that over a month later, if there's a simple error that's corrected quickly, the lab might not remember why the error occurred, especially if it was something small like a typo. The member stated that if you catch an error in the moment it should be reported in the moment, and if you catch it post-transplant it should be reported in the post-transplant form.

Staff asked if there is a benefit to have the form separately from any patient safety reporting. A member asked if there is any way in the OPTN Computer System to tell if a file was taken down and a new file uploaded in its place. Staff answered that there is an audit log for that, but that it would be hard to tell systematically how many replaced files were HLA-related, and it would need to be reviewed one by one.

A member stated that if we're going to collect data on discrepancies, we need a way for people to notify in the moment. Staff asked if there was a trigger for the current form so people could create their own form would it fulfill that requirement. A member stated that there's a lack of standardization in the reporting process current, and if we come up with multiple reporting pathways for different situations they're not going to be used. The member felt that we need to improve the post-transplant reporting options and the patient safety portal reporting options, and there shouldn't be a new way to report.

The SRTR representative asked what the member meant by the attached PDF reports. The member clarified that it was just an example of a change to a donor record mid-match run. The SRTR representative stated that the OPO should be auditing PDF attachments. The member stated that they agreed, and the most likely party to be notified first about that issue would likely be the OPO. A member stated that's more of a generalized phenomenon, not restricted to HLA typing, since donors have many source documents uploaded. The member also stated that that can happen with any piece of information that's manually uploaded.

Staff asked if having root cause analysis information for post-transplant forms would be helpful. A member stated that it is helpful, that the members should be performing a root cause analysis, and it should be required to be provided not upon request. Another member agreed, and stated that a root cause analysis can also contain a corrective action plan, notes about adverse patient safety events, and information on impacts to organ allocation.

Staff asked if it would be helpful for labs to be able to see historic discrepant typings reports. Members agreed that they should be able to search those, especially if they need to correct them in the future. One member also stated that it should be clearly visible what personnel entered and edited that data.

Staff stated that members currently have 60 days to report a resolution to the discrepancy, and asked if that timeframe is appropriate. Staff also asked what should trigger review of HLA discrepancies, and if it should just be a quarterly report to the Committee or if they should always review certain types of events like sample switches. A member asked what the consequence of the review would be. They stated that right now it's only to better understand them, and that all critical errors are meaningful to be reviewed in that way. They stated that they would also be in favor of a Membership and Professional Standards Committee (MPSC) review for every critical discrepancy. They also stated that it's likely not an overwhelmingly burdensome number, and that it would hopefully reduce in time, given that they know they will be reviewed and required to provide a root cause analysis, and that there is an API being introduced to help reduce some of these. The member also stated that the Committee shouldn't recommend certain actions to the MPSC, that the outcomes of review should be left to the MPSC. Staff stated that the Committee could provide recommendations and policy on what is a concerning or reportable event, but wouldn't be reviewing individual cases and providing a recommendation on member actions for individual cases.

A member asked if the current definition of critical discrepancy is such that a laboratory should be able to or responsible for submitting a root cause analysis or corrective action plan based on the discrepancy.

The SRTR representative asked if there was a way to obtain data on how many labs are reporting erroneous typings by year, and if labs have a certain number of discrepancies they could be referred to the MPSC for review.

One member asked if there was a perceived transparency issue with only reviewing discrepancies categorized as critical? They stated that it was a question that came up at their regional meeting, for what is critical or not, who determines it, and if it's accurate. Staff stated that critical is current defined as anything that's not equivalent at one or more locus based on the equivalency tables, and that it was put into policy a few years ago and done automatically. They added that this used to have to be hand

sorted because there were a lot of parent and split typings, but that the report has been updated with the equivalency tables logic so it no longer requires the same level of sorting.

One member stated that the 60 day timeframe for resolving discrepancies was born out of requests from the community for additional time, and that it is an appropriate timeframe to resolve a discrepancy. They also clarified that there's separate policy for timeframes to report a discrepancy, but that the resolution may take additional time.

Staff asked if it would be helpful for the discussion about referrals to the MPSC to pull a list of labs with discrepancies in the past few years to see what the spread of discrepancies across labs was. A member agreed, and also stated that in the past the conclusion was that there weren't many repeat offenders. Staff agreed that this was the conclusion the last time the data was reviewed.

Staff asked if there were additional points to consider for the meeting. The SRTR representative stated that the post-transplant histocompatibility forms should be automated using an API. Staff stated that there is currently an API under development for deceased donor HLA typings, but that the Network Operations Oversight Committee (NOOC) has not discussed the post-transplant forms at this point for an API.

**Upcoming Meetings**

- June 20, 2023, 1 PM ET
- July 18, 2023, 1 PM ET

**Attendance**

- **Subcommittee Members**
  - Jerome Saltarrelli
  - John Lunz
  - Kelley Hitchman
  - Laurine Bow
  - Omar Moussa
  - Valia Bravo-Egana
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katherine Audette
  - Rajalingam Raja
- **UNOS Staff**
  - Courtney Jett
  - Laura Schmitt
  - Susan Tlusty
  - Thomas Dolan
- **Other Attendees**
  - Crystal Usenko
  - Hemant Parekh