

**OPTN Histocompatibility Committee
Meeting Summary
April 11, 2023
Chicago, IL**

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

Introduction

The Histocompatibility Committee (“Committee”) met in Chicago, Illinois on 04/11/2023 to discuss the following agenda items:

1. One-Year Monitoring Report: HLA Discrepancies
2. Public Comment Feedback
3. Donor HLA Typing API Update
4. Remove CPRA 99-100% Form
5. Update HLA Tables
6. Virtual Crossmatching Data Collection
7. Molecular ABO

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

1. One-Year Monitoring Report: HLA Discrepancies

The Committee heard a presentation from Staff on the one-year monitoring report for their proposal *Require Notification of HLA Typing Changes*.

Data summary:

On September 1, 2021 the Require Notification of Human Leukocyte Antigen (HLA) Typing Changes policy proposal went into effect. This policy change sets forth the requirements regarding when Organ Procurement Organizations (OPO) and Histocompatibility labs need to provide notification of critical HLA changes. Any time an HLA typing is changed to a non-equivalent value at one or more loci, no matter the cause of the change, a notification as described above is required.

Summary of discussion:

A member noted that, while there seemed to be an increase in efficiency, there was not conclusive evidence about whether this proposal was diminishing the error rate.

A second member asked if the number of matches that are rerun due to changes in HLA typing be calculated pre- and post- policy change. The past Chair pointed out this would only count the changes that are discovered prior to or during allocation. They added that this also was not truly the intent of the policy change.

A member asked why the error rate for HLA entry was marginally higher post policy change. Staff suggested this could be due to the implementation of the data lock policy. The Chair suggested it could also reflect staff not changing homologous typing results which are flagged by the system.

It was suggested that, for the two year monitoring report, staff should identify a metric that is not related to the error rate of HLA entry as that is not the intent of the policy change. It was also suggested that the number of typings that are changed to a higher resolution typing be analyzed.

Next steps:

Staff will incorporate the Committee's feedback into their next monitoring report.

2. Public Comment Feedback

The Chair presented feedback and next steps on the Committee's public comment proposal *Require HLA Confirmatory Typing for Deceased Donors*.

Data summary:

There were significant concerns from members about:

- Increasing costs for HLA typings
- Potential to introduce operational challenges
- Potential need to increase turnaround time for HLA typings
- Increasing processing time may increase organ discard
- Insufficient data to support this level of change

Community feedback recommended additional data sources be reviewed and taken prior to a policy proposal. Additionally, a more granular fiscal impact analysis was requested.

Staff noted that a root cause analysis of the 94 reported critical discrepancies in the patient safety portal would be presented in the Committee's May meeting.

Summary of discussion:

A member asked if there was a way to track discrepancies identified before match runs. Staff replied that that information may be contained within the audit logs from the HLA section of the OPTN Donor Data and Matching System. However, critical discrepancies are only tracked through the patient safety portal, and there is no requirement for reporting.

It was suggested that the discrepancy rate of labs performing confirmatory typing already be compared with those that are not to understand if it makes a difference.

The Vice-Chair proposed that, if this proposal is revisited as a policy requirement, the fiscal analysis include a section that notes some programs are already performing confirmatory typing. In current practice, confirmatory typing is being performed inefficiently because multiple programs may be confirming the original typing without sharing their results. Any future proposal should state that this has the potential to reduce the number of duplicative confirmatory typings performed.

A member suggested that a guidance document be put forward instead of a proposal, and, if data can be gathered which shows that programs are still not performing confirmatory typing, a policy proposal be reconsidered. This would provide a much more data-driven proposal.

A second member felt that there had to be some response to public comment feedback which, in summary, stated that any discrepant typing errors should have a root cause analysis performed. The Chair responded that the basis for a root cause analysis would be the report submitted to the patient

safety portal, which was still voluntary, not a requirement. They noted there could be a spin-off proposal which requires reporting of discrepant typing results, but it would need to be separate from the one that went through public comment. The Chair agreed, however, that there should be a separation of the controversial and non-controversial aspects of the proposal. Multiple members felt there was strong community support for reporting and follow-up action when a discrepancy was found; This action should also specify whether discrepancies are reported to the patient safety portal or directly to the Membership and Professional Standards Committee (MPSC).

The Vice-Chair considered a possible two-pronged approach: 1) reach out to labs to encourage them or provide best practice on using the patient safety portal to report discrepancies; this would inform 2) data analysis on how discrepancies occur and what steps can be taken to prevent them. A member asked if there would be consequences for not self-reporting discrepancies. Staff replied that it would likely have to be a policy proposal and clarified to a second member that the reporting of discrepancies was only required to be reported to the OPO and the transplant program, not the OPTN.

It was suggested there be a differentiation between discrepant typing reports due to clerical errors and discrepancies reported correctly but with incorrect results.

The Committee reviewed proposed solutions:

Multiple testing methods or assays may reduce likelihood of error

A member felt that this would reduce the number of errors due to incorrect results but would not impact the number of errors due to clerical input. Furthermore, this would also not address incorrect typings due to sample switches.

The past-Chair reiterated that there were multiple routes for error, which meant that it was unlikely a single change would address all errors. They suggested the Committee prioritize the ones that would address the most errors first; they also felt this would be a challenging task without adequate data on discrepancies.

Automatic upload for HLA typing

Increase training/QA/QI initiatives

Informatics tools to analyze typing data and identify potential mistypings

Guidance on reducing and resolving HLA discrepancies

The past-Chair stated that part of the issue in addressing critical discrepancies is the lack of actions available to the Committee to investigate the events further. From their perspective, it would make sense for the Committee to be able to follow up with labs that submitted discrepancy reports to determine the root cause of the issue.

A member proposed working with external agencies to potentially gather more data on discrepancies. The vice-Chair agreed but emphasized that there needs to still be consistent reporting practices within the OPTN to ever use the OPTN data. There should be one pathway that gathers discrepancies reported before the match run, during the allocation process, and retrospectively. A member agreed, supporting the idea to allow the Committee to reach out to the program that self-reported the discrepancy. A second member noted there should also be clearly delineated responsibilities for who submits the report.

Staff introduced two options for next steps: The Committee could continue with endorsing the proposal and send it to the Board of Directors for review or retract the proposal and change details that would be outside of the scope of post-public comment changes. The Vice-Chair supported the second option. A

second member agreed but emphasized the need for this type of proposal due to the community's interest in having critical discrepancies reviewed. A third member added that outreach and education should be driven by the Committee in the interim to encourage reporting in the patient safety portal.

A member asked if there were data on whether it was a small number of labs generating the majority of critical discrepancies. Staff replied that there were no major outliers.

It was suggested that the Committee pursue a data collection project to increase the efficacy of root cause analyses. Staff responded that this could be considered during one of the next two meetings as a project.

Next steps:

The Committee will not pursue a policy proposal to go to the Board of Directors for their June 2023 meeting. Staff will provide feedback from the Donor and Recipient Histocompatibility Forms Review Subcommittee at the May meeting to inform what data will and will not be collected. The Committee will also consider the possible new data collection project at their June meeting.

3. Donor HLA Typing API Update

Staff shared an update on the state of API imports into the OPTN Computer System from HLA typing software.

Data summary:

- It is currently possible for donor HLA to be imported
 - The formatting was not designed for labs to use the import
 - Deceased donor HLA submission is slotted for development
 - Currently targeting summer 2023
 - Current system will not be deprecated
 - Planned API will only allow import while donor disposition is open
 - This will also not validate the Donor Histocompatibility Form (DHS)
- Donor HLA retrieval API was released in 2022, but has had limited adoption
 - The lack of high-resolution typing stored in the OPTN Donor Data and Matching System has contributed to the low usage rate

Summary of discussion:

A member asked if the API would be inoperable while ABO verification was pending. Staff replied that they did not believe it to be a requirement, even if it had existed for the donor XML import.

A member inquired if there was potential for OPO donor XML imports to override API driven updates to HLA from labs. Staff responded that it was possible unless the OPO turned off HLA updates. The Chair suggested having a warning that flagged instances where donor XML imports would override existing HLA data. Staff replied that it was possible to include validation checks.

It was noted that there was movement from histocompatibility stakeholders to have a standard data structure for histoinmunogenetics markup language (HML). The Vice-Chair suggested that the OPTN also mirror this format for their API. They added that this would also put pressure on vendors to standardize their formatting. Staff replied that this format could be beneficial; however, it was likely that all the fields in HML would not exist in the OPTN Donor Data and Matching System, so some information from the import would be lost. This could be rectified by future updates, but a "lossy" system was currently the most efficient to produce.

The Chair noted that even after vendors have rolled out compatibility for OPTN APIs, the system's usability needs to be assessed. In some cases, they felt, the vendors produced a functional system, but not a highly usable one.

The Vice-Chair suggested that this API should be accessible to all labs regardless of which vendor they use. Staff responded that the API was agnostic about which program was using it, as it was functionally just a tunnel to provide information. The only difficulty could be in providing the correct import formatting if they are exporting from a non-supported vendor. A member suggested using the XML output from that software and using it to create an HML document. Staff added that if there were questions about the usage of OPTN APIs, support could be reached at APIhelp@unos.org.

A member noted that if there were to be an effort to increase the usage of both the donor HLA import and upload APIs, there would have to be a policy effort to provide high resolution typing within the OPTN Donor Data and Matching System. Additionally, typing products would need to convert resolutions more accurately and understand the limitations of conversion. The Chair noted that this is a current field limitation, as only some typings can be converted to high-resolution typing. They proposed having a field that indicated whether the typing was high-resolution or not.

The Vice-chair stated that high-resolution typing will soon need to be a feature of the OPTN Donor Data and Matching System with the advent of next-generation sequencing HLA typing.

The Chair contributed that some of the reporting will be made easier based on the proposed project to update the HLA equivalency tables.

A member noted that the donor HLA retrieval API should be advertised more, given that both them and their typing software vendor were not aware of its existence.

Staff noted that the unacceptable antigens API took approximately 6 months to see an uptick in use, so they hypothesized that the donor HLA upload would probably share the same lag time. A member added that each API should continue to be advertised due to the low usage rates; they said low usage likely stemmed from either lack of awareness or lack of compatibility with typing software. Staff asked if there were other or better ways to engage with the histocompatibility community. The Chair replied that the Committee was possibly the best way to share or gather information within members' networks.

The Vice-Chair proposed inviting the vendors to a joint meeting with the Committee to discuss the needs of the histocompatibility community and the OPTN. Members could then represent a unified front to the vendors.

Staff stated that there was an effort being undertaken by the Network Oversight and Operations Committee (NOOC) to provide a report of how much traffic is done via API versus how much is done manually. This would enable members to see how much automation their program uses compared to their peers. The Chair endorsed this, noting that they would be interested to see whether the discrepancy rate is lower for programs that have higher automation. The Vice-Chair suggested distributing a survey to histocompatibility lab members asking if they were using the existing APIs, and, if not assessing the barriers to access through a series of standard questions.

Next steps:

Staff will share any updates to the donor HLA upload API to the Committee.

4. POC Update

The Vice-Chair provided an update on the Policy Oversight Committee (POC), its subcommittees, and changes to new project review.

Summary of discussion:

The Chair noted that new projects should be considered like grant writing; the reviewer may or may not have any background in the subject they are reviewing, and the Committee should write accordingly.

Staff inquired if there were post-implementation metrics that should be considered for the upcoming Committee projects. The Chair agreed this was a key area to focus on, especially considering the increased scrutiny from the POC, the likelihood this metric would be evaluated during the monitoring report, and that form change proposals were likely to reoccur within the Committee. Given that the upcoming proposal, *Remove CPRA 99-100% Form*, was unlikely to significantly change number of transplants, they felt that the Committee should consider a metric that reflected on the project's goal to increase efficiency. Staff noted that each form must have a time estimate when submitted to the Office of Management and Budget (OMB); the Committee could propose that the time from registration to priority being granted should shrink by approximately the amount of time the form required.

A member asked if there were a way to accurately capture the amount of time the 99-100% form takes to complete. Staff noted that it could be calculated from the time when a candidate hit the sensitization level to when they are granted priority.

Next steps:

Staff will share the Committee's feedback with the POC. The Committee will consider the new proposed metric at their upcoming meetings.

5. Remove CPRA 99-100% Form

Staff reviewed feedback from the POC and the proposed policy language for their new project *Remove CPRA 99-100% Form*.

Data summary:

This project was approved at the POC meeting on 3/24/23. This project will remove the requirement for a 99-100% CPRA form to be submitted for highly sensitized candidates within that sensitization range.

Summary of discussion:

A member noted there could be significant variance in practice depending on what mean florescent intensity (MFI) level a program reports their candidates' unacceptable antigens at. The Vice-Chair suggested reviewing the percentage of each program's waitlist that was occupied by highly sensitized candidates. However, even if a program were using a lower MFI value to obtain higher waitlist priority, the OPTN has no purview over program-level practice. The Food and Drug Administration (FDA) only requires a minimum MFI value of 500, even though most programs use a higher value for accuracy. The Chair reiterated that the form was intended to provide a level of accountability, but, in agreement with the Vice-Chair, noted that it did not perform the intended task and became a limiter and an administrative burden.

With no further discussion the Committee voted unanimously to approve the policy language to be released for August 2023 public comment (x yes, y no, z abstain).

Next steps:

Staff will update the Committee on public comment feedback once it enters public comment.

6. Update HLA Tables

The Chair provided an overview of the project to update the HLA equivalency tables to match current practice and typing resolution capabilities.

Data summary:

- CIWD 3.0 Definitions:
 - Common: Observed in 1 in 10,000 individuals
 - Intermediate: Observed in 1 in 10,000 to 1 in 100,000 unrelated individuals
 - Well-Defined: Observed in 5+ unrelated individuals
- Historically, the tables have only included high-resolution typing available in assays
- Would it be appropriate to require HLA typing to be reported at the highest unambiguous resolution level known at the time of reporting?
- Two possible solutions for the update:
 - Use the CIWD 3.0 Definitions
 - Use the IMGT/HLA and CIWD 3.0 with P groups

Summary of discussion:

The Vice-Chair voiced support for a system that can be easily updated given the constant updates to the CIWD 3.0 tables. The Chair agreed, adding that the system also needs to be comprehensive enough to account for rare alleles given that ABDR will be used to assign points in continuous distribution.

The Vice-Chair supported using P-groups as the basis for the equivalency tables, as high-resolution typing can be folded into the P-group, and P-groups can be folded easily into the serologic equivalencies. This allows all levels of unacceptable antigen reporting (high resolution, P-group, or serologic) to be captured within the system. A member agreed that the Committee should aspire to reach this level eventually, but the community may not be ready to use the CIWD framework. They noted that some programs would not meet the resolution bar outlined within CIWD and most vendors are not analyzing alleles with the CIWD three bar framework. They endorsed just using P-groups rather than in combination with CIWD 3.0.

A member asked if this would require all labs to achieve two field typing. The Chair clarified that there would be a hybrid period in which some programs are still inputting serologic equivalencies.

A second member proposed adding a third digit option. They felt this would be clinically relevant in instances where the antigen is outside the antigen recognition domains. The Vice-Chair rebutted that they felt the P-groups were an intermediary step that did not require high resolution typing from all users but still provided more clarity than serologic equivalents. This would provide an adequate format for the vast range of typings to be folded down to antibody reactivity.

The Vice-Chair added that there were two problems to consider with high resolution typing in the OPTN Computer System. First, that the CIWD tables were constantly updating, which therefore meant that the typing for patients would also be slightly changing, and second, that there is no groundwork in the OPTN Computer System to capture high resolution typing and boil it down to antibody reactivity. Staff noted that P-group conversion from the current tables would be slightly easier than using CIWD 3.0 as the base.

Staff asked if the Committee would prefer having all of the alleles in the P-groups incorporated or have only one field P-groups. The Vice-Chair preferred having all alleles in the P-groups incorporated, especially if that process can be automated from an import. They also felt that it would be important to show the equivalents rather than have them be automatically converted. This would allow each lab to

determine whether equivalencies can be drawn based on the resolution of the typing. Furthermore, the Chair added that it would make explaining equivalent typings more accessible to clinicians. They suggested building out the DR logic and then applying the same to A and B. The Vice-Chair supported this, noting that DR had fewer groups than B.

Staff asked how the Committee should approach alleles that are in the same P-group but are not equivalent; in essence, what resolution should the system operate at. The Vice-Chair felt that, because all policies were built around serologic antigen matching, the system should operate at the serologic antigen level. However, it could also be possible, depending on how much high-resolution typing is being input, to change the policy references to refer to the high-resolution typing results rather than the serologic antigen. The Vice-Chair restated that there needs to be data collection on allele level typing to better understand the impact of specific alleles post-transplant. The Chair added that the OPTN Computer System was not designed to handle this much information as it was based on the histocompatibility needs from 15 years ago.

A member asked if labs would still be able to exclude specific species from the larger antigen subgroups. The Chair replied that it would have to remain based on non-equivalent antigen species that exist at an allele level. If the OPTN Computer System remains based at the antigen level, allele level exclusions are necessary.

Staff asked how best to display the equivalency tables within policy. The Vice-Chair responded that, if policy were to contain all the equivalency tables, it would be hundreds of pages. The Chair rebutted, noting that the function of equivalency tables was to ensure that unexpected equivalencies were documented. It may be more confusing for the community to have to interpret the “normal” rules within policy and then have to search for exceptions. Staff added that it could be beneficial for patient safety to provide all labs with the same equivalency tables.

Next steps:

Staff will proceed with the Committee’s decision to incorporate two field IMGT/HLA P-groups and provide a mockup of how this looks at their next meeting.

7. Virtual Crossmatching Data Collection

Staff presented on the Committee’s project to collect virtual crossmatching data. These data would evaluate the safety, efficacy, and efficiency of virtual crossmatching as a form of immunological assessment.

Data summary:

- Current crossmatching data collection is limited to physical crossmatching
 - These data also track if the crossmatch was prospective to transplant
- The Committee is considering adding virtual crossmatching data elements
 - Virtual crossmatch performed (y/n)
 - Predicted physical crossmatch (positive/negative)
 - At which loci were donor specific antibodies (DSA) detected

Summary of discussion:

The Chair noted these data would be beneficial for future analyses.

A member asked if there would be benefit to gathering data on instances when the virtual crossmatch was negative, but the physical was inconsistent with that result. A member felt that may be too much of a reach for the current state of virtual crossmatching data collection.

A second member proposed adding a field to track the result of the physical crossmatch. This would allow the committee to analyze how many candidates are transplanted against a crossmatch. The Vice-Chair replied there would be no good denominator for that analysis, as it would only be tracking the positive crossmatches that did proceed to transplant. They agreed that, from a data collection standpoint, it would be an interesting analysis, but the data collected may skew the results. Another member added that, if this were added, there should also be a “rationale” field to capture why the lab had inconsistent results. They noted that many inconsistent results would likely be due to the drug the candidate was on. Multiple members agreed that there should be a field to note any drugs that the candidate is on that could alter their crossmatch results.

It was noted by a member that there may be instances in which a lab does not know whether the crossmatch results were returned to the transplant program prior to transplant. They suggested the question should be phrased as “was the decision to transplant based on the results of a virtual crossmatch?”. The Vice-Chair agreed and clarified that the question should be interpreted as whether the virtual crossmatch or the operating room timing was scheduled first; they also added that OPTN policy requires documentation of an immunologic assessment to have taken place prior to transplant.

The Vice-Chair stated that they felt OPTN policy was somewhat vague around what immunologic assessment entailed. There was a difference, they felt, between informing the transplanting surgeon about DSA than writing a note in the candidate’s chart assessing their medical suitability. Policy does not outline what this assessment needs to be. Furthermore, there should be differentiation between virtual crossmatches followed by a physical crossmatch and virtual crossmatches used to inform transplant. A member proposed “final immunological assessment” for crossmatches used to inform transplant. This would also open the door to creating a billable code to differentiate between crossmatching and a final immunological assessment. The Vice-Chair suggested “crossmatching” and “final histocompatibility assessment”.

A member asked how beneficial information on predicted physical crossmatch results would be. The Vice-Chair replied that this could drive analyses on how center practice impacts outcomes, which in turn could inform policy. Staff noted that it was outside the purview of the OPTN to collect data for research purposes only. The Chair asked the Committee whether this question should be maintained. A member noted that there could be different responses from different programs depending on how they defined a positive crossmatch. In addition, the impact of collecting this new virtual crossmatching data could be influenced by whether the anticipated crossmatch result is positive or negative; this is not a research endeavor, as it will help develop guidance on risk tolerant practices. The Vice-Chair responded that there likely are too many variables in an assessment of post-transplant outcomes to ascribe causality to crossmatching results. Furthermore, there will still be no denominator of candidates that did not proceed to transplant based on positive crossmatching results. A member rebutted that this would be captured on a match run of candidates that are coded out on due to positive crossmatching results. The Chair responded that the key question the Committee was trying to answer with this question was if kidneys transplanted on only a virtual crossmatching result had better, worse, or indeterminate outcomes when compared to kidneys transplanted off physical crossmatches. Staff contributed that positive virtual crossmatch made up .18% of all refusal code usage, whereas positive physical crossmatch was .06%.

It was asked whether it was expressly prohibited to proceed to the operating room with only a virtual crossmatch. The Vice-Chair restated that the only requirement in policy was to have assessed the histocompatibility of the donor and recipient. There are no further stipulations upon how this is to be performed, and the Centers for Medicare and Medicaid (CMS) have not passed judgement on whether that assessment needs to be based off a physical result.

Another member proposed adding MFI value to be captured alongside crossmatching results. Because of the wide variance in practice and MFI values, they felt that drawing conclusions from the crossmatching results would be difficult without knowing what MFI value was used.

Next steps:

Staff will develop a mockup of the virtual crossmatching data collection based on the Committee's feedback.

8. Molecular ABO

The Committee examined a report published in the January 2023 edition of the American Journal of Transplantation (AJT) on ABO genotyping.

Data summary:

The study found that 65% fewer donors were identified as non-A1 by lectin testing than through molecular testing. This would increase the availability of donors for B blood type patients.

Following a meeting with Operations & Safety leadership, they recommended 1) a guidance document on current testing limitations and 2) data collection on molecular testing usage for potential policy work and discrepancy monitoring.

Joseph et al, Jan 2023 AJT, "ABO Genotyping..."

- **Group 1: 554 group A Deceased Donors**
 - 65% more A2 donors identified with molecular ABO than lectin testing (n=47 different/119 total A2)
 - 40% (n=48/119) determined to be A2 by genotyping had weak or strong lectin reactivity
- **Group 2: 210 Group A Living Donors**
 - 22% more A2 donors identified with molecular ABO than lectin testing (n=46 different/208 total A2)
 - 18% (n=38/208) determined to be A2 by genotyping had weak or strong lectin reactivity
- **Group 3: 124 Unclear Lectin Tests (weak or conflicting) sent to reference lab**
 - 82% found to be A2 by genotyping
- **Discordances found due to transfusion, variability in A antigen levels, and rare A2 sequences**

Summary of discussion:

A member asked if any donors in the cohort were transplanted into non-A1 individuals. They wondered if the significance of a weak positive via lectin test could have clinical relevance. The Vice-Chair did not remember if there was a section in the article on transplanted donors. They felt that the clinical relevance of weak positives in lectin testing could be documented in transfusion reports, rather than transplant reports. Furthermore, this was partly why the Committee should begin with a guidance document to garner feedback on where this subtyping nuance could have applications.

A member felt that it could be overstepping to create a guidance document on molecular ABO typing because the tests were not FDA approved. In addition, there is no data collection on the recipient side to determine whether there are similar nuances to subtypings. This lack of recipient data could lead to variability in their immune responses that would not be captured in any analyses. They also wondered if transfusion publications would contain the information that was brought up, noting that they traditionally only cared about the blood type. Finally, each center's practice would change how the titers

were captured. The Vice-Chair replied that the practice issue should be considered separately from the testing issue. Molecular testing also does not need to be completed at each lab; based on the newness of the technology, only some programs need to use it to evaluate its efficacy.

A member supported the stepwise approach to molecular typing, paralleling it to the development of the histocompatibility field which pursued progress in similarly small steps.

A second member asked if this fell under transfusion support per the FDA. The Vice-Chair replied that the Institutional Review Board (IRB) classified it as transfusion support but felt it was more closely aligned with transplantation support because it was being used specifically for transplantation.

The Chair said this could be used as a preliminary screening method for A subtyping while also using a lectin test. Furthermore, molecular typing allows labs to do HLA typing and ABO typing at the same time off the same sample, which improves the overall time required to evaluate a donor's histocompatibility.

Staff asked if the subtyping requirements for deceased donors following a transfusion should be applied to buckle swap samples for molecular typing. Members felt that the question should be addressed when writing the guidance document, as there would be more time for literature to be published on molecular typing.

Staff asked what data collection would be beneficial to support this project. The Vice-Chair suggested sample type, between buckle swap or peripheral blood draw. A second member suggested assessing whether typing was done with molecular or serologic methods. Staff clarified that current policy only allows serologic testing and proposed a revision to asking if molecular typing was done.

A member inquired if the paper addressed B blood group subtypes or variants. The Vice-Chair replied it was not addressed in the paper. However, from the blood group database, there is not much variability in that blood group. Staff also noted that type B was expressly addressed in the paper because of the equity issues in blood type B being the rarest blood type.

It was noted that, though there may not be much data collection on molecular typing in the OPTN Computer System, other sources could be used to inform the guidance document, such as recent literature, New Mexico Donor Project (NMDP), or the National Kidney Registry (NKR). A member felt that much of the NMDP data was based off molecular typing, as they had asked contracted labs to use only next generation sequencing methods.

Next steps:

Staff will compile the Committee recommendations and proceed with a guidance document project as the next step for molecular typing.

Upcoming Meeting

- May 9, 2023

Attendance

- **Committee Members**
 - John Lunz
 - Gerry Morris
 - Amber Carriker
 - Hua Zhu
 - Manish Gandhi
 - Marcelo Pando
 - Valia Bravo-Egana
 - Rajalingam Raja
 - Caroline Alquist
 - Laurine Bow
 - Yvette Chapman
 - William Goggins
 - Lenore Hicks
 - Reut Hod Dvorai
 - Andres Jamarillo
 - Peter Lalli
 - Omar Moussa
 - Manu Varma
 - Phyllis Weech
 - Qingyong Xu
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katherine Audette
- **UNOS Staff**
 - Alex Carmack
 - Betsy Gans
 - Carson Yost
 - Courtney Jett
 - Debra Vicars
 - Isaac Hager
 - Roger Brown
 - Sarah Scott
 - Stryker-Ann Vosteen
 - Susan Tlusty
 - Thomas Dolan