

**OPTN/UNOS Histocompatibility Committee  
Meeting Minutes  
March 13, 2018  
Chicago, IL**

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**Introduction**

The Histocompatibility Committee met in Chicago, Illinois, on 03/13/2018 to discuss the following agenda items:

1. Ad Hoc Geography Committee Update
2. Public Comment Presentations: OPTN/UNOS Strategic Plan 2018-2021 and Improving Committee Structure
3. Addressing HLA Typing Errors Project
4. UNOS Education Series Update
5. DR Priority Points and Improving Access for Pediatric & Highly Sensitized Kidney Candidates Kidney Project Discussion
6. Change CPRA Calculation Project
7. Deceased Donor Chains Workgroup Update
8. Membership Bylaws Discussion

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

**1. Ad Hoc Geography Committee Update**

Summary of discussion:

UNOS staff presented an update on recent work done by the Ad Hoc Geography Committee. One of the Committee members said it is important for the Geography Committee to address geographical disparities and they should incorporate community feedback into any final decisions by the Committee; the Committee member used the recent liver allocation changes as an example of when the community recently had a lot of feedback related to geography. Another Committee member asked for clarification on whether the purpose of the Geography Committee was to potentially redraw donor service areas or to develop principles that look at geography in terms of allocation. UNOS staff confirmed that the Committee was tasked with establishing principles for committees to use when developing allocation policies and not to necessarily do away with all geographical considerations that may impact allocation. UNOS staff reiterated that the goals of the Geography Committee were more high level, and they would not be telling each organ specific committee how to allocate organs.

Next steps:

The Committee will hear updates as the Ad Hoc Geography Committee continues to meet as necessary. Once the Ad Hoc Geography Committee develops principles, the Histocompatibility Committee may work with the Kidney Committee to address the principles if HLA is a consideration.

## **2. Public Comment Presentations: OPTN/UNOS Strategic Plan 2018-2021 and Improving Committee Structure**

### Summary of discussion:

The Committee heard two public comment proposal presentations sponsored by the Executive Committee: the OPTN/UNOS Strategic Plan 2018-2021 and Improving Committee Structure proposals.

#### *OPTN/UNOS Strategic Plan 2018-2021*

The Committee was generally in favor of the proposal, but had several key concerns with the proposed alignment. The Committee was concerned with taking away 5% from current Goal 3: Improve waitlisted patient, living donor, and transplant recipient outcomes. The Committee previously had project ideas put on hold due to over-allocation in this goal, so there was concern that taking away resources from this goal will disadvantage project work. While the Committee agrees that increasing the number of transplants is important, they also expressed that projects to improve outcomes are also important as they may lead to fewer re-transplants and then organs could go to more people. Another concern was that the alignment was changed three years ago so that may not be enough time to measure trends that justify changing the benchmarks again. The Committee suggested reexamining the benchmarks.

#### *Improving Committee Structure*

The Committee shared similar concerns to other committees about the proposed concept; specifically, the Committee was concerned that committees are already overloaded with project work and it would be difficult to balance committee proposals with proposals that come through the expert councils. Additionally, the Committee was concerned that the proposed structure would create tension between the subject committees and expert councils when the expert councils propose an idea that is triaged to a committee that may not share the expert council's views on the urgency for the project. The Committee agreed that there should be an effort made to better engage members and involve them in the policy development process. There were additional financial concerns about the amount of resources needed to run the proposed committee structure. Instead, the Committee suggested increasing member/community engagement by better utilizing the regional representatives and improving the communication amongst and between regions.

## **3. Addressing HLA Typing Errors Project**

### Summary of discussion:

UNOS staff reviewed recent work done on this project by the Discrepant HLA Typing Subcommittee. The Committee heard information from UNOS Research staff on a recent data request that identified the affiliation of members entering discrepant HLA typing information into UNet<sup>SM</sup> between January and June 2017. Of the 64 discrepant entries, 47 (or 73.4%) were made by a lab member, 13 (or 20.3%) were made by an OPO member, and 4 (6.2%) were made by both members. Committee members were interested in these results, and found the information useful for future member education. The Committee reviewed the draft survey created to send out to laboratories to better understand center practices when entering and reviewing HLA information. The purpose of this survey is to gather information that is not captured by current OPTN data.

UNOS IT staff presented several IT options that the Committee had previously explored in order to make sure the IT plan had not changed since it was last discussed. The Committee agreed that the IT solution they would propose during public comment would be double entry of HLA data by the same person, as well as locking down the Crossmatch and HLA tab in UNet after

HLA data is entered. The double entry would require one person to enter the HLA information, “submit” it, and then re-enter the information again on a new screen (i.e. user would not be able to see first set of HLA entered). If there was a discrepancy between the first set of data and the second, a message would appear to show the user which data did not match. The user could then fix the discrepancy. The Committee discussed the merits of the double entry by the same person vs. two people. Namely, the Committee did not want to create an extra burden on smaller centers with fewer staff, and also wanted to accommodate HLA data being entered after hours when only one person may be available. The Committee asked UNOS IT staff if they could see a mockup of what this may look like in UNet. UNOS IT staff agreed to create and present a mockup at a later Committee meeting.

The Committee then discussed the idea of mandating raw HLA data uploads in UNet. Committee members find these attachments that contain the raw HLA data useful for confirming HLA typing by other centers. This could help labs identify discrepancies if they got different HLA information from their own tests. Since labs and transplant centers may have different MFI levels used to determine which antigens to report, the labs would also be able to use the raw data uploads to better understand the HLA data entered into UNet. This could improve efficiency and make resolving discrepancies easier for members. A Committee member asked if there was any precedent in policy for mandating uploads. UNOS staff will review policy for any possible examples and use that as a possible model for this project. Another Committee member mentioned other types of existing source documentation used for ABO. The Committee generally agreed that if these other policies already existed, it may be beneficial to create the mandating raw uploads piece to mirror that language.

Next steps:

The Committee will continue to discuss the implications of mandating raw data uploads on the next full committee call. UNOS staff will review policy and present possible options for how to incorporate this language into policy. The Committee will also finalize the survey.

#### **4. UNOS Education Series Update**

Summary of discussion:

The Committee heard an update on the UNOS Histocompatibility Education Series. There are currently three learning modules available on UNOS Connect: Predicting the Future by Virtual Crossmatch, Let’s Talk HLA, and The Basics of Immunology. The next modules in development discuss different types of testing methods. Another future offering will share the impact of HLA on non-lab transplant professionals’ jobs, such as transplant coordinators and nurses.

Next steps:

The Committee will continue to hear updates on the education series as needed.

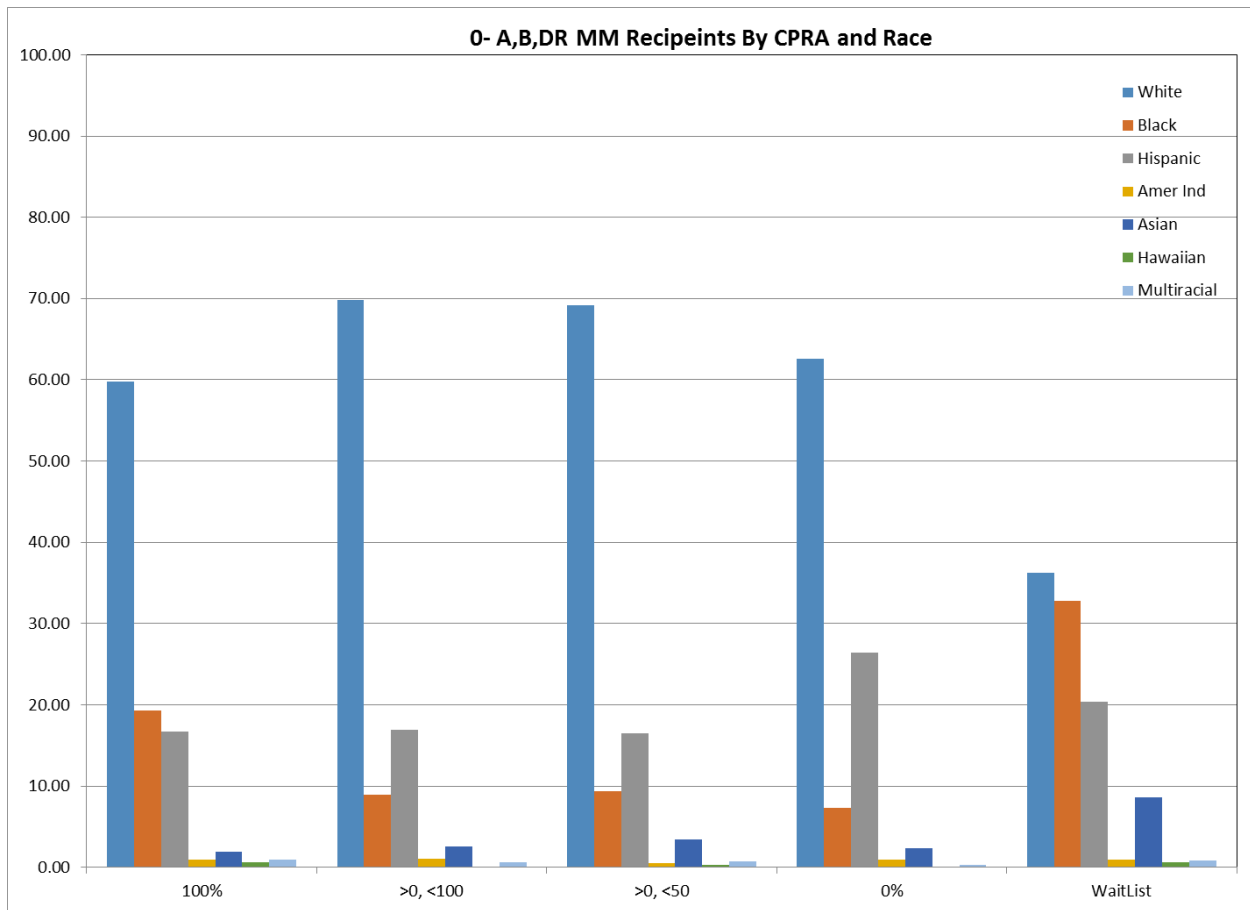
#### **5. DR Priority Points and Improving Access for Pediatric & Highly Sensitized Kidney Candidates Kidney Project Comment Discussion**

Summary of discussion:

The Committee heard an update about a newly approved project sponsored by the Kidney Committee. This project addresses several parts of the kidney allocation system (KAS), focusing on access for pediatric candidates and highly sensitized candidates. The Kidney Committee identified the need to include the Histocompatibility Committee during project development, and will have several Histocompatibility Committee members participate in a workgroup focusing on the highly sensitized portion of the project.

The Committee then reviewed a previous project idea that would reexamine the priority points for 0-ABDR candidates. This project idea came from research suggesting that graft survival outcomes are improved by have zero HLA-DR mismatches, and not A or B. The Committee reviewed data that showed that the current 0-ABDR priority points also largely advantage white candidates at every CPRA level (Figure 1). A Committee member shared information that the number of 0-ABDR transplants has gone down since the new KAS was implemented. They also shared that changing the allocation points to only DR mismatches could improve candidate outcomes and possibly help reduce the racial disparity.

**Figure 1: 0-ABDR Mismatch Recipients by CPRA and Race**



The Committee was generally in favor of pursuing this project idea again; the project had been put on hold in 2015 when the project portfolio was realigned. Committee members shared that the impact of DR on transplant outcomes is a timely topic in the community.

UNOS staff questioned whether pursuing the DR project idea at this time would be impacted by the Kidney Committee project, since both affect allocation and could make modelling difficult. This will be a consideration as the project idea continues to be developed. The Committee agreed to get data on the graft failure rates when DR mismatches are lower for adults and pediatrics. The Committee also requested additional data on 0-ABDR transplants. UNOS staff will develop the data request with committee leadership following the meeting.

## **6. Change CPRA Calculation Project**

The Change CPRA Calculation project was recently approved by the Executive Committee in February 2018.

### Summary of discussion:

The Committee discussed what data was needed to pursue this project. The discussion focused on a recent presentation to the Committee from a member of the group that created a CPRA calculator using allele level data from the National Marrow Donor Program (NMDP). The Committee developed questions to bring back to the group involved in the creation of this NMDP CPRA calculator. Since the genesis of this project was to incorporate other HLA loci that are not currently captured in the calculation (such as HLA-DPB1), the Committee decided a count based model would more easily incorporate these loci and be easy to update on a regular basis. Additionally, it would also make calculating a CPRA value much easier for members and also be easily interpretable by the community.

Because the Committee originally agreed that there were many merits to a count based approach, they discussed asking the NMDP calculator group if they could alter the programming of the calculator to be count based instead of haplotype based, which it was when it was presented to the Committee in February. One member of the group who was able to join via teleconference said this should be possible and would bring this feedback to the group. Given the computational model, the donor count method should be able to be developed though it may take some time to develop. The Committee also discussed any benefits of the haplotype model that would not be captured by the donor count model. Committee members agreed that the haplotype model would be unable to incorporate DP antigens accurately due to poor linkage with DP. The group member articulated that the NMDP had seen success using the haplotype approach with DP, and would follow up with the group to share that data with the Committee. One Committee member noted that if the data showed the NMDP was able to “solve” for the poor DP linkage, the Committee may be more inclined to continue with the haplotype model.

One Committee member shared that the haplotype model used to create the current OPTN CPRA calculation was a product of the time, and as the field developed it could not accommodate new HLA discoveries. The Committee member continued that the donor count model appears to be more dynamic and easily updateable in the future, but advised the Committee to consider future adaptability for all models as much as possible.

### Next steps:

The Committee will send their questions about the NMDP calculator to the group for review.

## **7. Deceased Donor Chains Workgroup Update**

During the October 2017 in person meeting, the Committee heard an update from UNOS staff on the status of the Allowing Deceased Donor Chains in the OPTN KPD Pilot Program project. UNOS staff shared information about the Deceased Donor Chains Workgroup for this project, and the Histocompatibility Committee wanted a member from the Committee on this workgroup.

### Summary of discussion:

The Histocompatibility Committee member on the Deceased Donor Chains Workgroup presented a brief update on recent work done by the workgroup. The Committee member shared the charge of the workgroup, and next steps that the workgroup will take based on recent discussions which include identifying parameters for whichever model they decide on, continue to discuss optimization analysis with the SRTR that will help define constraints and effects of the change on the current system, and then send out a concept paper for more community feedback.

### Next steps:

The Committee will continue to hear updates on workgroup progress as necessary.

## **8. Membership Bylaws Discussion**

The Committee previously identified several parts of Appendix C: Membership Requirements for Histocompatibility Laboratories that could benefit from clarification or removal.

### Summary of discussion:

The Committee discussed the parts of Appendix C that they wanted to consider changing as part of a Bylaws cleanup project. These bylaws were either identified by the Committee from member experiences, referred to the Committee through memos from the MPSC, or identified by UNOS staff:

- Change Vice Chair Election Process
  - This action would align the vice chair nomination process with other committees to make the process standardized and more efficient.
- Define length of time a lab director can be out of practice and then return to practice
  - This is defined in the ASHI regulations but not UNOS bylaws, and the Committee previously expressed interest in aligning the UNOS bylaws with ASHI regulations.
- Clarify technologist vs. technician
  - The MPSC sent the Committee a memo in 2017 asking for clarification on responsibilities of histocompatibility technicians vs. technologists. Appendix C contains a definition for a histocompatibility technician, but this position is not mentioned elsewhere in the bylaws. The MPSC suggested that the Committee review the bylaws and ensure that the appropriate positions are listed accurately.
- Clarify what needs to be reported when there is a change in laboratory personnel
  - Committee members have reported the burden associated with reporting changes in key laboratory personnel to UNOS. When a couple of members had changes in key personnel, they were made to submit records of all laboratory personnel in addition to the change in key personnel. Members felt this was burdensome and took time to track down updated all employees of the lab when the only change was in key personnel. Members are interested in exploring ways to clarify this policy to make it so only the key personnel changes are reported and not all lab personnel.

### Next steps:

The Committee agreed that this project idea was important and would take limited resources to make a sizable impact on laboratory requirements. The Committee will create a subcommittee to address these issues, and plan to bring the project idea to the POC soon.

## **Upcoming Meeting**

- April 11, 2018

## Attendance

- **Committee Members**
  - Robert Bray
  - Cathi Murphey
  - Adam Bingaman
  - Laurine Bow
  - Cathy Gebhart
  - Steven Geier
  - Chantale Lacelle
  - Peter Lalli
  - Mayra Lopez-Cepero
  - John Lunz
  - Gabriel Maine
  - Allen Norin
  - Rajalingam Raja
  - Carley Shaut
  - Craig Van De Walker
- **HRSA Representatives**
  - Joyce Hager
- **SRTR Staff**
  - Katie Audette
  - Howie Gebel
- **OPTN/UNOS Staff**
  - Alison Wilhelm
  - Ronald Brown
  - Betsy Gans
  - Casey Humphries
  - Erica Inge
  - Emily Kneipp
  - Anna Kucheryavaya
  - Elizabeth Miller
  - Liz Robbins Callahan
  - Chad Southward
  - Kimberly Taylor
- **Other Attendees**
  - Evan Kransdorf
  - Marcelo Pando Rigal