OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
September 23, 2022
Chicago, Illinois

Zoe Stewart Lewis, M.D., Chair
Scott Lindberg, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) virtually via Citrix GoToTraining in open and closed session on September 23, 2022. The following agenda items were discussed during the meeting:

1. OPTN Histocompatibility Committee Referral: Require Confirmatory Human Leukocyte Antigen (HLA) Typing for Deceased Donors
2. Continuous Distribution
3. Redefining Provisional Yes and the Approach to Organ Offers
4. Optimizing Usage of Kidney Offer Filters
5. Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations,
6. Apply Transplant Notification Requirements for VCA Program Inactivation

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

1. OPTN Histocompatibility Committee Referral: Require Confirmatory Human Leukocyte Antigen (HLA) Typing for Deceased Donors

The OPTN Histocompatibility (Histo) Committee Chair presented their project to require confirmatory HLA typing for deceased donors based on information the Histo Committee has received from the community to solicit feedback from the MPSC. There is a concern that there is a lack of required redundant HLA typing comparable to ABO typing. HLA and ABO typing are both critical to determine patient/donor compatibility. Inclusion of incorrect HLA typing during a match run may mean that offers are given to patients who are highly sensitized against the donor. The recommended steps to mitigate risk are to increase safeguards to ensure correct HLA typing by requiring some redundancy in the OPTN Donor Data and Matching System for collecting HLA typing and a requirement in OPTN Policy for redundant HLA typing. The Histo Committee feels that the critical discrepancies shown by the data can be overcome by redundant HLA typing requirements.

The Histo Committee recommends that deceased donors have two HLA samples run, drawn at two separate times, similarly to ABO typing requirements. Both of the samples should be typed at a molecular level for all loci and would require raw HLA typing data be uploaded for both samples in the OPTN Donor Data and Matching System attachments.

Summary of discussion:

A Committee member asked if this would increase the cost and does the data show if the discrepant typing are happening when the samples are collected. The presenter noted that it is difficult to determine when and where the discrepancies are occurring because they themselves are not present in the labs when they occur. That said, the discrepancies could be clerical or sample errors, but the data provides insight into the potential for sample switching or interpretive errors that the Histo Committee hopes will be alleviated by redundant HLA typing. The presenter added that there are known cases where the HLA typing has been repeated and the match run has been performed again, which may mean that the lab may have recognized an error such as sample switching.

A Committee member asked if a discrepancy occurred, based on what the Histo Committee is proposing how would it be resolved in a timely fashion. The presenter explained that current policy states that HLA laboratories should have a mechanism where they resolve any discrepancies that are discovered and the expectation is that they should be able to resolve the discrepancy depending on where the error occurred (i.e. redrawing a sample). The presenter added that this question gets to the crux of why they are pursuing this change because the intent is to identify any discrepancy at the beginning of the organ allocation process so they can be resolved before it is a patient safety issue.

The Committee member also asked if there are certain labs where these discrepancies are happening more frequently or if they are more random events. The presenter said they have not been able to identify specific laboratories that have had difficulties with this process through their quarterly reviews, and noted that if a trend with a member was identified they would refer the member to the MPSC.

A Committee member asked about HLA performed off of lymph node samples and if that could be paired with typing done off of a blood draw sample. The presenter explained that the Histo Committee has considered guidance for using two sample types and while two types of samples may be a best practice, it was recognized that not all organ procurement organizations (OPOs) have the opportunity to collect two types of samples and that for certain types of donors the lymph node collection would occur post-match run so the Histo Committee wanted to leave that option up to the member's discretion as to be not overly restrictive.

A Committee member asked if there were operational considerations from a HLA laboratory standpoint because while this is being compared to ABO typing, HLA typing is more complicated and technical. The presenter explained that the Histo Committee reviewed processes and methodology in place and came to the conclusion that with the current methods being used (i.e. real-time polymerase chain reaction (PCR)) the two samples could be analyzed simultaneously or in quick succession within the timeframe that they are needed.

2. Continuous Distribution

UNOS Staff presented an overview of Continuous Distribution, highlighting areas that may affect the MPSC. Continuous Distribution is a shift in allocation from a classification based system to a points based system for all candidates. While each organ will have the same high level goals, the attributes within each goal may be different (i.e. utilization of post-transplant survival or candidate size).

Immediate benefits of Continuous Distribution have already been identified in the pre-implementation modeling for lung, including a one third drop in waitlist mortality. Continuous Distribution also means smarter distribution, which means that organs are only traveling further distances for the most urgent candidates.

To develop Continuous Distribution for each organ, community input is being used through each phase of development to inform evidence-based rules for the new system, including a partnership with the

Massachusetts Institute of Technology (MIT) to utilize artificial intelligence to simulate thousands of match runs to see how different scenarios compare to each other.

Currently, *Establish Continuous Distribution of Lungs* has been approved by the OPTN Board of Directors and will be implemented early 2023, the OPTN Kidney and Pancreas Transplantation Committees and the OPTN Liver and Intestinal Organ Transplantation Committee have concept papers out for this public comment cycle, and the OPTN Heart Transplantation Committee has begun work on its Continuous Distribution framework.

Summary of discussion:

A Committee member noted that the ideas behind Continuous Distribution are great, but one downfall is the use of nautical miles (NM) and asked if moving away from NM and using population density was considered. The presenter acknowledged that it is not the same in every area of the country, and that many options were considered but with the data that is currently available, the decision was made to move forward with miles to be re-evaluated in the future. Scientific Registry of Transplant Recipients (SRTR) staff noted that the member brought up a valid point, and that the complexity of a match run with acuity circles have been felt harder in certain areas of the country and it supported looking into other possibilities than NM with modeling such as the work being done by MIT.

The presenter also noted that the Committees have been considering the current impacts of organs allocated out of sequence and this is a topic that the groups working on Continuous Distribution have been considering in their discussions. When discussing smart distribution, how can it be ensured that organ offers are made to programs and candidates where they will be accepted versus OPOs having to go through extensive match runs trying to get to an organ acceptance?

UNOS staff also mentioned that another benefit to the MPSC receiving this overview for Continuous Distribution is that it will provide context when reviewing the projects and provide additional insight when discussing how the MPSC monitors allocation.

3. Redefining Provisional Yes and the Approach to Organ Offers

The OPTN Operations and Safety Committee's Vice Chair presented their concept paper, which proposes a three-tiered framework, and associated responsibilities, that will standardize organ offer, review, and acceptance practices. Rather than a single provisional yes response with no associated responsibilities, each tier would represent the various stages of communication and responsibilities necessary between OPOs and transplant programs within the organ offer process. The committee members did not have any questions or comments on this concept paper.

4. Optimizing Usage of Kidney Offer Filters

The OPTN Operations and Safety Committee's Vice Chair presented their concept paper, which provides an update on the ongoing work on kidney offer filters and seeks to increase community awareness on the benefit of using offer filters. This concept paper also introduces the following offer filter options to increase usage:

- Default offer filters: automatically enables filters by default. Kidney programs would not receive offers from donors that meet these default filter criteria unless they specifically opt-out and disable the filter(s).
- Mandatory offer filters: make offer filter usage mandatory based on what kidneys a transplant program accepts, but allow for a change in offer filter criteria if a transplant program can show a change in acceptance behavior.

Summary of discussion:

A member stated that with the mandatory filters, they would be worried about the impact of medical/surgical staff moving to different transplant hospitals since offer acceptance is driven by the physicians and surgeons. The member mentioned that they wouldn't want a hospital to have to provide justification to change a filter when a new physician or surgeon is hired.

Another member added that the environment may change at the transplant program (i.e., resources offered or the aggressiveness of the program). A member also asked how the filters, if mandatory, would be communicated to the patients and whose responsibility it would be to communicate that. The presenter stated that the OPTN Operations and Safety Committee (OSC) discussed that and wondered if providing a standard place where that data would be available could be helpful.

A member mentioned that their hospital uses the voluntary filters and they have worked perfectly and resulted in better management of offers. The member noted, however, that there is the fear of missing out and suggested that more transplant hospitals may be willing to use filters if there was an avenue to speak to OPTN staff and review offers that the hospital missed. This would also help the transplant hospitals analyze whether they should change their filters. The presenter explained that there is a data tool available for transplant hospitals to view the offers that they aren't receiving and noted that the OSC wants to address this educational piece.

A member inquired how transplant hospitals can demonstrate a change in acceptance behavior if offers are being filtered out. The presenter stated that the transplant hospital can request the mandatory offer filter be removed and have a period of time for evaluation or the mandatory filters can be turned off for a random duration of time during the year and their behavior can be evaluated then.

A member asked if offer filters are going to be used across organs or if this is just specific to kidney. The presenter stated that currently, offer filters is specific to kidneys.

A member noted that technology changes, such as the Organ Care System (OCS) Heart System, could affect transplant hospital behavior as well and all these factors would need to be considered when determining how often to evaluate transplant hospital behavior.

A member highlighted that it is important to first establish if transplant hospitals are seeing the offers that they should be seeing based on the filters. The member also inquired if labelling the offers, so hospitals can still see the offer but know that they won't take it, would achieve the same result as filters.

An SRTR representative mentioned that mandatory filters can be used to widen or constrict the behavior of a transplant hospital. For example, a hospital can have a broad distance filter and accept offers from donors at a specific distance and, once that becomes the behavior, the hospital can expand the filters even more. The SRTR representative also mentioned that, currently, there is no transparency regarding offer acceptance for the patients and patients don't know what type of offers programs typically accept.

5. Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations

The OPTN Kidney Transplantation Committee's Vice Chair presented its proposal to address waiting time modification for registered Black candidates who were affected by race-inclusive eGFR calculations and who meet documentation and timeframe criteria. This is in response to the OPTN Board of Directors approved policy change to require that eGFR is calculated with only race-neutral calculations to allow a pathway for affected candidates to regain waiting time lost due to race-inclusive calculations.

The proposed required documentation would include either a candidate's eGFR values for Black and non-Black candidates or a candidate's eGFR with a race-inclusive calculation and a re-estimation of eGFR

with a race neutral calculation. The proposed timeframe for waiting time modifications to be submitted is 365 days and affected candidates may regain all lost waiting time with no cap on the maximum time regained.

Summary of discussion:

A Committee member wanted to address the topic of unintended consequences for other candidates who may have been affected but will not qualify under this policy since this could be contentious, but was not sure there is a proper answer to address it. The presenter did acknowledge that there may be requests for other types of waiting time modifications especially candidates referred pre-dialysis, but as for now, this would just be for Black candidates affected by race-inclusive calculations.

Another Committee member commented that this will only apply to Black candidates noting that these calculations only affected Black candidates. The Committee member added that if this is an error that needs to be remedied, this is something that should be considered as mandatory because if it is optional it continues inequity in the system. The presenter explained that making this mandatory has been a theme in the comments so far, but the Committees are also considering how this may be operationalized at programs knowing that there is a strong feeling in the community that this is required. They added that the Committees have been discussing the impacts for programs and that it may affect programs in differing ways depending on what candidate information is available to them. The Committees are very interested in getting more feedback regarding impacts at the program level to help with these decisions.

A Committee member mentioned that they see where these waiting time modifications could be misused. They explained that it seems that the waiting time modifications would be primarily for preemptive candidates who have been referred and there is a wide discrepancy in eGFR in the timeframe from referral to listing which may be problematic. The presenter stated that this proposal provides an opportunity for programs to address candidate inequity due to race-inclusive calculations. They added that the spirit of the proposal is for programs to move forward with race-neutral calculations and rectify candidates who were negatively affected by race-inclusive calculations, for example candidates who would have qualified pre-dialysis.

6. Apply Transplant Notification Requirements for VCA Program Inactivation

UNOS Staff presented the OPTN Vascular Composite Allograft (VCA) Transplantation Committee's proposal to remove the VCA exclusion from *OPTN Bylaws, Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* and update the *OPTN Bylaws, Appendix J: Membership and Personnel Requirements for VCA Transplant Programs*. The committee members did not have any questions or comments on this proposal.

Upcoming Meetings

- October 26-27, 2022, Chicago
- December 8, 2022, 1-3pm, ET
- January 20, 2022, 3-5pm, ET
- February 16-17, 2023, Chicago
- March 20, 2023, 3-5pm, ET
- April 24, 2023, 3-5pm, ET
- May 22, 2023, 3-5pm, ET
- June 21, 2023, 3-5pm, ET

Attendance

- **Committee Members**
  - Maher Baz
  - Alan Betensley
  - Timothy Bunchman
  - Anil Chandraker
  - Todd Dardas
  - Robert Fontana
  - Reginald Gohh
  - Barbara Gordon
  - Lafaine Grant
  - Robert Harland
  - Kyle Herber
  - Victoria Hunter
  - Ian Jamieson
  - Catherine Kling
  - Michael Kwan
  - Dianne LaPointe Rudow
  - Carolyn Light
  - Scott Lindberg
  - Melinda Locklear
  - Gabriel Maine
  - Amit Mathur
  - Kenneth McCurry
  - Nancy Metzler
  - Bhargav Mistry
  - Regina Palke
  - Michael Pham
  - Pooja Singh
  - Jason Smith
  - Zoe Stewart Lewis
  - Laura Stillion
  - J. David Vega
  - Candy Wells
- **HRSA Representatives**
  - Shannon Dunne
  - Marilyn Levi
  - Arjun Naik
- **SRTR Staff**
  - Ryutaro Hirose
  - Jonathan Miller
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - James Alcorn
  - Sally Aungier

- Matt Belton
- Tameka Bland
- Rebecca Brookman
- Alex Carmack
- Aileen Corrigan-Nunez
- Robyn DiSalvo
- Demi Emmanouil
- Katie Favaro
- Liz Friddell
- Jasmine Gaines
- Asia Harden
- Kay Lagana
- Lindsey Larkin
- Krissy Laurie
- Trung Le
- Ann-Marie Leary
- Ann McPherson
- Sandy Miller
- Amy Minkler
- Sara Moriarty
- Jacqui O'Keefe
- Rob Patterson
- Dina Phelps
- Kelley Poff
- Michelle Rabold
- Sharon Shepherd
- Olivia Taylor
- Stephon Thelwell
- Susan Tlusty
- Marta Waris
- Betsy Warnick
- Joe Watson
- Joann White
- Trevi Wilson
- Claudia Woisard
- Emily Womble
- Karen Wooten

- **Other Attendees**
  - Jim Kim
  - Kimberly Koontz
  - John Lunz