

## **OPTN Organ Procurement Organization Committee**

### **Meeting Summary**

**July 20, 2022**

**Conference Call**

**Kurt Shutterly, RN, CPTC, Committee Chair**

**PJ Geraghty, MBA, CPTC, Vice Chair**

### **Introduction**

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 07/20/2022 to discuss the following agenda items:

1. Welcome and Introductions
2. Histocompatibility Committee – Require Confirmatory Typing Project
3. Kidney and Pancreas Continuous Distribution – Facilitated Pancreas Allocation
4. Committee Orientation

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

#### **1. Welcome and Introductions**

Staff and Leadership welcomed several new members to the Committee, and all Committee members introduced themselves.

#### **2. Histocompatibility Committee – Require Confirmatory Typing Project**

The Chair of the Histocompatibility Committee presented a project to require confirmatory human leukocyte antigen (HLA) typing for deceased donors.

##### Presentation Summary:

This project stems from a letter written by a histocompatibility lab director who was concerned about the current lack of required redundancy for HLA typing, as compared to ABO typing. Both are critical to determine patient and donor compatibility.

The Histocompatibility Committee discussed these concerns and risks:

- Inclusion of incorrect HLA typing in the match run may mean offers are given to patients highly sensitized against the donor
- Virtual crossmatching or assessment of immunologic risk requires correct HLA typing to determine candidate/donor matches and donor service area (DSA)
  - This affects both acceptance/rejection of an organ offer and peri-transplant care for the recipient
- Crossmatches and confirmatory typings often occur after transplant for hearts and lungs
  - Potential for hyperacute or accelerated rejection

The Histocompatibility Committee decided to recommend several steps to mitigate risk and increase safeguards to ensure correct donor HLA typing. This includes some redundancy in the system of HLA typing and requiring confirmatory HLA typing in policy.

- Deceased donors should have two HLA samples run, drawn at two separate times, similar to ABO
  - Possibly further discussion on best practices for different sample types or assays
  - Did not want to create requirements that would increase the time to allocation or burden on staff
  - Both typing results would be required at the same reporting timeframe as current policy
    - Necessary to ensure typings are not discrepant and to ensure efficiency and safety
  - Samples able to be run in parallel so as not to increase turnaround time for HLA typing
- Both samples should be typed at a molecular level for all loci
- Require raw HLA typing data to be uploaded for both samples as an attachment

Summary of discussion:

One member asked for clarification that the discrepancies are primarily not clerical data entry errors, but rather errors that require re-typing, such as the samples themselves being switched. The member asked what happens in such situations. The Histocompatibility Chair explained that the data does not provide that level of granularity, but that the Histocompatibility Committee recognized that they can differentiate when errors are clerical, but not what errors require re-typing. The Histocompatibility Chair shared that in 2018 there were 27 non-clerical errors, in 2019 there were 18 non-clerical errors, and in 2021 there were 16 non-clerical. The Histocompatibility Chair explained that there is potential there were those type of sample swaps that may have occurred in those situations.

A member explained that the discrepancies their organization has caught are almost always data entry, and so their OPO typically double checks all of their data. The member noted that this proposed project would not prevent these types of errors. The member remarked that the two sample draws would be similar to how ABO samples are drawn, with five minutes between draws. The Histocompatibility Chair confirmed that is correct, and added that drawing the second typing sample would be the most logistically appropriate way to obtain the second typing sample.

One member asked what volume of specimen would be require for the second blood draw. The Histocompatibility Chair responded that this would be specific to each lab, but that typically for an adult donor, and it was recommended that a typing can be accomplished with one acid citrate dextrose (ACD) yellow top tube. The member asked if this would be common across most histocompatibility labs, and the Histocompatibility Chair noted that it should be, as it would be standard that you could get the same amount of deoxyribonucleic acid (DNA) to perform the typing test from the single sample, but that the Histocompatibility Chair can't speak for all labs and their requirements. The member noted that the documentation for this project noted that many labs are currently doing this, and asked what percent of labs do this now. The Histocompatibility Chair explained that the exact percentage is not available, but that it's been brought up at national histocompatibility meetings, with an increasing number of labs doing this either because they have experienced typing issues or because they recognize this as a best practice to ensure the typing being produced is accurate.

A member asked what occurs when a discrepancy is found, noting that this could cause significant confusion if discrepant typings are both uploaded to the donor's summary in the OPTN Donor Data and Matching System. The Histocompatibility Chair explained that there is policy describing how histocompatibility labs need to handle discrepancies in typing, but that the practice described in this project would provide instantaneous recognition at the lab level that there is an issue with the samples or with the testing performed. The lab would recognize what was going on and resolve it before the information was entered into the OPTN Donor Data and Matching System.

One member shared that their OPO had a recent issue where the histocompatibility lab had re-run a different donor's sample and reported those results as a new donor. The member shared that their OPO implemented a safety net policy so that the lab director reviews every result and compares it with the last two weeks of donor results to see if there are any identical results. Identical results are flagged, and the lab would then need to resolve the issue. The member explained that this proposed solution would lead to twice as many samples in the lab, with two of them being deliberately identical. The Histocompatibility Chair remarked that such a review process is a good one, and that the OPTN Histocompatibility Committee would recommend that labs have a good policy in place to segregate samples appropriately, so that pre-analytical errors can be avoided. The Histocompatibility Chair explained that, particularly in circumstances where there are multiple donors at once, these type of fail safes proposed in this project would be enough to recognize a sample mix up, so that the lab could investigate and understand where the error occurred and correct.

A member noted that typically, their histocompatibility lab is doing the typing for 6 to 8 donors at a time, and that they have to move slowly, as the lab can't run testing simultaneously. The member pointed out that this solution would require the labs to run typing for each donor twice. The member asked if the typing can be done independently and quickly, or if this will add a lot of time to the process. The Histocompatibility Chair explained that this is dependent on the methodology in use at the lab, but the first step is to isolate DNA from the tubes and set up the assays. The Histocompatibility Chair explained that there are two different types of assays run – one to run donor typing on a plate and the other is a higher throughput – that can be run simultaneously and on the same plate. These assays can run in parallel or sequentially from their processes. The Histocompatibility Chair shared that, particularly when utilizing this information to crossmatch virtually for highly sensitized patients, the labs are extremely dependent on accurate typings being available. Anytime patients go forward to transplant without other immunological matching than a virtual, there is a risk that the typing is incorrect. The Histocompatibility Chair noted that this type of strategy can reduce that risk of discrepancy.

One member asked if the concern is that the lab itself is running too many samples and switched them, or if the concern is around improper labelling of tubes, or incorrect data entry. The member noted that it seemed this solution intended to address specifically instances where the lab could potentially swap samples when running samples for multiple donors. The Histocompatibility Chair explained that there are many places in the testing phase where an error could occur, including mislabeling. The Histocompatibility Chair pointed out that a policy change was implemented a few years ago that required double entry for human leukocyte antigen (HLA) typing into the OPTN Donor Data and Matching System. The Histocompatibility Chair shared that the idea behind this project is that if there are two samples, and something goes wrong, you could see that there is a discrepancy between the two samples and correct it.

A member requested that the Histocompatibility Committee follow up to see if there was truly an impact from increased testing, as these small changes do add up in the case timing, and case timing is one of the biggest reasons OPOs lose consent. The Histocompatibility Chair agreed that there are several points that will be looked at in post-implementation monitoring. The Histocompatibility Chair added that, at least in his practice, the typings proposed in this project would be able to be performed in the same time frame as serological testing.

One member asked if the Histocompatibility Committee has done a cost analysis on what the additional testing would cost to the system. The Histocompatibility Chair responded that point has not been reached, but that the Histocompatibility Committee recognizes there would be an increased cost, but that would be dependent on the methodology each lab uses.

A member asked if there was agreement on what was considered a discrepancy. The Histocompatibility Chair confirmed that, in the analyses, the Histocompatibility Committee pays close attention to differentiate non-critical and critical typings, and what could be just a difference in interpretation versus a clear error. Staff added that there was a policy change implemented with regard to critical HLA discrepancies, which introduced a definition for critical discrepancy in policy.

One member asked if there had been any adverse patient events as a result of the discrepancies. The Histocompatibility Chair explained that analysis wasn't available on true adverse events as a direct result of discrepancies, but that there were 37 patient safety reports due to discrepant typings from January 1, 2018, to April 1, 2021.

The Chair summarized the feedback given thus far, including concerns regarding turn-around time, the volume of typing material needed, and a need for standardization in volume of typing material needed.

One member shared that their OPO utilizes a high volume, high complexity lab, and remarked that this project would increase cost and turn-around time. The member asked if both typing results would also need to be entered into the OPTN Donor Data and Matching System. The Histocompatibility Chair noted that, at this point, the Histocompatibility Committee will not ask that both typings be entered, but that the typings would be entered as a single result entered in duplicate, as per current protocol. The Histocompatibility Chair explained that this project does not plan to include information technology implementation, but that the Histocompatibility Committee does recommend the raw data are uploaded into the OPTN Donor Data and Matching System as an attachment, so that independent labs can interrogate that information more granularly. The member recommended that this project be mirrored with ABO policy, such that two different users must enter the data, to avoid data entry errors. The member added that often, the discrepancies are due to difference in resolution.

A member recommended that the Histocompatibility Committee consider the level of training for staff to identify the discrepancies, and asked who will be responsible for determining when a discrepancy exists. The member noted that OPO staff should not be asked to interpret HLA, and that the project should specify who is responsible for identifying the discrepancies. The Histocompatibility Chair explained that the Histocompatibility Committee is looking at automating that type of system with the expansion of typing information available. The Histocompatibility Chair continued that, for deceased donor analysis and analysis of potential discrepancies, that would be the responsibility of the histocompatibility technologist that performs the test with whatever review policy they have in place.

### **3. Kidney and Pancreas Continuous Distribution – Facilitated Pancreas Allocation**

Staff presented a question from the Kidney and Pancreas Continuous Distribution Workgroup on how facilitated pancreas should operate in a continuous distribution system.

#### Presentation summary:

Facilitated pancreas is outlined in OPTN Policy 11.7: Facilitated Pancreas Allocation, which describes transplant program qualifications to receive facilitated pancreas offers and when OPOs are permitted to make facilitated pancreas offers.

Current policy utilizes 250 nautical miles (NM) as a surrogate for challenges in placing the pancreas, if all offers within 250NM have been declined, and for transplant program willingness to transplant hard to place pancreata, as programs only qualify to receive facilitated pancreas offers if they have transplanted two pancreata from outside 250 NM within the past two years.

At the May 18, 2022, meeting, the OPO Committee noted that facilitated pancreas is not frequently utilized, and that there are challenges with the time frame. Particularly, the three hours prior to

scheduled donor organ recovery timeframe present challenges when coordinating a recovery team willing and able to procure pancreata and other recovery logistics.

The Pancreas Committee had the following recommendations to transition the Facilitated Pancreas tool:

- OPOs and the OPTN are permitted to make Facilitated Pancreas offers if no pancreas offer has been accepted five hours prior to the scheduled donor organ recovery.
- Apply facilitated pancreas bypasses to candidates registered at transplant hospitals greater than 100 NM from the donor hospital.

The Pancreas Committee will be discussing the following considerations during their upcoming meeting:

- Qualifying criteria for facilitated pancreas programs
- Kidney-Pancreas (KP) candidates on the facilitated pancreas list
  - Currently, facilitated pancreas bypasses apply to pancreas candidates only, and KP candidates are not bypassed.
  - Is there a benefit in bypassing KP candidates in non-facilitated programs once facilitated pancreas is initiated?

#### Summary of discussion:

One member remarked that cases often move at different times, and offered that the OPTN Pancreas Committee could consider utilizing the number of centers who have been offered the organ and declined as a trigger to move to facilitated, rather than a set time point.

One member noted that including the KP candidates in facilitated would allow an OPO to allocate through the list more quickly, as they could bypass the KP candidates in the non-facilitated programs. The Chair agreed. The member continued that time is critical, as it can be harder to place a solitary pancreas. Another member agreed, adding that this could save allocation time. Staff noted that it seemed the OPO Committee did not have too many concerns about including KP in facilitated pancreas allocation.

#### **4. Committee Orientation**

New members were oriented to the ongoing work of the Committee and the structure of the OPTN.

#### Summary of discussion:

The Chair remarked that Staff typically does a good job on information sharing, and encouraged Committee members to engage in Workgroups and on other Committees' projects.

#### **Upcoming Meeting**

- August 17, 2022 – Teleconference

## Attendance

- **Committee Members**
  - Kurt Shutterly
  - Bruce Nicely
  - Chad Ezzell
  - Clint Hostetler
  - Donna Smith
  - Doug Butler
  - Erin Halpin
  - Judy Storfjell
  - Leslie McCloy
  - Lindsay Larkin
  - Meg Rogers
  - Samantha Endicott
  - Sharyn Sawczak
  - Valerie Chipman
- **HRSA Representatives**
  - Vanessa Arriola
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Nick Wood
- **UNOS Staff**
  - Robert Hunter
  - Kayla Temple
  - Courtney Jett
  - Joann White
  - Katrina Gauntt
  - Kevin Daub
  - Krissy Laurie
  - Lauren Mauk
  - Lauren Motley
  - Ross Walton
  - Sarah Booker
  - Taylor Livelli
  - Thomas Dolan
- **Other Attendees**
  - John Lunz