OPTN Operations and Safety Committee Meeting Summary
February 23, 2023
Conference Call

Alden Doyle, MD, MPH, Chair
Kim Koontz, MPH, Vice Chair

Introduction

The OPTN Operations and Safety Committee (the Committee) met via Citrix GoToMeeting teleconference on 02/23/2023 to discuss the following agenda items:

1. Public Comment Presentation: Improve Deceased Donor Evaluation for Endemic Disease
2. Public Comment Presentation: Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors
3. Public Comment Presentation: Identify Priority Shares in Kidney Multi-Organ Allocation

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

1. Public Comment Presentation: Improve Deceased Donor Evaluation for Endemic Disease

The Committee received a presentation on the OPTN Ad Hoc Disease Transmission Advisory Committee's (DTAC) *Improve Deceased Donor Evaluation for Endemic Disease* proposal.

Summary of discussion:

The Committee Chair voiced general support for the proposal and asked how widely available the testing being proposed is, specifically for Chagas confirmatroy testing. The DTAC representative clarified that the Chagas confirmatory test is an antibody test and is available in commercial labs as well as through the Centers for Disease Control and Prevention (CDC). The DTAC decided not to require the confirmatory testing results prior to transplant because it does take some time to result.

The Committee Chair commented that as an extension of this, was there any concern for potential barriers to this type of testing. The DTAC representative confirmed that the DTAC conferred with several organ procurement organizations (OPOs) and received confirmation that none of the testing would potentially be a barrier. There is acknowledgement that there can be timing issues, but the impression was that this could be overcomed and that some of the OPOs were alreadying doing this testing for their deceased donors.

The Committee Chair continued by asking if testing for other tropical diseases were being considered. The DTAC representative stated that there are other endemic diseases being discussed, such as West Nile virus and tuberculosis. For the purposes of this proposal, the DTAC wanted to focus on those diseases that would require less discussion for implementation to occur and are most prepared to address.

A member questioned Strongyloides being found in the kidney. The DTAC representative confirmed that there have been cases where an individual has allocated an organ that comes from a donor who has antibody positive for Strongyloides and that it can be transmitted through any of the organs.

The Committee Vice Chair voiced support for the testing but also provided some concerns regarding the timing of the testing results being available before transplant. From experience, the Vice Chair shared that their OPO's current lab was not able to do the testing which resulted in their OPO having to ship out the testing for Chagas. From further discussion with their medical Advisory Board, there was the thought that the testing would not need to be done prior to transplant. The results should be known, but it was felt that the risk of Chagas disease reactivation was not immediate post-op but more likely weeks later in the setting of the high dose of immunosuppressants.

The DTAC representative stated that this feedback would be taken back to the DTAC to discuss further and added that one of the concerns about not having the results available is that if the heart is being considered, and a donor is Chagas positive, the likelihood of the heart being accepted would be much lower because the pathogen primarily can affect the heart and have long term effects. The DTAC representative agreed that for other organs, this is a delayed issue, but the question would come back to offering the heart or not.

The Committee Vice Chair stated that this feedback was from their heart transplant experts but agreed of the concerns the DTAC representative outlined.

A member asked what percentage of OPOs are currently screening and performing this testing. The DTAC representative stated that there was a recent manuscript where they looked at this and it was a voluntary reporting as part of a research survey. It was found that this testing was common for Strongylodes but for Chagas, it is less common and focused mainly in regions where there are larger populations of individuals who were born or had spent significant amount of time in one of the endemic countries. The member continued by stating that in order for what is being proposed to work universally, it would be up to proper education of OPO staff. The member asked if there would be specific questions in the OPTN Computer System that would ask where a patient was born or traveled to be able to identify these precursors.

The DTAC representative confirmed that the focus would be on the country of origin and that education would be rolled out to OPOs to train them and assess as best as they can to functionally identify it. There was a question asked that if the country of origina was unknown, would testing be required. Since the incidence of positivity is fairly low in the general community, this would not be required. There would be a multi-prong effort including educating not only the OPOs, but also the transplant centers and how to respond to a positive test.

A member stated that the average organ donor takes over 50 hours of time from the time brain death occurs until recovery is completed. If shipping and availability of testing is limited and there is a need to get the results back prior to allocation for some organs, there is concern that there will be some organs that may not be able to be recovered from a timing perspective. This could be attributed based on the stability of the patient and the donor family's requests. The extending time on donor cases doesn't lead to more organs being more suitable for donation but instead can lead to less organs actually becoming suitable.

Another member voiced agreement to the points made by the OPO representatives on the Committee. The member continued that their experience has been in having to have testing performed externally and as long as there are no delays with traveling and everything aligns perfectly, the turnaround is typically 5-7 days. The member voiced the same sentiment and concerns in adding additional time on donors and the potential of losing organs.

The DTAC representative clarified that the testing would not be universal for Chagas, but instead only be required of those populations who are coming from endemic areas. If the patient has traveled and an

OPO has a higher level of testing threshold, this would not be a requirement for those individuals to have their testing results come back.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

2. Public Comment Presentation: Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors

The Committee received a presentation on the OPTN Histocompatibility Committee's *Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors* proposal.

Summary of discussion:

A member asked in regards to ABO verification that is done in the operating room prior to patient transfer onto the bed (nurse and physician having to go in and verify donor and recipient ABOs along with the OPTN Computer System information sheet), what type of verication is occurring within the HLA lab when samples are received. The member asked for clarification of how the verication process of a sample is operationalized in the HLA lab.

The Histocompatibility Committee representative stated that the only requirements are that the samples are labeled and come with requisitions. There are some requirements for the nurse who draws the sample to sign the tube but there is not a multi-step verification of the sample that occurs either at collection or once it comes to the laboratory. The representative continued by stating that there is an opportunity between sample collection and sample arrival in receiving the correct sample but there is uncertainty at what one point that intervention should be applied.

The member continued by stating that if there is a missample; in the review of these cases, has it been determined where the error occurred? The Histocompatibility Committee representative stated that there is variation in who is collecting the sample (the phlebotomist, the nurse, etc) having a lot of patients and mislabeling a tube that gets drawn. There are also cases where the sample comes into the lab and is correctly labeled but mishandled. For deceased donors, typically, there are not multiple donors being drawn simultaneously but this doesn't mean it could not happen. The incident reports reviewed by the Histocompatilibility Committee does not provide the granularity to determine where the sample switches are occurring.

The member continued by stating that they were not against confirmatory testing but there should be a more robust system of verifying or checking in some verification system. The Histocompatibility Committee representative replied that the thought on this was in having two separate samples and two separate draw times would decrease the probability of a mislabeled tube or miscollected specimen. The same would occur for an in lab switch where if a sample were misprocessed, it would be less likely to occur with two independent samples.

Another member asked that if there were two samples with two different results, how would this be reconciled? The Histocompatibility Committee representative stated that the proposed language mirrors the ABO policy that states that the HLA laboratories would need to have a policy for resolving discrepancies. The recommendation would be that there would need to be another sample or some confirmatory look back at how a sample switch could have occurred.

A member asked for clarification of this becoming more of an issue as more virtual cross matches are being performed. The member asked of the twelve sample switches that were observed, were more cases occurring during the latter half of the 2018-2021 timeframe observed. The Histocompatibility

Committee representative stated that the potential impact is higher and that when all kidneys had a perspective cellular cross match, there was always an opportunity to intervene, look at the results, and try to understand if there is a laboratory error or some unexpected biology. The representative continued by stating that not having the backstop of a physical crossmatch would mean that there would need to be more confidence with the virtual crossmatch. If there was an error in typing, there would be no way of knowing this until the organ was transplanted and the patient had an adverse outcome. It is unknown if the change in the rate of identified critical HLA discrepancies.

Another member stated that this would double the cost for HLA testing for what known risk that has negatively impacted a transplant. Additionally, this would potentially increase the time significantly if the tests cannot be run concurrently because the HLA lab does not have the staff or equipment to do this.

The Histocompatilibity Committee representative agreed that cost is always an issue. Costs would vary among OPOs and their arrangements with the laboratories that serve their testing. In the grand scope of the cost of organ procurement and transplant, the cost is a relatively small increase in cost to avoid a potentially bad outcome. The representatives continued that there was not a very detailed cost benefit analysis performed because the Histocompatibility Committee knew that what is available is underreporting descriptors – the question becomes what is the cost of avoiding a catastrophic medical error? The impact in time to perform the match run seems to be minimal from the discussions the Histocompatibility Committee has had and from feedback received from other stakeholders.

The Committee Chair stated that it is better to understand this because although it may be a modest dollar amount, the denominator is huge. This may add up to a big cost and there may be some unintended consequences related to logistics of this. The Committee Chair continued by suggesting that as the Histocompatibilitiy Committee develops this proposal, there should be a sense of the costs and unintended logistical consequences, what the underreporting is and other solutions in which the sample handling can be better tracked.

The Commmittee Vice Chair agreed with this and added that there should be some better understanding of the discrepancies by collecting data to provide more insight.

A member stated that there may be more buy in if this was positioned being more proactive rather than trying to address the sample mismatches because it is not believed this proposal addresses this.

Another member stated that from the transplant center side, there would be less opposition than on the OPO side of things. The member continued by agreeing that this is a patient safety issues and is in support of the proposal, but there needs to be better processes in regards to verification. There is going to be a division when looking at when looking from a clinical vs. the OPO side of this proposal.

The Histocompatibility Committee representative voiced agreement with this and acknowledged that on the transplant program side of things, there is concern about turnaround times and how this may delay how long it would take for transplant. On the OPO side, there is focus on the expenditure although there has been general positive feedback when discussing increasing efficiency. The representative continued by agreeing that framing this as a prospective intervention to facilitate allocation and patient safety is a much better framing of the issue.

A member asked if there were other solutions that were considered. The Histocompatibility Committee representatives stated that this proposal is a follow up to a previous project some years ago on a requirement for double data entry for HLA typing for donors. The double data entry resulted in a significant impact in reducing HLA typing erros that required re-allocation of organs but it didn't

eliminate them. There were then requirements to uploading of raw typing data from the actual typing instrument.

A member asked a question regarding the differential clinical impact of erroneous report based on the level of sensitization to the recipient. The representative stated that granular level of data is not available to give an accurate account of this but the highly sensitized patients would be more likely to have an incompatible antibody.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

3. Public Comment Presentation: Identify Priority Shares in Kidney Multi-Organ Allocation

The Committee received a presentation on the OPTN Ad Hoc Multi-Organ Allocation Committee's *Identify Prioirty Shares in Kidney Multi-Organ Allocation* white paper.

Summary of discussion:

A member stated that pediatric kidneys are a small group of patients who fall through the cracks with multi-organ offers. There is concern that as more kidneys are combined with other organs, this will affect pediatric patients.

The Committee Vice Chair voiced support with the list outlined in the white paper and agreed that this was a good start. Other members agreed with this as well. A member stated that there should be clear education and support once this project gets to a point of being made policy. Allocation is becoming more complex and when adding in these different rules, the lists that OPO members receive do not necessarily align with the rules so OPOs are constantly trying to figure out how to move forward. The member stated that this is a complication of the system and there are many variables attributed to this so there should be consideration in terms of how this comes across for the training for the OPO staff members who are involved.

The Committee Chair asked the Committee their thoughts for instances of when there are three kidneys going with three multi-visceral offers and if there should be guidance here for OPOs. A member responded that guidance should be in place if there are multiple multi-visceral cases in determining how these offers are ranked in comparison to the kidney list. The member continued by cautioning that the more complex these cases become, the likelihood of an error occurring increases.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

Upcoming Meeting

- March 23, 2023 (in person, Chicago, IL)

Attendance

- **Committee Members**
  - Alden Doyle
  - Andy Bonham
  - Audrey Kleet
  - Mony Fraer
  - Greg Abrahamaian
  - Jami Gleason
  - Jennifer Smith
  - Jillian Wojtowicz
  - Julie Bergin
  - Kimberly Koontz
  - Sarah Koohmaraie
  - Norihisa Shigemura
  - Renee Morgan
  - Susan Stockemer
- **HRSA Representatives**
  - Arjun Naik
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Betsy Gans
  - Carlos Martinez
  - Courtney Jett
  - Isaac Hager
  - Joann White
  - Kerrie Masten
  - Taylor Livelli
- **Other Attendees**
  - Lara Danzinger-Isakov
  - Gerald Morris
  - Lisa Stocks