OPTN Operations and Safety Committee
Meeting Minutes
March 26, 2020
Conference Call

Michael Marvin, Chair, MD
Chris Curran, Vice Chair, CPTC, CTBS, CTOP

Introduction

The OPTN Operations and Safety (the Committee) met by teleconference on March 26, 2020 to discuss the following agenda items:

1. Public Comment Update and Discussion: Modify Blood Type Determination and Reporting Policies, Guidance on Blood Type Determination
2. Committee Discussion on Coronavirus Disease 2019 (COVID-19)
3. Other Updates

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

1. Public Comment Update and Discussion: Modify Blood Type Determination and Reporting Policies, Guidance on Blood Type Determination

The Committee reviewed and discussed the public comment response of the Modify Blood Type Determination and Reporting Policy proposal and Guidance on Blood Type Determination.

Summary of discussion:

The Committee had a policy proposal and guidance document addressing blood type determination out for public comment. There was overall support among the transplant community and public for both the policy proposal and guidance document.

There was a comment from the OPTN Histocompatibility (Histo) Committee that a number of the testing methodologies presented in the guidance document requires additional expertise and carries additional CLIA requirements. Resources among histocompatibility labs vary throughout the country.

The Committee acknowledged the variation of resources among labs and clarified that the intent of the guidance document is to provide information of the various tools that are available and can be considered in the case that additional testing methods are needed to help address indeterminate blood type results.

The Vice Chair added that there were some members who stated they were already using the guidance document as a reference and that it is a very resourceful document. There were no additional questions or comments.

The Committee was called to a vote. The Committee voted unanimously in support of both the guidance document and policy proposal to be submitted for review and vote by the OPTN Board of Directors.

Next Steps:

- The guidance document and policy proposal will be submitted for review and vote by the OPTN Board of Directors.

2. Committee Discussion on Coronavirus Disease 2019 (COVID-19)

The Committee discussed their experiences, challenges and best practice measures taken in response to the COVID-19 crisis.

Summary of discussion:

The Committee Chair stated that their program has been very selective at this time and have shut down their living donor program.

A member stated that currently, there have only been two cases at their hospital. At this time, their institution is still doing deceased and living donations. The Committee Chair stated that the status of transplant programs are depenedent to some degree on their location.

Another member stated that at their institution, they have stopped living donations and are selective on recipients. There is a high rate of COVID-19 cases in their area; all deceased donors are being tested, but there is not great access to testing for recipients.

The Committee Chair commented that a concern regarding patients having the resources to do what is needed post-transplantation when they go home. A member stated that at their institution, their social workers go through their active list and identify patients whose caregiving arrangements may put the patient at risk. They are also looking at post-discharge planning to determine how to limit exposures to those patients.

A member stated that another concern is delayed graft function due to long cold times. The concern is in sending those patients back to dialysis centers that could put them at risk.

The Committee Chair asked members what is being done from an Organ Procurement Organization (OPO) standpoint.

The Vice Chair stated that most OPOs are up and running with testing. The testing turnaround time varies greatly among OPOs. There are screening procedures in place, such as risk assessment and travel assessment questionnaires and then following the standard processes. There is a limit in staff response on site and being more selective in this process at this time.

A member stated that similar protocols are done at their institution with risk assessments, access to testing with turnaround time of 24 hours. There has been a decline in donor potential and a spike in family refusals. The member continued that there has also been limited access to donor families because the families are not going to the hospitals as they normally do. There are no living donations being done locally and being very selective when it comes to recipients at this time.

Another member stated that their OPO is experiencing the same situation and that all centers in their respective area have put living donations on hold. The DCD heart trials are on hold as well. Tranport has brought about challenges, specifically with flying. Some hospitals are being required to bring their own masks. The requirements and challenges experienced vary each day.

A member stated that in their area they have been fortunate where they have a local lab that helps with testing. Their program has been trying to do as many recoveries with their recovery and local surgeons to limit the number of personnel in allocation. The member commented that the biggest challenge is

that if the cases of COVID-19 continues to spreak in their area, they may be limited by availability of hospital beds.

Another member commented that there is going to be a second wave where health providers and patients have already been exposed. Would you use a donor who has shown immunity? A member asked if there is supposed to be reinfections? The member stated that there was no proven reinfections. There were some reported reinfections from data in China, but the data is not very clear on wether you could or could not be reinfected.

The Committee Chair asked members if there was any policy or metric that we were dealing with before the pandemic that should be addressed or modified. A member stated that testing is variable among programs and should be evaluated more. It may be helpful to have language or guidance for centers and OPOs of when they should test. A survey may be helpful to better understand what is being done among members.

The Vice Chair commented that this topic was brought up to the DTAC and it was asked if they were going to develop guidance for OPOs. UNOS staff clarified that DTAC is currently collaborating with the American Society of Transplantation (AST), Americal Society of Transplant Surgeons (ASTS), the Organization for Transplant (NATCO), amd the Association of Organ Procurement Organizations (AOPO) to develop consistent guidance. Further follow up will be done to determine if anything additional guidance is being provided.

The Committee Chair commented that guidance would be ideal, but that guidance comes with experience. It is hard to provide guidance when it is all best guess and judgement. As time goes on, guidance will be important because there will be more experience.

The Vice Chair agreed with this but stated that in this circumstance, the OPOs have no experience treating patients who are at risk of COVID-19. There is evaluation of these patients to determine suitability for donation without any guidance on what testing methodologies, samples, or platforms that should be used. What is available right now is how to best assess the donors for their risk of COVID-19. There should be a cohesive message on this from the infectious disease experts.

The Committee Chair called for a poll among members on whether OPOs should be testing every donor. The Committee unamimously agreed that testing should be done on all donors.

The Committee Chair encouraged members to use the AST site as a resource. The AST has a thread that is used by various experts who share valuable information addressing COVID-19. There were no additional comments or questions.

Next Steps:

- Feedback received from this discussion will be shared with the OPTN DTAC Committee and UNOS to help in providing guidance on current COVID-19 efforts.

3. Updates: HLA Initiative, DonorNet® Functionality, Post-Transplant Reporting Project

The Committee was updated on the status of pending IT projects.

Summary of discussion:

HLA Initiative

Currently, the project is pending until the completion of Board approved projects by the Histocompatibility Committee.

The Histocompatibility Committee have been on three projects that have to be completed before the HLA initiative is worked on. The Committee has just completed an API project. The Histocompatibility Committee is now working on an OPTN Board project. The last project is a customer innovation project.

DonorNet® Functionality

Currently, the project is pending until the completion of a DonorNet® Mobile project.

The DonorNet® Mobile project will begin with a pilot by the end of Quarter 1 of 2020 and run for 3 months. Following the pilot, there will be evaluation of any additional functionality that is needed with a goal of a nationwide roll out before the end of calendar 2020.

Post-Transplant Reporting

A pilot is scheduled to begin in July 2020.

Next steps:

- The Committee will continue to be updated on the progress of the standing projects.

Upcoming Meeting(s)

- April 23, 2020 (Teleconference)