

**OPTN Operations and Safety Committee
Meeting Summary
April 23, 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 April 23, 2020 to discuss the following agenda items:

1. Policy Oversight Committee (POC) Update
2. OPTN Data Advisory Committee (DAC) Update
3. Research Update
4. Coronavirus Disease 2019 (COVID-19) Discussion
5. Updates: HLA Initiative, DonorNet Functionality, Post-Transplant Reporting Project

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

1. Policy Oversight Committee (POC) Update

The Committee Vice Chair provided members with an update on the OPTN Policy Oversight Committee (POC).

Summary of discussion:

A member suggested a potential project that could promote, track, and evaluate local teams getting organs rather than traveling teams.

The Committee Vice Chair agreed with this and stated that this was brought forth as a question to the POC as whether or not there should be a mandate of local recovery teams in response to Coronavirus Disease 2019 (COVID-19). The consensus among the POC was in alignment with the American Society of Transplantation (AST), where they strongly encourage a reliance on on local teams when available. It was not believed that this should be mandated.

The Committee Vice Chair continued by suggesting that it may be beneficial during this time to see what can be learned about the reliance of local recovery centers during this time of COVID-19 and analyze how it is working.

The Committee Chair stated that there are three main reasons that push transplant hospitals to send their own teams:

- Patient centered – this allows for an accurate assessment of the donor organ and better coordination when a transplant hospital sends their own team.
- Training of the fellows – this is especially important for programs that have large fellowship programs for those fellows to get experience for organ recovery.
- Financial – many organ recovery procedures are fairly well reimbursed for surgeons. Those funds often times go back to their transplant programs.

The Committee Chair continued by adding that this is a multifactorial process and that to some degree, it does make more sense to have local teams recover organs as fast as possible.

A member added that in looking at the other side of finance, there comes a challenge when an organ is recovered locally and the accepting team feels there is surgical damage or some other issue. This poses the question of who is responsible for paying for that organ.

United Network for Organ Sharing (UNOS) staff clarified that during their April 3, 2020 meeting, the OPTN Executive Committee did consider this mandate and decided against it, deferring to guidance. Although a mandate was not pursued, the POC is in the process of developing a workgroup to discuss this topic in further detail to look at more specific detailed operational aspects of local recovery to determine if any projects or initiatives should be worked on. There will be Operations and Safety representation on the workgroup which members were encouraged to volunteer if they were interested.

Next Steps:

- Workgroups will be developed by the POC on topics related to efficiency in allocation. Operations and Safety will have representation on these workgroups as they become developed.

2. OPTN Data Advisory Committee (DAC) Update

UNOS staff provided the Committee with an update on the OPTN Data Advisory Committee (DAC).

Summary of discussion:

Members reviewed the new required for projects that involve data collection or modifications to data fields. The DAC will collaborate with the Committee on any data related projects, such as the broader distribution data collection project the OSC plans to continue developing.

There were no comments or questions.

Next Steps:

- The DAC will be updated on any developments of OSC projects that involve data collection.

3. Research Update

The Committee reviewed and discussed the January 1, 2016 – December 31, 2019 Patient Safety Data.

Summary of discussion:

The Committee Vice Chair asked if there was any data regarding transportation events that led to loss of an organ. UNOS research staff clarified that based on the data currently, there was 1 transportation event for non-recovery of an organ, and 10 for discard of an organ.

The Committee voiced concern that these issues are vastly underreported. A member asked if there was a change in practice that would result in an increased number in the data. UNOS research staff will follow up on this. The Vice Chair stated that the data appears to show a downward trend, but it would be valuable to know what the true number is.

A member stated that the data including categorization of the data, there showed a decrease. UNOS research staff clarified that the current categorization of the data is representative of the data from the first half of 2019 (data ending in June). UNOS staff will share June 2019 – December 2019 categorizations when they are ready.

The Committee Vice Chair asked in regards to the testing cases, are any of them related to blood type determination issues? UNOS research staff will follow up on sub category testing.

The Committee Vice Chair continued by asking if there will there be a shift in the blinding of data so the committee can have more insight. Has there been any more movement on this issue? UNOS staff clarified that there was some discussion about the possibility of doing this but will follow up on the specificity of reporting and how particular cases would be selected for review and what that would look like.

A member asked if increase in volume being shown in 2019 included non-events (reports that are non-reportable). UNOS research staff confirmed that this did include reports of non-events. The member continued that including these reports would cloud the data and asked if this information may be removed. UNOS research staff will follow up on this.

The Committee then reviewed and discussed the extra vessel monitoring data. The Committee Chair commented that in looking at the data of extra vessels reported after 21 days from the donor recovery date, it would help to see what percentage, for example, was greater than 30 days. In looking at the 2.5%, it may show that a good percentage of this is due to a reporting being done 22 or 23 days from the donor recovery date and it may not be as significant.

The Committee Vice Chair commented that this brings up the issue of date of donation, which had been passed off to the OPTN Data Advisory Committee (DAC) to address but had not heard back on a resolution to that discrepancy. Is the percentage related at all to the discrepancy between the donation date being captured by UNOS versus the actual date being the cross clamp date. UNOS staff will follow up with DAC on their status of addressing this.

The Committee Vice Chair continued by stating that it would be valuable to know the disposition of the vessels that were sent to another transplant program. This may need to be discussed further to determine if this is a potential project.

The Committee then reviewed the TransNet dashboard data. The Committee Vice Chair commended all who were involved in the successful work on TransNet.

There were no additional comments or questions.

Next Steps:

- UNOS research staff will follow up on inquiries regarding the data presented.
- UNOS staff will follow up with DAC for further information on clarification of the definition of the date of donation and the accuracy of this being reported in the data.

4. Coronavirus Disease 2019 (COVID-19) Discussion

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

Summary of discussion:

A panel consisting of representatives from the OPTN Ad Hoc Disease Transmission Advisory Committees (DTAC), OPTN Organ Procurement Organization (OPO) Committee, OPTN Kidney Transplantation Committee (Kidney Committee), and the Thoracic Organ Transplantation Committee (Thoracic Committee), provided insight on best practices and challenges among transplantation processes amid the COVID-19 pandemic.

The Committee Chair asked the panel what they have observed at their respective programs. One of the panelists stated that their living donor liver and kidney programs were shut down in March. Their program is still doing selective deceased kidney, liver and heart transplants.

The Committee Chair asked the panel if there were any post-transplant patients seen developing COVID-19. One of the panelists stated that at their program, they have observed this. From data being tracked from their respective program, there were a little over 100 patients who developed COVID-19. Not all of these patients had been hospitalized; about 30-40 of these patients have been hospitalized. The biggest learning curve of this disease is that COVID-19 is not a linear disease and very unpredictable. There has not been a specific pattern being observed as to whether patients who were close from post-transplant vs. patients further out from post-transplantation in developing the disease.

Another panelist asked if the patients who were not doing well had other factors that may have been able to help predict their development of the disease, such as diabetes, cardiovascular disease and lung disease. The panelists confirmed that these comorbidities can play a role.

A member asked the panelists if a patient is stable on dialysis, and they are in a hospital where COVID-19 is not prevalent but does exist, is it more risky to transplant or have the patient remain in kidney failure and on dialysis?

A panelist stated that in New York, every program has different processes and protocols in place. At their respective program, some selective kidney transplantations are done depending on the recipient. There is a policy they have in place where candidates are screened before transplant. The candidate would have to have a negative COVID-19 screen within 24 hours of transplantation. They have the ability of a turnaround time of 8 – 12 hours as well as a rapid test that comes back within an hour. Additionally, their program has non COVID-19 units both pre and post-transplant.

Another panelist stated that one of several considerations in transplantation is the risk of death on the waiting list and the risk of the patient receiving a suitable offer in the near term future. If a patient is having significant complications, the risk of coming into the hospital, maintaining isolation, and doing pre-transplant screening of the donor and recipient may be less than being in the community and having ongoing risks of potential exposure that is unrecognized.

A panelist added that this is often dictated by the prevalence in each community. Fortunately, there is increased testing being done which allows it possible to gauge the local prevalence down to the county level and sometimes even within some of the individual hospitals. This also allows to gauge what resources are available based on the proportion of hospital admissions.

The Committee Chair asked about the latest data on the effectiveness of hydroxychloroquine. A panelist stated that based on current literature, it is not believed that hydroxychloroquine is effective. There are some studies currently being done, which will have some additional data to provide more information.

Another panelist stated that testing availability is still very limited, but there are more tests being approved by the Food and Drug Administration (FDA). The Committee Chair asked if OPOs have been partnering with hospitals for testing.

A panelist stated that their program in New York has weekly calls with their partnering hospitals to help with expediting testing of their donors. Another panelist stated that in the Midwest, this has been more difficult based on the testing capacity at their partnering hospitals. The situation is getting better, but it is still challenging for OPOs.

A panelist stated that within the last week, there was a townhall by the Association of Organ Procurement Organizations (AOPO) where all of the OPOs were reporting they have been able to get testing donor testing done 100% of the time without much problem. The biggest challenge has been turnaround time; many reported that it still takes about 12-24 hours for results to come in.

The Committee Chair asked the panel if there are more false negatives than is being realized. A panelist confirmed that this does exist and that it is a concern. Some of this does depend on how the specimen was collected, the sensitivity of the assay that is being used, and other factors related to testing methods.

Another panelist stated that there have been several cases that have come to DTAC for review. None of the cases have been fully adjudicated at this point in time. From what has been observed, there has not been any definitive transmission episodes, but they are still being fully evaluated. The Centers for Disease Control and Prevention (CDC) is also involved in all of the cases that are being investigated at this point in time.

A member asked if there has been any transmission being observed due to surgery to surgeons and staff? The panelist stated that there was a case where a transplant surgeon contracted COVID-19 from an asymptomatic living donor. It was thought that the donor was asymptomatic at the time.

Another panelist added that there has been guidance from the surgical societies. A lot of the comments from the surgical societies has been around the airflow and aerosolized procedures done in the operating room. Additionally, it is being strongly recommended that only essential personnel be in the operating room during procedures such as bronchoscopies and extubations. At their respective program, it is mandatory for all medical personnel to wear N95 masks for aerosolization procedures.

The panelist continued by asking what should be done with a donor who in the past has been COVID-19 positive. Additionally, as testing becomes more available, is there a sense of the role of antigen testing in the post-transplant population.

A panelist stated that there are a few commercial labs that would be providing serology testing soon. There is a question of how specific, sensitive, and clinically relevant the tests are.

Another panelist stated that at the moment, there is not enough information to say what should be done with a donor who has been COVID-19 positive in the past. At this point in time, it is easier to say that a donor who is PCR positive, this would be a donor that would not be found acceptable. Additional data would be needed to evaluate this further.

UNOS staff asked if a lack of eligible donors or risk aversion around potential exposure of donors that may be driving this a decrease in donors. A panelist stated that their hospital emergency room utilization has gone down 48%. Another panelist stated that among pediatric institutions, the emergency rooms were down 70% and inpatient has been down 50%.

A panelist added that with more people staying at home has decreased the risk behaviors that may lead to donation. There is also reluctance for people to seek medical care for other conditions which may mean that people are not making it to the hospital in time to become donors. Another panelist stated that this also is dependent on location.

Another panelist commented that due to the complexities and limitations of visitation in the hospital, there has been an increase in telephonic approaches with donor families, which is not yielding the same number of donors as a face to face encounter would.

A member asked what is being done with recipients who have tested positive for COVID-19 in the past. A panelist stated that at their respective program, there has been stratification based on how acutely a

patient requires an organ. For patients who tested positive and are stable at home would have a waiting period of 28 days before placing them back on the list. Another panelist added that some emerging data has shown that people with the infection may have longer periods of Polymerase Chain Reaction (PCR) positivity that would need to be handled on an individual basis.

The Committee Vice Chair commented that programs have different practices for testing as there is no consistency currently about how to evaluate asymptomatic candidates and donors prior to transplant for COVID-19. Is there any plan to provide some guidance to have more consistent practices among programs?

A panelist stated that due to the amount of regulatory oversight, by the time the approvals would come, there would be new data which would make that guidance out of date. After a great amount of discussion, the American Society of Transplantation (AST) took on being the lead in trying to help provide some guidance. This information is updated as frequently as possible.

UNOS staff added that from the OPTN has launched a COVID-19 focused collaborative forum that will be available during the duration of the pandemic. The information that is provided in the forum will help the OPTN in the development of guidance or additional policy actions. Members were encouraged to provide any topics that the OPTN should discuss further and consider addressing.

A member asked if there has been any discussion from the UNOS standpoint on how programs will be reviewed within this period. UNOS staff clarified that the OPTN Membership and Professional Standards Committee (MPSC) has put out a statement regarding being mindful and use common sense when it comes to reviews. It is not accurate to say that monitoring will not occur during this crisis but the MPSC will evaluate all the reviews using clinical judgment taking the current situation into consideration.

The Committee Vice Chair asked if a decision was made on the imminent or ineligible definition and how COVID-19 donors would be classified. UNOS staff clarified that there is still discussion on this and at this time, it is being suggested that OPOs use their best judgement of utilizing the policy.

There were no additional questions or comments.

Next Steps:

- UNOS staff will follow up with the Committee to provide resources mentioned in the discussion for more information on COVID-19.

5. 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

- May 28, 2020 (Teleconference)