

OPTN Operations and Safety Committee

Meeting Minutes

October 24, 2019

Conference Call

Michael Marvin, MD, Chair

Christopher Curran, CPTC, CPTBS, CTOP, Vice Chair

Introduction

The OPTN Operations and Safety Committee (OSC) met via Citrix GoToMeeting teleconference on 10/24/2019 to discuss the following agenda items:

1. Data Collection Public Comment Document
2. Committee Charge
3. Policy Oversight Committee Update, Strategic Priorities, Project Ideas
4. ABO Project Update
5. Notification Limits Project
6. New Project Idea: Saline in Packaging Materials
7. TransNet Update
8. Patient Safety Data
9. Other Updates – HLA Initiative, DonorNet Functionality, Patient Safety Report

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

1. Data Collection Public Comment Document

Members reviewed and discussed the public comment response themes and next steps of the public comment request for feedback.

Summary of discussion:

This public comment document was not voted on for sentiment. Feedback was solicited at all eleven regions, where there was overall support of the data collection efforts by the Committee. The Committee reviewed and discussed the common themes from public comment:

Feedback on suggested data elements:

- *Transportation Mode and how, specifically, the organ was transported:* Options should indicate if organ was transported using different transport services or to detail if staff used their own private vehicles.

The Committee Chair then asked the Committee to consider what the goal is of collecting this data and what is the point of each data element? Will this help understand what is going on to help design a better system or is it to get sentiment?

Another member stated that some of the comments from regional meetings was about not just the transportation mode but who's transportation mode – courier, OPO, transplant program driving. Was it just the organ being transported or was there a recovery team transporting the organ.

The Vice Chair stated that when talking about assessment of cold ischemic time (CIT) and travel time, is it important to capture if a person from the team has the organ in their possession or not? A member stated that if there is a recovery surgeon, the travel time would be shorter.

The Vice Chair added that another data point that would need to be collected with each leg of travel is the hold time. There are many circumstances where an organ is recovered at midnight and then held at an OPO until later in the morning. There is not necessarily cold ischemic time, but rather scheduled cold ischemic time.

A member asked if the data could be collected stating whether the organ is accompanied by a recovery team or not. The Committee Chair stated that this would vary among organs. Typically, kidneys are not taken directly by the surgeon. Livers are typically accompanied by a recovery team but as allocation policies have changed, this would become more local. How important would this data be to have and how does it help with the overall goal?

The Vice Chair stated that some comments were concerning why this data was being collected when there is nothing to compare it to. The focus is to establish the current baseline and assess what it looks like. When there are policy changes moving forward in the future, there would be data to compare it to. Right now, the data being collected is to know what the current state is to identify the impact of future policy changes on transportation and CIT.

The Committee Chair asked the Committee what would be the best way to capture transportation mode. The Vice Chair stated that capturing the various transportation modes is important for knowing how often organs are flown or driven, but it would not show how long the organ was in transit with each mode.

The Vice Chair stated that the focus should be travel time vs. waiting time. While it is believed that OPOs enter this information currently, it is not in usable data format. If this information were able to be uploaded like other data elements, it would reduce the administrative burden. The more granular the data collection efforts are, there will be more pushback from OPOs in collecting this information.

Another member stated that there should be a list of the various modes of transportation with the members to check all modes that apply (car, helicopter, airplane, drones, none). There could be an "Other" field where additional modes not specified can be entered. The Committee agreed with this.

- *Who recovered the organ?:* There are many variations in recovery teams. This may not be a simple answer.

The Committee agreed that the three options are typically the primary accepting recovery team, OPO recovery team, and recovery team recovering on behalf of another center.

A member stated that there should be an ability to analyze who the primary center is based on acceptances/refusals. There are some instances where the initial primary team goes to recover the organ, declines it and then recovers the organ for another program.

A member asked why it would matter if the primary team or another team in the OR recovers an organ for another team. Another member answered that there are studies that suggest that behavior changes. As this becomes more frequent, it would be important to understand what these behaviors are. The member continued that this data may not be easily obtained in determining who the primary accepting center is.

The Vice Chair suggested the use of two drop down options: who recovered the organ and the disposition of the organ. There would be data of where the organ ends up going if the initial primary center does not accept the organ.

The Vice Chair stated that the intent should be assessed – is the organ being recovered by the recovering team or is the team recovering the organ for another center?

The Committee Chair suggested documenting the surgical team that recovered the organ and then the intent being for self or other. In regards to intent, it would be when the recovery team enters the OR. The Committee agreed that these particular points would be important to assess further.

- *Time (hours) of organ transport from donor hospital to recipient hospital:* This is a variable data element. There are other factors to be considered that would influence this data element such as weather, traffic, and OR coordination.

The Vice Chair stated that the challenge with this data element would be when the organ is held for a certain period of time. If an organ is recovered, and the choice is made to not deliver the kidney immediately, and it is waiting on a pump, there can be an inaccurate depiction of the actual time. These two data points do not take into consideration that a lot of this time could be due to allocating. The organ may not be placed for 12 hours and transportation would not be due to the delay.

The Vice Chair asked that when an organ gets checked-in, is this done by scanning the TransNet labels. A member stated that for their process, when the organ arrives at the transplant center, it is sent to their transfusion services, who check the organ into their program. The organ is held until the OR is ready for the organ. If the check-in is used at the center, rather than in the OR, this would be more accurate in determining when the organ arrives. However, it would not take into account how long the organ may be held at the OPO.

Another member stated this data element is variable by organ. If kidneys were excluded, the delays and cold ischemic time have a big impact on the allocation. Kidneys have a bit more room for cold time.

The Vice Chair stated that there should be a time for when transportation begins and ends. The Committee Chair stated that for the non-renal organs, the time the organ label was scanned to organ check in would be the best data points to collect for the purposes of travel.

The Committee Chair asked what would be the best data points to consider for kidneys? The Vice Chair suggested looking at the time the kidney was picked up for delivery. A member cautioned this because it could be that the organ was held on a pump at the OPO before going out for delivery. Do we have to consider the change over time? The Committee agreed to discuss this in further detail.

A member stated that there were comments regarding GPS tracking organs. The Vice Chair clarified that this is done by some OPOs but this is something that cannot be mandated.

Feedback on suggested data sources:

- *Use of the Deceased Donor Registration (DDR) form to collect data:* There was overall agreement that the use of the DDR is most reasonable.
- *OPOs:* There was overall agreement that OPOs would have the information needed to record the majority of the suggested data elements. It would be more reasonable for the transplant programs to collect organ check-in data.
- *Transplant Recipient Registration (TRR) form:* Feedback received suggested that the TRR form would be the most appropriate source for transplant programs to collect organ check-in data.

The Committee agreed with the feedback received.

Additional Suggestions:

- *Costs:* Although challenging to collect, the majority of the feedback received suggested that there should be some type of methodology for cost assessment.

The Committee agreed that this information would be great to obtain, but due to variations, there are many challenges of collecting this information. The data could be extrapolated from the data collected.

- *Data should be collected to reflect coordination time/allocation:* Several commenters suggested collecting data points that influence the suggested data elements, such as acceptance and decline (late turndown) rates.
- *Preservation Mode:* Several commenters suggested capturing data on whether or not an organ was placed on a pump and the mode of preservation that was used (cold vs. warm, static vs. continuous, other).

The Committee agreed that these data point should be included.

- *Organ Discard Rates:* There were a few commenters who suggested evaluating the organs that were discarded due to transportation challenges.

The Vice Chair commented that there have been conversations around how long organ donation cases are taking now. Longer allocation times are being observed even if the OR is being pushed off because allocation is taking so long, and not having anything to do with logistics.

Concerns:

- *Administrative Burden:* Many commenters voiced concern on the administrative burden of collecting additional data.
- *Data/Other Factors:* There were a few commenters who cautioned that as travel increases, there will be other factors that would need to be taken into consideration, such as procurement team staffing and pilot availability.

The Committee considered the desire for data and tried to balance it with the concerns of administration burden in their decision making.

Next Steps:

The Committee discussed next steps for the data collection project. There are two proposed projects:

- *Collaborate with UNOS Labs in cold ischemic time (CIT) project:* Currently, UNOS Labs is working on a pilot to collect data related to cold ischemic time (CIT). UNOS Labs will conduct the data collection and will provides updates to the Committee. The Committee will have the opportunity to analyze the data and determine next steps and data elements for a future data collection proposal.
- *Potential project/Research Paper – Increased case time due to broader distribution:* Research paper that would evaluate the time of authorization to the time of cross clamp.

The Committee Chair provided members with an overview of the potential research paper. CIT is a valid data element to consider, but it does not take into account surgeon judgment and donor hospital OR availability. It is believed that due to this, organ check-in is a valid data element because organ check in is when the organ got to the recipient hospital. It takes away the judgment of the surgical team of when they start and the logistics of the recipient hospital.

The Committee Chair continued that as far as case time is concerned, there is no data that has been observed that discusses that case time increases due to whatever reason. The Vice Chair stated that there are time periods in the course of policy change implementation where the impact of case time prior and following those changes. It is believed that there is readily available data right now that could help in the evaluation of this.

The Committee Chair asked what resources could be used and what steps would be needed to gather and analyze the data. UNOS staff stated that this type of project would not be a typical Committee project that would need to go through the public comment process since it is research based. The Committee would need to decide what parameters they would like to analyze. UNOS research staff would then pull the data, and create some statistics and figures to use. The full data set is also available. The Committee was encouraged to decide what specifically they would like to get out of the analysis.

A member stated that this was something they are working on at their OPO to increase length of case times. They have been realizing that in just looking at the data, some of the context is missed. For example, who is setting the OR time and can this really be linked to allocation? How are other factors considered?

The Vice Chair stated that the nuances being discussed have always been factors before allocation changes went into effect. When looking at aggregate data, it can show a trend prior to and after allocation changes. The data would likely support that there are statistically significant changes to allocation time.

Another member asked if there was an increase in utilization observed as well. The Vice Chair stated that there are papers out from the UNOS organ-specific groups that have looked at the impact of policy changes. There was a nine month report for lung and it was found that the utilization was very similar, but the shift where transplant occurs changed

The Vice Chair added that the changes are not just about discard rates, but also about recovery rates. Did the recovery rates change because organs that previously would have been placed because of length of time of allocation or other factors, didn't get recovered that would have in the past?

The Committee Chair suggested in forming a small group to work on the research paper further. The group would discuss what data fields are available and what data should be requested and develop a hypothesis.

Next steps:

- OPTN Board of Directors Meeting: December 2-3, 2019 in Dallas, TX

2. Committee Charge

The Committee reviewed the revised Committee charge and voted to move it forward for Board approval.

Summary of discussion:

The Committee members were provided with an opportunity to review the current charge and make revisions. The Committee drafted a revised version of the Committee Charge which was sent to the Executive Committee for review and feedback. The Committee reviewed the revised Committee Charge and made one change by changing the term "process" to system" in the first sentence. The Committee voted to approve the following language by a vote of 15 in support, 0 opposed, and 0 abstentions.

The Operations and Safety Committee seeks to improve the quality, safety and efficiency of the organ donation and transplantation ~~process~~ system. The Committee reviews de-identified transplant and donation-related adverse events and near misses reported to the OPTN by the transplant community, in order to identify potential improvements and policy revisions that may prevent future such occurrences. Based on input from the community and committee experience, and with collaboration from other committees as needed, the Committee may initiate, develop and recommend projects to the Board.

Next steps:

The Committee Charge will go to the OPTN Board for review and vote during the BOD meeting in December.

3. Policy Oversight Committee Update, Strategic Priorities, Project Ideas

The Committee Vice Chair provided members with a Policy Oversight Committee (POC) update.

Summary of discussion:

The purpose of the POC is to advise the Committees and Board of Directors on:

- Strategic planning activities
- Prioritization of OPTN policy development activities
- Evaluating policy proposals prior to public comment
- Coordinating policy issues that have broad implications across OPTN committees; and
- Ensuring that all OPTN governance groups consider and justify compliance with the requirements of the final rule as part of the policy development process.

The POC's work to identify potential strategic policy priorities has led to the identification of the following three themes:

- Continuous distribution
- More efficient donor/recipient matching to increase utilization
- Improved equity for multi-organ and single organ candidates

The goal is to maximize benefit to the transplant community and provide recommendations to the Board of Directors. Individual committees will sponsor specific projects.

The Committee was asked to brainstorm on projects the OPTN should pursue in relation to the themes that were selected.

The Vice Chair stated that for the more efficient donor/recipient matching to increase utilization theme, there was discussion on the dynamics that go into the process for organ allocation. Currently the process is not efficient and it was suggested that unless it is an urgent matter, it may be more realistic to make organ offers during daylight hours (7am – midnight).

A member stated that in regards to the multi-organ and single organ candidates theme, there should be qualifying criteria for kidney with other organs as well as safety net. Based on the success of liver/kidneys, this makes sense to do so for other organs.

The Committee Chair stated that when talking about kidney allocation and kidney discards, there should be consideration on the outcomes of the recipients. There should be some data to look at what organs should be discarded/should not be used.

The Vice Chair stated that the decision would be at the discretion of the surgeon and the patient. There should be a safety net for recipients who receive marginal organs. A member stated that this could lead to gaming of the system.

The Committee Chair stated that it may be more beneficial to have a centralized location for biopsies. For high KPDI kidneys, these organs would be placed on a pump and a biopsy would be performed after a certain timeframe.

A member stated that relationships lead to getting more done and this is not accounted for in the system. Increasing visibility in DonorNet would be helpful in allowing members to log in and check the status of offers.

The Vice Chair stated that in addressing how to improve process, discussion regarding what's best for the patient needs to be at the forefront. A member added that transplant programs be held accountable as well.

A member stated that in regards to continuous distribution, the lung community is not convinced that this is the best approach. DSAs did help with getting sicker patients transplanted. It was suggested that there be a modification to the Lung Allocation Score (LAS) and including waiting time as part of the LAS. This project idea would be sent to the Thoracic Committee for consideration.

Another member suggested that there should be data on non-productive donors. Observing what trends are there could help in boosting the efficiency of the system. The Vice Chair agreed with this and stated that the trends observed could help answer the question of whether there are similar donors in other areas of the country where the donor would have been used?

A member stated that there are wide variations that are hard to justify. With a growing number of enrollment in the HOPE Act, this is a great opportunity to increase. Using the data would allow the OSC the opportunity to inform the community. Another member stated that Hepatitis C donors used to be address conservatively as well.

Another member asked that if the PHS guidelines are revised, are there conversations happening of what that would mean for the OPTN mandate? A HRSA representative stated that the feedback received regarding the PHS guidelines are under review and discussion of the final regulations.

A member stated that the Ethics Committee put out a white paper last year regarding multi-organ transplant. It was suggested that the OSC should review the Ethics white paper. The recommendations in the white paper should be considered for a potential project.

Next steps:

The Committee will continue to brainstorm project ideas that align with the POC themes.

4. ABO Project Update

The Vice Chair provided an update of the Committee's ABO project.

Summary of discussion:

Committee leadership provided an update on this project that will result in both a guidance document and policy changes. The Committee Vice-Chair provided an overview of the sections of the guidance document. The workgroup will continue to finalize both the guidance document and policy language in order to develop proposals that will be distributed for Spring 2020 public comment cycle.

Committee leadership encouraged the members to review the proposed documents.

Next steps:

The Committee will vote on final documents during **the next Committee meeting**.

5. Notification Limits Project

The Committee reviewed and provided feedback on the Allocation Based Notification Limits project.

Summary of discussion:

The proposed solution for the notification limits project is to:

- Replace local/non-local limits with fixed limited defined by the OPTN
- Limits will be based on match type/allocation (higher limits based on donor criteria)

- Program limits only (no candidate limits)
- Remove pre versus post recovery limits
- Balance organ placement efficiency versus notification volumes

The benefits of these changes would:

- Allows for different limits across organ types
- Consistent with allocation policy so more transparent for members
- Easier to incorporate into continuous distribution

A member stated that this project does not take into consideration the relative behaviors of transplant programs. Weighting the notifications of offers sent to transplant programs that would be known to take the organ could help in avoiding delays in the offer process.

The Vice Chair stated that transplant centers set who is going to receive the local vs. import offers. As DSAs are going away, these dynamics would need to change. UNOS staff stated that this is something that is being looked into and there is discussion on the ramifications that this may entail as well.

A member commented that on high KDPI's, the number of centers should be rounded up to 20 instead of 15.

The Committee agreed and supported the proposed notification limits that was presented. A member asked if these notifications would change as cold ischemic time (CIT) increases. UNOS staff stated that the notifications would be system based and set. They can be changed upon evaluation (6 months, 1 year, etc.).

The Vice Chair asked how this would impact the Organ Center making the national offers. Would this give OPOs more control on making national offers? UNOS staff clarified that the limits would be taken into affect of the circle sizes that are determined for each organ. Anything within the circle size would be at the control of the OPOs and anything outside of the circle size would go to the Organ Center.

A member asked if there was any conversation about allowing transplant programs to know how many centers the offers have gone to. There should be some transparency to the process.

Next steps:

The Committee will provide any additional feedback and questions they may have on the notification limits project.

6. New Project Idea: Saline in Packaging Materials

The Committee reviewed a proposed new project idea regarding saline in packing materials.

Summary of discussion:

To date, there have been 8 cases reported of kidneys that were either partially and fully frozen. There has been an inability to determine the root cause of these cases, but it is believed that the saline in packaging mixed with ice caused the organs to freeze. Committee members were asked their thoughts on if this was a project that should be taken on by the Committee and what approach should be used to address the issue.

The Committee members agreed that this would be a project they should address. A member stated that an educational video would be helpful. The video would have the ability to show the pieces of the packaging process.

The Vice Chair also suggested that a review of *OPTN Policy 16.3.A: Internal Packaging* would be helpful as well. There is variation among OPOs in how organ are being packaged. There may need to be more detail in the policy.

A member stated that the policy does not mention what exactly goes between the required barriers. The temperature of the ice is a factor when packaging organs.

Another member stated that this would not be just for OPOs, but also for transplant programs who are doing KPD's that are shipping and doing their own packaging. These transplant programs are at an increased risk of not understanding some of these mechanisms in packaging. The more detail or best practices that can be provided would be a great help to those programs.

Next steps:

The Committee will continue to discuss a project plan to best address this issue.

7. TransNet Update

The Committee reviewed and discussed the January 2017 – September 2019 TransNet Data. Members also discussed TransNet updates.

Summary of discussion:

A member stated that it is difficult to determine what causes the outliers in the data. It could be a temporary inability to access TransNet.

Members were updated on current projects regarding TransNet. The extra vessels labels project has been completed. Currently, there are bug fixes being done and autlogs included in the TransNet app. There has been more TransNet training opened to provide a descriptive educational offering in how to troubleshoot issues with TransNet. The first training will begin in December.

There has been a trend seen among the community of device usage. At the beginning of the year, the usage of Android vs. iOS was 50/50 and has now shifted to 80% of iOS usage to 20% Android usage. As this trend continues to lean towards iOS, this would allow for support other platforms within iOS.

A member stated that their program has been moving towards using iOS due to problems with Android. It is unclear whether this is due to the device or software.

The Vice Chair asked what the frequency of use of TransNet is in the ICU for labeling specimen vs. in the OR. UNOS staff stated that this varies among OPOs but that it appears some members are trending towards more use while others are less use because of the expense of having multiple devices.

The Committee Chair asked for an update on the transplant center app. Currently, there is work being done to share data between TransNet and electronic medical records (EMRs).

The Vice Chair asked if there has been any discussion on intergrating TransNet into DonorNet. Additionally, is there any move towards transferring data as used rather than checking in and out of the system to upload this information. UNOS staff explained that there are still some security logistics that has created a challenge. Most of the issues are due to offline activities in the mobile apps.

Next steps:

The Committee will continue to be updated as **TransNet data and projects progress.**

8. Patient Safety Data

The Committee reviewed and discussed the January 1, 2016 – June 30, 2019 Patient Safety Data.

Summary of discussion:

The Committee Chair asked if the decrease in patient safety events are truly due to there being fewer safety events. UNOS staff stated that it is hard to determine how many events there truly are since the events included in the data is only what is reported to the OPTN.

A member added that in the past, the policy language became more clear with extra vessels, resulting in patient events related to this to decrease. The awareness these changes have made could be accounted for the decrease in these types of events.

The Vice Chair stated that with broader sharing, the relationship between members could affect how cases are reported. The relationships between transplant programs and OPOs may not be as close as they used to be. It may be more likely that an out of region transplant program may report an event rather than call the OPO.

The Committee Chair stated that there should be an asterisk by death for living donor related events data that distinguish that the deaths are directly related to organ donation or not.

The Vice Chair asked if the Data Entry information shared is what is reported through the patient safety portal. There are lots of DonorNet data entry errors. When looking at DonorNet - ABO in 2018, it is known that there was an error and it may have been categorized as a testing error. It is unsure where this would be shown in the data.

A member asked how much of the “event impacts on any organs” is related to broader distribution? The Committee Chair stated that the data was regarding non-recovery of an organ and that this is something that should be tracked when considering broader distribution.

The Vice Chair stated that policy should have a list of events that are required reporting to patient safety. Currently, there is no obligation for reporting. The reporting should not be done punitively, but it would be helpful to know what to look at to determine what needs to be improved.

A member stated that there will be a challenge where members may self-report in a way to get out of policy violations. The Vice Chair stated that this should not be assumed and that there are some things that fall into the category of needing investigation, which would be standard for any quality event, management process, or root cause analysis.

The Vice Chair stated that some of these cases are not all patient safety events but instead an issue of lost opportunity. This should be clearly categorized so that members do not see them as punitive to promote reporting.

The Committee Chair stated that loss donors would be important data to consider with broader distribution. The Committee agreed to look at trends during the spring meeting and yearly to further evaluate the patient safety reporting data.

9. Other Updates – HLA Initiative, DonorNet Functionality, Patient Safety Report

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

Summary of discussion:

HLA Initiative

The Committee Chair summarized the project. This project is an initiative to get HLA software to communicate directly into DonorNet.

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

DonorNet® Functionality

The DonorNet® Functionality project is to help provide real-time communication from the OR to respective parties on information such as when the patient is in the OR, incision time, cross clamp, and final packaging of the organs. The Committee is working with UNOS IT staff to work on this process.

Currently, the project is backlogged due to other IT priorities. There is a DonorNet mobile project that is being worked on. This 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

The Post-Transplant Reporting project addresses post donor recovery results and the ability to report these results to transplant programs in a consistent way. The idea of this project is to build a module in DonorNet® to report these results electronically and have a central repository for transplant programs to receive these results. There are five OPOs that will begin this pilot in the near future to evaluate this process further.

A HRSA representative asked how this would work with the Ad Hoc Disease Transmission Advisory Committee (DTAC). Is there a mechanism to know that a transplant center is aware of results? The Vice Chair stated that this communication will be a part of the pilot, that will begin in December.

Next steps:

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

Upcoming Meeting(s)

- November 21, 2019 (Teleconference)
- December 19, 2019 (Teleconference)