OPTN Organ Procurement Organization Committee
Meeting Summary
March 27, 2024
Houston, Texas

PJ Geraghty, MBA, CPTC, Chair
Lori Markham, RN, MSN, CPTC, CCRN, Vice Chair

Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met in Houston, Texas, and via WebEx teleconference on 03/27/2024 to discuss the following agenda items:

1. Membership and Professional Standards Committee (MPSC) Referral (Late Turndowns)
2. Expeditious Task Force Update
3. Project Discussion
4. Pronouncement of Death Project
5. Update: HRSA Directive to Expand Data Collection (Ventilated Patient Referral)
6. Committee Open Discussion

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

1. MPSC Referral (Late Turndowns)

The Committee learned about a referral from the MPSC surrounding late turndowns.

The MPSC is requesting that the OPO Committee review potential data collection efforts around late declines to improve understanding of the problem and determine opportunities for better utilization.

- More data might be beneficial in tracking trends and enabling the Committee to see if any outliers might be addressed.
- It was acknowledged that late declines could have different parameters for each organ and suggested an organ-specific approach, beginning with an organ that might have more easily definable criteria (i.e., not kidney).

Summary of discussion:

There were no decisions regarding this agenda item.

The Chair noted that it is difficult to define a late turndown, even by organ, because it means different things in different circumstances. A member pointed out that their OPO has a late decline policy that they follow and report the centers that violate it to the MPSC, adding their recognition for how strict their policy is if it is broken. The Vice Chair highlighted the data aspect of this referral, adding that they feel that more data surrounding late declines must be collected. However, getting that data will be a challenge because the system inherently does not allow for OPOs to capture that. They voiced a concern that the data will not reflect the actual problem, which will likely cause frustration from the Committee because it will not be the information that the MPSC requested. A member agreed and recalled when they assisted on the project to change the decline codes in the OPTN Computer System and although they added several codes, there are still many more that could be added.

A member shared that their OPO documents the late declines and has had other centers question how the OPO will be holding the late-declining center accountable. One member recommended that this be reported as a patient safety concern so they can accurately capture the data points for each area. They added that additional documentation would only show that OPOs did everything they could to get the organs transplanted, but they did not meet the metrics and would not give the information that the MPSC requested. A member questioned if OPOs document these late declines consistently and in the same manner, as they feel that there may not be a framework to support a data request.

A member added that during the Committee's previous project of Modifying Organ Offer Acceptance Limit, they had data that reflected that a majority of the late declines are the result of accepting two organ offers at the same time. They continued, suggesting the Committee wait until the policy change goes into effect to see the outcomes of that policy, including behavior and practice changes around late declines.

One member voiced their concern about the word "late", as they feel that all declines have a downstream effect on all parties. They added that they believe looking at the data surrounding the time of declines and analyzing any trends would be beneficial. A member agreed with this idea.

A member indicated that they have served on the OPTN Board of Directors for several years and they have never seen a desire for change like they currently do. They encouraged the Committee to consider this when reflecting upon previous attempts to solve this issue, as there may be a different outcome than what the Committee previously encountered.

A member questioned if it was possible to get the decline codes, as they believe this will also be beneficial for the Committee to look at. A member agreed, adding that transplant centers will be attached to that so the Committee can identify trends amongst transplant programs.

Next steps:

The Committee will determine if a formal data request is needed.

2. Expeditious Task Force Update

The Committee received an update from the Expeditious Task Force.

Summary of discussion:

There were no decisions regarding this item.

A member commented that a lot of the inefficiencies their OPO struggles with are that they cannot do biopsies on weekends or nights and questioned if the Task Force was considering challenges like this. A Task Force member responded that they are considering this.

The Committee reviewed the following Task Force recommendations:

Standardize Donor Management Protocols to Minimize Negative Impacts on Organs (Policy 2.13)

A member indicated that standardization may be difficult due to regional and transplant center variability. A member who is a transplant surgeon mentioned that this is not necessarily a big issue, and a better idea may be the dissemination of best practices. They added that critical care centers have proven to minimize these negative impacts on organs. The Vice Chair indicated that some OPOs are fortunate to have critical care partners to ensure they have the most up-to-date donor management protocols, but not everyone has them. They added that they believe this would be a very difficult project for the Committee to partake in, and another member agreed. A member recommended that rather

than making this a policy, perhaps having a project that addresses best practice guidelines. The Chair agreed, suggesting that the OPTN organ-specific committees create best practices, as they are the experts. A member agreed that the organ-specific committees would be best equipped for a project like this. Another member voiced their support, adding that the organ-specific committees will be able to determine how the quality of organs will be evaluated and ensure that those metrics are in alignment.

Data Collection for Incidents Leading to Organ Loss (Transport, Late Decline) (Policy 18.1)

The Vice Chair questioned what happens with this data once it is collected. A member who has reported an incident leading to organ loss noted that they met with OPTN Contractor staff so they could gather feedback, but nothing resulted from that meeting.

Improve Processes Around Biopsies/Pathology (Policy 2.11.A)

A member voiced their concern that they have heard that pathologists are not supportive of artificial intelligence (AI) reading biopsies and slides. They added that mandating all OPOs use the same AI platform may be problematic and take time to adapt and with many pathologists leaving the hospital setting, it is very challenging to get these diagnostic tests read at a hospital or lab. A member added that due to many pathologists leaving the hospitals in their service area, they have begun cutting slides themselves which has posed a challenge for OPO staff and has resulted in organ loss, especially when they notice one sample may be malignant. They indicated that this is an opportunity for hospitals to employ on-call teams for pathology to avoid potential organ loss if a specimen is malignant. A member noted that their OPO has an on-call team for those unanticipated situations. Their OPO also noticed that a trend of programs in their service area has contracted out their labs with private corporatized labs for pathology services.

The Chair believed that AI is not currently in a place to be reading biopsies but could be in the future. A member indicated a trade-off with centralized pathology services is that although the results will be consistent, there will be significant delays in larger service areas. A member pointed out the need to have pathology slides quickly and the biggest challenge they experience is getting the slide created with the lack of staff employed within hospitals. The Chair agreed. A member voiced another concern they have is when they go into smaller community hospitals and many pathologists lack experience with liver biopsies, which makes the OPOs feel uneasy.

Improve Communication/Partnerships with Donor Hospitals

The Chair pointed out that this may be an area in which the OPTN does not have much authority but may be a good opportunity for the Committee to make some recommendations or craft a guidance document for donor management protocols and assemble some best practices to distribute. A member mentioned that this is where bringing in organ-specific committees is essential, especially for pathology and critical care-related aspects. A member noted that unless there is a policy in place for hospitals to comply, there will still be hospitals that are unwilling.

Another point of discussion was donor care centers, as a member mentioned how many hospitals are disincentivized to transfer patients to them due to the Centers for Medicare and Medicaid (CMS) cost report. They added that most transplant programs are housed within academic institutions, thus they have a lot of competing priorities and oftentimes, transplant is not at the top of the list. They mentioned that it should be reflected and OPOs should be given some relief from CMS since hospitals are disincentivized to use donor care centers. A member added that every hospital that services patients who have Medicaid or Medicare has cost reports from CMS and the biggest gap that is left by the government in their opinion is that every hospital should be incentivized to bring in donors. They continued appreciating the 60,000-transplant goal set by the Task Force, but the disparity of goal

settings and performance settings from interested parties across all organizations is never uniform and should be connected, including the regulatory bodies. The Chair agreed, highlighting that incentives are typically never the same and can even be opposite so having all of the relevant parties on the same page is essential.

Require All Organ-Specific Donor Information Needed for Organ Assessment at the Time of the Offer (Policy 2.11)

The Chair noted that this was an issue brought to them by the OPTN Lung Transplantation Committee and is aware that this is an issue amongst all organ-specific committees. The Vice Chair mentioned that this was brought up during the last OPTN Policy Oversight Committee meeting and the OPTN Operations and Safety Committee wants to lead this initiative, but the Committee may be consulted to provide insight on this project. A member added that not all technologies are available at hospitals and that should be considered. The Chair questioned if the Committee should recommend a periodic review of this policy by the organ-specific committees to ensure it's still valid or not.

The Vice Chair felt that there could be some leeway with this policy, as long as documentation is provided. A member voiced their support for having the organ-specific committees review this information on a routine basis.

Increased Communication Around Potential DCD Donors and Expedited Placement for DCD Organs as Needed (Policy 2.15)

The Chair indicated that the OPO-level perfusion is the answer to some of this. A member said that some standardization and additional fields in the OPTN Computer System would be helpful. They said having the neurological status by the hour would be useful, especially since their electronic medical record (EMR) documents that, thus keeping consistency would be a good practice. The Vice Chair said in the meantime, the Committee can encourage OPOs to document neurological status in the "Donor Highlights" section of the OPTN Computer System.

A member questioned if there is a tool that has validity that helps provide clarity on what to do with some of these organs. The Chair indicated there is currently no tool like that and normothermic regional period (NRP) is the closest thing to it.

Utilize Better Transportation Possibilities (Policy 16.7)

The Chair mentioned that their OPO hand-carries organs if there are no direct flights and although it is more costly, their OPO has found that to be very effective. A member pointed out that it is the responsibility of the transplant program that is accepting the organ to be aware of the logistics, including challenges, within their area. They added that finding the right vendor and using that consistently has alleviated a lot of the pressures that come with transporting organs. Another point raised by this member is that no one knows the traffic and flight patterns as well as the accepting center, so it's the transplant center's responsibility. The Chair agreed, adding that OPOs are also somewhat responsible. One member agreed but added that better communication and relationship-building between transplant centers and OPOs would help remedy some issues.

A member added that they view an expedited placement as drivable versus flyable. They added that being upfront and transparent in conversations makes allocation much easier for everyone from start to finish. A member agreed, emphasizing how big of a role logistics play a role in allocation and communication. The Chair indicated they felt that this would be best in a guidance document.

Standardize Practices Within and Among OPOs (Policies 2 and 5)

The Chair mentioned that what works in their OPO may not work for other OPOs. They added that if there is an issue with the OPO, transplant centers should be the ones to reach out to develop a solution that satisfies all parties. A member felt that the Committee would benefit from establishing national normothermic regional perfusion (A-NRP) standards for OPO-led programs. The Chair agreed, however, they mentioned that the Association for Organ Procurement Organizations (AOPO) is already looking at how to do this. The Vice Chair emphasized the need to have standards around NRP. A member commented that having something like guidance is much easier to follow rather than an OPO trying to figure it out for themselves.

A member added that a big part of this issue is the lack of communication, especially with third-party vendors. A member noted that when they have issues with third-party vendors, they give them a warning but if they recognize repeat offenses, they will move on.

The Chair indicated that it's important for the Committee to work with other organizations to make NRP guidelines to ensure OPOs have adequate representation.

One member commented that they wish the entire transplant community would listen into the conversations the Committee has to understand the challenges that OPOs encounter. They added the transplant community is so siloed, and most organ-specific communities are only focused on their problems rather than looking at the big picture. They encouraged the community to communicate better with each other to approach wider issues in the transplant field.

Improve Coordination of Operating Room (OR) Time (Policy 2.14.G)

The Chair indicated that this is difficult to manage, as it varies on a case-by-case basis. A member added that a lot of this has to do with the donor OR, as they may not have anticipated having to do a transplant, which can be logistically challenging.

Next steps:

The Committee will continue to find ways to engage the Task Force in future project work.

3. Project Discussion

The Committee discussed and provided information surrounding a potential project idea: Machine Perfusion Data Collection.

Summary of discussion:

No decisions were made regarding this agenda item.

Machine Perfusion Data Collection

The Chair indicated that their experience with machine perfusion is mostly transplant center-driven and so for allocation purposes and information sharing purposes, it is not critical to have it input into the OPTN Computer System unless for research purposes. They noted that NRP is going to be important to allocation, but all of that information is collectible by the OPO. They concluded that while both NRP and machine perfusion hold value from a research perspective, only NRP is valuable from an offering perspective and therefore the Committee should evaluate the data. A member voiced their opinion that data should be collected but thinks it overlaps with a previous conversation about what is being collected already and whether it can be used somewhere else. A member suggested doing some sort of data exchange, especially since many of the anticipated data fields are already being collected. One member agreed that the Committee should figure out what data they want to collect and ask machine perfusion companies to work with the OPTN to get the data into the OPTN Computer System. Another

member chimed in that it would be beneficial to make this compatible for future iterations and added that they struggle to understand where data following a device failure is stored once it is reported to the Food and Drug Administration (FDA), which oversees medical device compliance.

The Vice Chair added that the Committee is going to have to work with the organ-specific groups to help navigate this project, especially to understand what is needed. A member pointed out that there needs to be a better definition of whose jurisdiction the organ falls under after it goes on a commercial device and is not accepted for the intended recipient. One member suggested that if there is an NRP workgroup, this project would fall under their work. A member agreed, emphasizing that if one of these outside entities has a bad outcome, how will that be tracked? Currently, OPOs email each other if there is an issue with an outside entity, but that isn't necessarily the best practice, and going forward, having a centralized method would be useful. The Chair mentioned that at previous external discussions, a centralized method was brought up, but it can cause legal actions from companies, however, they voiced their support for some way of identifying what is important and how to appropriately share that information.

A member suggested identifying the key information needed for deciding on each organ, then going to the different machine perfusion vendors and showing them the key data points needed. They added that having the organ-specific committees determine those points would be best, since they are the experts. A member brought up that the Committee should consider the possibility of optional filters in the future for these data points, like offer filters.

A HRSA representative reminded the Committee of a presentation given by the FDA regarding reporting events related to perfusion devices and that any safety reports or malfunctions must be reported to the FDA by the center. They added that the OPTN website will have a link to the FDA form that can be filled out and submitted to the agency directly. They also noted that anyone can fill out the form, including OPOs, but it's anyone who is experiencing issues with a device. A member voiced their concern that this is not a typical device and a lot of new devices come with services, which makes it more complicated. A member added some organs leave the OPO's control and asked the HRSA representative what happens with this data once it's reported. A HRSA representative recommended asking the FDA that question.

Next steps:

The Committee will continue to work on developing this project.

4. Clarify Requirements for Pronouncement of Death Project

The Committee reviewed the feedback received from their *Clarify Requirements for Pronouncement of Death* project that was out for public comment in Winter 2024.

Summary of discussion:

The Committee unanimously approved the policy language to keep it as it was distributed in the proposal during public comment.

The Chair felt that the recommendation from AOPO could not be implemented, as the purpose of the policy is to prevent perceived conflict of interest. A member indicated that this was mentioned during initial Committee discussions and felt that it did not warrant further conversation. The Chair questioned what is considered to be the 'recovery procedure', as that is the only hesitation they had when looking at policy language, since if that includes donor evaluation, would impact their decision on changing the language. The Vice Chair noted they do not read it that way. One member agreed with the Chair, questioning if the Committee should clarify the language to say "surgical recovery procedure" so that

people do not assume it includes the diagnostic aspect of the recovery procedure. A member spoke up, mentioning that this is really about the person declaring death and ensuring they are not the ones getting the organ. They added that this does not include everything that happens in between like donor management but is to ensure that the person declaring is not the one who is receiving the organ. The Chair concluded that they felt inclined to leave the language as it was presented in the proposal. A member indicated that there is no need to get very specific because it is not productive to the proposal and going down the specificities may do more harm than good. A member emphasized that several OPOs do not have resources and they are important to consider when making changes. When the Chair asked if anyone felt the need for changes, no one spoke up, thus the Committee voted on the proposal. The proposal received unanimous support to keep the policy language as it was when it was distributed for public comment.

Next steps:

This proposal will go to the OPTN Board of Directors in June 2024 for approval.

5. HRSA Directive to Expand Data Collection (Ventilated Patient Referral)

The Committee discussed the HRSA Directive which is aimed at expanding data collection.

Summary of discussion:

No decisions were made regarding this agenda item.

The Vice Chair encouraged everyone on the Committee to be aware of this and noted that this will be very different for OPOs and the data they must submit and will likely force OPOs to begin collecting data as early as this fall. Continuing, the Vice Chair emphasized the need for the OPO community to be aware of this change and that enterprise data management organizations will need to be notified since they will have to adopt quick changes in an expedited timeframe. They added that the Committee has the responsibility to provide timely and thoughtful feedback once the directive becomes available.

A member commented that one of the enterprise data management organizations has struggled with all the recent OPTN changes, especially since they do not have staff to keep up with the changes. One member echoed that the community should have a voice in this and the Workgroup that was tasked with this did a great job of compiling the necessary information. A member concurred with the Vice Chair's sentiments about the significance of commenting and providing feedback. One member questioned how the data fields were chosen and what purpose they served, as they felt some of the fields were unnecessary. It was explained that there is no published reasoning, explanation, or definitions for any of the data fields within the new form.

The Chair noted that among the data points that are being collected, some are available at the moment of referral, but others are not. They added that with the current death notification record (DNR), some information has a minimum timeline of 30 days. The Vice Chair commented that it's complicated, as most OPOs have this information on most patients who end up becoming donors, but it's important to keep in mind that this information will be collected on every single ventilated referral, so on a medically complex patient, OPOs will still get the referral, which will alter the mindset of OPOs.

A member felt that this would have a drastic impact on the relationship between hospitals and OPOs. The Vice Chair agreed, highlighting that this was an issue brought up by the workgroup. A member voiced their disappointment, as they believe this will be perceived as if there was no collaboration from the Committee, including in news releases, and felt that despite the efforts provided, there was no recognition. A member agreed, highlighting how this did not feel transparent and encouraged keeping

public trust at the forefront of all efforts. They added that collecting payor status from donors must be approached with caution. The Chair agreed, noting that it could be challenging to get payor status and it may change over time, thus it may not be entirely accurate.

Next steps:

The Committee will provide feedback on the HRSA Directive once it becomes available for commentary.

6. Committee Open Discussion

The Committee had an open discussion to discuss any relevant topics that were not mentioned during the meeting.

Summary of discussion:

Contractor staff asked if the Committee had seen errors with heart-lung allocation, specifically that there was a group who allocated with status 1-4 versus classifications 1-4. A member said yes, noting there are a few ways this can be done incorrectly since multi-organ allocation is not uniform and very complex. A member commented that they have a case manager who runs all the matches, and they have guidance on each case to reduce those issues. One member added they do a pre-allocation huddle, which is extremely complex and complicated. A member noted that programming changes would be the best way to fix this issue. The Vice Chair pointed out that once OPOs allocate multi-organs, and a program backs out, the OPOs cannot go backward on the match run.

Upcoming Meeting

- April 18, 2024, at 1 PM ET (teleconference)

Attendance

- **Committee Members**
  - PJ Geraghty
  - Lori Markham
  - Doug Butler
  - Greg Veenendaal
  - Lee Nolen
  - Micah Davis
  - Samantha Endicott
  - Sharyn Sawczak
  - Stephen Gray
  - Clinton Hostetler
  - Theresa Daly
  - Jim Sharrock, Visiting Board Member (Virtual)
  - Daniel DiSante (Virtual)
  - Donna Smith (Virtual)
  - Judy Storfjell (Virtual)
  - Kurt Shutterly (Virtual)
  - Leslie McCloy (Virtual)
  - Valerie Chipman (Virtual)
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jon Miller
  - Katherine Audette
- **UNOS Staff**
  - Robert Hunter
  - Kayla Balfour
  - Alina Martinez
  - Houlder Hudgins
  - Kaitlin Swanner
  - Kevin Daub
  - Krissy Laurie
  - Nadine Hoffman
  - Sharon Shepherd
  - Susan Tlusty
- **Other Attendees**
  - David Marshman (virtual)