OPTN Organ Procurement Organization Committee
Meeting Summary
November 9, 2023
Teleconference

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

Introduction

The OPTN Organ Procurement Organization (OPO) Committee met via WebEx teleconference on 11/09/2023 to discuss the following agenda items:

1. Organ Offer Acceptance Limit Proposal
2. Pronouncement of Death (Policy Language Review- Voting Item)
3. Continuation of New Project Discussion

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

1. Organ Offer Acceptance Limit Proposal

The Committee received an update on the Organ Offer Acceptance Limit proposal.

Summary of discussion:

There were no decisions regarding this item.

The Chair noted that only two percent of dual offer acceptances were pediatric cases. They requested that data for pediatric cases be available for the Board of Directors meeting on December 4th. The Chair voiced their frustration with the current policy and emphasized the necessity of changing it.

Next steps:

The proposal will be presented to the Board of Directors at their December 4th meeting.

2. Pronouncement of Death (Policy Language Review- Voting Item)

The Committee reviewed and voted on the policy language for their Pronouncement of Death project.

Summary of discussion:

The Committee unanimously supported sending the modifications to *Policies 2.14.A: Conflicts of Interest* and *2.15.G: Declaration of Death* out for public comment in January 2024.

A member asked the Committee if their OPO has a pulmonologist that pronounces a donor on a DCD and it's a lung donor for reintubation, can a pulmonologist do that based on the new policy language? A member said yes because it is not part of the recovery or transplant of the organ.

Next steps:

The public comment proposal will be drafted and will go out for public comment in January 2024.

3. Continuation of New Project Discussion

The Committee continued to discuss new potential projects: Flush Solution Documentation and Machine Perfusion Data Collection.

Summary of discussion:

No decisions were made regarding this agenda item.

Flush Solution Documentation

A member believes the current policy regarding flush solution documentation is clear and expressed that if the solution is not affecting other organs, then it should not be the responsibility of the OPO. They mentioned that their OPO documents storage solution and if they provide the solution, they will document it. The Chair agreed, noting that when the organ is no longer in the body, it is no longer the responsibility of the OPO and anything that is flushed out afterward is not necessary.

The Vice Chair recommended that if the transplant program brings in machine perfusion or other devices, and they're going to put preservation solution through an organ, then the responsibility would fall on the transplant program. A member voiced their support for this idea and noted their concern that if they aren't the one purchasing the flush solution, they will not get the recall notification, which defeats the purpose of documentation. They elaborated that the transplant program that purchased the flush solution would get the recall notice and would have to go back into their database to see if they ever used it on a patient, and if so, which patient. They pointed out that it would then be their responsibility to notify the transplant center that received the organ. A member agreed, noting that it's the OPO's responsibility to document flush solutions, and if there were to be a recall, the responsibility would fall on the OPOs. They continued, emphasizing that a challenge is that there is no standardization and there are many different technologies and machines, like normothermic regional perfusion (NRP) devices, that make it more complex, as there is a wide variability on how different transplant centers and OPOs approach that. They added that NRP is especially challenging because the organs have not been removed from the donor, so if the Committee decides that's where the OPO responsibility stops, it may be okay since they are still in the operating room and the data can be collected. A member agreed.

A member suggested adding clarifying language to Policy 2.14.C, that indicates where the OPO's responsibility ends for documentation, specifically when the donors or organs leave the operating room. A member agreed, noting that is an important aspect. A member expressed concern about reallocating an organ, specifically when the organ is on mechanical preservation. They questioned if the OPO has some responsibility to provide what interventions were performed on the organ at the time it was on a device. A member commented that when their OPO puts an organ on a device, they have a report that details all the information. They questioned if machine perfusion companies supply this information, in the event of necessary reallocation. A member responded that it is the machine perfusion company's responsibility, as they have had to reallocate an organ after it has been on machine perfusion, and they have documentation of laboratory tests, medication administration, and perfusion flow. They continued, commenting that they believe it is the responsibility of whoever is doing the perfusion, whether that is an OPO or another company.

A member suggested modifying bullet 6 of policy 2.14.C to say "OPOs responsible for all in situ flush solutions and additives, static preservation, packaging storage solution" and adding in a separate bullet "whoever is operating a perfusion device, takes the responsibility for documentation of the flush solutions". A member agreed. A member recommended adding "machine perfusion companies should provide the OPOs with the report as part of their record to show the condition of the organ throughout

the entirety of the process". A member commented that it may be useful for the companies to upload that report to the OPTN Donor Data and Matching System so that if reallocation were to occur, the report is already in the computer system. The Chair mentioned that perfusion companies no longer have access to the OPTN Computer System. A member expressed that it was not a bad request for perfusion companies to provide OPOs with this information.

Machine Perfusion Data Collection

The Chair stated that this is a big, but necessary project, as they have heard from different transplant programs that there is no standardized reporting of machine perfusion or normothermic regional perfusion (NRP). They continued, observing that lung transplant programs are seeing difficult outcomes with their recipients from NRP donors. They believe that there needs to be more information about machine perfusion so that the transplant community can make better decisions about how to move forward with this technology. The Vice Chair added that OPOs are the ones who ultimately know if an organ goes on machine perfusion or not. A member remarked that to capture the data, the responsibility falls on the OPO since the Committee just noted that machine perfusion companies do not have access to the OPTN Computer System. They continued, noting that even if machine perfusion fields were available, organizations and transplant programs do not have access to the system to document this information.

The Chair affirmed that this policy will likely result in documentation and will have to mandate that transplant programs provide necessary data elements to the OPO within a specified number of hours of the organ recovery or transplant. They added that they also will have to add data elements for organs that do not get transplanted, since that too is important data. The Vice Chair mentioned that they had lost an organ due to their machine perfusion device not working, which resulted in the OPO being unable to reallocate, despite efforts to try to fix the device.

A member advised that when determining the type of data that should be collected, it is important to engage the liver and thoracic organ communities. They commented that they do agree that this data is important to collect, especially since ex-vivo organs are traditionally discarded organs. The Chair agreed, emphasizing that once the Committee identifies what the data fields they want to collect are, it will be crucial to have OPO, transplant program, and machine perfusion vendor representation.

A member believes that this data should be collected, as their center does not currently use machine perfusion, but is in the process of engaging with machine perfusion vendors and they believe having a reliable source of this information would be useful. They noted that it would also be helpful for centers to identify how they will use this technology, as they have heard from colleagues who are currently using machine perfusion and have said that there is no consistency, and it adds a significant cost and logistical challenge. They continued, emphasizing that there must be a benefit identified in using machine perfusion and that there is no harm to the potential recipients. A member agreed, adding that having this data collected would enable OPOs to track outcomes for recipients.

A member agreed with all comments, highlighting that the most important thing is getting feedback from cardiothoracic and liver communities on what data they want to see collected because some of the data they want to collect may be unrealistic.

A member expressed concern that depending on how many data points are collected, it's going to be a lot of data entry for a procurement coordinator in the operating room. A member commented that once the surgeon has accepted the organ and it is on machine perfusion, it then becomes the vendor's responsibility to provide the surgeon with the machine parameters, not the OPO's responsibility. They believe that is why it is important to engage organ-specific communities, but also machine perfusion vendors to figure out who is providing what data.

The Vice Chair commented that this is an important project that they think should be a high priority, but mentioned they also feel strongly about the "Timing of Family Discussion" project. They said the "Timing of Family Discussion" project needs to be addressed, especially since there is no standardization of the timing of family discussions across OPOs. The Chair agreed, stating that the "Timing of Family Discussion" project can be solved much quicker and easier than the "Machine Perfusion Data Collection" project. A member commented that the "Solution Documentation" project ties in with the "Machine Perfusion Data Collection" project, since it is a minor change, but it has some overlapping pieces.

Next steps:

The Committee will potentially address the Timing of Family Discussion project.

Upcoming Meeting

- December 7, 2023 (teleconference)

Attendance

- **Committee Members**
  - PJ Geraghty
  - Lori Markham
  - Kurt Shutterly
  - Clinton Hostetler
  - Donna Smith
  - Greg Veenendaal
  - Judy Storfjell
  - Lee Nolen
  - Leslie McCloy
  - Micah Davis
  - Sharon Sawczak
  - Stephen Gray
  - Valerie Chipman
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Robert Hunter
  - Alex Carmack
  - Houlder Hudgins
  - Kayla Balfour
  - Katrina Gauntt
  - Kevin Daub
  - Krissy Laurie
  - Meghan McDermott
  - Ross Walton