

OPTN Organ Procurement Organization Committee

Meeting Summary

September 30, 2024

Detroit, Michigan

PJ Geraghty, MBA, CPTC, Chair

Lori Markham, RN, MSN, CCRN, Vice Chair

Introduction

The OPTN Organ Procurement Organization Committee (“Committee,”) met in Detroit, Michigan on 09/30/2024 to discuss the following agenda items:

1. Machine Perfusion Data Collection Project
2. Donation after Circulator Death (DCD) Policy Review – New Project
3. Ad Hoc Multi-Organ Transplantation Committee – Update and Discussion
4. HRSA Data Directive (Ventilated Death Data) Update
5. Pancreas for Research – New Disposition Codes
6. Late Decline – Data Request
7. Research Department Orientation
8. Open Discussion
9. Closing Remarks - Adjournment

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

1. Machine Perfusion Data Collection Project

Presentation Summary

The purpose of this project is to collect data on the use of machine perfusion and normothermic regional perfusion (NRP). Perfusion data is currently collected by Organ Procurement Organizations (OPOs), transplant programs, device companies, and the Organ Procurement and Transplantation Network (OPTN) but there is a lack of a centralized data collection system. What data the OPTN system does have is limited and getting better data will help the community understand the impact of this technology.

New data collection as part of a past project has been approved by the OPTN Board of Directors and is awaiting Office of Management and Budget (OMB) approval. This will add DCD clinical information into the OPTN Donor Data and Matching System, including information about, when NRP recovery was used, the date and time of initiation of NRP.

Considerations for the project include.

- More data fields increase cost and complexity of the project
- Organ specific parameters
- Transplant programs are unable to upload info into the OPTN Donor Data and Matching System
- Adaptability to add new devices/technologies
- Data sharing/transfers
- Responsibilities for reporting data

The next steps for the project include.

- Clear definitions and instructions for each data element
- Identify how the data fields will look in the system
- Where in the system these data fields should be located
- What the appropriate response options are
- If the data element is a lab value, how is it collected?

Summary of Discussion:

No decisions were made regarding this agenda item.

A member asked how organ specific information relevant to this project will be obtained. Representatives from organ specific committees are part of the workgroup and they will be bringing information back and forth between their committees and the workgroup to ensure organ specific field data is handled appropriately. The workgroup will also give periodic updates to organ specific committees and there will be public comment periods for this project.

A member expressed concern that the new data collection waiting on OMB approval may be outdated by this project. An individual responded that this project is likely years away from completion so it will still be important to collect the data currently awaiting approval in the interim, even if it is only for a short time.

There was some discussion about whether there was any way of speeding up the timeline for this project, but the consensus was that it cannot be done any faster.

Next steps:

The workgroup will examine data elements for NRP and machine perfusion separately even though there is some overlap. They will start with NRP data elements first as they anticipate those will be easier to identify.

2. DCD Policy Review – New Project

Presentation Summary

The current donation after circulatory death (DCD) policy has been in effect since March 1, 2014 and given developments in technology needs to be reviewed.

The scope of this project is as follows.

- Review the timing of family DCD donation discussions
- Review all DCD policies
- Evaluate the need for machine perfusion and normothermic regional perfusion (NRP) policies

The project has been submitted to the Policy Oversight Committee (POC) for review during its October 10, 2024 meeting. The workgroup will include members from the Organ Procurement Organization (OPO) Committee, the Ethics Committee, the Membership and Professional Standards Committee (MPSC), and the Operations and Safety Committee.

Summary of Discussion:

No decisions were made regarding this agenda item.

There was a call for six volunteers to join this project.

Next steps:

The next steps for this project are to get the workgroup roster of committee members willing to join this workgroup and have an initial call scheduled for November.

3. Ad Hoc Multi-Organ Transplantation Committee – Update and Discussion

Presentation Summary

Multi-Organ allocation generally has Organ Procurement Organizations (OPOs) place thoracic organs first, then abdominal organs because there are restrictions for 2nd and 3rd organs that are determined by medical eligibility criteria. Some multi-organ transplant candidates can accept single organs, but some can't and there is currently no codified way for OPOs to handle this.

The Multi-Organ Allocation policy proposal is designed to promote equitable access to transplants among multi and single organ candidates that is consistent and efficient throughout the allocation process. This goal will be achieved by providing a direct order for OPOs to allocate organs when a donor has more than one organ available for transplantation. This prioritization will not change the ranking order developed for specific policies.

A potential information technology (IT) solution is being considered to handle the prioritization process for multi-organ allocation. This solution currently has six algorithms that are expected to cover 96% of multi-organ transplantation (MOT) according to data from July 2021 to December 2023. This IT solution works by having OPOs determine which organs will be offered then running all relevant match runs at the same time. The system will then generate an allocation plan for the OPOs to follow.

Summary of Discussion:

No decisions were made regarding this agenda item.

A member asked if this IT system was one single match run or if it still relied on multiple match runs. An individual responded saying the IT system still requires multiple match runs but it is an interactive and dynamic system designed to guide the user between match runs as required. It has guardrails in place to warn users when they need to switch match runs.

There was a suggestion from a member for the IT system to allow offers to be sent directly from the allocation plan rather than from the match runs. This ability would eliminate the need for OPO staff to work back and forth between match runs. There was a consensus that would be a nice thing to include in the proposed system if possible.

There was a question about how the system would handle a transplant program backing out of a primary offer and whether the user would have to start the process over to account for the requirement to hold single organs for multi-organ transplants. There was a reminder that a new policy in effect as of July 2024 no longer requires OPOs to hold single organs for multi-organ transplants if the primary backs out of an offer.

There were more suggestions to add to the allocation plan where candidates were ranked on different lists for various organs, details about organs to the plan screen for each match, and to have pop-up warnings if a user was trying to make an offer out of allocation policy order.

Next steps:

The next steps for this project include.

- Identify how to get the algorithms to cover the remaining 4% of transplant candidates

- Continue developing the IT solution
- Continue iterating on mockups and gather allocation coordinator feedback
- Present new iterations to the OPO Committee to gain valuable feedback

4. HRSA Data Directive (Ventilated Death Data) Update

Presentation Summary

The Health Resources and Services Administration (HRSA) gave initial notification to the OPTN in the Fall of 2023 and an official directive in February 2024 that required new data collection for pre-waitlist and ventilated patient referral data. A revised ventilated patient form was provided by HRSA in June 2024. The data collection must go through the Office of Management and Budget (OMB) for approval but there is no exact date for that at this time.

The OPTN will prepare a public comment response for both postings on the Federal Register. HRSA has provided guidance on how the response will be prepared. The Data Advisory Committee will lead in preparing the response and there will likely be an opportunity for the OPO Committee in that process.

Summary of Discussion:

No decisions were made regarding this agenda item.

There was no discussion of this agenda item at this time.

Next steps:

The OPO Committee will be updated as necessary.

5. Pancreas for Research – New Disposition Codes

Presentation Summary

Centers for Medicare & Medicaid Services (CMS) issued a memorandum requiring Organ Procurement Organizations (OPOs) to report data related to pancreata procured for research. The existing reporting codes were not specific enough to capture whether a pancreas was used for islet cell research. CMS, HRSA, and the OPTN created new codes to differentiate between pancreata used for islet cell transplantations or research and pancreata used for non-islet cell research. Pancreata are considered used for research if they are accepted for use in bona fide research conducted by a qualified researcher.

The memorandum also requires retrospective clarification of disposition codes for research pancreata recovered since 01/01/2021 using the revised reason codes. CMS will distribute revised preliminary 2024 performance reports on 01/10/2025 and OPOs will provide comments on those reports by 01/27/2025. CMS will then distribute the final reports to the OPOs by 02/11/2025.

Summary of Discussion:

No decisions were made regarding this agenda item.

There was no discussion of this agenda item at this time.

Next steps:

The revised disposition reason codes will be active in the OPTN computer system by 10/09/2024 and OPO reports will be available in the OPTN computer system by 10/10/2024. OPOs must clarify data for 2021 and 2022 by 11/01/2024.

6. Late Decline – Data Request

Presentation Summary

Currently there is no established definition for late declines. The goal of this project is to assess the frequency of late declines to inform standard definition(s) and inform policy development. There is a small group of OPOs participating in this project and there was a 40-day feedback period where participants submitted information including late turndowns, surgical injury, and transportation issues.

Twelve OPOs participated and they had a total of 211 instances of late declines with liver making up 48% of late declines. The reasons for late declines varied but the most common reasons were recipient status, organ quality, and donor history in that order. The project is currently on hold due to competing priorities of the taskforce such as Rescue Pathways.

On March 27, 2024 the Membership and Professional Standards Committee (MPSC) requested the OPO Committee review data collection efforts regarding late turn downs and to clarify the definition of a late turn down. The OPO Committee expressed interest in reviewing potential transplant recipients (PTR) data to see how often an acceptance response from a patient changes to a decline. The Committee also wanted to review the number of scheduled OR times per donor to determine the frequency of operating room time (OR) rescheduling.

The findings of this data request are as follows.

- The average number of OR times rescheduled has steadily increased between 2017 and 2023
- The percent of donors with no OR time values entered has steadily decreased over time
- The average number of acceptance-turned-no responses per donor has increased between 2020 and 2023 for liver, lung, and heart offers
- The average number of acceptance-turned-no responses per donor for kidney offers increased between 2017-2022, then decreased between 2022 and 2023

Summary of Discussion:

No decisions were made regarding this agenda item.

There was a question from a member asking if the Committee needed to provide a formal memo to MPSC letting them know the Committee has not forgotten about this task but that it is on hold. An individual agreed that was a good idea.

Next steps:

- The project will be restarted in early 2025
- Send a formal memo to MPSC notifying them of the status of this request
- OPO leaders should remind their staff to update the OR time within OPTN Donor Data and Matching System

7. Research Department Orientation

Presentation Summary

The research department supports committees by fulfilling data requests to provide the data committees need to make informed decisions.

UNOS Research Core Functions include.

- Biostatistics

- Research Science
- Behavioral Science
- Epidemiology
- Surveys
- Data Science

The OPTN now requires project goals and at least one key metric at the time of project approval to determine if a policy project achieved the intended goals. To align with this new framework the research department will no longer produce a single static report but instead produce a report and a dashboard that will reflect important components of organ allocation systems. The dashboard will be updated periodically as information becomes available. As a result of this change monitoring reports will now be known as key metric reports and static reports will no longer contain demographic sections as that information will be available via the dashboard.

Data requests should align with the committee policy development project, but OPTN committee members can write abstracts or manuscripts based on data/monitoring reports stemming from OPTN projects for publication. If these publications are on behalf of the committee, they are subject to HRSA review prior to submission/presentation. The UNOS Research department may help develop manuscripts at UNOS leadership's discretion. If the UNOS Research department is not able to lead the work, they can provide support by writing the methods/results, formatting tables/figures, and providing edits to the overall manuscript.

Summary of Discussion:

No decisions were made regarding this agenda item.

There was no discussion of this agenda item at this time.

Next steps:

There are no next steps for this agenda item.

8. Open Discussion

Summary of Discussion:

No decisions were made regarding this agenda item.

There was some discussion about whether bronchoalveolar lavage (BAL) testing for Covid-19 was still necessary on donors for lung transplants. Some locations don't have testing centers that run Covid-19 tests on BALs in their area which can be an operational challenge that increases time and costs. An individual asked if these delays were delaying transplantation and the answer was no. Another individual felt that these tests should still be required as BAL testing is more reliable than nasal swaps in testing for Covid-19.

One individual suggested standard respiratory viral panel testing be done on donors during flu season. This viral panel tests for 7-8 viruses and has a turnaround time of 6-7 hours. The same individual

suggested if the standard respiratory viral panel testing wasn't available there are smaller rapid tests that could be performed. The Committee discussed possible recommendations or reminders for such precautions was warranted but wasn't prepared to recommend requiring these tests as not all OPO areas have the same testing capacity.

An individual asked if there was a way to check the credentials of advanced practice coordinators who do testing. Several committee members noted that there were no standardized qualifications for advanced practice coordinators or doctors between different facilities. A suggestion was made to include video or pictures of echocardiograms in the OPTN Donor Data and Matching System to eliminate concerns about qualifications. This received general support as a good idea.

One individual noted that organ offers going out in the middle of the night might be leading to a greater number of turndowns. Another member responded that trying to shift offers to more reasonable times may be helpful but that it's not always possible.

Next steps:

There are no next steps for this agenda item at this time.

9. Closing Remarks - Adjournment

Presentation Summary

October 10th meeting is cancelled due to the committee meeting twice in September.

Summary of Discussion:

No decisions were made regarding this agenda item.
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There was no discussion of this agenda item at this time.

Next steps:

There are no next steps for this agenda item.

Upcoming Meeting

- November 21, 2024

Attendance

- **Committee Members**
 - PJ Geraghty
 - Lori Markham
 - Ann Rayburn
 - Clint Hostetler
 - Dan DiSante
 - Donna Smith
 - Dough Butler
 - Greg Veenendaal
 - Jasleen Kukreja
 - Judy Storfjell
 - Kerri Jones
 - Lee Nolen
 - Micah Davis
 - Shane Oakley
 - Sharyn Sawczak
 - Stephen Gray
 - Theresa Daly
- **HRSA Representatives**
 - Jim Bowman
 - Brianna Doby
 - Marilyn Levi
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Robert Hunter
 - Susan Tlusty
 - Viktoria Filatova
 - Kaitlin Swanner
 - Laura Schmitt
 - Sarah Roache
 - Alina Martinez
 - Sara Langham
 - Ross Walton
 - Kevin Daub
 - Krissy Laurie
 - Bonnie Felice
 - Houlder Hudgins
 - Sharon Shepherd
 - Katrina Gauntt
 - Darby Harris
- **Other Attendees**
 - Lisa Stocks