

**OPTN Machine Perfusion Data Collection Workgroup  
Meeting Summary  
October 23, 2024  
Conference Call**

**Theresa Daly, MS, RN, FNP, Chair**

## **Introduction**

The OPTN Machine Perfusion Data Collection Workgroup (the Workgroup) met via WebEx teleconference on 10/23/2024 to discuss the following agenda items:

1. Highlights from 9/25/2024 Conference Call
2. Overview of Data Collection Process
3. Review of Draft Normothermic Regional Perfusion (NRP) Data Elements

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

### **1. Highlights from 9/25/2024 Conference Call**

OPTN Contractor staff highlighted the discussion from the Workgroup's initial conference call held on September 25, 2024.

#### Summary of Presentation:

The Workgroup's initial thoughts on this project included the following:

- Concern about access to third party data
- Current state of machine perfusion (lack of standardization)
- Gaps in machine perfusion data
- Data flow – Machine devices to electronic health records (OPO/transplant center) to OPTN Computer system
- Agreement with two pathways
  - Organ evaluation
  - Research/outcomes

The Workgroup identified the following tasks for this project:

- Identify data elements
  - Operationally required
  - Clinically required
  - Wish list/desired data
- Clarify responsibilities
  - OPOs need to collect
  - Transplant programs need to collect

The workgroup members agreed to initially focus on NRP data.

#### Summary of Discussion:

**The Workgroup did not make any decisions.**

A member suggested that an “end of case” form be developed so that information collected by the device companies and transplant programs can be provided to the OPOs. This was based on the concern that information provided later in the deceased donor registration (DDR) might be difficult to collect. Additionally, this could also help collect information about why an organ was turned down or not used after it left the OPO.

Another member expressed concern about creating an additional form that would require the manual entry of data. A better approach is for the Workgroup to identify the NRP data elements that currently exist so they can be uploaded into the OPTN system at appropriate times.

## **2. Data Collection Project Process**

OPTN Contractor staff provided an overview of the data collection project process.

### Presentation summary:

OPTN Contractor staff provided an overview of the OPTN Data Advisory Committee’s (DAC) role in the process. Committees working on data collection projects are required to work with the DAC to ensure the proper steps are followed during policy development and conform with the principles of data collection. Staff noted that the OPO Committee completed the first required DAC check-in during the “problem analysis” phase prior to submitting the project to the Policy Oversight Committee for review and approval. A second check-in is required during the “evidence-gathering” phase and will be done once the workgroup is further along in its work and prior to public comment.

OPTN Contractor staff provided an overview of the 2021 Data Standardization Checklist that the Workgroup will be required to use during its work on this project. The purpose of this checklist is to provide a consistent, systematic approach to aid OPTN Committees in the assessment of data they seek to add, modify or remove, either as part of a public comment proposal or ongoing data review of OPTN data collection instruments. The goal is to improve the quality, usefulness, and trustworthiness of OPTN data. The components of the checklist include the following:

- Purpose - What is the intent or purpose of collecting this specific data element?
- Definitions – Clear and understandable, units of measurement (if applicable) or responses, and evaluation of unknown values
- Availability – Is it currently being collected or does it require additional testing?
- Burden – Is there an additional burden (e.g. cost, staffing) to report?

### Summary of discussion:

<b>The Workgroup did not make any decisions.</b>
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There were no questions or discussion on this agenda item.

## **3. Review of NRP Data Elements**

The Workgroup began their review of the NRP data elements. OPTN Contractor staff developed an NRP data element worksheet that was distributed to the Workgroup in advance of the meeting. The initial list of data elements include the following:

- Organs intended to recover
- Organs recovered for transplant
- Thoracoabdominal NRP or abdominal NRP
- Time of heparin administration

- Form of heparin administration
- Dose of heparin administration
- Time of withdrawal of life sustaining measures
- Systolic blood pressure (SBP) < 50 intervals
- Cannulation Site
- Modality type
- NRP run time
- Autologous perfusion period
- Cross clamp time
- Time of cold flush of organs
- Lactate levels
- NRP circuit flow

Summary of Discussion:

**The Workgroup agreed to develop a workflow to help map out what data should be collected at certain timepoints.**

*Initial Comments*

A member commented that NRP circuit flow was vague and should be clarified. Is it meant to look at achieved perfusion levels on the pump and could it be a separate measurable category? The member added that donor blood pressure while on the machine might be important to capture as well.

A member questioned whether medications should be added to the list of data elements, specifically medications given during NRP.

A member noted that the issue is the purpose of the data and when it is collected. Is this specific to NRP or can it also be applied to all DCD donors? Additionally, the data needs to be specific about NRP versus machine perfusion. The member added that data would essentially be collected at three timepoints:

- Initial data at the procurement site
- Data collected on machine perfusion/NRP
- Data collected at the transplant hospital

A member noted that the workgroup also needs to be clear about what data will be collected in real time for organ offer evaluation and what data will be collected after the fact for research/outcomes. Some of the data might be similar, but serve different purposes, including the expected outcomes reported by the Scientific Registry of Transplant Recipients (SRTR).

A member noted that even though the initial focus is on NRP data, the workgroup needs to ensure that the data definitions can be applied to all the modalities such as machine perfusion. Additionally, the workgroup needs to agree on fundamental things like defining functional warm ischemic time as it applies to both NRP and machine perfusion.

*Intent to Recover Organs*

The Workgroup members discussed the “Organs Intended to Recover” data element. There was some concern about using the word “intended” as it has implications for other regulatory agencies outside the OPTN. There was discussion about the purpose of this data element and a suggestion to use language such as “To identify all organs intended to be recovered that are impacted by NRP.”

A member commented that it's important to distinguish between intended to be recovered for transplant versus intended to be recovered for research. There could be three radio button options – yes or no for recovered for transplant and yes for recovered for research.

Another member noted that when an OPO makes the decision to go to the operating room (OR), they are intending to allocate organs for transplant or research and this information should be captured along the way. An example was provided about how the intent might be to recover the liver and kidney, but during the “NRP process” the second kidney recovers and becomes transplantable. Since there are now three organs available, it needs to be accounted for during data collection.

Members discussed the scenario where transplant programs are initiating NRP instead of the OPOs. Therefore, the data collection should be clear about which organs the OPO intends to allocate, and which organs will be recovered using NRP, whether that is determined by the OPOs or transplant programs. A member agreed that the purpose statement should clearly separate those two decision points.

A member added that organ disposition data entered into the DDR describes what happened with each organ but does not identify how the organs were recovered.

An OPO member described the following steps in the process:

- OPO determines which organs are suitable for transplant
- OPO execute match runs, identifies intent to perform NRP recovery
  - OPO-based NRP recovery planned, if available
    - Notify transplant programs
  - Transplant program NRP recovery planned
    - *Note:* OPO might not be aware of this until organ(s) are accepted

A member noted that OPOs will know if they are going to recover organs using NRP, so the key data points are what is happening when the donor goes to the OR.

The Workgroup agreed it was important to capture information about the following scenarios:

- NRP planned but eventually not performed
- NRP performed but flows are not good, convert to cold flush rapid recovery
- NRP performed, but organs not utilized due to extra warm time
- NRP performed for some organs but not for others
  - For example, thoracic organs recovered using rapid recovery while abdominal organs are recovered using NRP

### *Process Map*

Workgroup members suggested the development of a wire diagram that outlines the process from donor evaluation to transplant. Identifying the stages will help identify where data needs to be collected and help the workgroup better identify the purpose and definitions for the individual data element. A member suggested reaching out to OPOs that routinely use NRP to see if they would be willing to share their processes.

### Next Steps:

Staff will work with leadership to develop an NRP workflow for review.

### **Upcoming Meeting**

- November 20, 2024

## Attendance

- **Workgroup Members**
  - Theresa Daly
  - Aaron Ohearn
  - Chandrasekar Krishnan
  - Donna Smith
  - Edward Cantu
  - Kim Baltierra
  - Anja DiCesaro
  - Matthew Hartwig
  - Snehal Patel
  - Stephen Gray
  - Micah Davis
  - Christine Maxmeister
- **HRSA Representatives**
  - Mesmin Germain
  - Jim Bowman
- **SRTR Staff**
  - None
- **UNOS Staff**
  - Robert Hunter
  - Susan Tlusty
  - Ethan Studenic
  - Joel Newman
  - Kevin Daub
  - Alina Martinez
  - Laura Schmitt