

OPTN Machine Perfusion Data Collection Workgroup

Meeting Summary

January 22, 2025

Conference Call

PJ Geraghty, MBA, CPTC, Chair

Introduction

The OPTN Machine Perfusion Data Collection Workgroup (the Workgroup) met via WebEx teleconference on 01/22/2025 to discuss the following agenda items:

1. Continue Review of Normothermic Regional Perfusion (NRP) Data Elements

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

1. Continue Review of NRP Data Elements

Presentation Summary

SBP50 Intervals

The workgroup decided last meeting to not make changes to this data element but instead require Organ Procurement Organizations (OPOs) to monitor and upload donor vitals from the moment of withdrawal of life support until declaration of death on a minute-to-minute basis. Questions for the workgroup to consider regarding this data element include:

- Will there need to be changes to the current definition for agonal phase in the Deceased Donor Registration (DDR)?
- Will this cause confusion with the calculation of warm ischemic time?

Anticoagulant (NRP Circuit)

The workgroup decided to create a new field for anticoagulants administered in the NRP circuit to avoid confusion of heparin administered into the donor and concerns about possible heparin allergies.

Questions for the workgroup to consider regarding this data element include:

- Will this data element be a binary response?
- Should the data element also capture the type of anticoagulant?

NRP "Cross-Clamp" Time

The workgroup needs to address the confusion between current cross-clamp definition and what cross-clamps mean for NRP. Questions for the workgroup to consider regarding this data element include:

- If there needs to be a separate NRP cross-clamp field and definition?
- Does the data element need to specify which vessel(s) are cross-clamped?
- How does this data element affect the definition of cold ischemic time?
- Does the workgroup need to address clamping of cerebral vessels?

Time of Cold Flush of Organs

This data element is already collected in the DDR and is defined as “core cooling flush is initiation of in on site (situ) cold perfusion using standard in situ preservation fluids.” Questions for the workgroup to consider regarding this data element include:

- What is the intent or purpose of collecting this data element?

Lactate Levels

This data element does not have a current definition. A proposed definition is “to help detect hypoxia and other diseases that cause excess production or reduced removal of lactate from the blood.”

Questions for the workgroup to consider regarding this data element include:

- Is this drawn from the donor or the NRP circuit?
- Is this drawn multiple times and if so at what intervals?
- Is this assuming serum lactate?
- What is the range of millimoles?

Summary of Discussion:

No decisions were made regarding this agenda item.
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Systolic Blood Pressure (SBP)50 Intervals

The Workgroup confirmed that OPOs would monitor vitals of donor patients minute by minute and upload that information so that transplant centers could determine their own agonal phases and warm ischemic time. The vitals that the OPO would upload include heart rate, systolic and diastolic blood pressure, mean arterial pressure (MAP), and oxygen saturation (SpO2). These vitals would be collected from the withdrawal of life support to arrest, from withdrawal of life support to time of death, and from withdrawal of life support to the flush of organs. The Workgroup felt this was the appropriate action because different transplant centers use different internal definitions of the agonal phase and warm ischemic time as well as using different blood pressures. The Workgroup debated using a SBP of 50 and an SBP of 80 and giving both those benchmarks to transplant centers but they felt that due to the changing nature of the field it would be better to provide all the relevant information and let the transplant centers decide for themselves.

The Workgroup discussed the effects of removing definitions like warm ischemic time and agonal phase from the DDR. They noted that any field in the DDR must have a definition and that removing something like warm ischemic time would create an issue because some calculations are based off that data element. They also noted that any new calculations using already existing fields, such as arrest, would likely require review by the Office of Management and Budget (OMB).

Anticoagulant (NRP Circuit)

The Workgroup discussed whether the heparin field should be called anticoagulant for the rare case when donor patients have a heparin allergy. The Workgroup felt these instances were so rare it was not worth using resources to change the name of this field. The Workgroup discussed what elements of heparin administration would be important to collect. They felt they would need to collect when heparin was given, how much heparin was given, and if additional heparin was given. The Workgroup debated not including additional heparin given, instead just capturing total heparin given. They also debated having multiple fields for each additional dose of heparin given. They decided to have a field that captures the amount of heparin given in the first dose and then a second field to capture the total amount of heparin given so they could capture any additional doses. They felt that capturing if

additional heparin was given could help in understanding NRP practice but felt that capturing each additional dose in its own field would be excessive.

Cross-Clamp Time

The Workgroup discussed the data element cross-clamp time and observed that the naming convention for this element is confusing. Historically cross-clamp time and organ flush time happened one right after the other and so cross-clamp time and organ flush time were used interchangeably. The Workgroup questioned whether these two things still happened in unison when NRP is being used. The traditional cross-clamp time is for the cross-clamping of the aorta and is used in calculations in the DDR.

The Workgroup considered removing the cross-clamp time and using flush times instead because those are what matters for NRP. There would be four flush times that needed to be captured, abdominal aorta, thoracic aorta, portal vein, and pulmonary artery. A staff member noted that flush times were going to be captured in the system with an upcoming implementation. The Chair noted that the system needs a field for clamping cerebral vessels and if they were vented.

The Workgroup debated on different ways to generate a second cross-clamp time in the system for when abdominal organs were being recovered via NRP. One suggestion was to have a child question generated from the cross-clamp time to capture if a second cross-clamp time was needed for abdominal NRP. One member pointed out if the Workgroup is going to have two cross-clamp times, the old one needs to be relabeled thoracic cross-clamp time and the new one abdominal cross-clamp time for clarity.

Times of Cold Flush of Organs

The Workgroup felt this data element did not need to be adjusted as it is part of an upcoming implementation package being reviewed by the OMB.

Lactate Levels

The Workgroup discussed how lactate levels are collected. One member noted that when collecting lactate levels, many time points need to be captured because with lactate levels, what matters is the overall trend of the lactate level, rather than a single absolute value of lactate. They also noted that when performing NRP, checking lactate levels was just to ensure they are trending downwards. Another member mentioned they do not follow lactate levels at all unless the organ is being perfused by machine. The Chair noted the Workgroup may want to keep machine perfusion lactate fields separate from NRP lactate fields, especially because sometimes donors switch between machine perfusion and NRP or vice versa. The Chair suggested that Workgroup members gather practices around lactate levels from their own organizations before the next meeting.

Next Steps

- Collect general practices regarding lactate levels before the next meeting.
- Review possible ways to program the generation of an additional cross-clamp time data field.

Upcoming Meeting

- February 19, 2025

Attendance

- **Workgroup Members**
 - PJ Geraghty
 - Theresa Daly
 - Cassie Hertert
 - Aaron Ahearn
 - Christine Maxmeister
 - Anne Krueger
 - Jason Smith
 - Ed Cantu
 - Joel Newman
 - Micah Davis
 - Anja DiCesaro

- **SRTR Staff**
 - Jonathan Miller
 - Katie Siegert

- **UNOS Staff**
 - Susan Tlusty
 - Kaitlin Swanner
 - Ethan Studenic
 - Kevin Daub
 - Houlder Hudgins
 - Alina Martinez