

Meeting Summary

OPTN Machine Perfusion Data Collection Workgroup Meeting Summary December 18, 2024 Conference Call

Theresa Daly, MS, RN, FNP, Chair

Introduction

The OPTN Machine Perfusion Data Collection Workgroup (the Workgroup) met via WebEx teleconference on 12/18/2024 to discuss the following agenda items:

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

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

1. Continue Review of NRP Data Elements

Presentation Summary

A Review of Previous Data Elements

The NRP Intent data element will need separate data fields, one for organ offers and one for the type of NRP intended, Thoracic NRP (TA-NRP) or Abdominal NRP (A-NRP). The timing of this data element will be important for organ offers to be made and need to be prior to the donor going to the operating room (OR).

The Heparin Administration data element is currently collected on all donors with beginning and end times for administration and the number of units administered. This information is captured in the OPTN Donor Data and Matching System and in the Deceased Donor Registration (DDR). The Workgroup still needs to decide if they need to collect heparin administered into the NRP circuit and if they should collect alternatives to heparin.

The Time of Withdrawal of Life Sustaining Measures data element is currently being collected. The DDR definition is "Withdrawal of support is the withdrawal of life sustaining treatments; the actual point where the patient's attending physician or designee begins the process of removing life sustaining treatments." The DDR instructions are "enter the date, using the standard 8-digit format of MM/DD/YYYY format, and military time of the withdrawal of support. The date must be between the referral date and the date and time of death."

New Data Elements

SBP50 Intervals

- Draft purpose: To identify the start of functional ischemic time? Agonal phase?
- Suggested American Society of Transplant Surgeons (ASTS) definition: The time from the first minute that systolic blood pressure drops below 50 until the start of NRP in the donor.

In the OPTN Donor Data and Matching System warm ischemic time is entered in minutes. If the donor is a (DCD) donor the warm ischemic time is from the agonal phase onset which is defined as the time of cardiac arrest when the systolic pressure meets certain conditions for different age ranges for greater

than 5 minutes. In the DDR the agonal phase begins when systolic blood pressure or O2 blood saturation falls below certain numbers for different age ranges for greater than 5 minutes.

Cannulation Site(s)

- Draft purpose: To evaluate if cannulation sites impact outcomes for NRP.
- No current definition

Autologous Perfusion Period

- No current proposed purpose
- Technique used in cardiac surgery to prime the cardiopulmonary bypass circuit with the patient's own blood.

NRP Run Time

- Draft purpose: To help assess organ viability based on NRP time.
- No current definition

Cross Clamp Time

- No current proposed purpose
- OPTN Donor Data and Matching System and DDR definition: Enter the date/time aorta was cross clamped.

Summary of Discussion:

Decision #1: Collect NRP intent and distinguish between OPO vs transplant program initiated. Collect this information at least 6 hours before organ recovery

Decision #2: Collect anticoagulant administered into the NRP circuit.

Decision #3: Require OPOs to monitor and upload donor vitals from the moment of withdraw of life support until declaration of death on a minute-to-minute basis. (*Policy*)

Decision #4: Drop the cannulation sites data element.

Decision #5: Drop the autologous perfusion period data element.

The Workgroup reviewed the data element NRP Intent. They felt it would be best to have this information collected before organ offers are made. They also felt that it would be beneficial to collect information on if the OPO or transplant center would be performing NRP. At minimum, the Workgroup felt that NRP Intent needed to be collected at least six hours before the donor goes to the OR so that if the transplant center is the one performing NRP, their surgeons will know what they need to bring.

When reviewing the Heparin Administration data element, the Workgroup felt that it should capture if the heparin was administered into the NRP circuit itself. There was some concern this may create a desire within the community for collecting additional information about any antibiotics or medications administered through the NRP circuit. The Workgroup also discussed if Heparin Administration was the proper name for the data element. Some members felt it would be better to label the data element Anticoagulant Administration for the rare cases in which a donor had a heparin allergy and an alternative anticoagulant needed to be used.

For the SBP50 Intervals data element, the Workgroup considered adopting the ASTS definition recommendation which is the time from the first minute that systolic blood pressure drops below 50 until the start of NRP in the donor. The Workgroup felt this was a reasonable suggestion with one

member noting that blood pressure dropping below 50 is a commonly used mark within the transplant community. The Workgroup decided against this definition because there does not appear to be a consensus in the field, with different transplant centers using different blood pressure marks to define their agonal phase and functional ischemic time.

One member noted that many OPOs record vitals on a minute-to-minute basis from the moment of withdrawal of life support until NRP is started. The consensus of the Workgroup was that this is a common practice among OPOs and that mandating this minute-to-minute collection of vitals and uploading the information would allow transplant centers to determine their own agonal phases and ischemic times to make their decisions based on their patient's needs. They felt this would be more appropriate than trying to mandate a specific and somewhat arbitrary number. One member noted that if needed, they could go back and review data after implementation to look for an average blood pressure number used among the community. The Workgroup decided to remove the current definition for SBP50 Intervals and have policy requirements that the OPO report donor vitals from withdrawal of life support until declaration of death in one-minute intervals.

The Workgroup discussed the data element Cannulation Sites. One member noted there are two main cannulation sites, femoral and intrathoracic. The Workgroup discussed possibly collecting this information to learn more about pre mortem cannulation or the preference for cannulating peripherally versus centrally. The Workgroup felt it would be more important to know what organs were perfused rather than the cannulation sites. The Workgroup agreed to not collect cannulation sites because they felt it might create more confusion as sometimes the organs being procured need to be switched and the original site of canulation wouldn't be very beneficial information to have.

The Workgroup discussed the Autologous Perfusion Period data element. This data element was an ASTS recommendation, and the Workgroup felt it was likely ASTS wanted the period of time where the NRP circuit was turned off before, in the instance of heart donations, letting the heart start up again. One member noted this was not really a common practice anymore, most transplant centers usually see that the organ is working on NRP, cross clamp the organ, and move to transport it. Furthermore, the Workgroup agreed that donor patient blood wasn't normally used to prime the pump for NRP, instead packed cells or intravenous solutions are used. One member noted it would be more helpful to know how long the donor was on NRP rather than how long the NRP pump was primed for. The Workgroup decided to drop this data element from consideration for collection due to it not being very relevant anymore and not providing beneficial information.

The Workgroup discussed the Cross Clamp Time data element. They identified the need for two cross clamp times, one for (TA-NRP) and one for (A-NRP). They discussed potential ways for this data element to show up in the system including having one cross clamp time that shows up for TA-NRP and then generates a second cross clamp time of A-NRP if it is indicated that A-NRP will also be performed. They also discussed simply having a field for both TA-NRP and A-NRP regardless. Currently only cross clamp time is collected for when the aorta is cross clamped. The changes the Workgroup discussed would require changes to OPTN Organ Labeling, Packaging and Tracking System.

Upcoming Meeting

January 22, 2025

Attendance

• Committee Members

- o PJ Geraghty
- o Theresa Daly
- o Chris Sonnenday
- o Anja DiCesaro
- o Christine Maxmeister
- o Donna Smith
- o Jason Smith
- o Kim Baltierra
- o Micah Davis
- o Cassie Hertert
- o Stephen Gray

• SRTR Staff

o Jonathan Miller

UNOS Staff

- o Robert Hunter
- o Kaitlin Swanner
- o Ethan Studenic
- o Alina Martinez
- o Laura Schmitt
- o Kevin Daub