

Meeting Summary

OPTN Operations & Safety Committee

Normothermic Regional Perfusion (NRP) Workgroup

Meeting Summary

October 27, 2024

Conference Call

PJ Geraghty, MBA, CPTC, Chair

Introduction

The Normothermic Regional Perfusion (NRP) Workgroup (the Workgroup) met via Microsoft Teams teleconference to discuss the following agenda items:

- 1. Welcome and Introductions
- 2. October 23rd Meeting Recap
- 3. Finalize Draft of Initial NRP Communication
- 4. OPTN Member Solicitation Request NRP Policies and Practices

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

1. Welcome and Introductions

The Chair welcomed members of the Workgroup and new members of the Workgroup provided introductions. The Chair highlighted a few key roles that are missing from the roster and hope to fill in the upcoming weeks.

2. October 23rd Meeting Recap

During the October 23rd, 2025 meeting, the Workgroup reviewed the background on previous OPTN work related to NRP and the NRP critical comment. The Workgroup roster was reviewed with additional key roles identified to be included as well as the meeting cadence. The Workgroup identified potential topics for discussion and deliverables and reviewed a draft of the initial NRP communication.

Summary of discussion:

When reviewing the potential topics for discussion and deliverables, the Chair asked whether the solicitation request for policies and practices related to NRP from OPTN members should occur at the same time as the initial communication about NRP. A HRSA representative stated that those two deliverables do not need to be combined but if they are ready at the same time, it could be beneficial to combine them.

The OPTN President asked for details on what work the OPTN has previously undertaken on the topic of NRP. The Chair responded that the OPTN OPO Committee previously worked on a project to add NRP related data elements to the OPTN Computer System that has since been placed on hold. The Chair also stated that the OPTN also has previously requested policies and practices related to NRP from organ procurement organizations (OPOs) which may provide a starting place for the Workgroup.

3. Discuss and Review: Initial Communication on NRP

The Workgroup reviewed a draft of the initial communication on NRP and discussed areas of revision.

Summary of discussion:

The OPTN President suggested that a sentence should be added to clarify that the Workgroup will build upon existing NRP work previously developed by the OPTN.

The Chair asked whether OPOs that submitted information during the last request should be asked to resubmit. Members agreed that NRP policies and practices may have changed within the year so it would be beneficial to collect policies and practices from all OPTN members.

A member asked whether the communication should include information on the potential concerns around reperfusion. Members agreed that those specific details may not be necessary in the initial communication but will be important for future policy changes.

Another member advocated that the solicitation request for NRP policies and practices should be included as part of the initial communications. Other members agreed. The OPTN President suggested that if the solicitation request is not ready by the time the initial communication is ready to be sent, then the communication should note that the solicitation request will be a forthcoming next step.

A HRSA representative recommended to include a sentence in the initial communication about the rigor with which absence of cerebral circulation is confirmed in potential donor patients undergoing NRP. The OPTN President agreed.

Next steps:

The Chair and the OPTN President will work to finalize the draft communication to submit to HRSA for review.

4. OPTN Member Solicitation Request – NRP Policies and Practices

The Workgroup began discussing the request to solicit information on any policies or practices related to NRP from OPTN members to evaluate the system-wide use of NRP. This solicitation and evaluation will inform a subsequent communication to the community as well as other potential deliverables of the Workgroup.

Summary of discussion:

The Chair stated it would be useful to collect NRP policies and procedures from all OPTN members, explaining that it will be important to understand which potential donor patients are undergoing NRP and when cannulation occurs. The Chair added that it would be important to know what techniques are utilized and what methods are used to monitor cerebral perfusion. The Chair emphasized the importance of having the Workgroup review the contents of policies and protocols themselves, rather than requesting certain discrete data elements via a survey. The Chair stated that the policies or protocols could be de-identified prior to the Workgroup's review.

A member emphasized that the community should understand that this effort is not an attempt to take punitive actions against individuals but rather to help develop safety standards and best practices.

Another member suggested that it will be important to understand whether there are standards or exclusions for NRP for particular potential donor patients based on their clinical history. The member stated that knowing the types of methods that are used for occlusion would also be helpful. The member added that knowing which OPOs are using third party vendors and what the standards are for those vendors would be beneficial. The member continued that it would be helpful to review OPOs' consent language describing the NRP process. Another member stated that understanding the exact details of clamping is important because of the potential variation across OPTN members.

The Chair suggested that a survey could be built after the policies and procedures are collected, as the Workgroup's review of the policies and procedures could inform which specific questions to ask the community.

A HRSA representative suggested that the communication could include a reference to the American Society of Transplant Surgeons' (ASTS) recommendation for venting vessels. A member responded that the procedure of venting has associated challenges, especially in relation to procurement of the heart, and there is a lack of data to support its effectiveness in eliminating the possibility of cerebral blood flow. The member stated the Workgroup should develop data-driven policies. The HRSA representative stated that venting may cause organ procurement to be more technically difficult, but it remains a feasible technique to minimize the risk of cerebral reperfusion. The HRSA representative reminded the Workgroup that this effort is in response to verified reports of establishment of reperfusion to the brain and if the solution that the Workgroup develops means that safety comes at the cost of making procurement a more technically difficult procedure than that is the cost. The OPTN President suggested that the recommendations and solutions developed by the Workgroup should be done so to establish safeguards so that NRP is performed with an abundance of caution. The HRSA representative recommended that the communication should include recommendations of how NRP should be performed safely to maintain community trust.

A member supported venting as a procedure to ensure donor safety. However, the member added that it may be confusing to include it as a recommendation in the communication as it is not required in OPTN policy. Another member advocated for venting because it is the only means of protection for lungs while NRP is ongoing.

The Workgroup members discussed other areas of NRP that may benefit from standardization such as neuromonitoring, medication administration, reintubation, and verification. The OPTN President agreed that including recommendations for some of these topics would be beneficial to send to the community in a communication and will work on including these suggestions in the initial communication for the Workgroup to review. The Chair stated that the initial communication should impress upon the community members how serious the Workgroup is about the information provided and including a request for each member's policies and procedures seems logical. The Chair added the communication should acknowledge that while a similar request was made of OPOs recently, the Workgroup would like to receive any updated policies from those members who had previously participated. The OPTN President agreed and added that the communication should include information on areas that the Workgroup is looking to develop specific requirements for standardization of procedures.

A member clarified that the concern regarding administration of paralytics is that if there was restoration of cerebral activity or function it would not be known and so the case would proceed in circumstances where it should not.

Next steps:

The Workgroup will finalize the communication and solicitation request for members' NRP policies and practices.

Upcoming Meetings

November 3, 2025

Attendance

• Workgroup Members

- o Brendan Parent
- o David Foley
- o John Magee
- o Joseph Turek
- o Kris Croome
- o PJ Geraghty
- Steve Weitzen

• HRSA Representatives

- o Ray Lynch
- UNOS Staff
 - o Joann White
 - o Matt Cafarella
 - o Meghan McDermott
 - o Nadine Rogers
 - o Susan Tlusty

• Other Attendees

o Doug Fesler