

Meeting Summary

OPTN Operations & Safety Committee

Normothermic Regional Perfusion (NRP) Workgroup

Meeting Summary

October 23, 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. Overview: HRSA Directive for NRP
- 3. Discuss and Review: Initial Communication on NRP
- 4. Discuss: Workgroup roster, meeting cadence, topics for discussion, and deliverables

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

1. Welcome and Introductions

The OPTN President welcomed members of the Workgroup and the members provided introductions.

2. Overview: HRSA Directive for NRP

The Workgroup reviewed the previous work the OPTN developed on the topic of NRP. This includes the OPTN Board of Directors approved *Ethical Analysis of Normothermic Regional Perfusion* white paper as well as two projects related to NRP data collection and guidance that were in development. Additionally, the Workgroup reviewed the background of the NRP critical comment and the specific deliverables charged to the Workgroup.

Summary of discussion:

The OPTN President asked for more information on the process of collecting policies and procedures related to NRP from OPTN members. A HRSA representative stated that some organ procurement organizations (OPOs) submitted their NRP policies and procedures last year in response to a request. The HRSA representative noted literature that showed about half of OPOs have established NRP policies and procedures, but that information gathered through an updated request may show this has changed. The OPTN President asked whether the Workgroup will need to require OPTN members to submit their NRP policies and practices. A HRSA representative responded with hope that OPTN members will share this information in an effort to support the OPTN to develop policies that protect patient safety.

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 asked for clarification on the process to have the draft communication approved and disseminated.

The OPTN President supported the content of the draft communication and stated that the length seemed reasonable.

The Workgroup discussed including a sentence that highlights the potential that recent critical press regarding NRP has resulted in individuals removing themselves from donor registries. A member felt this was speculative and added that in their research they are finding a common reason cited was related to DCD more generally which may or may not be related to NRP practices. The OPTN President stated it may be beneficial to include a sentence that emphasizes the need to maintain public trust. Members agreed to wordsmith a sentence to highlight the importance of trust and safety.

Another member asked if it was within the Workgroup's scope to develop modifications to the process of agreeing to be an organ donor. The OPTN President responded that this Workgroup's work will focus on processes that occur after death. The OPTN President added that the DCD Workgroup is developing a project that includes DCD policy updates. Another member stated that this Workgroup could develop standards for how OPOs are expected to approach and get authorization from family members. The member stated the Workgroup could consider whether there should be specific consent to NRP regardless of whether a person initially agreed to become an organ donor. The member stated that there is data from surveys of donor families that could help inform any education standards.

Next steps:

The Workgroup will continue to finalize the initial communication.

4. Discuss: Workgroup roster, meeting cadence, topics for discussion, and deliverables

Summary of discussion:

The OPTN President stated that including a transplant coordinator involved in NRP processes would be important to include on the Workgroup. The OPTN President also stated they will recommend a representative from the Operations & Safety Committee to join. A member noted their experience with TA-NRP. The OPTN President stated that adding a lung surgeon to the Workgroup would be helpful to add to the TA-NRP expertise.

The OPTN President mentioned that the guidance document that was in development by the Operations & Safety Committee will be a helpful starting point for the Workgroup. The OPTN President recommended that the draft of the guidance document be sent to the Workgroup.

The Workgroup determined potential topics for discussion and deliverables. The OPTN President stated that the policy and guidance deliverables will be critical. A member emphasized the importance of standardizing NRP across OPTN members.

The OPTN President stated that with policy requirements there may be additional considerations the Workgroup will need to decide in regard to monitoring and enforcement. A HRSA representative responded that it may be situational and there is precedent that documentation is kept in medical records for potential audits. The HRSA representative stated that undue burden should not be placed on members when considering potential monitoring and evaluation decisions. The HRSA representative added that policy is preferrable because that ensures uniformity since it is enforceable as compared to guidance.

Next steps:

The Workgroup will submit the proposed roster, meeting cadence, topics for discussion, and deliverables to HRSA.

Upcoming Meetings

- October 27, 2025
- November 3, 2025

Attendance

• Workgroup Members

- o Brendan Parent
- o John Magee
- o Joseph Turek
- o Kris Croome
- Steve Weitzen

• HRSA Representatives

o Ray Lynch

UNOS Staff

- o Cole Fox
- o James Jobes
- o Keighly Bradbrook
- o Lindsay Larkin
- o Matt Cafarella
- o Meghan McDermott
- o Tory Boffo