

OPTN Lung Transplantation Committee

Meeting Summary

April 10, 2025

Conference Call

Matthew Hartwig, MD, Chair

Dennis Lyu, MD, Vice Chair

Introduction

The Lung Transplantation Committee (Committee) met via Webex teleconference on 4/10/2025 to discuss the following agenda items:

1. Normothermic Regional Perfusion discussion

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

1. Normothermic Regional Perfusion discussion

In March 2025, the Committee received a letter from a member of the lung transplant community highlighting concerns with the use of normothermic regional perfusion (NRP) during donation after circulatory death (DCD) procurement. Prior to the meeting, Committee members were asked to review the submitted letter and related literature.

Summary of discussion:

The following themes emerged during the solutions-focused discussion:

- Importance of dissemination of technical best practices
- Need for robust data collection to help community track use & associated outcomes
- Importance of pre-procurement communication around use of NRP

There was a review of the submitted letter that outlined issues such as pulmonary edema, primary graft dysfunction, and ethical dilemmas associated with NRP. The Committee was also updated on multiple ongoing OPTN projects addressing NRP (Appendix A). Additional initiatives under review aim to standardize practices and collect more robust data on machine perfusion and NRP to better evaluate outcomes (Appendix B).

Committee members spoke about opportunities and challenges associated with NRP, as well as the OPO perspective. A transplant surgeon from a lung program with extensive experience in thoracoabdominal-NRP (TA-NRP) reported positive outcomes, including reduced waiting times at their program; one case in which lungs were damaged; and challenges with abdominal-NRP (A-NRP) during rapid recovery due to significant blood loss. The member stated that their program's procurement surgeon performs NRP and felt this is a significant factor in their success.

A Committee member from an OPO commented on the utility of NRP in increasing yield of allocated organs. The OPO member noted that current literature does not support anecdotal concerns that NRP creates delays in the process.

The following themes emerged during the solutions-focused discussion:

- Importance of dissemination of technical best practices
- Importance of pre-procurement communication around use of NRP
- Need for robust data collection to help community track use & associated outcomes

Technical best practices

There was broad agreement that standardization of clinical practices for NRP is critical to promoting positive outcomes when using NRP. A clearly outlined protocol anecdotally improves success. Some materials outlining technical best practices have been created and should be disseminated broadly to promote standardization.

Communication and decision-making surrounding NRP use

Communication and decision-making practices surrounding the use of NRP throughout the donation and allocation process may vary. NRP may be initiated by the OPO or requested by transplant programs during allocation.

A committee member reported that their transplant hospital has not yet approved transplantation of organs that have undergone NRP. The member shared an experience in which their program had to decline lungs after accepting them because the OPO honored a request from abdominal organ procurement teams to begin NRP, despite opposition from the lung procurement team. In addition to the candidate's lost opportunity for transplant, there were financial implications for the lung program, which had already made travel arrangements for procurement. The member expressed concern that lung allocation could be de-prioritized in NRP decision-making relative to other organs. A member from an OPO reported that if transplant programs disagree about using NRP, their approach is to facilitate a discussion between the transplant programs.

Another member from a lung transplant program reported an experience where they were not aware NRP was being performed until they arrived at the donor hospital to procure the lungs. Committee members encouraged pre-procurement communication with transplant programs about the use of NRP to promote transparency and prevent wastage of time and resources.

Data collection

The Committee supported centralized data collection on NRP. OPTN data collection on NRP recovery and initiation is pending implementation. The Chair encouraged committee members to reflect on current data collection efforts (Appendix B) and submit feedback on data elements they deem crucial, especially from a lung transplant perspective. The Chair noted the practical limitations of the OPTN system but underscored the importance of informed input to shape future improvements.

There was some interest in better understanding how often a lung offer is declined due to the use of NRP and whether those lungs are eventually transplanted.

Next steps:

A summary of the Committee's discussion will be provided to the appropriate stakeholders and OPTN Committees engaging in NRP efforts.

Upcoming Meetings

- April 14, 2024, teleconference, 5PM ET

Attendance

- **Committee Members**
 - Matthew Hartwig
 - Dennis Lyu
 - Marie Budev
 - Brian Keller
 - David Erasmus
 - Thomas Kaleekal
 - Wayne Tsuang
 - Jody Kieler
 - Ernestina Melicoff
 - Jackie Russe
 - Jordan Hoffman
 - Joseph Tusa
 - Siddhartha Kapnadak
- **HRSA Representatives**
 - None
- **SRTR Staff**
 - Katie Siegert
- **UNOS Staff**
 - Kelley Poff
 - Kaitlin Swanner
 - Leah Nunez
 - Sara Rose Wells
 - Chelsea Hawkins
 - Samantha Weiss
 - Holly Sobczak
 - Laura Schmitt

Appendices

Appendix A: OPTN work on NRP, including project status.

Committee	Project Title	Status
Organ Procurement Organization	Enhancements to OPTN Donor Data and Matching System Clinical Data Collection	Board approved, Implementation pending OMB approval
Ethics	Ethical Analysis of Normothermic Regional Perfusion	Board approved, Implementation complete
Organ Procurement Organization	Machine Perfusion Data Collection	Summer 2025 public comment (tentative)
Operations and Safety	Standardize Practice in the Use of Normothermic Regional Perfusion in Organ Procurement Guidance Document	TBD
Organ Procurement Organization	Review of Donation After Circulatory Death (DCD) Policies	Part 1, Policy 2.15: Summer 2025 Public comment (tentative) Part 2, to potentially include policy changes to NRP: TBD

Appendix B: List of OPTN NRP data collection evaluated by the OPO Machine Perfusion Data Collection Workgroup throughout the development of *Machine Perfusion Data Collection*.

Data Element	Status
NRP Recovery	Awaiting implementation
Initiation of NRP	Awaiting implementation
Organs placed (final acceptance)	Currently collected
Organs recovered for transplant	Currently collected
Heparin administration	Currently collected
Time of withdrawal of life sustaining measures	Currently collected
Cross clamp time	Currently collected, 4 flush times awaiting implementation Add second cross clamp time <ul style="list-style-type: none"> • Potential child-question from existing cross-clamp field to capture second cross clamp time for abdominal NRP • Rename existing cross clamp time to “thoracic cross-clamp time”
Time of cold flush of organs	Currently collected
Cannulation site	Don’t add
Autologous perfusion period	Don’t add

The data elements “NRP Recovery” and “Initiation of NRP” were approved as part of [Enhancements to OPTN Donor Data and Matching System Clinical Data Collection](#).

Data Element	Status
NRP Run Time	Add end time (start time is awaiting implementation)
Organs intended to be recovered using NRP	Add
Thoracoabdominal NRP vs. Abdominal NRP	Add
Total Heparin Administered into the NRP Circuit	Add
SBP50 intervals	Require OPO to enter vitals on minute-by-minute basis **Policy
Lactate levels	Add – 2/19 discussion - system should not limit the number of lactate draws, not dictate this in policy, recurring field capturing date/time and value out to two decimal points
NRP Circuit Flow	2/19 - More input/discussion from thoracic surgeons needed 3/19 – <u>Do not collect</u> , weight based and potentially difficult to interpret data