

Meeting Summary

OPTN Ethics Committee Normothermic Regional Perfusion (NRP) Workgroup Meeting Summary August 25, 2022 Conference Call

Keren Ladin, PhD, Chair

Introduction

The Normothermic Regional Perfusion (NRP) Workgroup met via Citrix GoToMeeting teleconference on 08/25/2022 to discuss the following agenda items:

1. Proposed ethical areas of focus

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

1. Proposed ethical areas of focus

UNOS staff introduced and detailed the four major areas of ethical focus for the white paper: the legitimacy of NRP in the context of death designations, edge cases, patient autonomy and consent authorization, and public support for NRP and its implications. These areas of focus have emerged from the previous workgroup meetings. Today, the committee's discussions on these topics were summarized and presented for additional feedback and consideration. The workgroup will break out into subgroups to address each of the four topics and develop a plan for writing these sections of the white paper. Members reviewed the assignments for subgroups and are encouraged to join additional subgroups if they are interested.

Summary of discussion:

Members discussed how to approach writing the white paper if consensus is not met within the workgroup. In this case, the workgroup could highlight the ethical considerations within the different perspectives, identify areas of overlap, and provide guidance if it would be appropriate on how to approach NRP ethically. Some members stated that patient access could be limited if the Committee came out against NRP. Alternatively, a member suggested the Committee take a stronger position in the white paper, urging that the ends cannot justify the means. Oftentimes, Ethics Committee white papers explore the nuances of both sides of an argument and consider how something could be pursued ethically, which is a similar approach in much of the existing NRP literature. A member proposed descriptively outlining where the concerns of each side are rooted, for example, if ligation could cause death, to detail all of the various conclusions or impasses the workgroup arrived at.

A member cautioned against claiming that circulatory death is converted to brain death since if the initial death declaration stands then no conversion occurs. Alternatively, a member suggested that proponents of NRP are supportive of the transition of death designation from circulatory criteria to neurologic criteria as a further indication of permanence.

A member highlighted that NRP may not fit within the existing definitions of death through circulatory or neurologic criteria and may, alternatively, need a separate definition or categorization. A member considered if it were possible to consider the ethical implications of NRP apart from the current parameters of the UDDA, which are under current review and potential revision. The scope of the OPTN requires the workgroup to consider NRP within the context of the existing system of law, which includes

the UDDA. The overlap between ethical and legal concerns was highlighted, noting the potential for something to be legal but not ethical and vice versa. The workgroup is tasked with considering NRP in the context that it is currently being pursued and whether the practice itself is ethically permissible.

A member suggested including conscientious objection in the edge case section, highlighting that this is not common in the transplant community but could occur in the instance of NRP. A member also suggested including pediatrics as an edge case as they may require additional considerations beyond what is needed for adult donors or recipients. A member elaborated that the edge case section is intended to be constructive in analyzing situations where additional considerations or protections may be needed. These scenarios are meant to consider the worst-case scenarios where multiple things go wrong and develop a checklist to address and move forward if determined to be ethically acceptable.

Next steps:

Staff will reach out to schedule the subgroup meetings. If members are interested in participating in additional subgroups, please reach out to staff to be included on that correspondence.

Upcoming Meetings

- September 8, 2022
- September 22, 2022
- October 13, 2022

Attendance

• Committee Members

- o Andy Flescher
- o Erin Halpin
- o Jonathan Fisher
- o Julie Spear
- o Laine Fredman Ross
- o Matt Hartwig
- o Nader Moazami
- o Rosa Guajardo
- o Sanjay Kulkarni
- o Sena Wilson-Sheehan
- o Sophoclis Alexopolous

• HRSA Representatives

- o Edna Dumas
- o Jim Bowman

UNOS Staff

- o Cole Fox
- o James Alcorn
- Keighly Bradbrook
- o Kim Uccellini
- o Laura Schmitt
- o Matt Belton
- o Matt Cafarella
- o Stryker-Ann Vosteen

• Other Attendees

- o Kaitlyn Fitzgerald
- o Kristine Browning