

Meeting Summary

OPTN Ethics Committee Normothermic Regional Perfusion Workgroup Meeting Summary March 2, 2023 Conference Call

Introduction

The Normothermic Regional Perfusion Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 03/02/2023 to discuss the following agenda items:

- 1. Overview of the work
- 2. Perspectives
- 3. Next Steps for the white paper

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

1. Overview

The Chair of the Workgroup highlighted the main goals of the call and the anticipated next steps in developing the paper, encouraging members to engage fully and provide any contributions they deem necessary for the paper.

Summary of discussion:

The conversation was initiated with information about abdominal NRP (A-NRP) and thoracoabdominal NRP (TA-NRP), and whether any significant ethical differences between these two procedures existed. A member voiced that the emphasis on whether the heart is bypassed during the procedure or not is besides the point, and that both procedures have the same ethical implications. Another member brought up their concerns that the paper does not provide a balanced view of NRP and that there are significant inaccurate claims which need to be addressed before this paper is ready for public consumption. This member felt that the paper should emphasize no evidence is present to date that there is blood flow to the brain during NRP. The Chair and other members noted that positive evidence of lack of harm is different from absence of evidence, which is not sufficient. Additionally, that member opined that any ligation of blood vessels is to allow the process of brain death to occur unabated after circulatory death has been declared for that patient. The implication of cerebral blood vessel ligation has been debated and discussed extensively within the Workgroup and in the literature.

The Chair acknowledged the member's concern while highlighting that a key element of the paper is to review the potential for harm related to utilization of NRP. Another member spoke of the concern for maintaining public trust in the OPTN and the transplant system, thus requiring a rigorous examination of NRP and all potential ethical considerations, which must be taken into account by this Workgroup.

The Chair affirmed that should any inaccuracies be found in the draft, members should make them aware of these inaccuracies and they would be addressed.

A member affirmed that they have no additional concerns about A-NRP versus TA-NRP as the former is a closed circuit and there would be no cerebral perfusion possible. Additionally, they agreed that that the paper is balanced as the discussions occurring in the transplant community mirror those being had in

the Workgroup, thus the paper represents the myriad of opinions and ethical dilemmas that are being voiced already.

A member recommended restructuring of the paper to ensure arguments relevant to the ethical implications are identified and defined prior to providing the Workgroup's discussion. Another member expressed concern that the white paper could have the effect of stymying organ transplantation, depending on how the discussion on nonmaleficence is presented. Members also noted the language around circulation and potential for pain should be carefully reviewed for clarity and to ensure appropriate and consistent usage. All feedback from the Workgroup will be considered for incorporation in an updated draft that will be disseminated for further review.

2. Perspectives

Members took this time to discuss any additional outstanding questions or perspectives on the draft thus far, with one member stating that the donor families they have worked with are oftentimes thrilled that the heart or other organs would be recovered in such favorable conditions due to NRP.

Another member vocalized that raising a concern does not necessarily mean opposition, and it is important to note the utility that NRP could provide in the transplant system.

One member recommended adding an executive summary to the paper which could address all of the points of the paper before diving into deeper discussion, so that there is no bias one way or another going into the paper. Other members agreed that this would be helpful to the paper.

3. Next Steps

The Workgroup agreed to some next steps before the next meeting, such as reviewing the discussion of harm for consistent and appropriate language, providing an executive summary and modifying structure to support the flow of ideas. Additionally, the Workgroup was informed they would receive another draft for more review and feedback. Furthermore, any feedback they wanted to provide in the meantime on the paper could be sent to the Chair of the Workgroup and noted for the next meeting.

Upcoming Meetings

- April 13, 2023
- May 11, 2023
- June 8, 2023

Attendance

Workgroup Members

- o Andy Flescher
- o Amy Friedman
- o Carrie Thiessen
- Jonathan Fisher
- o Julie Spear
- o Kevin Meyer
- o Sanjay Kulkarni
- o Keren Ladin
- o Nader Moazami
- o Rosa Guajardo
- o Sena Wilson-Sheehan
- o Lanie Ross
- o Sophoclis Alexopoulos
- o Erin Halpin
- Matthew Hartwig

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi

SRTR Representatives

o Bryn Thompson

UNOS Staff

- o Cole Fox
- o James Alcorn
- o Kieran Mcmahon
- o Kim Uccellini
- o Krissy Laurie
- o Kristina Hogan
- o Laura Schmitt
- o Matt Belton
- o Rebecca Murdock

Other Attendees

o Kristine Browning