

OPTN Ethics Committee

Meeting Summary

May 19, 2022

Conference Call

Keren Ladin, PhD, Chair

Andy Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 05/19/2022 to discuss the following agenda items:

1. Update: *Transparency in Program Selection* white paper
2. Normothermic Regional Perfusion discussion

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

1. Update: *Transparency in Program Selection* white paper

The Chair updated the Committee on the progress of the *Transparency in Program Selection* white paper, which the Committee will vote on during the June 16th committee meeting. This white paper outlines the ethical principles that underpin the need for transparency in program-specific information for patients to inform where to pursue transplant evaluation and registration. During the next meeting, the Committee will vote to send the white paper to be released for Summer 2022 public comment. In the months following public comment, the Committee will review the feedback and vote on a final version for the OPTN Board of Directors to review during their December 2022 meeting.

Next steps:

To ensure the Committee has quorum to hold the vote, members are asked to inform UNOS staff if they are unable to attend the June 16th meeting.

2. Normothermic Regional Perfusion (NRP) discussion

Leadership recapped the Committee's discussion from the March in-person meeting¹ and highlighted the discussion that the OPTN Heart Transplantation Committee had during their in-person meeting.² The Chair noted that legal concerns surrounding the definition of death will be acknowledged but will not be under consideration by the Committee. This analysis will proceed in the legal context that currently exists. The Committee discussed the ethical principles that are pertinent to this analysis.

¹ OPTN Ethics Committee, "Meeting Summary," March 17, 2022, accessed June 14, 2022, https://optn.transplant.hrsa.gov/media/23bh4eiz/20220317_ethics_meeting-summary_draft.pdf.

² OPTN Heart Transplantation Committee, "Meeting Summary," April 19, 2022, accessed June 14, 2022, https://optn.transplant.hrsa.gov/media/df3leyhb/20220419_heart_meeting-summary.pdf.

Summary of discussion

Patient Autonomy, Transparency, and Issues Related to Consent

A member shared insight about NRP practices in the United Kingdom detailing that these clinicians do not undertake an additional informed consent process with the donor family and only noted that there was a new procurement process that was used that increases the chances of a successful donation. Alternatively, a member from an organ procurement organization (OPO) that is currently conducting NRP shared that they transfer their patients to the transplant hospital so additional authorization is required for transportation. This OPO also details the use of cardiopulmonary bypass, as opposed to extracorporeal membrane oxygenation (ECMO), with the donor family when explaining the procedure.

A member inquired about the prevalence of conscientious objection and allowing providers to opt-out of the practice, noting that this does not occur in other areas of organ transplant. The Chair responded that conscientious objection has not been a component of organ transplant historically but has occurred in the use of NRP due to ethical concerns or objections. A member noted there has been objection to donation after circulatory death (DCD) largely by the anesthesiology community, adding that their institution has not experienced any conscientious objection concerns. A member noted that there may be a possibility of conscientious objection on behalf of a recipient who does not want an NRP organ due to religious beliefs.

A member inquired for additional clarity on how the use of NRP could be interpreted as using patients “as a means to an end” in a different way compared to other alternative organ procurement methods. A member noted legal concern that some see NRP as a “workaround” to the dead donor rule as opposed to a true ethical concern.

A member inquired if a survey had been conducted to understand community attitudes around NRP. Unfortunately, there is no published survey in the literature that has been reviewed. It may be possible for the Committee or the OPTN to develop a survey, but it may require OMB approval, which can delay the process. A member added that the American Society for Transplant is working on a response to a statement of concern on NRP but their work is more focused on outcomes and clinical practices.

A member shared a question from their region on whether or not anesthesia was used during NRP. This question stemmed from concern about the donor potentially feeling something during procurement. A member shared that there is an anesthesiologist present during procurement, as protocol, but the anesthesiologist does not administer anesthesia to the donor.

When posed with the question of withdrawal of care versus active blockage, a member responded that no active blockage or halt of care occurs. The donor is managed as every other patient receiving end-of-life care is, the only technical difference in procurement occurs after death is determined. A member shared sentiment that the definition of death ought to be revised to reflect a transitional process of death as opposed to a binary distinction. The member noted that in the declaration of death following circulatory arrest tests of brain activity are not completed.

With regard to the legal framework, the Chair clarified that this white paper is not starting from a blank slate. This white paper is operating specifically within the current U.S. legal framework, which may require a disclaimer on interpretation, and could include a section that articulates areas where clarification of the law may be useful.

Implications Related to Utility

Members considered the potential negative impact on utility that could occur if the public had a negative perception of the practice. A member noted that public perception of organ transplant tends to

be very positive and seen as a standard of care,³ but highlighted the potential for this practice to be polarizing within a more divided political climate.

Members noted that current literature depicts positive outcomes at the program level but these have been small-scale and shorter analyses. More time and data are necessary in order to understand and compare the outcomes of NRP organs to DCD or donation after brain death (DBD) transplants.

A member suggested developing an overarching document that considers how allocation and procurement have evolved and developing an algorithm for considering how evolving technologies will impact increasing the organ supply. The Chair responded that within the scope of this white paper many of those questions will not be able to be answered given the focus on NRP and the January 2023 public comment timeline.

Next steps:

The Vice Chair will be presenting the NRP project to the Policy Oversight Committee (POC) for approval on their June 13th meeting.

Upcoming Meeting

- June 16, 2022

³ U.S. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, *2019 National Survey of Organ Donation Attitudes and Practices: Report of Findings*. Rockville, Maryland: U.S. Department of Health and Human Services, 2019.

Attendance

- **Committee Members**
 - Amy Friedman
 - Andy Flescher
 - Carrie Thiessen
 - Catherine Vascik
 - Colleen Reed
 - David Bearl
 - Earnest Davis
 - Ehab Saad
 - George Bayliss
 - Glen Cohen
 - Keren Ladin
 - Melissa Anderson
 - Roshan George
 - Sanjay Kulkarni
 - Sena Wilson-Sheehan
 - Tania Lyons
 - Thao Galvan
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Cole Fox
 - Eric Messick
 - James Alcorn
 - Kim Uccellini
 - Kristina Hogan
 - Laura Schmitt
 - Rebecca Murdock
 - Stryker-Ann Vosteen
- **Other Attendees**
 - Jennifer Dillon