

**OPTN Ethics Committee
Meeting Summary
October 5, 2023
Conference Call**

**Andrew Flescher, PhD, Chair
Sanjay Kulkarni, MD, Vice-Chair**

Introduction

The Ethics Committee (“Committee”) met via Webex teleconference on 10/05/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Review Normothermic Regional Perfusion (NRP) Public Comment Feedback and Discuss Possible Changes

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

1. Welcome and Announcements

Presentation summary:

The Chair and Vice Chair welcomed members to the call. Staff noted that the in-person meeting will be held on 10/10 in Detroit, Michigan.

2. Review Normothermic Regional Perfusion (NRP) Public Comment Feedback and Discuss Possible Changes

The Committee reviewed public comment feedback by themes and then discussed possible revisions to the NRP white paper in response.

Presentation summary:

The NRP white paper (WP) released for public comment from July 27, 2023 to September 19, 2023 received 284 comments inclusive of 64 substantive written comments, some regarding disclosure and ethical considerations. All written comments and respondents are featured on the Organ Procurement and Transplant Network (OPTN) website. Public comment was supportive of the WP with a total sentiment score of 3.6 on a Likert scale of 5 (1 representing ‘strongly oppose’ to 5 ‘strongly support’). The overall sentiment score of 3.6 indicated support for the WP, with some concern and opposition from stakeholders, namely, Organ Procurement Organizations (OPOs), patients, stakeholder organizations, and transplant hospitals.

A qualitative analysis of the public comments showed eight major themes. Four of these themes are discussed during the meeting on October 5, 2023. The other four are scheduled for discussion on October 10, 2023. Staff reviewed the questions that members should keep in mind when reviewing public comment feedback including questions on perspective, themes of the WP, and balance of feedback. Generally, commenters supported the goal of the WP to provide an ethical analysis of NRP and noted the timeliness, neutrality, and sensitivity to a wide range of perspectives. However, some commenters felt as though minority and clergy communities may have been excluded in the analysis. Additionally, 13 comments recommended further elaboration on the ethical differences between TA- and

A-NRP from a variety of stakeholders. Broadly, commenters suggested that TA-NRP has additional ethical and political implications related to the standard in death declaration compared to A-NRP. Globally, A-NRP is more ethically accepted and practiced, and some commenters suggesting that the OPTN should endorse A-NRP fully. also discussed other relevant considerations regarding TA and A-NRP, including the potential for confusion on the different procurement strategies and the variation present in procedures among transplant centers.

Additionally, the community provided feedback on appropriate information to disclose and how to approach disclosure to donors and next of kin regarding NRP. The feedback discussed:

- Facilitating donor wishes;
- The ethical obligation to explore all available options;
- The need for greater transparency;
- Whether NRP undermines autonomy;
- Recommendations for authorization as it pertains to children;
- And uncontrolled NRP.

Comments received were largely consistent with the approach recommended for disclosure and authorization. However, feedback was mixed on whether the conversations should be standardized or mandated, with the OPTN OPO Committee indicating the importance of consistent standards. On the other hand, the Association for Organ Procurement Organizations (AOPO) noted that forcing a uniform disclosure is not supported by the OPO community because each conversation is family-specific and standardization neither aligns with the ethical goals nor is it legally required.

Other comments discussed that graphic language may not be relevant or appropriate in conversations with families. Comments were additionally divided on the need to disclose ligation of cerebral vessels. Several comments discussed the potential for recipients and/or opt-out rights for NRP, while also balancing the burden of decision on families. Some comments pointed to the possibility of using DCD and other machines perfusion technology, with noting that discussing different types of procurement could cause some mistrust or confusion.

Feedback was mixed regarding the conclusion to proceed, with recommendations to gather additional data and analysis before continuing NRP. Comments mentioned that the NRP should not proceed until the ethical questions are solved and that the WP should be more comprehensive. The community suggested expediting the work to create policy and standardize protocols related to NRP within OPTN as well as discuss the role of clinical trials and research.

Summary of discussion:

The Chair and Vice Chair both highlighted the balance of the paper, while also taking note of the public's criticisms on certain topics such as "last gift" and respect for persons. Suggestions were received that specifically called attention to the analysis of the "last gift." Lastly, the last gift argument is strengthened by additional disclosure in the autonomy space. A member shared concerns raised at various Committee meetings regarding the appropriate balance of ethical principles.

One Committee member mentioned a strong argument for NRP and an emphasis on resuscitation. The Vice Chair mentioned the complexity of disclosure and autonomy. Another Committee member remarked on the debate of the ethical concerns between TA and A-NRP, arguing that it should appear clearer in the WP.

One Committee member mentioned the need to receive more information within the space of additional organ preservation techniques before being committal. Another Committee member noted that framing language appropriately and keeping information specific would be additionally helpful.

The Chair noted that some commentors felt as though the Committee did not follow the logic of their analysis, and asked for clarification on what was meant by "proceed, but proceed cautiously." The Chair stated that Leadership recommends altering the conclusion slightly to remove "proceed cautiously," and that the Committee will discuss this further at the in-person meeting.

Next steps:

The Committee will review additional public comment themes during the in-person meeting. Members with suggested revisions to the paper should provide them via email to Leadership.

Upcoming Meeting

- October 10, 2023

Attendance

- **Committee Members**
 - Andrew Flescher
 - Dr. Sanjay Kulkarni
 - Andrew Courtwright
 - Ms. Shelia Nichols Bullock
 - Jennifer Dillon
 - Dr. Keren Ladin
 - Laura J. Jokimaki
 - Dr. Ehab E. Saad
 - Lois Shepherd
 - Lisa Paolillo
 - Ms. Sena A. Wilson-Sheehan
 - Ms. Felicia Wells-Williams
 - Dr. Carrie Thiessen
 - Dr. Erica J. Stohs
 - Ms. Megan Urbanski
- **HRSA Representatives**
 - Marilyn Levi
- **UNOS Staff**
 - Cole Fox
 - Kim Uccellini
 - James Alcorn
 - Rebecca Murdock
 - Kieran McMahon
 - Kristina Hogan
- **Other Attendees**
 - Laura Butler