

OPTN Ethics Committee

Meeting Summary

July 20, 2023

Conference Call

Andrew Flescher, PhD, Chair
Sanjay Kulkarni, MD, MHCM, Vice Chair

Introduction

The Ethics Committee met via Citrix GoTo teleconference on 07/20/2023 to discuss the following agenda items:

1. New Member Welcome
2. Multiple Listing, *Updates and Discussion*
3. Normothermic Regional Perfusion (NRP) Update
4. Brainstorm New Projects and Next Steps

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

1. New Member Welcome

Summary of discussion:

The Committee Chair introduced a new member to the Committee.

2. Multiple Listing, *Updates and Discussion*

Results from the Board of Directors meeting regarding the Multiple Listing White Paper were presented to the Committee. The Committee discussed non-approval implications, asked for clarification on uncertain items, and brainstormed ways to move forward.

Summary of presentation:

An update on the Multiple Listing White Paper (MLWP) was presented. The Committee Chair informed members of the Board of Directors' (BOD) decision to decline approving the MLWP while noting that the decision was not unanimous. The Chair expressed disappointment citing all the time and hard work that went into the MLWP, but noted the presentation of the MLWP at the BOD meeting resulted in a robust discussion.

From the discussion, multiple concerns were brought up by the BOD—one such concern was the role of the Committee as it relates to the larger organization. The Chair emphasized that the Committee's role is to provide ethical analysis, not post hoc justifications, and the Committee starts tabula rosa to evaluate issues. The Committee's charge is not to write policy but guide it; some BOD members saw the MLWP as a change to existing policy. Another concern was confusion about the final message of the paper. Again, the Chair emphasized the Committee's charge.

The Chair thanked everyone on the Committee for their hard work on this project and reviewed lessons from this experience. The Committee was asked to think about solutions to better communicate post public-comment changes to BOD members, as this was an area of confusion. Another lesson was identifying a potential gap between the BOD's understanding of the Committee and the Committee's stated charge and purpose. Finally, the Committee needs to consider important stakeholders, including

the OPTN Minority Affairs Committee and the OPTN Patient Affairs Committee, as well as cultivate relationships with other OPTN Committees.

Before opening the floor for discussion, the Chair requested feedback on submitting the MLWP for publication outside the OPTN.

Summary of discussion:

A committee member started by emphasizing that the non-approval vote does not necessitate a failure on the Committee's part, and the Committee did exactly as it was charged to do. The Committee's charge and the OPTN's mission do not always align. The Chair agreed with this sentiment while stating that it is always disappointing when a project you have worked so hard on does not have the anticipated maximum impact.

Addressing the potential publication of the MLWP, the Vice Chair agreed that a robust ethical analysis is already within the paper, and it should be considered for publication outside the OPTN. Clarification regarding the stages of approval from the OPTN necessary before submitting was requested. Support staff responded by affirming that the paper has the potential to be published outside the OPTN if it is clear that the opinions stated do not belong in any way to the OPTN. Staff stated that there may be additional considerations regarding publishing the data used in the paper. Staff will confirm with research staff.

A Committee member shared their view that the BOD was missing vital information and were left with too many questions, so they did not feel compelled to approve it. The Chair agreed and felt the information the BOD was missing was vital to help elicit a complete representation of the BOD's view on the MLWP.

Next steps:

- Pursue publishing the MLWP outside the OPTN.
- Look to clarify the Committee's role and charge.
- Explore conversations about how to make the Committee's work more successfully communicated.

3. Normothermic Regional Perfusion (NRP) Update

The Chair presented updates made to the NRP presentation, answered any questions from Committee members, and discussed the upcoming regional and cross-committee meetings.

Summary of presentation:

The Chair began by informing the Committee that they were able to hear some feedback from the OPTN Executive Committee regarding the NRP paper before releasing for public comment. Committee leadership made non-substantive changes refining the paper's tone from this feedback.

Support staff began presenting the changes that were made to the paper. A paragraph from the paper was shown to the Committee and was informed that the BOD thought it would be better to move it to the Executive Summary section. Line 46 was modified by removing "morally." Lines 149 and 150 were modified by removing the second "that" and replacing it with "about;" the phrase "can, in the end, be normatively justified" was removed. The sentence starting on line 355 was de-bolded for formatting cohesion. The sentence beginning on line 647 was modified to add "but proceed." Line 648 was modified by removing "serious." All these changes were made to refine and focus the paper's tone. Support staff informed the Committee that these have already been updated in the NRP paper and presentation and reviewed by the OPTN Policy Oversight Committee (POC). The Chair reaffirmed their

support for these changes and their positive impact on the paper; they also prepped Committee members to be attentive to language and its effect on feedback during the public comment period.

The Vice Chair discussed their presentation of the NRP paper to the POC. The paper received approval with twelve members in favor, two against, and two abstaining. The presentation generated a constructive discussion. The POC reviewer acknowledged the paper's significance in raising crucial points for consideration. The primary issue to face considering public comment, the Vice Chair predicted, will be the "do no harm" principle and the need for validation that the donor is insensate at the time of donation. The Chair added that the reviewer started as a supporter of NRP but was influenced by the Ethics Committee's thoroughness to examine some of their convictions. The reviewer commended the Ethics Committee for their attention and care in the paper.

The Chair encouraged the members to discuss this further.

Summary of discussion:

A Committee member asked for clarification on who decides when NRP is utilized. They asked if the decision happens at the transplant center, Organ Procurement Organization (OPO), or OPTN level. The Vice Chair responded that it is usually up to the OPO when deciding whether NRP is utilized. Another committee member corroborated the response and added that it could be more of a collaboration between the OPOs and the transplant centers. Support staff agreed and stated the ethical analysis of NRP is critical so cohesive policies can be made and standardize the process.

Another Committee member asked for support on dealing with the Dead Donor Rule (DDR) and donors being insensate before donation. The Chair responded that Public Comment can be unpredictable but believes there will be some pushback on reperfusion in donation after circulatory death (DCD) donors violating the DDR. The Chair also prepared committee members that some may view the DDR as outdated or push back on the tone of "do no harm" used in the paper. The Chair also prepped Committee members on the response to raising the question of how sensate the donor is at the time NRP is taking place, and that should be part of the authorization disclosure process. The Chair also stressed that the goal of NRP on DCD donors is not to resuscitate. The Vice Chair agreed with these sentiments and clarified that current practice does not require disclosure, only authorization, and the NRP paper challenges the notion that authorization is sufficient.

The Chair reiterated that the duty of the Committee is to receive, deliberate, and respond to all questions and comments during the public comment period while sticking to the proposed timeline to present the NRP paper at the next BOD meeting. Support staff informed the Committee that public comment starts on July 27, 2023. Typically, the process begins with the proposals in front of the POC to determine if the committees have done their due diligence, which NRP was met with a resounding yes. Then the POC recommends whether the OPTN Executive Committee approves the proposal to go out for public comment. Support staff noted that the Executive Committee is meeting later that day, and we are anticipating a positive outcome.

A Committee member requested clarification on if future adoption of NRP is contingent on the OPTN's endorsement, or if will it be up to individual transplant centers to decide how to proceed with NRP. The Chair reminded the Committee that the scope of the Committee is to guide ethical analysis and not to write policy. The result from the analysis of NRP as it currently stands is to proceed but do so cautiously, a response that is ambivalent but not ambiguous. Support staff confirmed this and added that most papers generated by the Committee do not result in complete endorsements; instead, the product is the analysis of the implication of the processes if they were to be adopted into policy. The Chair echoed this and added that the BOD was impressed with the NRP paper's unambiguous guidance.

Another Committee member voiced their concern over the NRP paper ending up like the MLWP, with confusion regarding the message of the paper. This member asked for reassurance that there would be one or two strong points at the end of the presentation that would be clear enough as to what the NRP paper is saying. Support staff said this feedback will be considered in refining the slides for presentation at the cross-committee and regional meetings. The Chair reminded committee members to utilize the presentation prep sessions to voice any concerns they have about the presentation and make suggestions that would benefit the presentation's effectiveness. The Vice Chair added that the utility analysis of NRP is robust but agreed that the Committee needs to make their view regarding NRP as explicit as possible during the upcoming presentations.

Support staff encouraged committee members to contact them with any questions and feedback.

Next steps:

- Public comment for the NRP white paper will open on July 27, 2023.
- Regional representatives will attend a presentation prep session with support staff.
- Regional representatives will present the paper at the regional meetings.
- Committee members are asked to continue to engage with major stakeholders.

4. Brainstorm New Projects and Next Steps

Summary of discussion:

Support staff requested committee members to brainstorm and send ideas for new projects moving forward.

Upcoming Meetings

- August 17, 2023 (teleconference)
- October 10, 2023 (in-person)

Attendance

- **Committee Members**
 - Andrew Flescher
 - Sanjay Kulkarni
 - Andrew Courtwright
 - Carrie Thiessen
 - Ehab Saad
 - Erica Stohs
 - Felicia Wells-Williams
 - Jennifer Dillon
 - Laura Jokimaki
 - Lisa Paolillo
 - Megan Urbanski
 - Melissa Anderson
 - Sheila Nichols Bullock
 - Bob Truog
- **HRSA Representatives**
 - Jim Bowman
- **UNOS Staff**
 - Kieran McMahon
 - Cole Fox
 - Kristina Hogan
 - Elena Liberatore
 - Kim Uccellini
 - Laura Butler
 - Laura Schmitt