

OPTN Ethics Committee

Meeting Summary

April 20, 2023

Conference Call

Keren Ladin, PhD, Chair

Andrew Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 4/20/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Multiple Listing Discussion
3. Normothermic Regional Perfusion (NRP) White Paper Topics

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

1. Welcome and Announcements

Staff and the Vice-Chair welcomed members to the call. The Vice-Chair also welcomed some incoming members to the Committee and thanked them for their attendance.

2. Multiple Listing Discussion

Members discussed their take-aways from the in-person meeting and next steps for the project.

Summary of discussion:

The Vice-Chair began the discussion by explaining there was support for strengthening the ethical analysis in the paper and leaving the next steps to the OPTN Board of Directors. Some specific points of possible revision included adding veterans and pediatrics to the analysis, clarifying patient autonomy, and strengthening or updating the frequently asked questions document (to include as an addendum). The Vice-Chair added that the Committee should have a strategic discussion about how to move forward with this paper given the concerns noted from other OPTN Committees, the Board of Directors, and various stakeholders.

A member pointed out that the paper should balance autonomy and equity, and that the paper should be published with an acknowledgement that the magnitude of the equity issues found were not as large as originally thought. A member agreed with this recommendation and noted that the recommendation portion should be tempered. This member stated the Committee should consider what to do about the "hard to match" portion of the paper. A member stated that if the Committee moves to temper the recommendations, the paper may have limited use to the community and the Board of Directors. This member stated that the Committee has done a good job analyzing this issue, but now the question remains how to best use the analysis. A member agreed, and noted that perhaps the Committee should make a firm stance and proceed with the analysis and recommendations as a way to signal to the community that this issue does represent an area of inequity.

The Vice-Chair explained some options that the Committee has for this project: move forward with the paper with a few minor edits, move forward with the paper by tempering the recommendations, or

delay the timing and attempt to rethink the paper. Staff explained that if the Committee wishes for the paper to proceed to the Board of Directors in June 2023, they would need to decide that quickly in order to move through the appropriate processes. A member asked if a survey could be created so that the Committee could weigh in on the paper and then the path forward could be decided by a majority vote. Staff recapped the changes in the most recent draft of the paper, which incorporates feedback from the in-person call.

The Committee briefly reviewed updated white paper with the identified changes, which slightly temper the recommendations and leaves next steps up to the Board of Directors.

A member stated that it might be worthwhile to clarify the autonomy versus equity issue a bit further. Staff noted that a box was added to the draft that clarifies what is meant by autonomy. A member asked if the frequently asked questions section would be included with the paper. Staff noted that this can be published as an addendum. The Vice-Chair also noted that a response to the feedback gathered during public comment could be published as an addendum.

Next steps:

Staff will send out a survey of the Committee's options along with the updated draft.

3. Normothermic Regional Perfusion (NRP) White Paper Topics

The Committee discussed three portions of the NRP white paper: the dead donor rule (DDR), the use of the terms pain, sensate, and cerebral flow, and organ procurement organization (OPO) authorizations.

Summary of discussion:

The Vice-Chair briefly introduced each topic and how each is presented in the paper.

Regarding the DDR, the Vice-Chair explained that while there is debate about the interpretation of principle, Committee leadership felt it was appropriate to use the standard that the donor needs to meet death criteria at the time of organ procurement. A meeting attendee commented that depending on how you interpret the DDR, the ethics of NRP are framed much differently. A member added that the paper does not state that NRP violates the DDR, only questions that it may, and that this is important. A Health Resources and Services Administration (HRSA) representative commented that raising questions about NRP and the DDR may have implications for donation after cardiac death (DCD) in general.

A meeting attendee stated that it sounded like the Committee preferred the interpretation of the DDR that allows voicing the concern that the donor may not meet criteria for death at the time of procurement, but it may make sense to choose the weaker interpretation of the DDR (that the donor must be dead). The Vice-Chair explained that the Committee will need to decide which interpretation to use and why. Staff and the Vice-Chair stated that they will check on past Ethics Committee interpretations of the DDR. A member added that one of the values of choosing the weaker definition is it still does allow you to interrogate the causal role of the clinician in the procurement process and interrogate the ethics of that without necessarily prefiguring the conclusions with the stronger definition. A member stated that the Committee could consider the possible changes to the Uniform Determination of Death Act as a part of the discussions related to the paper.

Regarding use of the terms pain, sensation, and cerebral flow, the Vice-Chair explained that the paper no longer references pain, however, there is a lingering question of how to best articulate the concerns about do no harm. A member explained that the concerns for sensation and cerebral flow are valid, however, it is problematic to suggest that NRP advocates must prove an absence of sensation. This member explained that the concern lies in the level of resuscitation and if it presents ethical concerns. A member agreed. The Vice-Chair stated that the paper may not be sufficiently descriptive as to reasons

for ligation. A HRSA representative explained that in the papers they have read, some authors state that the purpose of ligation is mimicking typical DCD donation. This representative mentioned that this is not a HRSA opinion. A member explained that this interpretation is helpful when thinking about prior Committee discussion about allowing death to continue while preserving the organs such that they are transplantable.

Regarding how OPO authorization is handled in the paper, the Vice-Chair asked if members had ideas about how the Committee should present this. A member explained that in their prior work on NRP, they referred back to a reasonable person standard.

Upcoming Meetings

- May 18, 2023
- June 15, 2023

Attendance

- **Committee Members**
 - Andrew Flescher
 - David Bearl
 - Ehab Saad
 - Felicia Wells-Williams
 - George Bayliss
 - Jen Dillon
 - Sanjay Kulkarni
 - Laurel Avery
 - Megan Urbanski
 - Thao Galvan
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Representatives**
 - Bryn Thompson
- **UNOS Staff**
 - Cole Fox
 - Kieran McMahon
 - Kristina Hogan
 - Laura Schmitt
 - Stryker-Ann Vosteen
 - Roger Brown
 - Rebecca Murdock
- **Other attendees**
 - Andrew Courtwright
 - Laura Jokimaki
 - Lois Shepherd
 - Shelia Bullock