

OPTN Ethics Committee

Meeting Summary

May 11, 2023

Conference Call

Keren Ladin, PhD, Chair

Andrew Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 5/11/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Multiple Listing: Review and Vote/Next Steps
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 Chair welcomed members to the call.

2. Multiple Listing: Review and Vote/Next Steps

Members reviewed the draft and determined how to move the white paper forward.

Summary of discussion:

The Chair recapped the project and the results from the white paper being out for public comment, noting that the response to the paper was mixed. The Committee has been working on revising the draft based on the public comment feedback throughout the past few months. Staff showed the draft onscreen and members worked through specific sections.

Staff noted that the revisions to the paper included: tempered recommendations about the multiple listing policy, clarification of multiple listing's impact on autonomy, and addition of the vulnerable populations of veterans and pediatrics. The Chair stated that the main objections to the paper include the perception of taking away something that is currently available to patients and clinicians and whether or not to use multiple listing as a way of equalizing geographic differences. The Vice-Chair explained that an addendum has been added to the paper to explain some of the concerns received during public comment and to address each issue comprehensively. The Committee worked through specific line-item changes to the updated draft. The Chair noted that the definitions for autonomy and other ethical principles are the definitions commonly used by the OPTN and in past OPTN Ethics Committee papers, however, may differ from other definitions.

Staff asked if a reference to "highly sensitized patients" should be changed to "difficult to match" for consistency, and the Chair agreed. A member stated that the terms used should remain consistent throughout the paper. Another member added that at some point, the Committee may have to define what "difficult to match" means. The Vice-Chair explained that who should make the determination of who is considered "difficult to match" is addressed in the addendum. The Chair noted that the addendum explains that it is difficult to define, however, it should be the responsibility of relevant OPTN

Committees and stakeholders to do so. Another change to the paper was that the section containing data analysis was moved up, closer to the beginning of the paper. Minor clarifications to the data analysis were also made.

A member asked if it is explained why veterans are considered a vulnerable population in the paper. Staff noted that veterans are considered a vulnerable population according to the OPTN Minority Affairs Committee. The Vice-Chair noted that this is explained in the addendum. The Chair added that veterans have specific considerations because they are able to (and usually do) list at a Veterans Affairs (VA) hospital and another hospital. The addendum explains that veterans who served the country deserve compensation for doing so, one form of which may include national access to healthcare resources. The Chair and another member explained that this may not be the reason for considering them a vulnerable population, and that it may have more to do with the VA health system set up. Staff clarified that the public comment feedback received had to do with access for veterans. A member explained that the way that the VA hospital system set up geographically may mean that it would be reasonable for a veteran to multiple list. Members agreed to clarify the language used in the addendum and remove the reference to service to the country.

The Chair explained that in the updated draft, the language included states that “although recommendations are beyond the scope of this analysis, greater efforts ensuring that all patients are informed of this option and have the ability to exercise it are crucial to ensuring that it promotes the goals of the OPTN.” The Vice-Chair reiterated the purpose of the addendum and noted some key parts, including why the Committee chose to focus on multiple listing and considerations relating to autonomy and population ethics. The Chair also stated that there is an explanation about the relationship between geography and multiple listing included in the addendum. A member responded that the organ transplant system in the US invokes a special obligation to have a fair system. The Chair agreed, and asked if an additional few sentences should be added. The member explained that the point is implicit and in their view, it would not be necessary to add anything additional. The Chair stated that this could be explained in the briefing paper or the slides to the Board of Directors. The Chair explained that the Committee has an obligation to respond to policies that contribute to inequity while acknowledging that there are many pressing ethical issues in transplant.

Members then discussed the section of the addendum that addresses veterans and pediatrics as vulnerable populations. Because this is now addressed in the white paper itself, the section was removed from the addendum.

The Chair explained the Committee’s options for moving forward: 1) delay the project to work further on it, 2) put the revised draft that the Committee reviewed in this meeting forward to the Board, or 3) vote to hold the paper back and not bring it to the Board of Directors. The Chair stated that the paper is strong and it makes sense to send it to the Board of Directors, but noted that the paper has been met with some concern. The Vice-Chair agreed and stated that the paper reflects the Committee’s sentiments.

A member made a motion to send the white paper to the Board of Directors. A member seconded the motion. A roll call vote was taken, and all members on the call voted unanimously to send the white paper to the Board of Directors in June.

Next steps:

The white paper will be sent to the Board of Directors for approval in their June meeting.

3. Normothermic Regional Perfusion (NRP) White Paper Topics

The Chair and staff briefly recapped the status of the NRP white paper.

Summary of discussion:

Staff stated that the draft is close to finalized but still under review by leadership. The draft will be sent to the Committee by May 18th and the Committee will vote on the paper on June 8th. The Chair encouraged members to provide comments on the draft and attendance at the June 8th call to ensure quorum. The Vice-Chair explained that they plan to add descriptive clarification as to the purpose of litigation to the paper.

Upcoming Meetings

- June 8, 2023

Attendance

- **Committee Members**
 - Andrew Flescher
 - David Bearl
 - Bob Truog
 - Carrie Thiessen
 - Andrew Courtwright
 - Ehab Saad
 - Erica Stohs
 - Felicia Wells-Williams
 - George Bayliss
 - Glenn Cohen
 - Jen Dillon
 - Keren Ladin
 - Laurel Avery
 - Megan Urbanski
 - Sena-Wilson Sheehan
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Representatives**
 - Bryn Thompson
- **Other attendees**
 - Lois Shepherd
- **UNOS Staff**
 - Cole Fox
 - Kieran McMahon
 - Kristina Hogan
 - Laura Schmitt
 - Stryker-Ann Vosteen
 - Rebecca Murdock
 - Kimberly Uccellini