

OPTN Ethics Committee

Meeting Summary

August 18, 2022

Conference Call

Keren Ladin, PhD, Chair

Andy Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 08/18/2022 to discuss the following agenda items:

1. Transparency in Program Selection Public Comment Feedback + Regional Meeting Discussion
2. Update on Normothermic Regional Perfusion (NRP) Workgroup
3. Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations – Public Comment Presentation

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

1. Transparency in Program Selection Public Comment Feedback + Regional Meeting Discussion

The Committee reviewed the public comment feedback and sentiment from the regional meetings. Regional meeting support has been positive thus far with the majority of respondents agreeing that transparency is the right way forward. The public comment feedback has been primarily from patients providing insight on how transparency would improve the program selection process. The Committee discussed how regional meetings and cross-committee presentations were going and members who have presented shared their feedback.

Summary of discussion:

A member highlighted the misunderstanding in the community about white papers, specifically the confusion between the Committee's scope of ethically analyzing transparency and implementing transparency at the program level, which is outside of the Committee's scope. Members suggested clarifying the role of white papers during the regional meetings. However, the Committee was pleased to hear that the community is interested in more specific resolutions beyond the white paper. A member noted that how transparency is pursued in policy is something other OPTN Committees will need to consider. Staff will conduct targeted outreach for the opposition sentiment that is submitted during Regional Meetings.

Next steps:

The workgroup, and subsequently the full Committee, will review the feedback that is submitted and consider if they would like to make changes to the white paper before submitting it to the Board of Directors.

2. Update on Normothermic Regional Perfusion (NRP) Workgroup

In the recent NRP Workgroup meeting, the University of Minnesota presented its ethical considerations when determining whether or not to pursue NRP, specifically with regard to transparency and patient autonomy. The discussion identified a reoccurring concern of not wanting to place undue burden on

donor families during the donation process and the implications of obtaining informed consent. In a subsequent meeting, the Workgroup heard from Alex Glazier who presented on aligning law, ethics, and practice in declaring death and donation protocols.

Summary of discussion:

Members highlighted the challenging and robust discussions the workgroup has had during each meeting. One member brought up the ongoing question of how to ensure that the core issues are represented adequately and fairly, encapsulating difficult concepts such as autonomy, consent, and non-maleficence in the final white paper. One question that is still lingering for a member is the relationship between ligation and brain death. A member identified the challenge of ensuring that there is not a breakdown in trust and legitimacy in the declaration of death that would precede any organ retrieval. Members noted the other professional and clinical groups that are addressing the diagnosis of brain death and the juxtaposition to the Workgroup's own conversations. Members also discussed what public perception might be of NRP and the length of time out before procurement. The Committee also spoke about what approach the transplant community should take to educate and inform the public about NRP. The Chair also highlighted the need to address moral distress by clinicians and the impact that negative public perception could have on organ donation.

Next steps:

The Workgroup has established subgroups to address specific ethical questions and determine writing assignments for each section. The Workgroup will continue to receive presentations from professionals on their NRP experiences or concerns.

3. Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations – Public Comment Presentation

Martha Pavlakis, Chair of the OPTN Kidney Transplantation Kidney, presented the proposal, *Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations*, which is co-sponsored by the OPTN Minority Affairs Committee and currently out for public comment. In July 2022, the OPTN Board required the use of race-neutral eGFR calculations in all policies. The sponsoring Committees are requesting feedback on the eligible patient population, necessary documentation to apply for a modified wait time, and the general timeframe centers have to submit wait time modification requests.

Summary of discussion:

A Committee member suggested requiring centers to review and modify their patient's wait time, as opposed to allowing centers to voluntarily review their patient's wait time. Members inquired how far back the programs will look back for the first race-inclusive eGFR and what plans are in place when documentation is unable to be located. Member expressed concern that patients who have switched transplant centers, or face an administrative shortfall, could be further disadvantaged. The presenter recognized that there are many patient and center related variables and that there is no clear-cut resolution for every circumstance. A member inquired if patients who have already received a transplant could qualify for modified wait time if they require re-transplant. Another member asked if there would be a notification going out to patients about this modification pathway upon implementation. In the current proposal, there is not a pathway to notify patients, but the sponsoring Committees recognize that this modification is not restorative justice if the changes are implemented quietly and those affected are not notified. A member inquired if an apology or comment would go out to those who have been affected by the use of the race-inclusive calculation, in addition to the patient directed notice about the modification pathway. Members echoed this sentiment agreeing that it would be beneficial

and an act of restorative justice if comments and apologies were made to those who have been harmed by the previous policy.

Next steps:

The feedback from the Committee will be compiled and submitted as an official public comment.

Upcoming Meeting

- September 12, 2022
- October 21, 2022 – in person meeting Richmond, VA

Attendance

- **Committee Members**
 - Keren Ladin
 - Andrew Flescher
 - Bob Truog
 - Carrie Thiessen
 - David Bearl
 - Ehab Saad
 - Erica Stohs
 - George Bayliss
 - Glenn Cohen
 - Lynsey Biondi
 - Megan Urbanski
 - Melissa Anderson
 - Sanjay Kulkarni
 - Sena Wilson-Sheehan
- **HRSA Representatives**
 - Edna Dumas
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Catherine Parson
 - Cole Fox
 - Kayla Temple
 - Kelley Poff
 - Kim Uccellini
 - Laura Schmitt
 - Roger Brown
 - Stryker-Ann Vosteen
- **Other Attendees**
 - Martha Pavlakis