

OPTN Ethics Committee

Meeting Summary

September 15, 2022

Conference Call

Keren Ladin, PhD, Chair

Andrew Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 09/15/2022 to discuss the following agenda items:

1. *Continuous Distribution of Livers and Intestines Concept Paper* Public Comment presentation
2. Update on Normothermic Regional Perfusion (NRP) Workgroup
3. Update on Multiple Listing White Paper
4. Update on *Transparency in Program Selection* public comment feedback

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

1. *Continuous Distribution of Livers and Intestines Concept Paper* Public Comment presentation

The Committee heard a presentation from the Chair of the Liver and Intestine Transplantation Committee about the proposal out for summer public comment 2022 *Continuous Distribution of Livers and Intestines Concept Paper*. The Liver and Intestine Committee is in the process of identifying attributes for the composite allocation score (CAS) which will determine wait list placement for patients in continuous distribution. The Liver and Intestine Transplantation Committee is seeking feedback on whether there are other attributes that should be considered, and what kind of data collection, such as social determinants of health, needs to be included.

Summary of discussion:

A member asked what role social determinants of health (SDoH) will play in this policy, whether it might have an impact on the sobriety period or alcohol use limitations. The presenter clarified that SDoH refers more to the neighborhood deprivation index, to those individuals who are poor and/or live far away from hospitals and therefore tend to have worse health outcomes. The intent of incorporating SDoH is to develop risk adjustments for those patients and possibly incentivize programs and centers to treat these patients. However, this is not the primary focus at the moment nor a specific attribute of CAS; it will be incorporated later ideally when more specific patient data can be gathered. A member asked why socioeconomic status would not factor in as an attribute now, to which the presenter replied that there needs to be specific data and proof for socioeconomic status meaning worse health outcomes, and the OPTN does not have that data at this time. Another member suggested including frequent hospital admissions would fall in the frailty attribute.

Next steps:

The Ethics Committee will submit a public comment response summarizing feedback.

2. Update on Normothermic Regional Perfusion (NRP) Workgroup

The Committee was briefed on the progress of the NRP effort. Subgroups focused on specific topics were established and will meet to discuss different aspects of the ethical analysis for the white paper, which are: the legitimacy of NRP in the context of death designations; irreversibility versus permanence in the UDDA and its relationship to NRP; patient autonomy and consent; public perception; intent and time out/hands off period; and edge cases.

The first subgroup on legitimacy of NRP and irreversibility versus permanence met and discussed what is happening with NRP medically, biologically, and what other ethical principles to consider besides utility. The patient autonomy and consent subgroup met and identified the issues pertaining to autonomy and consent. The group discussed how much information is too much when obtaining consent, and what the first person versus third person designation might imply.

Summary of Discussion:

The Chair addressed questions about what edge cases might mean in relation to NRP, clarifying that it could include pediatric or uncontrolled DCD cases as clinicians have come to them and expressed concern about such cases. The Liver Committee Chair weighed in on the discussion, noting that NRP only initiates after death has been declared from circulatory causes, when DCD would also proceed. The initiation of NRP turns a DCD recovery into a DBD recovery essentially. They felt that questioning NRP could lead to questioning DCD and that is a slippery slope. The presenter also brought up that a number of new ex-vivo devices have entered the market, and those companies, potentially viewing NRP as a rival technology, have brought up some of the ethical concerns about NRP.

Next steps:

Subgroups will continue to meet to discuss their respective topics and contribute to the outline, which ultimately will inform a proposal the Ethics Committee will recommend releasing for public comment in the future.

3. Update on Multiple Listing White Paper

The Multiple Listing Subcommittee met and discussed the second data request. This request focused on the rates of multiple listing pre- and post-DSA removal, the proximity of secondary to primary listing, and transplant rates for single and multiple listed candidates. The Subcommittee finalized the outline and assigned roles, concentrating on the ethical principles and analyzing the impact of attributes such as geography, outcomes, advanced education, and insurance type, might have on multiple listing.

Summary of discussion:

A member asked whether the analysis included VA hospitals as they believe it would be a typical practice for some patients to list with the VA hospital as the primary and a civilian hospital as a secondary. Staff will follow up with research regarding this, noting that if the VA hospital is with the OPTN then they would show up on the analysis, but otherwise, all of the data used was OPTN data.

4. Update on *Transparency in Program Selection* public comment feedback

Staff presented feedback from regional meetings, noting that the majority of respondents support the white paper. Targeted outreach has occurred to gain insight on the opposition sentiment submitted without a comment. There has been strong patient participation and support, presenting suggestions that included dispersing info to the community clinicians to aid patients, developing a tool to compare factors across transplant centers, and OPTN committees highlighting information that would be most helpful to patients.

Summary of discussion:

A member brought up confusion surrounding the purpose of a white paper, some individuals working for transplant centers may have felt that this was going to introduce prescriptive measures. To avoid that confusion going forward, this member recommends making it explicitly clear the purpose of a white paper is not to be policy but to outline the ethical principles which could inform future projects.

Upcoming Meeting

- October 21, 2022
- November 17, 2022
- December 15, 2022

Attendance

- **Committee Members**
 - Andy Flescher
 - David Bearl
 - Ehab Saad
 - Erica Stohs
 - Felicia Wells-Williams
 - George Bayliss
 - Jennifer Dillon
 - Keren Ladin
 - Laurel Avery
 - Sena Wilson-Sheehan
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Catherine Parton
 - Cole Fox
 - Laura Schmitt
 - Matt Belton
 - Matt Cafarella
 - Stryker-Ann Vosteen
- **Other Attendees**
 - James Pomposelli