

**OPTN Ethics Committee
Meeting Summary
December 17, 2020 11:00 - 12:00 PM, EST
Teleconference Meeting**

**Keren Ladin, Chair
Andrew Flescher, Vice Chair**

Introduction

The Ethics Committee met via Citrix GoTo Meeting 884-431-893 teleconference 12/17/20 to discuss the following agenda items:

1. Ethical Considerations of Continuous Distribution
2. Social Determinants of Health Project Presentation
3. Reminder: General Considerations in Assessment for Transplant Candidacy - Rewrite
4. Closing Remarks

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

1. Ethical Considerations of Continuous Distribution

The project form for continuous distribution has been in development and was presented by the Chair for Ethics Committee review and feedback.

Summary of discussion:

Committee members provided a variety of suggested changes in verbiage to encompass the intentions of the document. The preamble was taken from the Final Rule and reflects many of the project forms pertaining to summarization. Suggested changes were tracked in the document.

The phrase 'identify the ethical principle supporting' sounds to one attendee like post hoc rationalization. The topic was discussed prior to the meeting and 'identify' seemed like an honest way of bringing attention to the rationale, as transparency is paramount.

The phrase 'articulate the appropriate ethical analysis associated with continuous distribution framework' was suggested. 'The procedural process and stakeholder inclusivity' will be moved under 'Pragmatic considerations of implementation.'

Committee members found it imperative to address the tradeoffs of continuous distribution. A member stated that benefit to one patient comes at the expense of another. Suggested verbiage: 'including a discussion of who will be disadvantaged, if even temporarily, by adoption of the framework.'

Committee members commented on the phrase 'circle of concern' which captures the geographical removal of the hard barrier. One member is not convinced that the application of this phrase and concept describes the UNOS region. Changes in verb phrase are recommended to describe the move beyond hard barriers.

The document should reflect more than just positive implications of the change to balance principles and weigh the tradeoffs. The phrase 'identify the tradeoff of removing hard barriers and adopting a more flexible and transparent process of organ allocation,' does not represent OPTN's ongoing transparency.

Any ethical analysis is subject to the possibility of an unexpected conclusion. If the Committee decides continuous distribution is ethically unsound, analysis becomes unnecessary. The grounding conundrum is the benefit of potential endorsement of the move to continuous distribution.

While patients are indeed the priority, the Committee should consider other stakeholders in the transition and include wider analysis in the project form. For example, the pragmatic details and outcomes for transplant centers as a result of the transition.

The project form is a voluntary Committee project, descriptive in nature, without a predetermined conclusion. UNOS has not formally addressed the implications of the transition. Several members feel that regardless of the conclusions, it behooves all parties to do the analysis.

Ultimately, a decision needs to be made whether moving forward with the project form on continuous distribution is a worthy enterprise. The Chair asks the Ethics Committee members to vote or abstain via the chat function (10 support; 2 do not support; 3 abstained).

Next steps:

Results of the poll will be discussed at the next meeting. Suggested edits from committee members will be considered and the project form draft will be revised for Committee review in January.

2. Social Determinants of Health Project Presentation

UNOS Research staff presented details of the Social Determinants of Health (SDoH) data acquisition and feasibility study.

Summary of Discussion:

Social Determinants of Health are conditions in the environment where people live and work that may affect population health. The purpose of the study is to acquire third-party SDoH data to link gaps and better inform OPTN about the transplant patient population.

The study employs the Healthy People 2020 framework, which measures economic stability, education, healthcare access, neighborhood, the built environment, and social and community contexts. The project creates a prospective cross-sectional data set for better understanding of the patient population.

The project will assess feasibility of acquiring third-party data; vendor ability to provide the most relevant, linkable data; accuracy of the linked data; and suitability of the data to describe the transplant population.

OPTN reviewed four third-party SDoH data vendors and rated them based on data availability, privacy, security, customer service, and budget. One vendor was eliminated due to security concerns in their proposal. Public data sources are considered based the level of data linkage and proxy challenges.

The study should expand in the future to include the living donor population. The Committee expressed concern that deceased donor families will have negative feelings about increased data sharing. No information has been gathered about these perceptions, though the process includes IRB review. A focus group or other consultation is suggested.

UNOS staff addressed Committee concerns about the intended use and potential misuse of the acquired data. A communication plan is in development for discussion at board meetings. Gathering feedback from groups like the Ethics Committee will aid in decisions and transparency.

The study IRB is set up as a traditional research project creating a private data set with vendor restrictions on use beyond the study. Recognizing environmental disparities exist, the study simply seeks to understand the most useful sources and types of data.

The OPTN makes policy changes, which could result in concern about data use beyond the study. Communication to the public might be in order should surprising or important information arise regarding disparities along the lines of social determinants.

To clarify, study findings would be public, not the gathered data. A report will be generated analyzing the feasibility of data acquisition, to be shared with the Ethics Committee, among others, for feedback. The published report will likely result in more questions and research; further discussion of implications is necessary.

Next steps:

A similar presentation will be made to MAC and DAC. The project continues to be in development and Ethics Committee feedback will be requested at a future meeting.

3. Reminder: General Considerations in Assessment for Transplant Candidacy – Rewrite

The Committee was briefly reminded that the CAT rewrite white paper is due for public comment in the third week of January.

4. Closing Remarks

The Chair found the discussion helpful. Committee members can expect communication from UNOS staff about further meetings. The Chair had no further comments and wished everyone a happy and safe holiday season and New Year.

Upcoming Meetings

- January 21, 2021
- February 18, 2021
- March 18, 2021
- April 15, 2021
- May 20, 2021
- June 17, 2021

Attendance

- **Ethics Committee Members**
 - Keren Ladin, Chair
 - Andrew Flescher, Vice-chair
 - Aaron Wightman
 - Amy Friedman
 - Catherine Vascik
 - Colleen Reed
 - David Bearl
 - Earnest Davis
 - George Bayliss
 - Glenn Cohen
 - Giuliano Testa
 - Mahwish Ahmad
 - Michael S Davis
 - Sanjay Kulkarni
 - Tania Lyons

- **HRSA Attendees**
 - Jim Bowman
 - Marilyn Levi

- **SRTR Attendees**
 - Bryn Thompson
 - Maryam Valapour

- **UNOS Attendees**
 - Alex Garza
 - Andrew Placona
 - Bob Carrico
 - Eric Messick
 - James Alcorn
 - Laura Cartwright
 - Ross Walton
 - Sarah Konigsburg
 - Susan Tlusty