OPTN Ethics Committee
Meeting Minutes
February 20, 2020
Teleconference

Elisa Gordon, PhD, MPH, Chair
Keren Ladin, PhD, Vice Chair

Introduction

The OPTN Ethics Committee (the Committee) met via Citrix GoToMeeting teleconference on January 16, 2020 to discuss the following agenda items:

1. Public Comment Discussion: Data Collection to Assess Socioeconomic Status (SES) and Access to Transplant (Minority Affairs Committee (MAC))
2. Project Updates: Facilitating Patient Navigation Project and CAT Rewrite
3. Additional Project Updates: Pediatric Collaboration and Vaccination Pre-Proposal Update
4. Discussion: Vice Chair Nomination and Selection Pilot

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

1. Public Comment Discussion: Data Collection to Assess Socioeconomic Status (SES) and Access to Transplant (Minority Affairs Committee (MAC))

The Committee reviewed and discussed the Minority Affairs Committee's (MAC) proposal, Data Collection to Assess Socioeconomic Status (SES) and Access to Transplant.

Summary of discussion:

The Committee Chair recommended that in the description of household income, it should be worded "total annual household income".

A member asked for clarification on "total household". There are instances where not everyone contributes to the household. Would this require a dollar amount?

The Committee Chair clarified by providing an example of a household with two working adults and two children. The total income would be based on the two working adults of the household. The Committee Chair continued by stating that this poses the question of how this information would be recorded. Ideally, the more that granular data can be collected from a study participant, the better. This is a sensitive matter to ask individuals. There are a number of standardized surveys that are used by government agencies where categories are offered. It is recommended that the MAC provide categories or ranges to reduce the discomfort that comes to asking these sensitive questions.

A member asked if this would be a requirement for patients to share in order to be registered and qualified for a transplant. What happens when a patient refuses to answer this question? This should not be a mandated question.

The Committee Chair voiced agreement to this point and added that it would be an undue influence to those patients who may be the most vulnerable.

A member voiced agreement that this information should not be mandated and instead should be voluntary. When asking this question, there should be an option that allow potential candidates to decline by either marking “Not Applicable (N/A)” or “Decline to Answer”. Additionally, there should be some verbiage included that states that this question does not have a direct linkage to a potential candidate’s eligibility for being listed or receiving offers. There should be some understanding to the patient that this question has nothing to do with their opportunity of getting a transplant.

Another member commented that in making this question voluntary will result in systematic gaps in the data.

A member stated that there is a concern that if the transplant personnel has access to this information, there can be some dangers to the usage. For example, if a patient were wealthy, they could be targeted for fundraisers, which would have nothing to do with the care the patient came in for in the first place.

Another member stated that this would be more of an issue of the usage of the information and less of the data collection itself. There should be restrictions to the usage and who has access of the data being collected.

A member stated that patients will be very uncomfortable with this question. This should not be a field that is included. Patients should have support for transplant, whether it is insurance or personal means, and should not feel excluded based on their income.

Another member stated that even though research shows that annual household income and household size may be the most accurate way to measure socioeconomic status (SES), there are other factors that are already being asked, such as level of education and zip code, which can give a relatively good idea of SES. Are the anomalies in the data collection significant enough to affect the goal of collecting this data to begin with? Why not use data that is already being collected that does not make patients feel uncomfortable and does not add data collection burden to the programs while providing a similar result to what is wanting to be evaluated.

Another member asked that if the total household income changes while a candidate is listed or after being transplanted, what bearing would this information have?

The Committee Chair stated that if this information is not tracked, it will be hard to determine what affects SES has on access to transplant. There is value to tracking this information while at the same time raises some ethical issues. The Committee Chair continued by stating that the MAC’s proposal mentions that zip code data is not as granular and instead is an estimate.

A member added that a zip code only applies to American patients. This does not apply to international patients. There is an inability to have granular data linking to financial access and ability to their zip code, especially when a patient is coming from another country. Patients coming from international locations are worried that if they fully disclose their income and the program realizes they can pay out of pocket, they will be at a disadvantage and will be asked to pay extra. There is work being done to try to help patients understand that this is not how the process works and that overall, the payment would be the same. With this concern among international patients, this type of data collection could amplify this misunderstanding and discomfort in filling out this information.

The Committee Chair posed a question on whether the MAC consulted with a social scientist expert on this topic. There are many other indicators that could be considered such as education and occupation. Occupation may be a question that could be considered. It is believed that education is already being collected.

A member asked what the MAC was trying to come up with – are they asking for more data on this issue specifically as we are simultaneously looking at broader distribution. What is it that this data will help us understand better? The member suggested areas such as economic insufficiency and resource insufficiency as additional potential measures.

The Committee Chair stated that in regards to the overall intent and upon review of the proposal, there was not a sense that this data collection was in relation to broader distribution. It seems the goal of this data collection is to identify potential sources of disparities. From the literature, ethnicity, race, and SES are associated with access to transplantations, but SES is not as systematically collected as much as desired. The Committee Chair continued by posing a question of why it is being thought that what is currently collected not enough.

A member agreed with this and stated that although the data currently collected is not as granular as household income and size, how much is that variation going to significantly affect the purpose of this data collection? Although education, zip code, or occupation are not the best measures of SES, are the variations going to be that significant?

Another member asked if there would be accuracy checking? Patients can inflate what they are reporting thinking they may have a better chance of being listed while others may under report their income thinking that if they appear lower status than they are they may get more assistance from the transplant program. It is not believed that patients may accurately report this information.

The Committee Chair stated that in weighing the benefits of doing this data collection with the unintended consequences, there are a lot of considerations that would need to be made. A preface to the question and explaining the rationale of the question being asked could be helpful in getting a desired response. Tracking this information is important to identify potential sources of disparities and correct it in the future.

A member commented that it sounds that the information being sought is for research purposes. This raises a concern of whether a subject participating in human subject research has been vetted by the Institutional Review Board (IRB) and whether potentially coercion for participation (fear that if the question is not answered, they will not receive an organ).

The Committee Chair stated that from review of the proposal, the data being collected would be for tracking purposes and not for any clinical purposes.

A member stated that an IRB may not be appropriate to discuss in the context of this data collection proposal because this is research for performance improvement. The purpose of this data collection is not for publication but instead to make the process better.

Another member commented that the data collection falls under the Quality Improvement /Quality Assurance (QI/QA) exceptions for research. It should be recommended that this is reviewed by the IRB to ensure that it is exempt and declared exempt. Additionally, there is various information that is required of transplant candidates and recipients for a period of time. The fact that social science information is being collected rather than medical information that serves the same purpose to improve the process of transplantation, does not make it coercive – it is part of the process of being transplanted.

A member asked if there was a way to propose to de-identify the response in this information. There could be a way to create a code and then trace back to see if that coded person was transplanted. This method could help in removing the information from the individual.

The Committee Chair stated that there are a lot of data that are collected on transplant candidates and recipients that becomes available for research to be done on it. There is not really any informed consent that is done in advance for the public to use this data set.

Next steps:

- The comments received by the Committee will be synthesized into a formal statement that will be sent to the OPTN Minority Affairs Committee (MAC) for their consideration and response back to the Committee as appropriate.

2. Project Updates: Facilitating Patient Navigation Project Update and CAT Rewrite Projects

The Committee was updated on the Facilitating Patient Navigation and CAT Rewrite projects.

Summary of discussion:

Facilitating Patient Navigation

The Workgroup held their last meeting on February 12, 2020. The Workgroup decided that the project would be a white paper that will provide patients with information that should be considered to help make informed decisions pertaining to the donation and transplantation process.

The Workgroup developed a list of survey questions and have divided these questions into sections to begin drafting an outline of the white paper. There are a few outstanding items such as data from the patient call center to help guide the project in determining what exactly patients want to know.

CAT Rewrite

The Subcommittee held their last meeting on February 19, 2020. The Subcommittee discussed potential new criteria to include in the rewrite of the white paper. There will be further discussion on these topics to determine if the proposed topics warrant being in the white paper. The project will be going forward to the Policy Oversight Committee (POC) for review during their February 21, 2020 teleconference.

The Committee Chair commented that the topic of intellectual disability could be included in the white paper, but it was cautioned that it should be limited to a short paragraph discussing this topic and not an in-depth analysis.

The Subcommittee Co-Chair agreed with this and clarified that this was discussed during the Subcommittee meeting where each new idea being added to the white paper will provide rationale and an outline of the context the topic will be addressed in the white paper. This will then go under internal review for additional feedback. The goal is to ensure that this project is thoroughly vetted to so that any concerns can be addressed beforehand.

Next steps:

- The full Ethics Committee will continue to be informed and updated at regular intervals on these projects.

3. Additional Updates

The Committee received an update on a proposed project collaboration with the OPTN Pediatric Committee, as well as an update on the vaccination proposal for a white paper.

Summary of discussion:

The Committee was updated that there's an outline drafted for the potential project collaboration on pediatrics. Both leadership form the Ethics and Pediatric Committees had a discussion on the project in further detail. It was decided that the gap analysis project would go forth to the Policy Oversight Committee (POC) for further review in March. Next steps will be determined after the POC meeting.

The Committee also received an update that the drafted outline for a proposed vaccination white paper is currently being reviewed by HRSA.

Next steps:

- The Ethics Committee will be kept updated regarding these potential projects as they develop.

4. Discussion: Vice Chair Nomination and Selection Pilot

The Committee reviewed and provided feedback to a proposed Vice Chair nomination and selection pilot.

Summary of discussion:

In an attempt to promote inclusivity, transparency and thorough vetting of candidates, the Committee were presented with a proposed pilot for the Vice Chair nomination and selection process.

A member asked if there was a list or place where people can access the qualifications for the Committee Vice Chair. UNOS staff stated that this information is accessible on the OPTN site but will be included in the e-mail for the call for nominations.

The Committee Chair stated that there are some qualifications for serving as a Chair that run across the Committees and then there are specific qualifications that the Ethics Committee Chair should additionally have. The qualifications specific to the Ethics Chair will be specified and should be considered by the Committee moving forward with this process.

A member stated that the inclusion of Committee members from the last 5 years is a good approach and will help get a sense of who may be a good candidate.

Another member voiced appreciation in the development of a process that will be repeatable and worked on improving. It speaks to the quality journey of the organization.

There were no additional comments or questions. The meeting was adjourned.

Next steps:

- The Committee will receive a call for nominations which will begin the pilot for the Vice Chair nomination and selection process.

Upcoming Meetings

- March 19, 2020 (Teleconference)
- April 15, 2020 (In-person, Richmond, VA)

Attendance

- **Committee Members**
    - Elisa Gordon
    - Catherine Vascik
    - Ashton Chen
    - Glenn Cohen
    - Trey Entwistle
    - Andrew Flescher
    - Amy Friedman
    - Tania Lyons
    - Colleen Reed
    - Robert Veatch
    - Aaron Wightman
    - Mahwish Ahmad
- **HRSA Representatives**
    - Jim Bowman
    - Marilyn Levi
- **UNOS Staff**
    - Joann White
    - Betsy Gans
    - Robert Hunter
    - Shannon Edwards
    - Joel Newman
    - Alison Wilhelm