

**OPTN Ethics Committee
Meeting Minutes
June 19, 2019
Teleconference**

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

Introduction

The Ethics Committee met via teleconference on 6/19/2019 to discuss the following agenda items:

1. Intellectual Disabilities Draft Memo
2. Committee's Mission Statement & Scope
3. Living Donor Social Media Project Update

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

1. Intellectual Disabilities Draft Memo

UNOS staff and Committee Leadership reviewed the Intellectual Disabilities draft memo with members.

Summary of discussion:

UNOS staff began by providing an overview of the Committee's Intellectual Disabilities (ID) project. During the Committee's last in-person meeting, the Health Resources and Services Administration (HRSA) notified members that they would need to hold off publishing any white papers or guidance documents pertaining to this issue until the Office of Civil Rights (OCR) completed their guidance. To help provide the OCR with the Ethics Committee's perspective on the issue, HRSA asked that the Committee develop and provide a memo that would be provided to the OCR. The goal of the Committee is to vote on the final language, which will then go to the Executive Committee.

A member asked why there was a halt in the Committee's original project. UNOS staff replied that due to the OCR currently working on guidance on this topic, the Committee was asked to halt their project to ensure there is consistency in the information provided to the community. The member continued by asking if there was anything in terms of content in the Committee's white paper draft that raised any red flags.

UNOS staff stated that there were no specific feedback on the content of the white paper draft. The concern was to maintain consistency between any guidance by the OCR and the OPTN Committee.

The Committee Chair began with a review of *Section II: Respect for Persons, item A*, and asked members what challenges to listing ID candidates should be mentioned in the memo?

A member stated that there was a challenge of compliance with regard to those specific individuals who are intellectually disabled and additionally do not have familial or other support post-transplant.

Another member stated that another challenge is assessing capacity, particularly for individuals who may not have institutional support set up such as guardianship or informal guardians in form of social support networks. For an evaluation, it is significant to note whether or not there is a legal guardian for a patient with intellectual disabilities. The member commented that in some cases there are financial obstacles for families to pursue legal guardianship.

UNOS staff suggested that the members send a draft of their mentioned edits. The members agreed with this and will develop the language for this section to send to Committee Leadership and UNOS staff for review and synthesizing for the memo.

The Committee Chair continued by reviewing *Item B - Decision-making and Informed consent*, and asked members if the section was too ambiguous and if the Committee is specifically discussing patient decision making or provider decisions in terms of evaluation. A member clarified that this guidance and framework were in regards to best practices of transplant centers and evaluating teams and suggested following up with the Vice Chair if further clarification was needed.

The Committee Chair moved on to the *Section III, Utility* and asked for clarification on this section. A member stated that the Vice Chair reviewed this information and that additional clarification on this section should be deferred to the Vice Chair. A member asked who would be assessing quality of life – would this be the families or clinicians? The member replied that this was based on precedence and medical ethics.

Another member stated that the data and literature on quality of life is limited. When looking at graft or patient survival in persons of intellectual disability vs. the general population, there is data that shows that there is no significant difference in the outcomes. There is no data on how quality of life can objectively be measured. Quality of life is oftentimes what is perceived by the family or a quality of life benefit that occurs with the whole family once the patient is not on dialysis and can be cared for without the burden of end-stage renal disease (ESRD). There is a discrepancy on how families feel vs. how the clinicians feel. In general, there is no difference in how this would be established. The member added that the information provided is very anecdotal.

UNOS staff suggested including a sentence to *Section III* to summarize this discussion by stating, “The paper acknowledges that arguments regarding quality of life are often subjective, data is limited, and does not find significant difference in data outcomes”. The Committee agreed with this edit.

A member commented by asking if the memo is speaking about a recipient with intellectual disabilities receiving a deceased donor or living donor organ. Secondly, there should be clarification on whether this memo pertains to pediatric or adult recipients.

Another member clarified that this memo incorporated both pediatric and adult candidates. From an ethics perspective, it is not believed that the recipient’s capacity or intellectual disability presents any ethical differences between deceased vs. living donors. A member stated that the practice in the past has been that some centers would not allow transplantation of deceased donor organs for patients with intellectual disabilities.

Another member added that the community at large may view this differently as opposed to someone who is living, related and aware of where the organ is going. These values have been questions in the past and it was suggested that including these concepts would be important.

A member suggested adding a sentence in the memo that states, “We acknowledge that there are discrepancies between transplant center practices regarding living and deceased donor donation options for patients with intellectual disabilities”. In this memo, the Committee would not be able to tackle this ethical question. The Committee agreed with this edit.

A member asked if the memo would be visible to the public. UNOS staff clarified that the memo would be internal between HRSA and OCR and would not be publicly posted. The member asked for clarification that if anything needed to be changed there would be flexibility to amend and this would not be a full reflection of the Committee’s stance on the issue. UNOS staff confirmed that this was the

case and reviewed the last statement of the memo that mentions that the work by the Committee and workgroup has not yet been completed.

Next Steps:

- Workgroup members will provide additional edits to Committee Leadership and UNOS staff to review and synthesize for the memo.
- Final language of the memo will be voted on by the Committee during the July Committee meeting and will be submitted to the Executive Committee for review and submission to HRSA.

2. Committee's Mission Statement & Scope

The Committee Chair provided an update on the Committee's mission statement and reviewed the drafted language with members.

Summary of discussion:

The Committee Chair reviewed the Committee's mission statement with members. From discussion with UNOS leadership, Committee leadership reviewed and revised the Committee's current mission statement to ensure that future projects are within the purview of the Committee and in alignment with the strategic goals of the OPTN.

UNOS staff confirmed that all Committees would be reviewing their mission statements and will make revisions as necessary. The Committees' mission statements would be presented to the Board for review and vote during the December Board meeting.

The Committee discussed the possibility of creating a more detailed document to guide the Committee's purview, such as a charter. A member suggested that the Committee could take inspiration from the charters of other organizations that are not necessarily related to transplantation, such as the American College of Obstetrics and Gynecology, or the American Society of Reproductive Medicine.

Next Steps:

- The Committee will vote on the revised Mission Statement language on their next committee call.

3. Living Donor Social Media Project Update

Members were given an update on the Living Donor Committee's Social Media Project.

Summary of discussion:

A member provided an update on the Committee's work with the Living Donor Committee on their Social Media Project. The Living Donor Committee are in the initial stages of developing a white paper for the project. The workgroup is currently reviewing the initial draft of the white paper. Members will be updated on any advancements made on the white paper during the next Committee meeting.

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

Upcoming Meeting

- July 18, 2019