

**OPTN/UNOS Ethics Committee
Meeting Minutes
February 16, 2017
Conference Call**

**Peter Reese, MD, Chair
Elisa Gordon, PhD, MPH, Vice Chair**

Introduction

The Ethics Committee met via Citrix GoToTraining teleconference on 02/16/2017 to discuss the following agenda items:

1. White Paper Addressing Financial Incentives for Organ Donation
2. Current Projects

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

1. White Paper Addressing Financial Incentives for Organ Donation

Summary of discussion:

The Ethics Committee (the Committee) vice Chair opened the meeting and explained that the *White Paper Addressing Financial Incentives for Organ Donation* had been withdrawn from public comment. She explained that the paper was expected to be controversial. After the white paper was released for public comment some respondents considered it to be a directive for OPTN leadership to lobby for modification of the National Organ Transplant Act (NOTA) to allow for financial incentives for organ donation. The Committee intended the white paper to start a conversation about potential research through a pilot study and acknowledged that NOTA would need to be modified for such research to occur. The white paper specifically asked for feedback regarding if a pilot study should or should not be supported. Committee leadership ultimately decided it would be best to withdrawal the white paper from public comment for revision and to plan to send the white paper for public comment in August 2017.

The vice Chair commented that the Committee had fulfilled all the required checks and balances prior to the start of public comment. Committee leadership had a conference call with the OPTN President and vice President and UNOS senior leadership to make certain they were aware of the potentially controversial nature of the white paper during its development. The white paper was reviewed and approved by the Policy Oversight Committee (POC) and the Executive Committee of the Board of Directors prior to the start of the public comment period.

Next steps:

The Committee plans to revise this white paper and anticipates it will again conclude that research is needed to determine how financial incentives might impact organ donation. The paper could be revised to propose that the structure of any future pilot study would need public support and approval in advance. The revision will further clarify that the white paper is not advocating for a change to NOTA. The paper will be revised to clarify which recommendations apply specifically to living organ donation. A member suggested asking the Organ Procurement Organization Committee to review the paper before it is sent for public comment in August 2017.

2. Current Projects

The Committee is working on three white papers for future public comment:

Guidance Regarding Organ Donation by Competent Terminally Ill Donors

Summary of Discussion

The lead author for this white paper was not available to participate in this meeting. This white paper was recently provided to all Committee members for review and feedback.

Next Steps

Finalize the white paper for public comment in August 2017.

Honoring First Person Consent and Extending First Person Consent to Include DCD

Summary of Discussion

The lead author for this white paper recently took a new job in a different region and consequently could not continue as a regional representative on the Committee. A member offered to serve as the new lead author for this resource. Several Committee members volunteered to assist with this project.

Next Steps

The new lead author will determine a path forward.

White Paper Addressing the Escalation of Treatment for the Purpose of Advancing a Patient's Status on the Transplant List

Summary of Discussion

The OPTN President requested that the Committee develop a white paper on this topic. This new project was recently approved by the POC and the Executive Committee of the Board. A work group for this white paper held its first meeting on 2/10/17, and a follow-up meeting will be scheduled. After the first meeting, the Committee liaison contacted liaisons for the Membership and Professional Standards, Thoracic and Liver Committees to make inquiries regarding the prevalence of "gaming" within the transplant system.

The Committee reviewed responses from UNOS staff working with the MPSC. The response follows:

I reviewed the problem statement in the project form and see that you are specifically interested in issues with the escalation of care to advance patients' waitlist statuses. I spoke with various MQ staff about this. While we recall a few cases where staff and/or the MPSC questioned whether someone may be trying to game the system, none of the cases involve the unnecessary or inappropriate escalation of care/treatment to influence a patient's listing. Nothing we routinely review would identify such concerns. Site surveyors review the criteria used to list someone at a particular status and will verify that the criteria/treatment was satisfied according to medical record documentation, but they would not question a physician's medical judgement as to whether that criteria was appropriate (or inappropriate) for the particular patient. Of course, we can't say it is not a problem, we can only say that it hasn't come across our radar. From our point of view, if a committee is concerned about it, the best approach would be to analyze listing data from pre- and post- allocation changes to evaluate whether there has been an increase in certain treatments

The Committee reviewed a response from a member of the Thoracic Committee which follows:

Consensus is that actual evidence is going to be hard to come by because programs are playing within the policy parameters, "gaming" is within the rules, i.e. bending the rules

rather than breaking them, I don't think there is going to be more than anecdotal evidence (or rarely MPSC for severe cases). How would we know how many children with DCM actually "needed" milrinone versus were not weaned off of it because it would have meant downgrading to status 1B, or how would we would know how many patients really "need" a PA catheter to manage their inotropes vs. being left on for urgency status. In all cases, the anecdotal evidence is that some patients who don't really need these therapies were left on them, but member quality is not going to identify them because there are no criteria in policy for the use of these devices (which is why I think the new policy is a vast improvement, because it at least attempts to define objective hemodynamic criteria for these patients).

Next Steps

Workgroup members will be polled to determine a date and time for a follow-up meeting.

Committee members were reminded to finalize their travel arrangements for the April 3, 2017, meeting in Chicago. A date for fall 2017 meeting was discussed.

The meeting was adjourned.

Upcoming Meetings

- March 16, 2017
- April 3, 2017