Introduction

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

1. Covert Factors Project Update
2. CAT Rewrite Project Update
3. Vaccination Pre-Proposal Update
4. Additional Updates
5. Cogswell Article

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

1. **Covert Factors Project Update**

The Committee was updated on the Covert Factors Project.

**Summary of discussion:**

The Subcommittee Chair reviewed the first Covert Factors teleconference, in which the Subcommittee discussed the scope of interest and concluded that living donors would be outside the scope given the purview of the Living Donor Committee to review and discuss issues related to living donors. The Subcommittee Chair clarified that “covert” refers to factors that patients may not know about and may need help to find out about. The concept of this project was to serve the needs of patients so that they have a full picture of the opportunities that exist. The Subcommittee has identified other tools that the Patient Affairs Committee (PAC) put together for patients, and believes that there is room for additional resources regarding non-adherence and insurance.

**Next steps:**

The Covert Factors Subcommittee will continue to meet on a monthly basis and discuss the project. The next meeting will be held February 12, 2020. The full Ethics Committee will continue to be informed and updated at regular intervals.

2. **CAT Rewrite Project Update**

The Committee discussed an update on the Committee’s CAT Rewrite project.

**Summary of discussion:**

The CAT Rewrite Subcommittee is focused on adherence and barriers to transplantation. The Committee is asked to send any comments or suggestions regarding the current CAT document to the Subcommittee. The current version of the document will be circulated to the committee for review.
Next steps:
The CAT Rewrite Subcommittee will continue to meet on a monthly basis and discuss the project. The next meeting will be held February 19, 2020. The full Ethics Committee will continue to be informed and updated at regular intervals.

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; pediatric leadership will be joining ethics leadership to discuss the project in further detail. After the leadership discussion the Committee will be updated again.

The Committee also received an update by the Chair that a draft outline of a vaccination proposal to work on a white paper will be distributed for review and feedback on January 17, 2020.

Next steps:
The Ethics Committee will be kept updated regarding these potential projects as they develop.

4. Cogswell Article
The Committee discussed an article on changes to heart transplantation policy and the Thoracic Committee’s response to the article.

Summary of discussion:
An article published very recently showed heart transplant mortality rates changed after modifications to the heart allocation policy. The analysis showed some improvement in waitlist survival, higher use of ECMO, longer distance traveled, longer ischemic time and worsening of post-transplant survival. The adverse effect on post-transplant survival is of concern.

The OPTN Thoracic Committee wrote a response to the article indicating that the analysis may be premature. The analysis had only applied to patients listed and transplanted after the change to the heart allocation policy, not to those listed before the change, whose status would have been changed to reflect the new allocation data. The Thoracic Committee’s response highlights that a decrease in waitlist mortality was the goal of the policy changes.

A Committee member in the thoracic transplant field indicated that they were “highly impacted” by the changes. The Committee member expressed concerns about the changes to the status criteria and the potential increase in using statuses by exception. The Thoracic Committee Chair who joined the call emphasized that the Ethics Committee should not put too much stake in the study reviewed because the follow up data are not complete because programs are not required to submit the follow up form until 6 months post-transplant. The Thoracic Chair also highlighted that the listed patients transplanted after the allocation changes occurred were at the highest risk, biasing the study to show higher mortality afterwards. UNOS analysis of the data did not show any mortality differences. The purpose of the allocation change is to give the opportunity for sicker patients to have greater access to transplant. Because of the challenges with the data, the Thoracic Chair recommended caution interpreting the study recently published.
The Committee received feedback that the updated UNOS data analysis will be released sometime in March. The Committee agreed to wait until March to have a richer data set with which to examine and obtain a clearer understanding before exploring the ethical implications.

Next steps:
The Ethics Committee will review the updated data analysis when it is released.

Upcoming Meetings
- February 20, 2020
- March 19, 2020