

## **OPTN Ethics Committee – General Considerations in Assessment for Transplant Candidacy (CAT)**

### **Rewrite Subcommittee**

#### **Meeting Minutes**

**February 19, 2020**

**Teleconference**

**Keren Ladin, PhD, Subcommittee Chair**

**Catherine Vascik, BSN, RN, Subcommittee Co-Chair**

### **Introduction**

The OPTN Ethics Committee CAT Rewrite Subcommittee (the Subcommittee) met via Citrix GoToMeeting teleconference on February 19, 2020 to discuss the following agenda items:

1. Recap of 1/15 Meeting
2. Discussion: CAT Outline (New Criteria Ideas)
3. Next Steps

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

#### **1. Recap of 1/15 Meeting**

The Subcommittee Co-Chair provided an overview of the discussion from the January 15, 2020 meeting.

##### Summary of discussion:

During the January 15, 2020 meeting, the Subcommittee continued to review and discuss the current CAT white paper and provided feedback on each sections.

- Preamble - The Subcommittee determined that this section needs to be rewritten. There should be more clarity on the intent of the document.
- Life Expectancy - The Subcommittee recommended to retain this section as written. There was discussion on providing more information regarding patient age, but concern was raised that the topic of age would be outside of the purview of this white paper.
- Compliance/Adherence - The Subcommittee recommended to retain this section. It was agreed that the term "compliance" should be replaced with the term "non-adherence". There needs to be clarification/delineation between the two terms.
- Repeat Transplantation Section - The Subcommittee recommended to retain this section, but should be revised to provide more detail and clarity.
- Alternative Therapies section - The Subcommittee recommended the removal of this section.

#### **2. Discussion: CAT Outline (New Criteria Ideas)**

The Subcommittee reviewed and discussed proposed new criteria to potentially be included in the rewrite of the CAT white paper.

##### Summary of discussion:

The Subcommittee proposed additional criteria to be considered the rewrite of the CAT white paper. The Subcommittee agreed that with each criteria being proposed, there would need to be rationale and further detail on the context each criteria would be addressed in the white paper.

A member provided four topics to be considered:

- **Review by second center?** – This topic addresses potential candidates who are turned down by a program and then reviewed by a second program. Should there be a statement of how much the first program should not bias the second program so that there is truly an independent evaluation by the second program?
- **Transplant as a bail-out?** – There are pressures sometimes on programs to save a patient they have committed themselves to with transplantation even if it is not necessarily the best idea for the program or for organ transplantation overall. Particularly with heart transplants, if a patient's only option is transplant, despite the patient not being a candidate, how should this be addressed?
- **Consistency in evaluation process of absolute and relative contraindications among different candidates**
- **Alternative list/marginal organs as an alternative therapy?** Should programs use alternate organs when the results/outcomes are not as good? Should there be a way to segregate those who are candidates for alternate list organs from those who are primarily looking for A or B quality organs.

A member stated that the discussion would not be around whether or not an alternative list is needed but rather if this is a topic that should be addressed or not in the context of this white paper.

Another member stated that this criteria seems to be a complex issue that goes beyond the context of this white paper. The weight given on certain criteria may be different from program to program.

The Subcommittee then reviewed additional proposed criteria:

#### Intellectual Disability

A member asked the Subcommittee what the rationale would be in including intellectual disability in this white paper. There was an understanding that the Ethics Committee had worked on a project around the topic and was then curtailed.

UNOS staff clarified that the Ethics Committee did work on a project previously on intellectual disability that was then stopped due to work being done by the Office of Civil Rights (OCR). This topic did come back in brainstorming on potential criteria that could be included in the rewrite of the CAT and was discussed during the initial Subcommittee meeting that this topic could be more generalized.

The Subcommittee was reminded that new topics could be proposed but should have rationale and further detail on the context each criteria would be addressed in the white paper. Once these topics are proposed, it would then be reviewed and vetted before work begins on the rewrite.

The Subcommittee Co-Chair commented that intellectual disability is a topic that should be included in the white paper. It does not need to be expanded on and instead a generic statement would be beneficial to the community.

A member voiced concern in skimming the surface of this topic. Explanations that require more information would not be well served in the context of this white paper. Another concern is the data available on this topic. Data exists in pediatrics where informed decisions can be made. This does not exist among adults, as assessments are not standardized. This topic could be mentioned by stating that

intellectual functioning alone should not be used as a criterion for exclusion. This topic is more nuanced than what appears to be the goal of this white paper.

Another member stated that having some level of guidance would be important especially for this topic of intellectual disability.

A member proposed a general statement saying intellectual disability or any disability should not be a sole reason for exclusion criteria and that this population has a right to be evaluated as every other candidate.

A HRSA representative commented that whatever criteria is decided should be an early discussion before any work has begun on the project. The proposed changes would need to be approved and vetted before going further into the project.

A member stated that if a program would exclude a low functioning patient that is exclusion on the basis of intellectual functioning around the basis of disability. Whether this is appropriate or not would be another discussion.

The Subcommittee Co-Chair proposed that if it is agreed that intellectual disability be included in the white paper, there should be a brief statement to address it. There was no opposition voiced to this.

#### Financial Challenges (inability to pay)

A member stated that a brief statement would be appropriate to address inability to pay as a criteria. There were no additional comments.

#### Incarceration status (current)

A member stated that there is a white paper that discusses this topic already. It was proposed that a brief statement should be included saying that current incarceration status should not be used as a sole determinant for acceptance.

Another member agreed with this and added that it is important to mention this topic in the white paper. Despite there being a white paper addressing this topic already, the CAT could be looked at as a summary document that addresses topics that are being discussed within the community.

#### Social Support

A member stated that this is an important determinant in an individual's candidacy, but it would vary by patient. If you have a more independent, highly functioning patient, their need for social support would be less than an individual with intellectual disability or debilitation from their disease where they will need support to get through the operation and recovery period.

Another member stated that the Subcommittee Chair's previous work on this topic has been compelling and it points out that many of the more stringent criteria are less justified. This white paper may not be the right venue to make broad statements about social support. The Subcommittee was asked their thoughts on what would be helpful in making a generalized statement on social support – should it be clear and objective; should there be social support determinants that are evidence based?

A member agreed with that this should be evidenced based and that there should be clear guidelines if it is determined that this topic is discussed in the white paper. There are a number of literature and

assessment tools that are used to evaluate patients. Social support is a huge discussion amongst the community and it is both patient and organ dependent.

#### Immigration Status

A member stated that this topic seems to be closely related to the financial challenges criteria. If immigration status restricts access to adequate insurance coverage, this becomes a financial constraint. In general, immigration status is not something that is a challenge.

Another member stated that in Washington state, there is access to state funds for undocumented immigrants. The question does tie into the ability to pay.

There were no additional comments. The meeting was adjourned.

#### Next Steps

- A project form outlining the scope of the CAT Rewrite project will be reviewed by the Policy Oversight Committee (POC) during their February 21, 2020 conference call.

#### **Upcoming Meeting**

- March 18, 2020