

**OPTN Ethics Committee**  
**Considerations in Assessment for Transplant Candidacy (CAT) Rewrite Subcommittee**  
**Meeting Summary**  
**March 24, 2021**  
**Conference Call**

**Keren Ladin, PhD, Chair**  
**Catherine Vascik, BSN, RN, Vice Chair**

## **Introduction**

The Considerations in Assessment for Transplant Candidacy (CAT) Rewrite Subcommittee met via Citrix GoTo 468-911-189 teleconference 03/24/2021 to discuss the following agenda items:

1. *Revise General Considerations in Assessment for Transplant Candidacy* white paper and considerations following public comment

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

### **1. Revise *General Considerations in Assessment for Transplant Candidacy* white paper and considerations following public comment**

UNOS staff provided an overview of the general themes and comments that were submitted during public comment and Regional Meetings. Committee members shared their feedback as regional meeting presenters. Overall, there has been primarily positive feedback from the community through public comment and regional meeting sentiment scores and comments.

#### Data summary:

The community provided general support for addressing/updating the criteria and inclusion of the self-injurious behavior and social support sections. The community did question why access to transplantation, financial considerations impacting access to transplantation, individuals with disabilities, and pediatric patients were not addressed within the white paper. There were a range of suggestions from the community on how to best assist transplant programs and develop standardization however the vast majority were out of the scope of the Ethics Committee and the white paper specifically.

#### Summary of discussion:

The Committee Chair initiated the conversation by informing the group that this white paper has been accepted as a welcomed contribution to the transplant center. Moving forward, the overarching response is that in an attempt to follow the length and brevity of the former white paper, this revision has fallen short in fully addressing the concerns of the transplant community. The subcommittee was in agreement on adding to the background and expanding the topical sections. A member expressed hesitancy for the Committee to be too prescriptive in their guidance as to not place undue constraints on centers. In order to address considerations made that are outside the Committee's scope, the background section will be expanded to elaborate on the role and limitations of a white paper.

One member suggested adding a notes at the end of the white paper stating 'future data collection could potentially include some of these nonmedical psychosocial criteria' to see how it impacts

outcomes and providing examples of best practices. Members responded that providing best practices to transplant centers or patient education, which was a frequent comment, was out of the purview of the Ethics Committee. While the Committee agrees with these suggestions on an ethical basis, it is not within their scope to develop or provide these types of resources and believes there are other OPTN Committees that would be a better fit. Alternatively, it is possible for the Committee to cite the literature around these suggestions but does not feel comfortable making an outright recommendation. Examples of this include adding a reference to the KDIGO guidelines or the SIPAT tool without sharing a full endorsement.

### **Financial Considerations**

The consensus of the Subcommittee members appeared to be that financial considerations should be acknowledged as an important consideration; but also note that this white paper does not spend a lot of time addressing the matter because the paper's intent was to address the evaluation criteria that are subjectively applied. Since this topic had such a heavy emphasis in the public comment, it is essential to note why it was not addressed in its initial revision. A member suggested noting this reflection within the Preamble and cautioned that it would require a substantial effort to expand beyond that. Adding to the difficulty of substantively addressing this topic in a short period of time, a member noted how quickly someone's financial situation could change and informed the group that different regions and centers use alternative sources, such as crowdfunding, to bridge a financial gap.

A member suggested applying the principle of "openness" to the topic of financial considerations, and have the discussion cover it at a very general level, in a few sentences. The white paper could reference the medical ethical standard to not limit care for financial basis or other existing ethical literature.

### **Disability**

Due to the volume of comments regarding disability, the Subcommittee finds it essential to include some language in the white paper about it but is conflicted on how to proceed while waiting for feedback from HRSA on their intellectual disabilities white paper. The Subcommittee discussed repurposing some of the content from their intellectual disability white paper into the CAT Rewrite white paper since the group does not tend to cite the work of other Ethics Committees. However, this would potentially end the possibility of moving forward with the existing intellectual disabilities white paper that is pending HRSA approval.

UNOS staff informed the Committee that their white paper is still on hold until the Office of Civil Rights (OCR) releases their updated guidelines. The Chair suggested citing the ethical principles around intellectual disability with respect to the CAT Rewrite since it would not be appropriate for the Ethics Committee to exclude the topic given the quantity of public comments submitted.

The HRSA representative on the call informed the Subcommittee that HRSA had not received an update from OCR. The representative explained the concern of OCR that the OPTN's guidance would be incomplete by excluding the OCR protocol that is being developed. Furthermore, the Ethics Committee's guidance may not align, or even contradict, that of the OCR. With that being said, the HRSA representative will share the concerns of the Ethics Committee with the Chief of the Organ Transplant branch at HRSA.

A member inquired if it would be possible to relay the information shared from the HRSA representative in the CAT Rewrite white paper and cite general ethical principles of nondiscrimination. The representative countered that it would be preferred to include intellectual disability within the disclaimer of what would not be addressed within the paper and HRSA would develop the language for the Ethics Committee to include.

## **Pediatrics**

Several public comments addressed how pediatric candidates are impacted by the use of social supports, immigration status, and other criteria in listing decisions. The Subcommittee agreed that this topic fit within the scope of the paper and should be included. There was discussion around how to best address the topic and the HRSA representative raised a few challenges that would arise with housing the topic under the social support section. In order to best approach this, UNOS staff will reach out to coordinate a call with the Pediatrics Committee leadership.

### Next steps:

Ideally the completed document will be ready for approval during the April 15 full Ethics Committee meeting. To move forward with revisions, the criteria sections will be assigned back to each person who contributed to them initially. UNOS staff will highlight the relevant public comments for them to address and send back the revised section, with references, to the Subcommittee. The Chair will draft the intellectual disabilities component once an update and preferred language is received from HRSA. Once all of the sections have been revised, UNOS staff will consolidate the edits into the final draft.

- April 14 – *Proposed* – Final Committee review and vote to submit for OPTN Board approval
- May 3 – Final version of white paper submitted to UNOS Executive Leadership for review
- May 20 – Board Policy Group review
- June 14 – OPTN Board of Directors meeting

## Attendance

- **Subcommittee Members**
  - Andrew Flescher
  - Catherine Vascik
  - Keren Ladin
  - Roshan George
  - Tania Lyons
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Shannon Taitt
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Eric Messick
  - Joel Newman
  - Laura Schmitt
  - Ross Walton
  - Susan Tlusty