Introduction
The Considerations in Assessment for Transplant Candidacy (CAT) Rewrite Subcommittee met via Citrix GoToMeeting teleconference on 08/19/2020 to discuss the following agenda items:

1. Review Drafted Sections
The following is a summary of the Subcommittee’s discussions.

1. Review Drafted Sections
The Subcommittee read over and discussed each section of the Considerations in Assessment for Transplant Candidacy (CAT) Rewrite draft document.

Summary of discussion:

Preamble
The Subcommittee first reviewed the preamble. The Chair noted that they removed superfluous language but it still has the opportunity to be made even more concise. A member commented that they support the changes.

Life Expectancy
The Chair noted that one of the goals of the white paper is to identify the applicable ethical principles and recommended that the ethical analysis be more explicit.

A member commented that using the word “align” may be more appropriate than “match.” “Match” is used in different ways in transplant. The Chair and the members agreed to change the word to “align.”

The Subcommittee discussed the last sentence in this section “While age related conditions may be used to assess transplant candidacy, age itself should not be used to restrict transplantation.” A member commented that there may be questions about this statement during public comment. The Subcommittee previously decided that age should not be used as a proxy for life expectancy. A member commented that life expectancy is not directly correlated with age for every individual.

A member agreed with how the sentence is currently written and noted that age, on a population scale, is correlated with life expectancy except when considering other age related comorbidities and confounding factors. The Chair suggested addressing these concerns with a clause that defines the use of the word age as being “adjusted age” or “comorbidities adjusted age” or “life expectancy contingent on condition.” The Subcommittee decided to leave the sentence written as is.
Organ Failure Caused by Behaviors

The Subcommittee discussed replacing the phrase “high-risk.” Suggestions from the Subcommittee included “potentially hazardous,” “potentially harmful,” “risky behaviors” which is language used in literature, “medically harmful behaviors,” or “high risk behaviors.” A member commented that “high risk behaviors” could include sky diving, scuba diving, or motorcycle driving. Behaviors that contribute to the failure of an organ or allograft loss are high risk. A member commented that they need to decide how broad or specific when it comes to what is considered as a “harmful” behavior, whether its unhealthy eating or substance use or other behaviors. There need to be examples to allow the public to understand the intent of this section.

A member suggested using the phrase “unhealthy behaviors” or “unhealthy lifestyle behaviors.” “Potentially harmful behaviors” could be a broad enough descriptor to include behaviors that are harmful medically or psychologically. A member agreed with using the word “potentially” as not every activity that may be unhealthy will necessarily have harmful effects.

A member commented that a large group of transplant professionals associate term of “high risk” with specific criteria from the U.S. Public Health Service Guideline. The Subcommittee agreed to not use the term “high risk” and to look at these activities more broadly rather than specifically calling out behaviors such as substance use.

A member commented that this document is about assessment for candidacy. There is some level of moral judgement about individuals who may be perceived as causing themselves organ failure through their behaviors. The Chair commented that the analysis in this section suggests that the consideration for candidacy does not rely on the link between behaviors and organ failure and rather focuses on the potential for medical benefit. To some degree, the Subcommittee needs to define what is included in scope of these potentially harmful behaviors. The section offers an example to attempt to clarify that these behaviors are not necessarily personal choice.

The Chair asked the Subcommittee if there is agreement on the level of detail in this section. A member pointed out that this section of the paper is lengthier than other sections. Members agreed to further edit down this section and retain the last sentence in the second paragraph as it is all encapsulating. A member suggested looking at the rest of document and then returning to this section.

Adherence

The word “compliance” was removed because this word is no longer being used in the latest guidance document and because this document aims to be patient centered.

Members agreed to remove the sentence “Hence, it is difficult to apply broad measures of adherence when assessing patients for transplant.”

Members agreed that the language in this section is prescriptive. A member noted that they align more with the final sentence of this section in which adherence is not described as being absolute and can be improved upon with assistance. The members agreed that the tone of this section should be around exploring and addressing barriers.

A member had a question about assessing non-modifiable barriers such as refusal to get insurance. A member responded that this should be considered as unwillingness rather than barrier and noted that unwillingness can be modified.

Repeat Transplantation

There were no concerns or comments on this section.
**Incarceration Status**

A question was raised about who qualifies as being higher risk for recidivism. A member responded that characteristics that contribute to recidivism have been studied. These characteristics, among others, include drug history, negative peer association, employment, and housing. Not all hospitals assess recidivism factors. Examples of these factors will be added to this section parenthetically.

**Immigration Status**

A member suggested describing the factors that are intertwined with immigration status as “psychosocial and financial.” A member commented that another factor relating to immigration to consider is access to on-going care and, ultimately, graft survival for those that are only in the United States for a limited amount of time and may be returning to their home country post-transplant. A member noted that these types of concerns apply to everyone, especially those that may not have access to insurance.

The members chose to not include or reference the “5% rule” as it was never policy.

The Subcommittee is leaving this section as is for the full Committee to respond to. The Chair suggested creating a second document of potential questions that may come up during public comment.

**Social Support**

The Chair noted that there have been some small studies about transplanting people with limited social support. Candidates who are in emergency situations and are not evaluated for social support have similar outcomes as those who are determined to have social support. The Subcommittee discussed the utilitarian functions of social support such as transportation, wound care, and general assistance and how this affects adherence. This definition of social support should be disentangled with an individual’s value being based on their social relationships.

A member suggested including a statement that social support, which may be defined by being a member of a family unit, has not necessarily been predictive of outcomes. A member suggested mirroring what is included in the adherence section around assisting candidates to overcome barriers. This section will be revised and sent to the Subcommittee for review.

**Conclusion**

The Chair suggested including a conclusion statement that describes that non-medical criteria can stigmatize judgement, are inconsistent, and are not always transparent to candidates. There should be a clarifying statement that the criteria included in this white paper vary from medical criteria in this way. A member suggested combining this statement with the statement at the beginning of the document before the preamble and moving both statements to the conclusion section. The Chair agreed and will further define the use of the term “bias.”

**Next steps:**

Edits discussed will be added to the draft document and sent to the Subcommittee to review. This draft version will be share with the full Ethics Committee at an upcoming meeting.

**Upcoming Meeting**

- September 16, 2020
Attendance

- **Subcommittee Members**
  - Aaron Wightman
  - Catherine Vascik
  - Keren Ladin
  - Roshan George
  - Tania Lyons

- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi

- **UNOS Staff**
  - Eric Messick
  - Joel Newman
  - Sarah Konigsburg
  - Susan Tlusty