Introduction

The OPTN Ethics Committee met via Citrix GoToMeeting teleconference on 10/07/2020 to discuss the following agenda items:

1. Policy Oversight Committee (POC) Update
2. Review of General Considerations in Assessment for Transplant Candidacy
3. Upcoming OPTN Ethics Committee project: Ethical Analysis of Continuous Distribution
4. Wrap-up, Q and A, closing remarks, and adjourn

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

1. **Policy Oversight Committee (POC) Update**

The Vice Chair provided an update on the activities of the Policy Oversight Committee (POC).

**Summary of discussion:**

The Vice Chair reviewed the three strategic priorities of the POC:

- Continuous distribution
- Multi-organ allocation
- Efficient donor/recipient matching to increase allocation

Continuous distribution uses a statistical formula that combines clinical factors along with other factors such as proximity to donor location to allocate organs. Under continuous distribution, candidates would receive a composite allocation score that informs their priority without the use of hard geographic boundaries. The Ethics Committee was invited to participate in determining which factors should hold more priority and will provide ethical analysis as the project continues to develop.

Multi-organ allocation refers to the placement of two or more organs from one donor into a single recipient. Two members of the Committee are currently participating in this workgroup. The project’s goal is to clarify language in *Policy 5.10.C: Other Multi-Organ Combinations* in order to create clearer rules for organ procurement organizations (OPOs) to promote consistency and transparency and establish clear sharing thresholds both in regard to distance and other factors. This project is not changing the order of the match run or increasing priorities, establishing eligibility criteria, nor establishing a safety net.

Efficient matching refers to mechanisms for reducing the time from offer to match to increase the utilization of organs.

The Vice Chair reviewed the number of projects underway that fall under these priorities noting that continuous distribution related projects account for the majority of the overall effort of the three
priorities. There are a number of other projects that do not fall under these priorities that are still important to pursue.

The Vice Chair noted that the POC will determine the extent to which Ethics will be involved in a project developing best practices in organ recovery at their October 14th meeting.

The Vice Chair showed the timeline for the General Considerations in Assessment for Transplant Candidacy (CAT) Rewrite and the Ethical Analysis of Continuous Distribution projects. CAT Rewrite is intended to go to public comment in Spring 2021.

The Vice Chair invited the Committee to ask questions about the POC and the priorities presented. A member commented that as a Baldrige examiner, the information presented exhibited integration and a focus on alignment.

The Vice Chair asked if the Committee would like to collaborate on the Best Practices in Organ Recovery Process project. The ex officio member commented that they would like to learn more about the project and may be interested in participating as the topic aligns with their professional research endeavors. The Vice Chair offered to contact the chair of the Local Recovery Workgroup to learn more. UNOS staff noted that the POC has placed this project at a lower priority, and as a result, may initiate at a later date. The Vice Chair noted that Ethics would likely contribute to this project by offering analysis on issues relating to consent and human subject considerations.

A member asked why the Ethics Committee would not be involved in the project. They commented that members of the Ethics Committee should be involved in every project in order to consult on ethical issues. The Vice Chair agreed and will let the POC know that the Ethics Committee would like to be involved in this particular project.

A member commented that representatives from the Ethics Committee should also provide ethical analysis for the Kidney Accelerated Placement project. They raised a concern that there may be an ethical dilemma in which the hospital is receiving priority over the candidate when making offers if the hospital is filtering out specific organs that would otherwise be matched and offered to the candidate. The Ethics Committee leadership will add this suggestion to a list of projects for the Committee to pursue. The Chair asked if this particular project would fall under the efficient matching strategic priority. The member agreed with this categorization.

Next steps:
The Vice Chair will follow up with the Local Recovery Workgroup leadership to learn more about the Best Practices in Organ Recovery Process project and will share more detail with the Committee.

2. Review of General Considerations in Assessment for Transplant Candidacy

The Chair gave an overview of the CAT Rewrite project sharing that this is an update of an existing document from 2015 that is currently available on the OPTN website. The Committee split into two groups to review the CAT Rewrite draft and then reconvened to share and discuss comments, recommendations, and revisions.

Summary of discussion:

Preamble

Group 1:
The group discussed the use of the word “neutral” when describing ethical analysis. The Chair commented that the intent of the word “neutral” is to clarify that the analysis that does not advocate
for or against the use of the criteria for any reason other than ethical. A member commented that the Preamble does not directly tell the reader why they should read the paper. The Chair commented that the intended use and audience for Ethics white papers is included on the OPTN website. The members agreed to remove the word neutral and add a sentence that explicitly states the purpose of the document.

The members questioned whether the document provides an overview or guidance. A member commented that the previous version includes language before the preamble that encourages programs to create their own guidelines for transplant candidate consideration and suggested this could be included in the current version. The Chair commented that the Committee is limited in its ability to provide prescriptive guidance and can only reinforce existing policy related to the criteria addressed in the white paper.

**Group 2:**

Members chose to include language that non-medical factors should be assessed consistently regardless of a candidate’s medical urgency to the second paragraph of the Preamble.

**Life Expectancy**

**Group 1:**

A member suggested including disability, in addition to age, as a factor that contributes to a shortened life expectancy in this section. A member commented that disability needs to be defined to be clear to the reader that it is distinct from a potential disability that may be transplant candidate specific such as end stage kidney disease.

UNOS staff asked if disability considerations would also fall under the ethical principle of justice. The Chair agreed that it would be considered an issue of both justice and respecting autonomy.

**Group 2:**

The members discussed if it is ethically permissible to use age as a factor if in conjunction with other factors. The members chose to add language to clarify that age, in conjunction with other factors, is ethically permissible as it pertains to considerations of longevity and success of the graft.

**Potentially Injurious Behaviors**

**Group 1:**

Members discussed examples of when health related behaviors are out of a candidate’s control. A member suggested additional language acknowledging that although some health related factors may be out of the candidate’s control, there needs to be a way to assess their ability to overcome certain behaviors if they are able. The Chair asked the group if they agree that Potentially Injurious Behaviors should not be a sole criterion for assessing candidacy for transplant. A member commented that describing the candidate’s ability to control some factors affecting their health as “little to no” versus “little” denies some agency to the individual.

The group decided to add language to acknowledge that there may be limited evidence available for some factors that may be considered potentially injurious on the success and functioning of the graft. An example provided was marijuana use. Although this behavior may be considered potentially injurious, there may not be data available that supports that the behavior causes injury to a transplanted kidney.
A member questioned whether there should be more clarity around current behaviors or history of behaviors. The group chose to leave general and not specify if the behaviors occurred in the past or present.

A member raised a concern about patients who exhibit non-adherence to medical recommendations having equal priority of a candidate that does. The Chair commented that there may be psychological or other factors that impact this behavior and should not preclude a candidate from receiving an offer. A member questioned how utility factors into this section. A member agreed that both the patient with potentially injurious behaviors and those that do not need to both be considered for transplant candidacy. A member commented that transplant programs should look into ways to support candidates in addressing underlying problems rather than create barriers to accessing candidacy.

**Group 2:**

The members edited the last sentence in the first paragraph to replace the word “unsettled” with “inconclusive” and “critical” to “essential” the better reflect that the evidence available for this section is lacking.

The members discussed whether additional benign examples would strengthen this section. The members agreed that the one simple example provided is adequate.

The members questioned how to best call out behavioral factors that may be in the candidate’s control. The members anticipate more discussion about what potentially injurious behaviors are and are not in a candidate’s control during a public comment.

**Adherence**

**Group 1:**

No comments were made on this section.

**Group 2:**

No edits were suggested for this section.

**Repeat Transplantation**

**Group 1:**

A member raised a concern regarding the prioritization of living donors who are repeat transplant candidates and the reasoning for why these candidates would be assessed in any way other than how all candidates are assessed. A member commented that living donors are given priority through policy and it may not make sense to include this content in the white paper. Members also questioned the language related to the physiology of the patient. The group chose to highlight a section to discuss further as a full committee.

**Group 2:**

The Vice Chair noted that the inclusion of living donors in this section has been discussed previously.

A member asked the group to consider making this section more balanced by including the word “futility” since there can be a point in which retransplantation may be futile. The Vice Chair suggested using the word “disutility.” A member questioned whether readers would understand what “disutility” means.

The ex officio member suggested adding a public comment feedback question to ask readers if they agree with the Committee’s phrasing, which avoids the use of the word futility, and solicit suggestions for alternatives.
A member commented that decisions concerning a candidate’s access to retransplant may be affected by the transplant program’s desire for positive outcomes data as retransplantation may carry higher risks.

A member raised a concern about including living donors in this paragraph as the intention for calling this population out is confusing. A member asked if living donors receive priority for all transplants, in addition to their first transplant. UNOS staff confirmed that previous living donors receive priority for kidney transplants including kidney retransplants. Edits were made to the sentence concerning living donors to increase clarity.

The group made additional edits to ensure the sentiment that a graft failure is a failure of the graft and not a failure of the repeat transplant candidate’s physiology is clearly conveyed.

_Incarceration Status_

**Group 1:**

A member supported the inclusion of language regarding the transportation and coordination of incarcerated patients required to receive the transplant. A member questioned why the coordination of care is not emphasized in other sections. No revisions were suggested.

**Group 2:**

The group decided add “for incarceration” to describe the type of recidivism being discussed in this section.

_Inmigration Status_

**Group 1:**

The Chair commented that this section was expanded in response to an internal request for elaborating on the ethical analysis. A member commented that the prioritization of those that donate to the organ pool is based on considerations of solidarity versus distributive justice. They also questioned why Rawls is referenced. A member agreed that this Rawls reference could be added as a footnote to be more consistent with the rest of the paper.

The group decided to keep the first paragraph and further discuss the rest of the section with the full Committee. The language about donating to the organ pool was removed from the third paragraph as it is inconsistent with the argument presented.

**Group 2:**

The group discussed incorporating a quote from the cited Wightman article. Some members raised concern that the quote may be interpreted as requiring donation in order to access transplant. The group decided to rejoin the other group discuss as a full Committee.

_Social Support_

**Group 1:**

No revisions were suggested.

**Group 2:**

Time did not allow for discussion.

_Final Rule Analysis_

**Group 1:**

No revisions were suggested.
Group 2:
Time did not allow for discussion.

Summary/Conclusion

Group 1:
The group decided to change the language in the last sentence to read “...transplant evaluations should not exclusively rely on...”

Group 2:
Time did not allow for discussion.

Full Committee Discussion of Suggested Edits

The Committee reviewed both edited documents side by side and were asked to raise objections to any changes they did not agree with.

The ex officio member questioned the removal of the word “neutral” when describing the ethical analysis in the Preamble. The Chair shared that Group 1 decided that the word was redundant when describing ethical analysis and offered to use the word balanced. The members discussed whether to use a qualifier to describe the ethical analysis but chose to readdress later and move on in the interest of time.

The Committee discussed the edits in the Life Expectancy section by Group 2. Members expressed that the intention of the edit was to clarify that although age by itself cannot be used solely as a criterion for assessing candidacy, it is ethically permissible to consider age along with other factors. The Chair acknowledged that there may not be uniformity or consensus around the ethical considerations for use of age and chose to move on and readdress with leadership and the members after the meeting.

The Committee discussed the Repeat Transplantation section. A member raised a concern about including information about living donors receiving prioritization for repeat transplantation. They noted that including this information is unnecessary since all candidates should be assessed using the same factors. Members suggested ways to make this section more concise. Committee leadership will take the comments into considerations and propose another version to the Committee.

Next steps:

UNOS staff shared that the next steps will be to consolidate the edits into a single document for the Committee to review. A quorum of members will need to vote on whether they agree to submit the document as written to public comment in the Spring at the October 15th meeting. Members must be in attendance to vote. There is no proxy voting.

3. Upcoming OPTN Ethics Committee project: Ethical Analysis of Continuous Distribution

Summary of discussion:

Due to time limitations, this agenda item was deferred to the November Committee meeting.

4. Wrap-up, Q and A, closing remarks, and adjourn

Summary of discussion:

Due to time limitations, the Committee did not address this agenda item.
Upcoming Meeting

Attendance

- **Committee Members**
  - Aaron Wightman
  - Andrew Flescher
  - Catherine Vascik
  - Colleen Reed
  - David Bearl
  - Earnest Davis
  - Elisa Gordon
  - George Bayliss
  - Giuliano Testa
  - Glenn Cohen
  - Keren Ladin
  - Lynsey Biondi
  - Mahwish Ahmad
  - Richard Sharp
  - Roshan George
  - Sanjay Kulkarni
  - Tania Lyons

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

- **UNOS Staff**
  - Eric Messick
  - Ross Walton
  - Sarah Konigsburg
  - Susan Tlusty

- **Other Attendees**
  - Jeff Cooper