Introduction

The OPTN Ethics Committee met via Citrix GoToMeeting teleconference on 11/18/2020 to discuss the following agenda items:

1. Ethical Considerations of Continuous Distribution

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

1. Ethical Considerations of Continuous Distribution

The Committee was provided an overview of Continuous Distribution and discussed the ethical considerations of this new allocation framework.

Summary of discussion:

UNOS staff suggested that the members of the Ethics Committee provide guidance to the organ specific committees throughout the life of the project over the next five years while this project develops. This would allow for a more iterative and ongoing work of the Committee rather than a single whitepaper that is developed during the first year of the Continuous Distribution project.

The Chair acknowledged the members’ multiple hats or roles and asked that the members participate in the discussion from their perspective as a member of the Ethics Committee. The Chair acknowledged that this is a challenging topic to address.

The members were asked to consider the following questions:

- How does the continuous distribution framework balance ethical principles of allocation?
- Are ethical principles appropriately considered in the proposed continuous distribution of lungs allocation framework?
- Does this approach appropriately balance between equity and utility?
- Procedural issues: whose preferences should matter? Are stakeholders appropriately consulted?

UNOS staff provided the background of how Continuous Distribution developed. OPTN Final Rule requires development of policies for the equitable allocations of cadaveric organs among potential recipients. These organs must be shared as broadly as feasible to candidates with the greatest medical need and any limitations on broader sharing must be justified by a finite list of reasons including, among others, medical judgment and best use of donated organ. There have been a number of articles that discuss how geography can be adjusted to better accommodate these limitations.

There were legal actions in 2017 and 2018 that challenged the OPTN policies’ compliance with the Final Rule by questioning the use of Donor Service Areas (DSAs), regions, and concentric circles as allocation factors. It was determined that the DSAs, regions, and concentric circles were not designed to optimize
allocation or distribution. In July 2018, HRSA directed the OPTN to adopt liver allocation policy consistent with “broader sharing” as required by the Final Rule by December 2018. This precipitated the creation of the Ad Hoc Geography Committee which identified Continuous Distribution to be the best approach and the preferred allocation framework. In December 2018, the use of the Continuous Distribution framework was approved by the Board of Directors (BOD) 2018 for the allocation of all organs. In the summer of 2019, the organ specific committees developed proposals to replace DSA and regional distribution with more rationally chosen and consistently applied boundaries. Currently, these revised policies have been implemented for lung, heart, and liver. Other organs will be implementing revised policies in the near future.

Continuous Distribution intends to address the tension between Final Rule’s requirements of medical priority and broader sharing by seeking to eliminate hard boundaries created by policy that preclude some candidates from being prioritized in front of others. Factors are assigned points and the resulting scores prioritize waiting list candidates. This allows the consideration of multiple patient attributes all at once through a composite allocation score instead of within categories by sequence. The aim is to provide greater transparency of weight placed on each attribute, promote more equity in the prioritization of candidates, and better balance evidence-based clinical and operational decisions with values-based decisions concerning multiple goals of a national, organ allocation system.

UNOS staff shared that attributes chosen for lung are medical urgency, post-transplant survival, candidate biology, patient access, and placement efficiency. Each attribute falls under the principles of equity or utility.

A member raised a concern about the weight one-year survival holds. One-year survival can be as high as 98% for some programs and because of this, the member suggested looking at longer term outcomes when assessing post-transplant survival.

The Chair asked for background on how the attributes were chosen and prioritized. UNOS staff commented that this first iteration of Continuous Distributions uses the same attributes as the current allocation policy. Attributes will be added or modified in future iterations. The chosen attributes are mapped to goals and clauses from the Final Rule. These attributes were also examined to determine how any hard cliffs such as geography or calculated panel reactive antibodies (CPRA), which calculates sensitization, could be smoothed to promote equity.

In agreement with the other member, a member asked if one-year survival is the appropriate outcome for the ethical principle of utility. UNOS staff responded that one-year data is what is currently collected in the existing system which allows access to analysis. The Lung Committee is interested in using two or three-year survival and is working with the Scientific Registry of Transplant Recipients (SRTR) to create modeling to support this. An SRTR representative commented that using one-year survival is a consequence of the lung allocation score (LAS).

A member commented that this work is absolutely terrific and questioned what type of modeling has been completed to assess the outcomes of adjusting the weights of the attributes. UNOS staff responded that the Lung Committee is currently entering that phase of the project and is putting together a modeling request to SRTR. There is also an interactive Tableau tool that shows the impact on a sample of match runs.

A member asked how this allocation model will be shared with candidates and raised a concern about it being difficult to understand. UNOS staff responded that this concern has been discussed. The Patient Affairs Committee is providing input. Describing how the point system works seems to be easier than
describing how the allocation model was developed. The SRTR representative commented that at the end of the day, the candidates are still receiving a score.

The Chair asked the Committee to consider if the attributes included in the framework are appropriate and if there are additional principles, beyond equity and utility that should be discussed. From a procedural justice perspective, the Chair asked the Committee to respond to who’s priorities should matter and whether stakeholders have been appropriately consulted.

UNOS staff shared that the prioritization exercise used analytic hierarch process (AHP). The goal was to reach out to out to the entire transplant community through targeted emails, presenting at the regional meetings as well as to OPTN Committees. Demographic information was collected on the participants including their relationship to transplant. When reviewing the responses, these various stakeholder groups were considered.

The Chair raised a concern that the prioritization and preferences may be overly reflective of specialized transplant professionals and under representative of patients. UNOS staff commented that this is an important consideration and invited feedback on how to have a broader reach to patient and patient groups when solicited input going forward.

The Vice Chair commented that they perceive two barriers for constituent buy-in. One being the dispensing of the previous allocation model and the second being how to weigh the criteria.

A member asked for the scope of the project. The Chair commented that one of the purposes of the meeting is to further define this. The goals of the project will be to provide an ethical justification for moving to Continuous Distribution, to justify and consider the attributes, and consider additional ethical principles beyond equity and utility that guide Continuous Distribution.

A member raised a concern about only evaluating attributes as equity or utility as these attributes may have many sub-principles that hold value but may also be in tension with one another.

A member raised concern about patient access to the prioritization exercise in order to be inclusive of all patients and not just those in positions of privilege. Another member raised a concern that that AHP exercise is generally difficult to understand and commented that there is no organization that represents patients with chronic obstructive pulmonary disease (COPD) that could provide feedback during public comment as other disease advocacy organizations do.

UNOS staff suggested that the Chairs of the other organ committees could join the Ethics Committee to provide Continuous Distribution updates and receive feedback. Rather than a whitepaper, there could be a dialog between the other committees and Ethics Committee members.

The Chair suggested planning the logistics on how to meet with other committees at the next Ethics leadership meeting. Meanwhile, the Committee will continue to discuss the ethical considerations of shifting to Continuous Distribution. UNOS staff suggested building a steering committee of multidisciplinary experts. The Chair suggested adding Ethics Committee members to workgroups of the other committees.

Next steps:

The Committee will begin working with the other committees to provide real time feedback as they develop their Continuous Distribution projects. The UNOS support team will begin drafting a project form for the Ethical Considerations of Continuous Distribution whitepaper.
Upcoming Meeting

- December 17, 2020
Attendance

- **Committee Members**
  - Aaron Wightman
  - Colleen Reed
  - David Bearl
  - Earnest Davis
  - Elisa Gordon
  - Andrew Flescher
  - Glenn Cohen
  - Keren Ladin
  - Sanjay Kulkarni
  - Roshan George
  - Tania Lyons
  - Giuliano Testa

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

- **SRTR Representative**
  - Bryn Thompson
  - Maryam Valapour

- **UNOS Staff**
  - Eric Messick
  - James Alcorn
  - Ross Walton
  - Sarah Konigsburg