

OPTN Ethics Committee**Meeting Summary****February 18, 2021****Conference Call****Keren Ladin, PhD, Chair****Andrew Flescher, PhD, Vice Chair****Introduction**

The Ethics Committee met via Citrix GoTo 884-431-893 teleconference on 02/18/2021 to discuss the following agenda items:

1. OPO Committee Presentation, *Clarify Multi-Organ Allocation Policy*
2. Policy Oversight Committee
3. Public Comment Update, *Revise General Considerations in Assessment for Transplant Candidacy*
4. Discuss *Ethical Analysis of Continuous Distribution in Organ Allocation*
5. Future Meetings

The following is a summary of the Ethics Committee's discussions.

1. OPTN Organ Procurement Organization:

The OPO Vice Chair presented the proposal *Clarify Multi-Organ Allocation Policy* which is currently out for public comment. The purpose of this proposal is to provide OPOs with clearer direction when offering certain multi-organ combinations.

Summary of Discussion:

This conversation started around the importance of multi-organ allocation using data driven decision making as soon as possible. At this moment, there is very little data to use for analysis, but once this policy has been implemented and there is a clearer set of expectations for OPOs, the next phase of this project will be increasingly data based. Ultimately, the Committee members reiterated the importance of continuing to review the data as it becomes available and advocated for continuous distribution policies to always be data driven.

A member inquired about eligibility criteria and questioned where the multi-organ transplant recipient should lie in the spectrum within the different classes to gain a better understanding of how many multi-organ allocations have occurred versus how many were critical. The OPO Vice Chair responded that this will be addressed in phase three of the project. At this time, the organ specific committees feel that due to the small data sample it would be more advantageous to wait for additional data based on this proposed policy.

In addition to using data to analyze who this policy change helps, a member noted that it is essential to gain a better understanding of who the policy does not help. Specifically, in regards to the breadth of need for kidneys, there was a concern that every multi-organ patient may take an organ away from a patient in need of a kidney only. When it comes to medical need and prioritization of one candidate over another, the consensus of the members was that this is an area that needs to be continually analyzed.

A member representing an OPO stated that this policy was a much needed clarification, stating 'the clearer the policy, the better.' However, another member was concerned that this policy would take

kidneys away from OPOs in regions with shorter waiting times to help OPOs in regions with longer waiting times. The members felt that exporting kidneys from one region to another would cause waiting times to go up overall and place a drain on the kidney waiting list.

The OPO Vice Chair responded that this policy will actually help kidney allocation because it will provide clearer guidance on who to allocate to and when, which the current policy falls short of. The OPO Vice Chair reiterated that prior to this clarification, OPOs had discretion on who the kidney went to but now it provides clarity on who it must allocate to. Furthermore, it is important to remember that DSAs are going away and this policy will help transition to continuous distribution. When eligibility requirements are implemented in phase three, it is possible that a kidney from a potential heart/kidney match would go to a no miss match kidney candidate if there is no multi-organ status 1-3 at the program. The OPO Vice Chair reiterated that decisions like this will be made once more data is available to justify selecting eligibility criteria.

A member supported the idea that this policy did not take from one region to give to another, instead the member viewed all organs as belonging to one common pool. By looking at the greater good, the organ should go to the patient who needs it the most and the mortality rate is likely higher for a liver-kidney recipient than a kidney only recipient.

A member inquired what the next steps of this project would be. The OPO Vice Chair updated that an Ad Hoc Committee is being formed to address eligibility and safety net criteria for phase three. Phase one was the white paper, phase two is the current clarification of *Policy 5.10.C: Other Multi-Organ Combinations*, and phase three will provide additional eligibility criteria.

A member asked what happens for patients who are a status 5 heart recipient. The OPO Vice Chair responded that the Committee discussed this and agreed it is up to the OPO's discretion to determine how they want to allocate to heart statuses 4 and 5, but affirmed that there are very few on those lists but those patients can still receive the multi-organ allocation.

A member requested the current data on multi-organ transplants, the OPO Vice Chair shared numbers from 2019 which were comprised of 219 heart/kidney, 45 heart/liver, 13 lung/kidney, and 12 lung/liver. A member was concerned that these numbers were likely to continue to increase, and while true, the OPO Vice Chair reiterated that it was still imperative to find a match for both organs which could be a lot harder than just a single kidney transplant.

2. Policy Oversight Committee

The Vice Chair provided a quick overview of the combination of goal one and goal three within the Executive Committee's Strategic Plan which is out for public comment. The Vice Chair also shared the inclusion of a HRSA representative during the latest POC Meeting who detailed their new three phases of an analysis for authority on new projects. The Vice Chair interpreted two core benefits from this being a better use of Committee time on projects and an improved relationship with HRSA.

3. Public Comment Update

UNOS staff provided a brief overview of the CAT Rewrite feedback from the first five regional meetings and Committees who have, and will, receive presentations.

Data Summary:

Thus far, only two opposition sentiments have been submitted creating an overall support for the proposal averaging a 3.9 score out of the 53 sentiments supported. The data were categorized by member type and region to gain a deeper understanding of who has shared sentiment for the white paper. To date, only two comments have been made on the OPTN website. The general themes and

specific populations of concern from the comments were shared for post-public comment consideration.

Summary of discussion:

The members who have already presented in their regional meetings shared that they all had conversations of support. A few suggestions from regional meetings included best practices for information sharing between transplant centers, gaining a better understanding of the diversity within a stable living situation, and concern that a formal recommendation on immigration status could place restraints on providing care. In line with past public comment periods, there is an anticipation that more comments will come in as the deadline comes to a close especially from advocacy organizations and private individuals.

Overall, while there were comments in regards to things that could be added, there was no major issue with any of the substance that is currently in the white paper. The Chair affirmed that the feedback the Committee has received has been exceptional and there is an appetite to see more in the paper from the community. UNOS Staff went over the next steps for the CAT Rewrite White Paper leading up to the OPTN Board of Directors meeting on June 14th.

4. Discuss Ethical Analysis of Continuous Distribution in Organ Allocation

The Vice Chair introduced the topic of continuous distribution and presented utility, justice, equity, "local priority," autonomy, transparency, and pragmatism as the guiding principles for the framework.

Summary of Discussion:

To start the conversation, it was asked that a few continuous distribution-related terms be defined to give the Committee a better understanding of the specifics of the conversation. First, the Vice Chair defined continuous distribution as a shift in model from regional boundaries to a more open transplantation model without the limitations of regions. Next, a question arose about what is meant by success and what a successful outcome looks like. A member echoed the importance of this, because for example, there is current consideration of whether the one-year post-transplant survival metric should be changed to a three-year or five-year window. Additionally, there is growing attention to patient perspective of success. The Vice Chair responded that the inclusion of success in the white paper and defining it are all fair game as topics for inclusion moving forward with this project. Lastly, efficiency was defined as limiting unutilized organs and/or redundancy. The Chair noted that defining these terms was essential for the Committee as their definitions may be different from the way the Committee is used to thinking about them in ethics literature or clinically. A member delved into the conversation of utility and the Vice Chair noted that there is a tension between the needs of the individual versus the needs of the group. Later in the conversation, a member mentioned communitarian concerns and how we move from one version of what we consider to be community to another version. The Chair responded that there is good reason to push back on this argument and question the normative relevance of discussing a community as a nation as opposed to a locality. Furthermore, the Chair affirmed the relevance for communitarian arguments within the normative and pragmatic concerns of the shift to continuous distribution.

A member expressed concern about the tension between the ethical analysis and theories at play versus the policy implementation. These concerns included decreased autonomy from less choice in organs and increased costs that could further reduce access to transplant. Ultimately, the primary concern of members was that the pragmatic concerns would have the focus necessary to ensure the credibility of the paper and not minimize the pragmatic tension. Committee leadership agreed that this tension was very relevant and responded that while this paper would address pragmatic concerns generally, the next

continuous distribution paper would focus primarily on the pragmatic issues with implementation and how to proceed ethically. While the Committee members work will be divided among small groups, the Chair ensured that no section would receive any less attention or discussion than any other section.

Next Steps:

Ethics Leadership requested UNOS staff to prepare a brief presentation and overview of continuous distribution. Leadership will follow up with Committee members on section assignments for the paper. They encouraged Committee members to reach out if there were any topical or ethical concerns they had to ensure it was included in future discussions.

5. Future Meetings

UNOS presented dates for the next scheduled Committee meetings.

Upcoming Meetings

- March 11, 2021 – Virtual In Person
- April 15, 2021
- May 20, 2021
- June 17, 2021

Attendance

- **Ethics Committee Members**

- Keren Ladin
- Andrew Flescher
- Aaron Wightman
- Amy Friedman
- Catherine Vascik
- Colleen Reed
- David Bearl
- Earnest Davis
- Elisa Gordon
- Gorge Bayliss
- Giuliano Testa
- Glenn Cohen
- Lynsey Biondi
- Mahwish Ahmad
- Michael Davis
- Sanjay Kulkarni
- Tania Lyons

- **HRSA Representatives**

- Jim Bowman
- Marilyn Levi

- **SRTTR Staff**

- Bryn Thompson
- Maryam Valapour
- Sommer Gentry

- **UNOS Staff**

- Eric Messick
- James Alcorn
- Laura Schmitt
- Robert Hunter
- Ross Walton
- Susan Tlusty

- **Other Attendees**

- Kurt Shutterly
- Ehab Saad