

OPTN Ethics Committee

Meeting Summary

October 21, 2022

Richmond, VA

Keren Ladin, PhD, Chair

Andrew Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met in Richmond, Virginia on 10/21/2022 to discuss the following agenda items:

1. Vice Chair Overview and Process
2. Transparency in Program Selection White Paper
3. Multiple Listing Data Request Presentation and White Paper Discussion
4. Tour: Organ Center and Donor Memorial
5. Social Determinants of Health (SDoH) Presentation
6. Normothermic Regional Perfusion (NRP) Discussion
7. Closing Remarks

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

1. Vice Chair Overview and Process

Committee support staff provided an overview of the vice chair application and selection process, in addition to sharing the responsibilities and preferred qualities for the position.

Summary of discussion:

The Chair and Vice-Chair expressed their preferred qualities along with the ones already listed by Committee support staff. Members discussed whether any additional qualities had been missed or not yet expressed.

Next steps:

Members will receive a call for nominations sent via email. Members who are interested in the vice chair role are asked to submit a personal statement and updated curriculum vitae.

2. Transparency in Program Selection White Paper

The Committee reviewed the public comment feedback and discussed the modifications the workgroup made.

Summary of discussion:

The Committee discussed the common themes of public comment and focused their discussion on the new sections that were added to the white paper. First, the Committee discussed the 'Patient Access and Socioeconomic Concerns' subsection that was added to the complicating questions section. The Committee opted to retitle the section to 'Access and Transparency' as they felt it highlighted the crux of the issues raised during public comment.

Next, the Committee discussed the new example of pediatric split liver living donor transplants that was included following public comment feedback. The Committee agreed that the example was sufficient to

address the concerns expressed and strengthened the white paper by considering pediatric populations. The Chair recommended earlier inclusion of the pediatric community for future white papers and Committee projects to address any potential concerns prior to public comment.

The Committee discussed potential next steps for the white paper, which are currently outside of the scope of the Ethics Committee but did arise during public comment. Additional comments were focused on operationalization transparency, as opposed to conceptualizing transparency which was the goal of the white paper. These themes are addressed in the briefing paper and will likely be discussed at the Board meeting and in future discussions about transparency in transplant.

There was a motion to call a vote and a second. The Committee was asked 'Do you support sending the white paper to the OPTN Board of Directors?' Members voiced unanimous support for sending the white paper to the Board for approval and implementation.

Next steps:

The Chair will present the white paper to the Board of Directors during their meeting on December 5, 2022 for approval.

3. Multiple Listing Data Request Presentation and White Paper Discussion

Katrina Gauntt, from *UNOS Research*, presented the key takeaways of the two data requests the subcommittee received and the Committee discussed the progress of the white paper.

Data summary:

The full data reports can be found on the Ethics Committee SharePoint.

- December 31, 2021- 6,710 (6.4% of all candidates waiting) multiple listed candidates
 - 6,525 kidney, 176 liver, 30 heart, 7 lung
- Demographics:
 - Kidney: a slightly larger percent who were black, had private insurance, advanced education, and were blood type O
 - Liver: a slightly larger percent who were 50-64 years old, white, had private insurance, advanced education, blood type A and lived in a zip code with a lower poverty ratio
 - Thoracic: a slightly larger percent who were 18-34 or 50-64 years old, male, white, had private insurance, advanced education, blood type O, lived in a zip code with a lower poverty ratio and higher median household income.
- Geography:
 - A majority of liver and kidney multiple listed candidates had a secondary listing in a different DSA than the primary listing.
 - Over $\frac{3}{4}$ of multiple listed kidney candidates had secondary listings within the 250nm of their primary hospital.
 - Just over $\frac{1}{2}$ of multiple listed liver candidates had secondary listings within the 150nm of their primary hospital.
- Transplant for single vs. multiple listed candidates:
 - Multiple listed kidney candidates had a statistically significantly higher transplant rate.
 - Multiple listed liver candidates had a higher transplant rate but was not statistically significant.
 - Both kidney and liver multiple listed candidates had significantly longer median times to transplant than single listed candidates.

- There was a slightly higher proportion of candidates with CPRA 98-100% multiple listed than single listed

Summary of discussion:

Data Request

The Vice Chair inquired about the decision to exclude the patients that were same day listed at two transplant hospitals. Staff clarified that they had been excluded from the data set because it was likely a systemic approach for those centers and not a choice by the candidates themselves. The Chair noted how many multiple listings occurred within the primary acuity circles and wondered how much of an advantage that offers patients by only minimally increasing the donor pool. A member wondered if candidates are directed to pursue multiple listing if they are medically complex or if they are exploring options at hospitals that have different profiles and might be more aggressive in the offers they accept.

A member asked how it is possible that multiple listed candidates are being transplanted at higher rates but are also experiencing longer waiting times. A member posited that it might be due to medically complex patients or regional differences that could impact wait times. A staff member noted that on average it was taking 6-8 months for candidates to decide to get multiple listed and that highly sensitized patients might also be factoring into that. A member stated that they were surprised that the data did not show as much of a disparity in socio-economic status between single and multiple listed candidates, outside of the trends for private insurance and higher education. The Vice Chair suggested doing a comparison between two similar candidates in the same region where one multiple lists and one single lists to provide insight into the impact of multiple listing in an isolated case.

The presenter confirmed that the data presented is different from results shown in prior studies and stated that it is likely due to the newer acuity circle allocation system. Additionally, most existing literature focuses on candidates that were multiple listed at distances further than 250 nautical miles (nm).

White Paper Discussion

The Chair focused the discussion on the White Paper by asking some of the ethical questions that need to be answered: Is multiple listing an advantageous practice in terms of getting people transplanted for frequently and if so, then is it only available to some? Is there evidence that shows systemic or structural disadvantage? The data shows that there is some advantage from multiple listing and there are trends that the practices is available or utilized more by certain groups, though it is not as significant as had been suspected. The Chair advised the Committee to decide how ethically concerning these trends are and if there are ways to make multiple listing more universally available. Another member noted that multiple listing might be being used to account for regional disparities, noting that their clinic has patients who have spent five or more years on a waitlist at a transplant center one state over and immediately begin receiving offers when they multiple list. However, this introduces a challenge of disadvantages local patients.

Another member brought up the issue of insurance, noting that some insurance companies will only cover one evaluation per year which limits many candidates' ability to seek out multiple listing. Alternatively, some insurance companies will only allow candidates to list at a transplant center that is identified as Center of Excellent which further limits a candidate's autonomy. The Vice Chair noted that listing all the different possible aspects of multiple listing that patients and providers should be aware of could add tremendous value to the paper. The Committee members agreed that overall there does seem to be an advantage to multiple listed patients.

Another member noted that in their experience, the center generally directs which candidates pursue multiple list, that they strongly recommend it for some medically urgent candidates but do not recommend it for most. The Chair noted that even though current policy requires transplant centers to inform their patients of the option to multiple list, there is a lot of variation in how this occurs. The Chair continued to say that the ethical implications of multiple listing are different if it is advancing the interests of candidates that have the most challenging time because of medical complexity, versus benefiting a group of patients that is otherwise privileged.

The Chair noted that an important ethical aspect of this practice is to decide if the policies in place only provide formal equity of opportunity, or if they provide fairness of opportunity, meaning that everyone can equally access it. If there is not fairness of opportunity, can that be achieved by making any changes and whose responsibility is that if the policy remains in place? Does making multiple listing equally available to everyone make it ethically just to continue? A member responded that geographic disparities are the first thing that come to mind and that inherently the system is not equal to everyone. The member continued by asking if the policy can take steps to address disparities but not eliminate them, is it still ethically just?

The Chair then asked the Committee to consider the issue of patient autonomy versus transplant center autonomy. A member asked if it was possible to develop criteria that states when it is ethically acceptable to multiple list a candidate and when it is not. A member suggested that transplant centers should be more responsible for adhering to some criteria about who is appropriate for multiple listing. The Vice Chair noted that as a body that does not make policy, the role of the Committee is to make an ethics-based argument and influence others to be better stewards of their charges. The Chair restated that as offering more active gatekeeping of a valuable resource however, it would be important to be wary of trying to curb candidates' autonomy. Another member stated that they felt that transplant centers should not be gatekeepers.

4. Tour: Organ Center and Donor Memorial

The Committee took a tour of the Organ Center, which assists OPTN members with any questions or issues related to organ allocation and candidate registrations, among many other essential tasks to ensure the transplant system runs smoothly. The Committee also received a tour of the Donor Memorial and had the opportunity to reflect on the impact of their life-saving work.

5. Social Determinants of Health (SDoH) Presentation

Tatenda Mupfudze, from *UNOS Research*, shared the work of the SDoH project, focusing primarily on the new findings and soliciting the Committee's feedback for future projects. The SDoH project was broken down into two studies, a population study and a waitlist outcomes study. Both studies focused on kidney recipients.

Summary of discussion:

The Committee discussed whether efforts are being made to understand how geographic areas impact candidate's ability to be wait listed, as the data shows a high waitlist mortality. Members recommended that future research could look at 5-year outcomes, as the current data reflects early outcomes of patients within the first year. One member suggested that the research department could take a closer look at a potential relationship between lower socioeconomic status and 1 year mortality after being removed from the waitlist. This member also mused, the event a patient is removed from the waitlist due to illness, to what level is their center then held responsible for mortality rates at 1, or even 2 years post removal, and how might that be related to low socioeconomic status?

6. Normothermic Regional Perfusion (NRP) Discussion

The Committee discussed the progress of the NRP Workgroup and reviewed the draft outline. The Committee provided feedback on various topics, including the proposed timeline.

Summary of discussion:

Members discussed at length the different interpretations of irreversible as this is something they feel the white paper will need to address. The Committee reassessed the ethical principles of nonmaleficence, respect for persons, and utility. They agreed that utility should not be achieved at the expense of nonmaleficence, and that the dead donor rule (DDR) is an ethical/moral principle underpinning the legal and ethical framework of organ transplantation. Members examined the recommendations made by the Workgroup, and discussed the areas that still need to be evaluated, such as uncontrolled NRP and pediatrics. The Vice Chair relayed feedback from the Policy Oversight Committee to the Committee, noting that the POC wants to know if the Committee will need more time to evaluate and vote upon the white paper before sending it out for public comment. The general consensus was yes, that the Committee, and therefore the Workgroup, would take more time on the white paper and it would not go out for Winter 2023 public comment.

Next steps:

The Workgroup will continue to meet and each subgroup will work on their section. The Committee will be updated periodically on the progress.

Upcoming Meetings

- November 17, 2022
- December 15, 2022
- January 19, 2023
- February 16, 2023
- March 16, 2023
- March 31, 2023
- April 20, 2023
- May 18, 2023
- June 15, 2023

Attendance

- **Committee Members**
 - Andrew Flescher
 - Bob Truog
 - Carrie Thiessen
 - David Bearl
 - Ehab Saad
 - Erica Stohs
 - George Bayliss
 - Glenn Cohen
 - Jen Dillon
 - Keren Ladin
 - Laurel Avery
 - Megan Urbanski
 - Sanjay Kulkarni
 - Sena Wilson-Sheehan
- **HRSA Representatives**
 - Edna Dumas
 - Jim Bowman
- **SRTR Representatives**
 - Katie Siegert
- **UNOS Staff**
 - Alex Garza
 - Catherine Parton
 - Cole Fox
 - Delaney Nilles
 - Houlder Hudgins
 - James Alcorn
 - Kim Uccellini
 - Katrina Gauntt
 - Krissy Laurie
 - Kristina Hogan
 - Laura Schmitt
 - Leonyce Moses
 - Robert Hunter
 - Roger Brown
 - Susie Sprinson
 - Stryker-Ann Vosteen
 - Tatenda Mupfudze
 - Terry Cullen
- **Other Attendees**
 - Earnest Davis