

# **Meeting Summary**

OPTN Ethics Committee Meeting Summary March 17, 2022 Chicago, IL

# Keren Ladin, PhD, Chair Andrew Flescher, PhD, Vice Chair

#### Introduction

The Ethics Committee met in Chicago, Illinois on 03/17/2022 to discuss the following agenda items:

- 1. Project Discussion and Timelines
- 2. Statement of Concern on Normothermic Regional Perfusion Presentation American College of Physicians
- Consensus Statement on Normothermic Regional Perfusion Presentation European Society for Organ Transplant
- 4. Farewell to Departing Members
- 5. Breakout Groups
- 6. Public Comment Presentation: OPTN Living Donor Committee, *Modify Living Donor Exclusion Criteria*
- 7. Public Comment Presentation: OPTN Ad Hoc Multi-Organ Transplantation Committee, *Establish Simultaneous Heart-Kidney and Lung-Kidney Eligibility Criteria and Safety Net*
- 8. Breakout Group Report Outs
- 9. Closing Remarks

The Chair provided a brief overview of the OPTN Policy Development Process and highlighted each of the Committee's projects. The Ethics Committee recently completed an internal memo on Transparency in Program Selection that was distributed to the OPTN Data Advisory (DAC), Minority Affairs (MAC), and Patient Affairs (PAC) Committees. The Committee is currently working on two projects approved by the OPTN Policy Oversight Committee (POC), which are the Ethical Evaluation of Multiple Listings and Transparency in Program Selection white paper. The Committee also wants to work on project concerning the automatic exclusion of inmates as living donors. Unless explicitly identified otherwise, all Committee projects are white papers.

## Summary of discussion:

A member inquired about the National Academies of Science, Engineering, and Medicine's (NASEM) recent report *Realizing the Promise of Equity in the Organ Transplantation System.* <sup>1</sup> The Chair responded that a lot of the work that the Ethics Committee is already doing aligns with the recommendations made in that report and asked for feedback on what types of projects members thought the Committee should prioritize. A member noted that one question that came up from the report was the potential to change the way time on dialysis is used in kidney allocation. Members discussed the process for topics arising in the community and then becoming projects for the Ethics Committee, which can sometimes

<sup>&</sup>lt;sup>1</sup> National Academies of Sciences, Engineering, and Medicine, *Realizing the Promise of Equity in the Organ Transplantation System,* February 2022, accessed April 3, 2022, https://doi.org/10.17226/26364.

hinder the ability for the Committee to get out ahead of the issue. The Vice Chair encouraged members always to submit project ideas for the Committee to pursue.

Members brought up challenges with not having an OPTN mandate for COVID-19 vaccination or addressing this issue from the Ethics Committee. Staff responded that the OPTN does not dictate program selection practices and thus has not made any vaccination mandate. The OPTN has released a summary of evidence document that recommends following guidance from the Center for Disease Control (CDC), which is to be vaccinated, but it has not required it in policy. The Chair elaborated on the ability to address this topic from an ethical perspective, on whether or not it would be ethical to implement a vaccine mandate. A member noted that a lot of the ethical feedback has been focused on the injustice to patients that occurs when the vaccine requirements are not consistent across transplant centers. A HRSA representative added that vaccine mandates are at a state-level decision, which has led to varied national requirements. A member noted that the Committee has discussed a potential vaccination requirement project pre-pandemic and that project was not approved at the time.

UNOS staff clarified that in general, the Ethics Committee has the authority to review any issue that the OPTN has the ability to develop policy on, so there could be some potential for this project under the authority of listing practices. A member noted that this could be done through a similar practice and manner as the *Revise General Considerations in Assessment for Transplant Candidacy* white paper.<sup>3</sup> The Chair noted that it would be important to identify if this project is different from other projects that the Ethics Committee has worked on and determine where those lines of authority are. A member added that a deeper dive into listing practices ties into the Committee's current projects *Transparency in Program Selection* and *Ethical Evaluation of Multiple Listings*.

# 1. Statement of Concern on Normothermic Regional Perfusion Presentation – American College of Physicians

Dr. Matthew DeCamp presented *Ethics, Determination of Death, and Organ Transplantation in*Normothermic Regional Perfusion (NRP) with Controlled Donation after Circulatory Determination of Death (cDCD): American College of Physicians (ACP) Statement of Concern.<sup>4</sup>

#### Summary of discussion:

A member questioned if it was possible for electrical brain activity to occur during or after the NRP protocol, to which the presenter responded that is presently unknown. A member inquired on the attitudes of the community on NRP, specifically within patients and families. At this time, no empirical work has been done to capture what information is dispersed to families and when. A member shared their center's experience with NRP and the extensive informed consent process that is undertaken for patients and families to feel fully comfortable with the procedure. The emphasis of consent coincided

<sup>&</sup>lt;sup>2</sup> OPTN Ad Hoc Disease Transmission Advisory Committee, Summary of evidence report details experience with COVID-19, February 2021, accessed April 3, 2022. https://optn.transplant.hrsa.gov/news/summary-of-evidence-report-details-experience-with-covid-19/

<sup>&</sup>lt;sup>3</sup> OPTN Ethics Committee, Revise General Considerations in Assessment for Transplant Candidacy, July 2021, accessed April 3, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/revise-general-considerations-in-assessment-for-transplant-candidacy/.

<sup>&</sup>lt;sup>4</sup> American College of Physicians, Ethics, Determination of Death, and Organ Transplantation in Normothermic Regional Peerfusion (NRP) with Controlled Donation after Circulatory Determination of Death (cDCD): American College of Physicians Statement of Concern, April 2021, accessed April 3, 2022, https://www.acponline.org/acp\_policy/policies/ethics\_determination\_of\_death\_and\_organ\_transplantation\_in\_n rp\_2021.pdf.

with ethical principles of patient autonomy and transparency. The presenter noted that the presence of consent does not determine the rightness or wrongness of any practice.

A member inquired if the act of causing the blockage is what made the procedure worthy of an ethical analysis, noting the potential for a naturally occurring, biological blockage to occur which may cause the same result as the NRP protocol. The presenter responded that it is causing the blockage that is inherently wrong and disagreed about the potential for the clinical example used.

A member noted the statement 'merely declaring someone dead does not make them dead' and inquired what the alternative declaration or definition of death may be. The presenter responded that death would be determined biologically. A member noted biological death and clinical death are not the same, wherein the former would not allow for organ transplant to occur. A member commented on the issue of killing someone versus letting him or her die. A member noted the difference between the withdrawal of care versus the act of expediting death. A member explained that the distinction between withdrawal and expediting is a key ethical distinction. A member emphasized that they may need to reopen the discussion on how death is defined in order to adequately address NRP.

A member noted the overwhelming utility benefit of improved organ quality through NRP. A member added that an additional utility concern would be of public perception to a procedure that may be unclear or ethically questionable. A member detailed their program's experience with NRP and the steps they undertook to familiarize all of the internal teams with the process and protocol. The member noted that they did not want to do anything 'in the dark' that could give even the appearance or implication of wrongdoing. A member noted the importance of public trust, but added that we may be underestimating the support the community has with organ transplantation.

A member inquired about the impact on justice, which the presenter expressed concern that NRP may disproportionately advantage and disadvantage various groups. For example, opioid victims may be disproportionately used as NRP donors, thus placing the risk and burden of this practice placed upon one community. However, a distinction was not made as to why or how this group may be overrepresented in NRP, specifically, and not with regard to organ transplant as a whole.

# 2. Consensus Statement on Normothermic Regional Perfusion (NRP) Presentation – European Society for Organ Transplantation

Dr. Amelia Hessheimer, Dr. Chris Watson, and Dr. Arne Neyrinck presented their experiences with NRP and the ethical considerations undertaken as part of *Consensus statement on normothermic regional* perfusion in donation after circulatory death: Report from the European Society for Organ Transplantation's Transplant Learning Journey.<sup>5</sup>

#### Summary of discussion:

A member inquired about changes in donation rates following the adoptions of NRP, noting the variance in countries between having an opt-in versus an opt-out organ donation system. Presenters shared the experience of increasing organ donation in Spain and Belgium. The U.K. has experienced a decrease in transplant due to COVID-19 but that number has since returned to the pre-pandemic donation rates. All presenters noted an increase in the number of organs procured per donor.

<sup>&</sup>lt;sup>5</sup> Ina Jochmans et al., "Consensus statement on normothermic regional perfusion in donation after circulatory death: Report from the European Socity for Organ Transplantation's Transplant Learning Journey," *Transplant International* 34, 11 (November 2021): 2019-2030, https://doi.org/10.1111/tri.13951.

A member inquired about real time monitoring for brain activity and the protocol if brain activity is detected. A presenter responded that while there are many different monitoring scans available generally, it is not feasible to utilize all of these devices at the time of procurement. The presenter emphasized the need for greater discussion and consensus on what scans ought to be used, while emphasizing that the intention of these devices is to detect brain activity and not the absence of it. The presenter highlighted the importance of having these discussions in open, public arenas that will allow for transparency and build public trust. The presenter added that protocol for responding to brain activity ought to be discussed proactively and urged the group to not wait until an instance of activity occurs.

A member inquired about the relevance of residual tissue oxygenation and electroencephalogram (EEG) activity. The presenter shared that this is ethically relevant and needs to be acknowledged, but added that after the vessels are cannulated the blood is de-saturated and black in color. The presenter added that minimal oxygenation needs to be acknowledged and considered but balance with malevolence to the donor and benevolence to the recipient. There is also an important distinction to be made of what is a significant flow versus just one or two oxygenated cells.

The conversation transitioned to the definition of death and the dead donor rule. A member opined that if death is the absence of life then life ought to be defined. The presenters emphasized that donation after cardiac death (DCD), which the public has widely accepted, utilizes the same protocol as NRP prior to death, emphasizing that the only distinction between the two occurs after death. A member questioned if this practice violated the dead donor rule and highlighted the distinction between killing and letting die. In both NRP and DCD, life-support is withdrawn and death is allowed to proceed, which is identified as irreversible. Utility of care was also acknowledged, wherein a point may be reached that continued care would not persist the life of the patient. The member emphasized the deeply seeded societal practice of not using people as a means to an end.

The presenters emphasized the necessity to build trust with the public and engage in these challenging discussions, like what it means to be dead, noting that often times the biggest concern of the public is that the donor is not suffering. There was an argument made for the utility of the donor's family and next of kin who either support organ donation or support withdrawal of life support regardless of donation.

In regards to building trust with the community, the presenters emphasized the importance of not assuming that the public would not support NRP, noting how well received it has been in their experiences. A member questioned if the ethical analysis of NRP ought to be calibrated to the society it is in and what that society wants. A presenter noted the different perception of organ donation across societies, but encouraged the group not to underestimate the wishes of the donor families. A presenter suggested considering NRP in the context of where it will be performed and to engage with the public as opposed to assume what they want.

A member asked the presenters to elaborate on how they promote transparency by sharing their experiences, best practices, and lessons learned with colleagues. In the U.K., there is a national body that has developed a mentoring program for new programs to learn techniques and best practices. This group meets on a monthly basis to discuss a case and share lessons learned. In Spain, these discussions are occurring in smaller and more informal settings, not at a national or regional level. In Belgium, there is not currently a formal system in place for discussing NRP, which is partially why the practice has been paused to develop this infrastructure.

### 3. Farewell to Departing Members

The Chair thanked the members who will be rolling off the Committee on June 30, 2022 for their hard work and dedication.

### 4. Breakout Groups

Committee members separated into three breakout groups. The members of the Transparency in Program Selection workgroup and Ethical Evaluation of Multiple Listing subcommittee met to discuss their respective projects. The remaining members considered three questions asked of the committee by the leadership of the OPTN Kidney and Pancreas Transplantation Committees.

## **Summary if discussion:**

# Transparency in Program Selection Workgroup

The Vice Chair shared the feedback he received when presenting the Transparency in Program Selection white paper to the OPTN Policy Oversight Committee (POC) for project approval. Primary concerns were that the Ethics Committee is dictating to transplant centers what they have to do and determining what metrics should be collected. The Vice Chair clarified that the paper will provide examples of ways in which information could be made accessible based on the ethical principles already outlined in the memo. The POC ultimately approved the project for the Ethics Committee to work on.

Members discussed what terminology was within and outside of the project's scope, most notably was the exclusion of the word 'metrics.' A member pushed back that patients would not be able to understand and utilize information provided to them if it did not have a benchmark comparison. The Vice Chair emphasized that developing benchmarks or thresholds is outside of the scope for the Ethics Committee. A member inquired about the examples that could be used, which the Committee ultimately has freedom to consider but cannot dictate how transplant centers operate.

The Vice Chair also noted the importance of the paper's tone. As the Ethics Committee, the purpose is to be objective and address all issues from a balanced and ethically grounded perspective. The group emphasized that in order for the paper to be impactful it was imperative to root the examples in the ethical framework and acknowledge all stakeholder perspectives. The group highlighted the importance of this document being read from the voice of the OTPN Ethics Committee.

The group discussed the potential to distinguish transplant centers as the audience of the white paper and patients as the customer. A member expressed concern that the white paper could lead to negative changes from transplant centers reacting out of fear of judgement. The Vice Chair shared similar feedback that he received when presenting the project to the POC for approval. It is important to recognize the potential for misinterpreting what the Ethics Committee is saying in the white paper.

Members discussed the structure of the 'Future State' section to strengthen the ethical foundations for transparency. The group considered organizing it by ethical principle with examples underneath or organizing by example with principles underneath. A member suggested using a similar format as the *Revise General Considerations in Assessment for Transplant Candidacy.* The group ultimately decided to organize the section by patient-specific examples, tie in the ethical justifications specific to each example, and remove the considerations of referral and listing phases.

The group discussed if the paper could say if certain information were provided to patients then utility could improve. It was agreed that would be acceptable, but noted that the paper needed to continue to read from the perspective of ethical considerations and not dictating practices to programs.

The members discussed the 'Impediments to Accessing Data' section. The group agreed that the structure of this section made sense and had a good flow. Members were assigned tasks of restructuring the 'future state' section based on today's discussion and will have individual discussions about content thereafter. Once the paper structure is revised, the group will delve deeper into the editing process.

### Ethical Evaluation of Multiple Listing Subcommittee

The members started their discussion by considering two timelines for proceeding with the project. The first option is to continue on for August 2022 public comment, which would mean a more compressed data request and a final product for the full Committee to vote on by June 16. The second option would be to delay until the January 2023 public comment cycle, which would allow for a more in-depth data request and more time to write and revise the white paper. Members discussed the level of importance that they felt the data had in supplementing the literature and elected to proceed with Option 2.

Members discussed the types of data that they felt would be most valuable to their ethical analysis. Members identified data around socioeconomic status (SES) to be a major gap in the existing literature on multiple listings. Members want to better understand if there was a discrepancy in the types of patients who are able to utilize multiple listings in order to better understand the scope of the practice. Of note, members suggested utilizing zip code data to serve as a surrogate for SES and inquired about the possibility of linking OPTN data to external data. The UNOS Research staff noted that zip code data can often inaccurately reflect an individual's SES because of the size of zip codes and the potential for zip codes to be incorrectly entered. There is a possibility to link the OPTN data with external data, but that would be a very lengthy process and require additional levels of approval since it is not a common practice. Members also discussed the potential to use some of the data collected from the Social Determinants of Health project. UNOS staff informed the members that they would be receiving a presentation update on that project during their April Committee meeting. A member inquired about the possibility to do geocoding, but that may not be an option. Alternatively, the group may have to use education level, income, and rural versus urban to supplement that information.

The group also discussed the definition of multiple listing that would be used for the data request. They agreed that they wanted to capture the data for patients who pursued multiple listing from the outset of their listing and those who pursued a second listing after spending time on the waitlist. The hope is to get a better understanding of why patients multiple list, whether due to geographic, sensitization, or means and access.

In terms of the final data request, the members are hoping to gain a better idea of the demographics for singularly listed versus multiple listed patients. The subcommittee would like to know which organ types are pursuing multiple listing, how often it occurs, and if there are different outcomes for these patients. The subcommittee also wants to identify the median time to transplant and the geographic prevalence of multiple listing versus single listing. The data will focus on allocation in acuity circles, following the removal of donor service areas (DSAs). The data request will be submitted within the next week and will be tentatively available for the May 11 meeting.

# Kidney-Pancreas Continuous Distribution

This breakout group was tasked with answering three questions posed to them by the leadership of the OPTN Kidney and Pancreas Transplantation Committees:

- 1. How ought the KP workgroup balance pediatric and multi-organ transplant (MOT) patients in the composite allocation score (CAS)?
  - a. Often times these populations will pull a similar quality of organ, potentially impacting the access of the other.

- 2. Is it acceptable for non-medically urgent, pediatric candidates to receive priority over medically urgent, adult patients?
  - a. Continuous distribution will include some level of priority for pediatric patients.
- 3. Are the attributes correctly assigned to equity and utility?
  - a. How closely should equity and utility be balanced? (50/50? 80/20? Etc.)
  - b. Should we aggregate the weights of the attributes or do you suggest a different method?
  - c. Section IV of the Continuous Distribution white paper explains how to resolve conflict between principles. How can we best apply balancing ethical principles for kidney-pancreas continuous distribution?

Members discussed the association of components in the CAS to equity and utility. One member shared medical urgency ought to be categorized as both equity and utility, while another noted that waitlist mortality ought to be attributed to utility, but underscored that all of these categories overlap. A member noted that equity and utility might not be the best way to categorize these and urged to seek a higher threshold than 1-year survival after transplant for kidney recipients.

In regards to the first question, a member noted that there are different levels of medical urgency depending on which MOT combination was being considered, noting that a safety net exists for simultaneous liver-kidney (SLK). A member noted that there is no set standard for how ethical principles should be balanced against each other, in the sense that equity is more important than utility, for example. A member countered that every attribute has equity and utility considerations within it and it is not a matter of balancing them against each other but in context of the system. A member commented that it would be helpful to include the number of MOT and pediatric patients to provide greater context to the question. Members discussed the challenges in comparing medical urgency between MOT candidates and the inadequacy of medical urgency in kidney transplantation alone.

A member urged that establishing a framework like this may allow for more consistent feedback than providing feedback to ad hoc questions. A member suggested referencing previous ethics white papers on multi-organ transplant and pediatrics to develop a response that would be consistent with where the Committee has stood on these issues in the past. A member pointed out that the framework was established in the Committee's white paper, *Ethical Considerations of Continuous Distribution in Organ Allocation*. Members discussed the importance of continuing ethical discussions with respect to each organ transitioning to continuous distribution.

A member inquired about the process for continuing to review the CAS and making adjustments, as needed. It is important for the group to better understand how the flexibility and adjustments will actually occur, such as if changes in the CAS will require public comment or if the weight can be changed by the Kidney and Pancreas Transplantation Committees. UNOS staff shared that the revision process would likely take six to twelve months to occur, but that the OPTN Executive Committee could make an expedited adjustment if necessary. A member suggested placing guardrails on the impact that any one attribute could have to reduce any potential adverse outcomes. A member urged that the collection of outcome data should be reviewed beyond one-year post-transplant outcomes in order to better inform the system.

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<sup>&</sup>lt;sup>6</sup> OPTN Ethics Committee, *Ethical Considerations of Continuous Distribution in Organ Allocation*, February 2022, accessed April 3, 2022, https://optn.transplant.hrsa.gov/media/mjzfpb3h/ethical-considerations-of-continuous-distribution-in-organ-allocation\_whitepaper.pdf

The members shifted their discussion to the second question. A member shared that all pediatric candidates could be considered as medically urgent in a different way than the clinical definition since it has a lifelong impact on them. A member noted that very few patients are determined to be medically urgent from the clinical categorization and therefore it would be acceptable for pediatric candidates to receive priority. Another member added that priority can still be given to pediatric candidates without greatly impacting the access for the medically urgent adult candidate.

Members briefly discussed question three. Of note, they inquired why this question was only focused on two of the ethical principles without considerations to other ethical principles. A member noted that while autonomy is part of the transplant system, it is challenging to incorporate autonomy in an allocation system. A member pushed back on the gaps in MOT allocation that can inhibit patient and transplant program autonomy.

In closing, the members noted some dissatisfaction with the wording of the questions asked and would like to have clearer communication between the Ethics Committee and Kidney and Pancreas Transplantation Committees regarding development of the attributes for continuous distribution.

# 5. Public Comment Presentation: OPTN Living Donor Committee, *Modify Living Donor Exclusion Criteria*

Dr. Nahel Elias, Vice Chair of the OPTN Living Donor Committee, presented the *Modify Living Donor Exclusion Criteria* policy proposal that is out for public comment.

#### Summary of discussion:

A member noted that while the diabetes section alludes to interpreting a patient's lifetime risk of complications, it is written in a vague way that ought to be clarified. The member noted that the interpretation from transplant programs could vary based on how they are reading the modification. Additionally, a member inquired if the Committee considered requiring a specific algorithm for transplant programs to use to determine lifetime risk. The Living Donor Committee decided to leave this decision to the transplant programs.

In terms of malignancy, a member noted that a high risk of transmission could occur after the fact. The member suggested rephrasing to 'more than a minimal known risk of transmission.'

A member noted that on the coercion rationale, inducement of some sort likely occurs when someone decides to be a living donor. The member suggested rewriting it to say 'undue inducement.' A member appreciated the expansion in language from just financial to include anything of value.

A member noted that while the living donor policy indicates that individuals with HIV have an increased risk for kidney disease, it does not call out the increased risk for Type 2 diabetes patients to develop kidney disease. The policy requires HIV positive donors to donate to HIV positive recipients but does not place additional restrictions on other potential living donors with a possible increased risk of kidney disease. The presenter noted that the lifetime risk was intended to capture more than just the risk of kidney disease, and noted the potential for the Committee to look into the language for HIV positive patients.

A member inquired about whether or not the Committee made any recommendations about transplant programs providing long-term follow up for living donors. The presenter informed the group that they are working with SRTR on ways to improve collection of long-term data on living donors.

### Next steps:

UNOS staff will formulate the public comment for the proposal on behalf of the Committee. Members are encouraged to submit their own public comments. The public comment cycle will conclude on March 23.

# 6. Public Comment Presentation: OPTN Ad Hoc Multi-Organ Transplantation Committee, *Establish Simultaneous Heart-Kidney and Lung-Kidney Eligibility Criteria and Safety Net*

Dr. Marie Budev, member of the OPTN Ad Hoc Multi-Organ Transplantation Committee (MOT) and Vice Chair of the OPTN Lung Transplantation Committee, presented the *Establish Simultaneous Heart-Kidney and Lung-Kidney Eligibility Criteria and Safety Net* policy proposal that is out for public comment.

## Summary of discussion:

A member inquired if this policy will require race-neutral eGFR calculations. The presenter responded that the eGFR calculations will reflect the eGFR changes made by the OPTN Kidney Transplantation and Minority Affairs Committee's policy proposal *Establish OPTN Requirement for Race-Neutral eGFR Calculations*, which is currently out for public comment. A member noted that the acute kidney injury (AKI) definition used in the proposal is static and suggested utilizing the definition from the Acute Kidney Injury Network.

A member inquired about the monitoring plan for the proposal. The presenter responded that the Committee will review the data at six months, one year, and two years. UNOS staff added that allocation analysts review matches at a two-month lag to determine if any policy violations occurred.

### Next steps:

UNOS staff will formulate the public comment for the proposal on behalf of the Committee. Members are encouraged to submit their own public comments and encourage their colleagues to do the same. The public comment cycle will conclude on March 23.

# 7. Breakout Group Report Outs

Members provided an overview of what each breakout group discussed and welcomed questions and feedback from other Committee members. The summaries below are of the feedback and discussion that occurred following the group report outs.

### Summary of discussion:

#### Transparency in Program Selection

The workgroup asked for feedback on the paper framing where the customer is the patient and the transplant system is the audience. A member supported this framing and noted the value that transplant professionals can provide in identifying information that would be valuable to patients but that patients may not know to ask for. Additionally, the Chair noted that the best way to serve patients' interests is to develop a balanced white paper that can be applied across the transplant community to represent the ethical framework for patient-centered decision-making.

A member noted the challenge to understand metrics, such as referral to evaluation time. The member noted that it may not be clear when the referral and evaluation processes have started. The Vice Chair clarified that language around metrics is being removed from the draft and will instead focus on information that would help patients in to make a more informed decision. This white paper will open up the discussion to the sorts of data that may have been overlooked and would be valuable to inform decisions, as opposed to metrics used to determine success.

### Multiple Listings

Members discussed the importance of the data request and made some suggestions on what information may be valuable to understand this issue. A member suggested looking at the distance between the primary and secondary listing centers, noting the means needed to be able to travel between them. Alternatively, a member suggested compounding the distance with geographic density data, adding that someone in the center of the U.S. would likely need to travel farther than someone on the east coast. Another member considered looking at regional saturation as a reason for pursuing multiple listing. The subcommittee representative noted that the distance is included in their data request but not within the context of geographic density, however, that seems like a reasonable ask in a follow up data request. A member noted that while it may not be very common to multiple list in a condensed area, it is possible that patients may multiple list because the patient is unaware that multiple listing has very little impact in condensed areas.

A member inquired about payer data, noting that some organizations, specifically universities, may limit multiple listing by requiring the use of their institutional payment plan. The subcommittee representative noted that the payment information that the OPTN collects is limited to private and public payer. This information will be included in the data request and the group is hopeful that they may be able to obtain additional data either through external sources or the SDoH project.

In terms of more specific examples, a member highlighted that New York state does not allow patients to be listed at more than one center in the state. UNOS staff noted that it may be able to find data on the impacts of this, but that it has been thoroughly analyzed in the existing literature. A member noted that literatures exists that outlines the benefit to the patient and transplant program by retaining clinical continuity within one program.

A member noted that it would be ideal to see every patient able to pursue multiple listing to increase access across the board. Another member countered that patients would be better served by reducing the systematic inefficiencies that allowed for an advantage through multiple listing. Member suggested that a change in the allocation system, specifically the development of continuous distribution, may eliminate the benefit of multiple listing and improve access for all patients.

The Vice Chair noted that feedback that was received from the POC, noting that if the data shows that multiple listing is inequitable then it will likely be highly scrutinized. The subcommittee representative responded that the group fully embraced pursuing the extended timeline and feels confident that it will provide them the time to combine the necessary data and literature to analyze multiple listing. The member added that it is essential for the OPTN to understand the ethics behind any potential inequality that may exist.

#### Kidney-Pancreas Continuous Distribution

Members discussed the goal of continuing to improve the collaboration between the Ethics Committee and organ-specific committees as they develop continuous distribution. A member echoed the sentiment that thresholds need to be set early and develop pathways for remediation at the outset as opposed to when a problem arises. The group agreed that ongoing evaluation would be pertinent.

Members noted the potential for remedying past injustices in current allocation through restorative justice. UNOS staff noted that improving clarity in communication between the Ethics Committee and Kidney and Pancreas Committees is a priority for effective collaboration on this project.

Members discussed the flawed association of attributes with equity and utility. Of note, there was dissatisfaction with how equity and utility are categorized and the heavy focus between the two ethical principles without consideration for others. A member added that if the Committee is unable to agree

on how each attribute ought to be associated with equity and utility then the Committee will not be able to weigh in on how the attributes ought to be balanced against each other.

# 8. Closing Remarks

The Chair thanked members for their attendance and contributions to today's meeting. Staff reminded members to submit their receipts for reimbursement through Chrome River. Members are encouraged to participate in the Analytic Hierarchy Process (AHP) exercise that the OPTN Kidney and Pancreas Transplantation Committees are sponsoring.

# **Upcoming Meetings**

- April 21, 2022
- May 19, 2022
- June 16, 2022

#### **Attendance**

# • Committee Members

- o Aaron Wightman
- o Amy Friedman
- Andrew Flescher
- Catherine Vascik
- Colleen Reed
- o David Bearl
- Earnest Davis
- o Ehab Saad
- o George Bayliss
- o Glenn Cohen
- o Keren Ladin
- o Lynsey Biondi
- Roshan George
- o Sanjay Kulkarni
- o Sena Wilson-Sheehan
- o Tania Lyons
- o Thao Galvan

# • HRSA Representatives

- o Jim Bowman
- o Marilyn Levi

# • SRTR Representatives

o Allyson Hart

#### UNOS Staff

- o Cole Fox
- o Courtney Jett
- o Damian Davidson
- o Delaney Nilles
- o Eric Messick
- o James Alcorn
- o Kaitlin Swanner
- o Kate Breitbeil
- o Kim Uccellini
- o Krissy Laurie
- o Kristina Hogan
- Laura Schmitt
- o Lauren Mauk
- Lindsay Larkin
- o Matt Cafarella
- o Megahn McDermott
- o Rachel Hippenchen
- o Rebecca Murdock
- o Robert Hunter
- o Susan Tlusty
- Tina Rhodes
- o Terry Cullen

# • Other Attendees

- o Arne Neyrinck
- o Amelia Hessheimer
- o Chris Watson
- o John Dark
- o Lois Snyder
- o Marie Budev
- o Matthew DeCamp
- o Nahel Elias