OPTN Ethics Committee
Meeting Summary
March 11, 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 03/11/2021 to discuss the following agenda items:

1. Introductions
2. Public Comment Presentation, *2021-2024 OPTN Strategic Plan*
3. Public Comment, CAT Rewrite
4. Living Donor Committee Update – *Prior Living Donor Priority*
5. Status update of other Committee activities
6. Overview of Continuous Distribution as an organ allocation framework
7. Overview of intentions for Committee's discussions of *Ethical Considerations of Continuous Distribution in Organ Allocation*
8. Normative Justification
9. Utility
10. Composite Allocation Score
11. Transparency and Autonomy
12. Justice and Equity
13. Pragmatic Concerns
14. Summary
15. Closing Remarks

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

1. Introductions

UNOS staff shared the agenda and what to expect during today's meeting. The Committee Chair kicked off introductions.

2. Public Comment Presentation, *2021-2024 OPTN Strategic Plan*

UNOS Staff presented the Executive Committee's *2021-2024 OPTN Strategic Plan* proposal which is currently out for public comment. Committee feedback will be developed into a public comment and shared with the Executive Committee.

Summary of discussion:

The Committee Chair started the conversation by inquiring on the substantive change of combining Goal 1 and Goal 3, which were referred to as being more stylistic than substantive. UNOS staff responded that the focus was determining if the percentages of the goals were appropriate and what metrics may be ideal for the OPTN to meet these goals.

A member shared that the overwhelming purpose of all of OPTN Goals is to increase the number of transplants so the rationale of combining Goals 1 and 3 is unclear. The member is concerned that combining these goals will lose focus on efficiency. Furthermore, the member inquired on the historic under population of projects focused on efficiency and whether or not that was a leading motive for the Executive Committee to combine Goals 1 and 3. UNOS staff responded that this information was not on hand at the moment and would follow up on this inquiry after the meeting.

A member identified the interconnection of Goal 1 and Goal 2 in which an increase in transplants would occur if there was a greater focus on equity and access to transplantation across all populations, specifically those who have been underserved.

The Committee Chair inquired about pre-waitlist data, which UNOS staff updated was part of the new initiative on social determinants of health data. There is also work being done by the Minority Affairs Committee to identify barriers to accessing transplantation for different racial, ethnic, and geographic groups.

A member commented that presumably the increase in transplantation will decrease waitlist mortality so why is that not a primary metric within the Strategic Plan. UNOS responded that this metric was housed within Goal 4, however the Committee's response was that it was still not enough of an emphasis. Ultimately, the members stated that all of the goals are trying to reduce waitlist mortality and it is essential for the OPTN to remember that transplant programs have an obligation to patients as soon as they are placed on the waitlist. However, the focus of all metrics is on outcomes while ignoring the obligations that are held to the care of the patient during the process of obtaining an organ prior to transplantation.

A member commented that with Goal 1 being 50% it is assumed that transplantation will increase by thousands during a three-year time span. UNOS staff clarified that Goal 1 is to have 50% of projects within the OPTN focused on increasing the number of transplants and not to increase the number of transplants performed by 50%.

The Chair commented that the 30% dedication to equity does a disservice to the transplant community as a whole by limiting resources available for equity focused projects. A member added that the vast majority of transplant metrics are connected to Goal 4, while the goal holds only 10% of the focus on the Strategic Plan. Thus, the remaining three goals of the Strategic Plan are unattainable for members to accomplish. Additionally, multiple members vocalized that the OPTN should be focused on 'increasing transplants for the sake of increasing transplants' and that the focus should be on quality of transplants, not always quantity. Members were concerned about outcomes and do not want to compromise the quality of organs that patients receive just to increase the numbers overall. Members shared concerns about their ethical obligations to their patients ensuring that they were making the best medical decisions for the individual not based on what the OPTN wanted. Ultimately, a member shared that due to the practical implications of the OPTN's Strategic Plan this needs to be a constant conversation and not a static decision.

UNOS staff responded that the OPTN never wants to compromise quality or safety but instead the Executive Committee proposed focusing on very specific projects that will contribute to an increase in organ transplantation from a system perspective through policy and improved system tools. In addition to the OPTN's Strategic Plan, the Policy Oversight Committee (POC) outlines policy priorities such as Continuous Distribution and multi-organ transplant. The Executive Committee is not just trying to increase transplant but improve the system through combining Goals 1 and 3.

Next Steps

UNOS staff will consolidate the notes from today's conversation to share with leadership for them to formulate into public comment. Leadership stated they will circulate the public comment document to the full Committee for feedback prior to submitting it. UNOS staff suggested the Committee provide very focused feedback for each category and suggestions for how the percentages could be changed to help the Executive Committee make edits moving forward.

3. Public Comment Update, CAT Rewrite

UNOS staff provided an update on the public comment feedback and sentiment scores from the first nine regional meetings. UNOS staff anticipates an influx in public comment posted on the OPTN website before the public comment period ends.

Summary of discussion:

The Chair shared that she felt members of the community are fundamentally confused about the role and purpose of the Ethics Committee but they feel positively about this proposal. Members shared that they received positive feedback during the regional meetings and sensed excitement from the community about supporting marginalized populations. The Chair shared that many members of the community were eager for the Committee to go further in their guidance.

Next steps:

UNOS staff will create a single, consolidated document with all feedback and themes to share with the Committee. The CAT Rewrite Subcommittee will meet after public comment ends to review all of the comments and sentiment submitted. The full committee will review the finalized document during the April meeting.

4. Living Donor Committee Update – *Prior Living Donor Priority*

An Ethics Committee member who has served as a representative to the Living Donor Committee provided an update on *Prior Living Donor Priority* and requested feedback from the Ethics Committee. This could be either a guidance document or priority statement.

Summary of data:

Four options are being considered to standardize Prior Living Donor (PLD) Priority across organs:

1. No PLD Priority
2. PLD Priority only for organ donated
3. PLD Priority for organ if causal connection to organ donated
4. PLD Priority for any organ needed
5. Any others?

All options will take medical necessity into consideration when allocating organs. This guidance does not apply to VCA at the moment, further discussion will occur when living donor VCA increases.

Summary of discussion:

The conversation started by discussing the ethical theories at play. First, 'making people whole' which could be similar to paying for health insurance for living donors. Second, 'heroism' or incentivizing individuals for donating, similar to priority given to veterans for their service. Third, communitarian approaches would suggest there are inherent values for people to donate if they are physically able to and there should be considerations for volunteering within a system that is unable to provide explicit risks of participation. Lastly, reciprocity for volunteers who have put themselves at risk deserve to be

compensated in some capacity. Members added that as long as the compensation wasn't monetary then the consideration should be in place and noted that the bribe effect is unlikely to occur with any of the PLD Priority suggestions. Members noted that the closer the compensation is to the risk the more justified it is and the farther the compensation is from the risk the less justified it may be. Finally, gaming the system is unlikely to occur and should not be a primary ethical concern.

A member expressed concern that option 4 was too closely connected to kidney swapping and felt like a more commercial approach to PLD Priority. However, there was confirmation that all options would be in line with NOTA and Final Rule. Members also expressed concern for the 'invisible patient' that will not receive an organ because it is prioritized to a PLD patient. The Committee member who presented to the group added that while this guidance would impact a small number of patients, likely around 30-40 annually, it should not deter the Committee from thoroughly considering the ethical basis and implications.

A member expressed concern about determining causal connection from the outset and requested feedback from medical professionals within the group to provide a better clinical understanding. Many members stated that it would be extremely difficult to determine causal connection from a medical perspective. A member shared that kidney disease could easily impact the health of any organ thus making causal connection a very wide net to pull from. Another member added that due to the difficulty in establishing causal pathways it would be ethically sound to justify allocating an organ to a PLD patient even if it was not the same organ was that donated. A member described causal connection as a "high bar to meet."

Alternatively, a member suggested a tiered level of priority for PLD patients. For example, if a kidney donor needed a kidney they should be at the top of the list without question. However, if a kidney donor needed a liver or lungs, there should be some level of priority without moving them straight to the top of the list. This member added that the societal benefit of living donation exceeds the reach of just the patient that receives the donation.

Sentiment Collection

Since consensus was unlikely, leadership asked for sentiment to be submitted through the GoToMeeting chat function. No members voted for option 1. Two members voted for option two, but one of the two voters suggested a hybrid between option 2 and option 3. Two members voted for option three. Eleven members votes for option four. One member abstained.

5. Status update of other Committee activities

UNOS staff was planning to provide an update on the ongoing Ethics Committee projects, however, leadership agreed to push this update to the April Committee meeting due to time constraints.

6. Overview of Continuous Distribution as an organ allocation framework

UNOS staff provided a background and overview of Continuous Distribution as an organ allocation framework. Continuous Distribution is a holistic approach to organ transplantation without the limitations of hard boundaries. This framework changes organ allocation from a classification based system to a points based system which will increase equity and access.

Summary of data:

UNOS staff provided examples of how hypothetical candidates might be allocated an organ in the current DSA system versus the Continuous Distribution framework. These examples depicted variance in medical priority and blood type to show which candidate would receive the organ in each of these frameworks. A hypothetical match run based on a points-based system was presented. This new points-

based system for organ allocation relies on the identification of the critical attributes associated with organ-specific transplantation and the Final Rule. Organ-specific Committees also determine the weight or importance to assign to each attribute. A patient-specific composite score is calculated based on the attributes and weights.

UNOS staff shared the existing concerns of transitioning to this framework, which included a decrease in efficiency and transparency questions around accuracy of composite allocation score weighting process.

Summary of discussion:

The Committee Chair shared that this is not a total disregard for geography but instead incorporating other aspects of the Final Rule and transplantation with geography into a composite allocation score. The geography component will be considered from the efficiency perspective. A member clarified that this system does not consider any different attributes, instead it changes the way that the existing attributes are formulated.

A member expressed concern about the placement efficiency category since it can easily disadvantage patients in rural areas who already have decreased access to transplant. UNOS staff responded that while the placement efficiency score will be factored into the composite allocation score, it will likely be a very low weight or percentage associated with it in order to not negatively impact patients in sparsely populated regions.

7. Overview of intentions for Committee's discussions of *Ethical Considerations of Continuous Distribution in Organ Allocation*

The Chair distinguished between the normative and pragmatic considerations and the necessity for these to be separated moving forward. This paper will focus on the normative considerations and the next paper will delve into the pragmatic concerns.

8. Normative Justification

The Vice Chair introduced the normative justification for an ethical analysis of a Continuous Distribution framework. This process allows for an increased distribution of resources by removing hard boundaries, which limit access to organs for candidates who are just outside of them, and allow for framework that is more consistent with requirements found in NOTA and the OPTN Final Rule. The normative justification explanation introduces the ethical factors of utility, justice and equity, and transparency and autonomy.

9. Utility

The group compared the components of the Continuous Distribution framework to the elements outlined in the Ethics Committee's *Ethical Principles in Allocation of Human Organs* white paper. Members presented a standpoint that if the Continuous Distribution framework balances the positive consequences as opposed to the negative consequences, then this framework is superior to alternatives. The purpose of this framework will be to keep small differences between candidates from leading to major differences in outcome.

Summary of discussion:

A member expressed concern that the lay audience would not necessarily understand the exclusion of disparities from this section and suggested its inclusion or it to be more uniformly understood by the community. The Vice Chair identified the natural tension between equity and utility but argued that in some respects equity was being co-opted as an attribute of utility questioning 'is equity reducible to utility?' On the contrary, utility is saying that all things equal, do the thing that maximizes good

consequences and Continuous Distribution is adding in components of equity into that system. Thus, it is balancing components of equity and components of utility within the final composite allocation score and not minimizing one under the other. The Chair added that with the weight of the composite allocation score, the Committee could argue that equity is the most important component and should be weighted more heavily than utility, adding in components of utility to an already equitable system.

A member shared a recent critique of utilitarianism that it has fallen short of its purpose, and not due to issues with prioritization or maximization, but instead cause by what is factored into utility and how it is accounted for as a whole. The Chair validated the critique but countered that it would be implicated if using criteria or metrics such as productivity or improvement in quality life, where instrumental value judgement is added in a potentially biased way. As a result of this conversation, a member suggested that the flow of the paper may be improved by analyzing what the composite allocation score is first and then breaking down the individual ethical frameworks instead of the current, opposite flow.

A member brought attention to discrepancies in the group's interpretation of utility especially as different organs view utility in opposing ways, either through length on the waiting list or post-transplant outcomes. A member responded that at this time, the Committee is defining utility as it defined in the *Ethical Principles in the Allocation of Human Organs* paper but recognized that it's possible the existing definition no longer serves the needs of the Committee. However, the issue posed it not with the definition itself but the innate conflict that occurs within the context of transplantation. The Chair suggested including what definitions or examples of utility ought not to be used especially since clinicians would have a better understanding of which factors have an adverse impact. Pragmatically, utility metrics can result in completely different outcomes depending on the definition so there needs to be either guidance or acknowledgement that these factors are in conflict. It was noted, however, that this framework could facilitate future standardization across organs and develop comparative data between organ systems.

UNOS staff clarified that utility factors will be different depending on the organ, but efficiency in the organ placement system and post-transplant outcomes are utility factors determined by the OPTN Final Rule. However, priorities may differ; for example, the Liver and Heart Committees may focus on waitlist mortality, while the Kidney Committee would likely focus on equity and the Lung Committee's priorities are more of a balance between the two. At the forefront, there could be an imbalance between equity and utility but in the next paper it could dive into if these attributes need to be an exact balance.

There was some uncertainty from a member about if the move to Continuous Distribution encompasses anything more than geography and the Chair responded that this system is one that will include all patients continuously without the hard boundaries of geography and posed the question 'are we trying to mimic the existing system or improve it?'

There was concern from members about how to move forward with an impactful paper while only discussing the principal of the system and not delve into the more substantive aspects of it. As a result, there was a suggestion to write this paper in favor of a move to Continuous Distribution in general across all organ groups and the second paper can be more specific organ by organ. This suggestion felt more feasible to the group as the specifics have not been developed by the organ specific Committees thus requiring a delay in their analysis.

A member suggested writing this paper with a lung candidate in mind, since the Lung Committee is the farthest along in developing a Continuous Distribution framework, and then a paper for kidney and so on, which a second member supported. Another suggestion was analyzing the fundamentally important ethical frameworks and each organ specific Committee will take those recommendations to develop a balance on how to weigh the different principles within the composite allocation score. The Chair

clarified that the purpose of this paper and timeline is to consider the proposal by the Lung Committee, what ethical principles justify it, where there are shortcomings, and ultimately, consider whether Continuous Distribution is justified.

Upon request, UNOS staff clarified that the initial transition to a Continuous Distribution framework will move the existing classification system into a points based system. It may be possible for some of the organ specific Committees to implement minor changes in that process, but the more complicated changes will occur down the road as the framework is in use. Essentially, the development of this framework will be continuous and likely see 2.0 versions and on.

10. Composite Allocation Score

The Committee Chair introduced the ethical analysis of the composite allocation score of a Continuous Distribution framework. There's a lot of normative and pragmatic questions that will need to be considered from an ethical point of view. *Note: The agenda has been changed following the meeting to reflect the chronological order in which these conversations occurred.

Summary of discussion:

The original charge from the OPTN Board to the Ad Hoc Geography Committee in 2018 was to develop a level of standardization across organs, in the short term, through an allocation system that is efficient, reproducible, and transparent. The longer term desires from the Board is to develop a framework that is positioned for continuous improvement.

The Vice Chair proposed the possibility of developing two scores, one focused solely on utility factors and another focused solely on equity factors, and balancing them between each other to create a composite allocation score that is split between these ethical factors.

The Vice Chair proposed three broad goals this paper could accomplish. First, explain generally why the conceptual move to Continuous Distribution is better than the existing system, given that it's done correctly. Second, substantively analyze the factors that complicate this system. Third, identify the next steps in developing a composite allocation score without weighing in on the math and selection of attributes. The final step will set up the organ specific Committees to make the decisions on the breakdown of the scores.

11. Transparency and Autonomy

Members introduced the transparency and autonomy analysis of a Continuous Distribution framework. Three main parts – what would this look like in a perfect world, why Continuous Distribution could be that answer, and lastly what the potential concerns may be. The conversation was framed around what the system would look like in a future state and an ideal state. *Note: The agenda has been changed following the meeting to reflect the chronological order in which these conversations occurred.

Summary of discussion:

After clarifying the definition of transparency, it became clear to members that the goal of this section was to share the rules and expectations of transplantation as a whole in order to place all patients on a level playing field. There was a group consensus that transparency should not be an unrealizable goal. A member added that as a patient, it is not possible to have autonomy without transparency, or vice versa, so it is essential to recognize the differences and interdependence of the two factors.

A SRTR representative clarified that there are mathematical equations to assist in developing a Continuous Distribution framework and its possible to develop guardrails within that but it must be tested mathematically to ensure it has the outcome it is designed to have. The SRTR representative

posed the questions 'is it transparent what the goals are of designing the point system' and 'is it transparent that these are the right points to give to different characteristics?'

The authors of the section also expanded their point that by having the ability for the OPTN to revise and modify the points system as data was collected, it created a system that could be empowering to patients as it monitored and rectified any inequalities or disadvantages. A member suggested explicitly stating how essential patient engagement is in the process of continued policy improvement in a Continuous Distribution framework.

12. Justice and Equity

Members introduced the justice and equity analysis of a Continuous Distribution framework. The group compared the components of the Continuous Distribution framework to the elements outlined in the Ethics Committee's *Ethical Principles in Allocation of Human Organs* white paper. *Note: The agenda has been changed following the meeting to reflect the chronological order in which these conversations occurred.

Summary of discussion:

The members who presented this section shared that their main concern was the potential for unintended consequences, specifically vulnerable populations or those who are already negatively affected, and to ensure consistent data monitoring so that corrections could be made as needed. UNOS staff informed the Committee that when modeling an allocation system with SRTR they perform a series of breakdowns for blood type, gender, age, and race. There are not many rural transplant centers, but there are isolated ones which have a higher concentration of rural patients.

The Chair expressed concerns that modeling based on past experience may not necessarily reflect future successes and inquired about the potential assurances OPTN has considered to correct for gaps that will occur. UNOS staff informed the Committee that there will be a robust post implementation monitoring plan as the Continuous Distribution framework is rolled out. With the flexibility of the composite allocation score, it will allow the OPTN to monitor allocation and add points when necessary for disproportionately impacted populations.

Additionally, the OPTN is partnering with Massachusetts Institute for Technology (MIT) to develop mathematical constraints on the composite allocation score to ensure that disparities are consistently and uniformly addressed. Committee members expressed surprise on this process, as it was not something they had been previously informed of. As a response, UNOS staff elaborated on the analysis processes that have been performed to date as part of the Lung Committee's Continuous Distribution efforts. These processes include the use of Reveal Preference Analysis (RPA) and Analytic Hierarchy Process (AHP). Both RPA and AHP were tested using the current, classification-based allocation system. By partnering with MIT, the OPTN will be able to mathematically optimize the composite allocation scores to have a better understanding of how and where points are added to impact an individual's score and placement on the waiting list. UNOS staff confirmed that the weights assigned to the attributes are ultimately going to come from the Committee and OPTN Board and then cross-referenced with SRTR and MIT modeling to ensure they have the intended results.

13. Pragmatic Concerns

In lieu of time restraints, the Committee leadership chose not to dedicate a full section to a conversation on pragmatic concerns. Instead, pragmatic concerns were discussed throughout the day's conversation and will continue to be a focal point of this ethical analysis as the Committee moves forward.

14. Summary

The Committee Chair emphasized the important role of the Ethics Committee to call attention to what the best balance may be when transitioning to Continuous Distribution. The Committee could do it minimally, and say a shift to a score may represent improvements in one manner and challenges in another. Potentially, the Committee could go further and articulate what types of metrics may lead to unintended consequences and how the system might address them. In particular, thinking about what the composite allocation score's implications are for utility, transparency, justice, and equity. While this may be seen as a herculean task, it will allow for important and meaningful contributions to the community.

Next steps:

The Committee Chair requested the members take the time to review the draft that was sent out. Meet with your topical workgroup and be prepared to review it at the next Committee meeting.

15. Closing Remarks

The Committee Chair thanked the members for their time and involvement in today's robust ethical conversation around Continuous Distribution. There is a lot of information to sort through and the group has made strides towards developing their point of view on the topic. This process may be long and arduous but it is valuable for ensuring the best possible outcome for the community.

Next steps:

UNOS staff will consolidate the Continuous Distribution documents and resources within the Committee's Sharepoint site. UNOS staff will also consolidate the public comment feedback ahead of the CAT Rewrite workgroup meeting on March 24th.

Upcoming Meetings

- April 15, 2021
- May 20, 2021
- June 17, 2021

Attendance

- **Ethics Committee Members**
  - Keren Ladin, *Chair*
  - Andrew Flescher, *Vice Chair*
  - Aaron Wightman
  - Amy Friedman
  - Catherine Vascik
  - Colleen Reed
  - David Bearl
  - Earnest Davis
  - Elisa Gordon
  - George Bayliss
  - Giuliano Testa
  - Glenn Cohen
  - Lynsey Biondi
  - Mahwish Ahmad
  - Sanjay Kulkarni
  - Tania Lyons
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Sommer Gentry
- **UNOS Staff**
  - Eric Messick
  - James Alcorn
  - Laura Schmitt
  - Lindsey Larkin
  - Ross Walton
  - Susan Tlusty
- **Other Attendees**
  - Ehab Saad
  - Heather Hunt
  - Sena Wilson-Sheehan
  - Thao N. Galvan