OPTN

Briefing to the OPTN Board of Directors on

Ethical Considerations of Continuous Distribution in Organ Allocation

OPTN Ethics Committee

Prepared by: Laura Schmitt, Abby Fox and Eric Messick
UNOS Policy and Community Relations Department

Contents

Ethical Considerations of Continuous Distribution in Organ Allocation

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Executive Summary

The development and implementation of a continuous distribution organ allocation framework raises ethical questions that impact all members of the transplantation community. This white paper provides an ethical analysis of the potential and manifest issues associated with a move to a continuous distribution allocation framework.

The Organ Procurement and Transplantation Network (OPTN) Ethics Committee (Committee) submits the Ethical Considerations of Continuous Distribution in Organ Allocation white paper in order to advise the OPTN Board of Directors (Board) on ethical considerations in a continuous distribution organ allocation framework. The white paper identifies how continuous distribution will affect utility, equity, and transparency, and provides considerations for how these ethical principles can be upheld and balanced in a new allocation framework. Notwithstanding the hurdles such a move entails, implementation of continuous distribution as an allocation framework can be justified on ethical principles and should improve the transplantation system overall. Given the widespread support of the white paper from the community during public comment, the Committee did not make substantive post-public comment changes.

Background

Continuous distribution is an organ allocation framework that prioritizes waiting list candidates based on factors such as medical urgency, post-transplant survival, candidate biology, patient access, and the efficient management of organ placement. The continuous distribution organ allocation framework is intended to make organ allocation more equitable, flexible, transparent, and agile compared to the existing classification-based system. While the current classification based approach draws hard boundaries between types of patients (blood type compatible vs. identical; sensitized vs not; inside a circle vs. outside), continuous distribution simultaneously considers many factors that contribute toward a successful transplant.[1,2] The holistic consideration of multiple factors, as opposed to a single classification, is one of the most important benefits of a continuous distribution framework.

As part of a continuous distribution framework and within each organ-specific allocation system, candidates are awarded points within each attribute based on their individual characteristics. Each attribute is assigned a specific weight, so some will have more impact than others on a total score; however, no single attribute will decide a match rather influence the candidate's priority. The points are combined to create a composite allocation score (CAS), which will determine a patient's position on an organ match. The CAS is constructed with multiple attributes, which align with the National Organ Transplantation Act (NOTA)[3] and the OPTN Final Rule[4]. The attributes used to calculate a CAS accounts for clinical characteristics and medical urgency while removing hard geographic boundaries to prioritize waiting list candidates and promote greater equity in the allocation system overall within the constraints of the Final Rule. The expectation is that the use of individual composite scores will better balance evidence-based clinical and operational decisions with the more global, values-based decisions associated with the multiple goals of a national organ allocation framework. The composite score also provides greater transparency into how the attributes are weighted against each other.

The development of a continuous distribution allocation framework raises questions related to the ethical principles of utility, equity, and transparency and autonomy that impacts all members of the transplantation community. The Ethics Committee suggests that transplant candidates can expect to experience some practical changes associated with the development of organ-specific continuous distribution frameworks. In the event that an organ-specific committee decides to adopt and develop a continuous distribution allocation system, it is important that each committee, and ultimately the OPTN Board, identify, and consider how such changes will alter the balance between utility, equity, and transparency. Equally important is establishing grounds for how the committees, and ultimately the OPTN Board, will evaluate the effect the new system has on individuals, as well as the ability to redress the impacts through changes to the system. Furthermore, it is critical to embed in each development effort, considerations and measures ensuring that changes in the organ allocation system do not inadvertently disadvantage vulnerable populations.

[1] OPTN Lung Transplantation Committee, *Update on the Continuous Distribution of Organs Project*, August 2020, accessed May 12, 2020, p.3, https://optn.transplant.hrsa.gov/media/3932/continuous_distribution_lungs_concept_paper_pc.pdf.
[2] U.S. Department of Health & Human Resources, Organ Procurement and Transplantation Network, "Continuous Distribution," accessed May 12, 2021, https://optn.transplant.hrsa.gov/governance/key-initiatives/continuous-distribution/.
[3] NOTA, 42 U.S.C. § 273 et. seq.
[4] 42 C.F.R. §121.

Purpose

The purpose of this document is to serve as a reference tool for the OPTN Board and its organ specific committees as they move forward in developing an ethically sound continuous distribution framework for organ allocation. The Ethics Committee highlights where areas of concern may lie and aims to assist organ specific committees in closing potential gaps in equity, utility, and transparency and autonomy. This document hopes to contribute to the development of the best possible continuous distribution system through advising members, and ultimately the OPTN Board of Directors, the ethical principles to consider while shifting to a continuous distribution allocation framework.

While data, references, and examples may be specific to the OPTN Lung Transplantation Committee and its proposal, *Establish Continuous Distribution of Lungs*[5], this document should be viewed broadly and considered during the development of each organ system's allocation framework. The data, references, and examples reflect the information that is presently available to the Committee.

While the outcomes and impacts of continuous distribution are presently unknown, it is imperative to commit to discussions around ideal outcomes and continually consider how they can be improved. As continuous distribution is integrated as an organ allocation framework, the Committee is committed to re-evaluating and expanding its ethical analysis as warranted.

Overall Sentiment from Public Comment

The Ethics Committee considers the public comment feedback in light of its efforts to advise the Board of Directors on ethical considerations related to organ transplant and to ensure consideration of all stakeholder perspectives. The white paper received support and appreciation for the Ethics Committee's efforts to provide ethical guidance and considerations, from a variety of stakeholders during public comment. This feedback included all 11 regions, seven OPTN committees (Kidney, Lung, Minority Affairs, Pancreas, Patient Affairs, Pediatric, and Transplant Coordinators) and eight societies – American Nephrology Nurses Association (ANNA), Association of Organ Procurement Organizations (AOPO), American Society for Histocompatibility and Immunogenetics (ASHI), American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), North American Transplant Coordinators Organization (NATCO), Society of Pediatric Liver Transplantation (SPLIT), Society for Transplant Social Workers (STSW).

[5] OPTN Lung Transplantation Committee, *Establish Continuous Distribution of Lungs*, August 2021, https://optn.transplant.hrsa.gov/media/4772/continuous_distribution_of_lungs-public_comment.pdf.

Figure 1 shows the public comment sentiment feedback by regions and **Figure 2** shows the sentiment by member type.[6]

Figure 1: Sentiment by Region

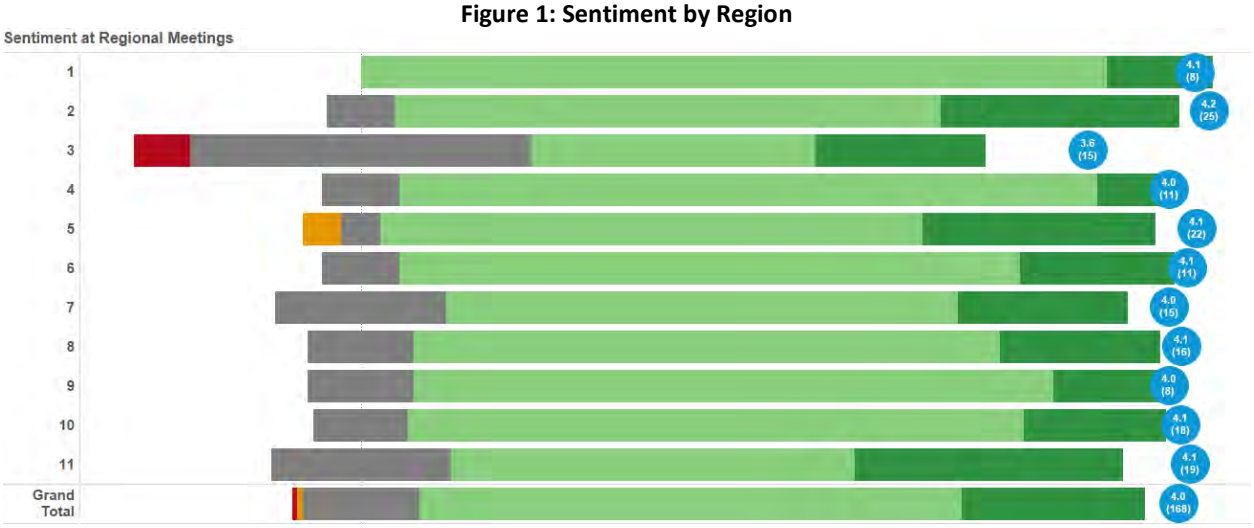
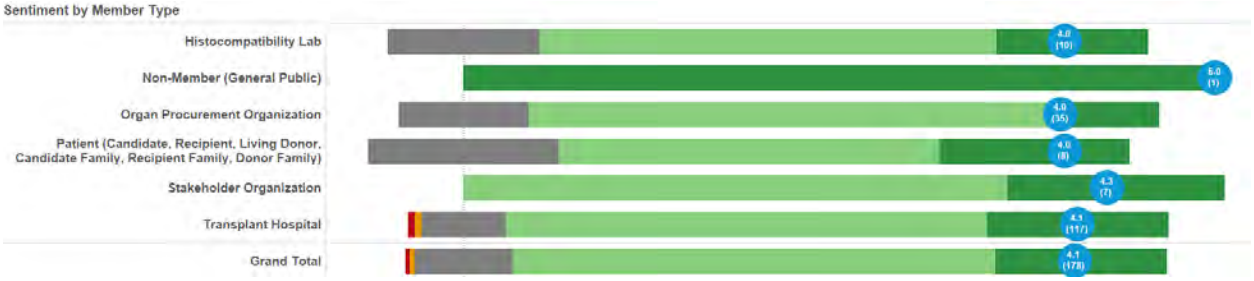


Figure 2: Sentiment by Member Type



Staff reached out to two members who opposed or strongly opposed the proposal. One member did not respond and the other member expressed concerns about how continuous distribution may have negative impact on the low socio-economic population. As such, this sentiment was aimed more at continuous distribution, in application, rather than the Ethics Committee's treatment and discussion of the ethical implications of continuous distribution. The overall sentiment data highlight that the community approves the product developed by the Ethics Committee and considers that it appropriately reviews the ethical implications of continuous distribution.

In the feedback received, themes included general support (with a focus on the equity and transparency sections, and the benefit to future policy proposals), financial implications of continuous distribution and impact on pediatric candidates. There were also some general comments related to technical clarifications. These themes and the Ethics Committee's responses are discussed in the sections below.

[6] Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

General Support

Help for Organ Specific Committees

The white paper received widespread support among a diverse cross-section of member types and regions. The support extended to the overall content of the paper and the role of the paper as guidance for organ specific committees. NATCO and the OPTN Kidney Transplantation Committee both identified that this paper will be helpful and important in developing policies of continuous distribution for the different organ allocation systems. The OPTN Lung Transplantation Committee noted that the lung proposal considered these ethical implications. The Ethics Committee appreciates these comments as confirmatory of the overall focus of the white paper to inform current and future policy changes to develop continuous distribution across different organ allocation systems.

Equity and Transparency

Two areas of support that were emphasized by members in their comments were the sections on equity and transparency. The OPTN Patient Affairs Committee noted that these areas, as well as the discussion of patient autonomy, were very important to patients. The STSW also expressed appreciation for the discussion of equity and transparency, and the continued focus on these important issues in consideration of the impact on at-risk and underserved patient populations as policies are developed.

Because these comments affirm the focus and content of the white paper, no changes were made based on the feedback.

Financial Implications of Continuous Distribution

Another theme of public comment was discussion of the financial implications of continuous distribution in the context of the ethical implications, including discussion of resource constraints and financial feasibility. The OPTN Transplant Coordinators Committee identified the importance of balancing equity with the utility implications related to financial feasibility, while still expressing support for the white paper. A member in Region 2 expressed concern for the financial implications of increased transportation costs. The ASTS noted the financial disparity and inequity caused by hard geographic boundaries and the benefit of removing this disparity using continuous distribution. ASTS still noted the importance of considering cost and resource implications in development of any OPTN policies.

The Ethics Committee appreciates the feedback received regarding the financial implications of continuous distribution. The Ethics Committee considered it important to consider this issue in the white paper itself, particularly the section entitled “Expense and logistics.” After review, the Ethics Committee affirms this section appropriately discusses the financial implications and reflects the concerns identified during public comment. Because the paper already reviews the financial implications in “expense and logistics” section, the Ethics Committee did not make any further changes to the document on this topic.

Pediatric Implications

Several community members and institutions expressed appreciation of the white paper’s discussion of pediatric candidates and the potential impact of continuous distribution on this vulnerable population. Transplant Families, the SPLIT, the OPTN Pediatric Committee, the OPTN Kidney Transplantation

Committee, and a member from Region 2 all discussed the hard boundary of when pediatric candidates become adults as concerning. The Pediatric Committee suggested the pediatric eligibility should be determined by the age of disease onset instead of age at listing. Some members of the community suggested a sliding scale that extends beyond age 18 since there are no biological differences. In addition to these comments, there was appreciation that the white paper acknowledged the vulnerability of this population, and requests that the white paper reference the Ethics Committee white paper specifically on pediatric transplantation (Ethical principles of pediatric organ allocation).[7] SPLIT noted the importance of considering post-implementation monitoring for all vulnerable populations including pediatric candidates in relation to any continuous distribution policy change.

The Ethics Committee appreciates the feedback received and the importance of considering all vulnerable populations, including pediatric candidates, in any discussion of the ethical implications of continuous distribution and in the subsequent respective organ-specific committee policy changes themselves. The Ethics Committee agrees that it would be helpful to cite the *Ethical principles of pediatric organ allocation* white paper and has updated the continuous distribution white paper accordingly. Given that the continuous distribution white paper already discusses the ethical challenges associated with a pediatric age cutoff, the Ethics Committee elects to not modify the white paper, but encourages the organ specific committees to consider this issue as they move forward. The Ethics Committee does not want to downplay the importance of these comments and will include them in their ongoing ethical discussions, especially as organ specific committees determine if they will adopt a continuous distribution allocation framework.

Other Feedback

AOPO suggested minor clarifications to the paper related to removing the terminology “circle of concern” and defining imports. The Ethics Committee made these minor changes to the white paper to add clarity and ease of use.

The Ethics Committee reviewed all the substantive and technical feedback received from the community and made only minor adjustments to enhance clarity. By remaining substantively the same, the white paper reflects the feedback of the community that supported the white paper and considered it appropriate in its discussion of the ethical implications of continuous distribution.

Compliance Analysis

NOTA and OPTN Final Rule

The white paper is proposed under the authority of the OPTN Final Rule, which states that the OPTN is responsible for developing, with the advice of the OPTN membership and other interested parties, polices for the equitable allocation of cadaveric organs.[8] The Ethics Committee offers the proposed white paper to advise the OPTN Board and its committees on the ethical considerations to undertake as they develop policies moving existing organ allocation systems to a continuous distribution framework.

[7] OPTN Ethics Committee, *Ethical principles of pediatric organ allocation,* November 2014, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/.
[8] 42 C.F.R. § 121.4(a)(1).

OPTN Strategic Plan

1. *Provide equity in access to transplants:* This white paper discusses the impact of continuous distribution through ethical principles of equity, utility, and transparency and autonomy. It specifically emphasizes the importance of ensuring that vulnerable populations do not bear disproportionate consequences as a result of changes to organ allocation with continuous distribution. The Ethics Committee advises the Board on ethical considerations to aide in an equitable transplant system for all candidates.

Conclusion

Development and implementation of a continuous distribution organ allocation framework raises ethical questions that impact all members of the transplantation community. This white paper identifies several aspects of moving to continuous distribution that should receive additional consideration against the ethical principles of utility, equity, and transparency and autonomy. It remains substantively the same as what was submitted for public comment, which reflects the support it received from the community and the fact that the majority of comments received did not disagree with the approach, focus or content of the paper.

Notwithstanding the formidable challenges enumerated in this white paper, which should be addressed as each organ-specific committee considers whether and how to adopt continuous distribution, the move away from arbitrary groupings is ethically sound and supported by the Ethics Committee. This move to a national plan, it is important to bear in mind, remains distinct from the larger issue of national sharing of resources. Therefore, it also will be important to make sure that with the changes to organ allocation, vulnerable populations in the nation do not bear disproportionate consequences as a result. There is reason to be optimistic, however, that the move to a continuous distribution framework *can* ensure that the OPTN Board and the sponsoring committees consider the ethical principles of utility, equity, transparency, and autonomy to assist them with incorporating the appropriate correctives for disadvantaged or underserved populations within the larger whole. The hope is that a move to continuous distribution will allow for a more granular consideration of attributes in order to allow for the maximum amount of attention to individual patient circumstances. Furthermore, the flexibility of this framework will allow for quicker revisions when needs for adjustment arise. Indeed, a scoring system of allocation, as opposed to a classification system, has the potential to be more patient-centered and is consistent with the goal of improving accuracy and increased attention to each individual patient. Overall, therefore, there are strong grounds to conclude that the move to continuous distribution is ethically justified and can improve the overall welfare and well-being of patients.

White Paper

Proposed new language is underlined (example).

Introduction

This white paper is intended as a reference tool to assist the OPTN Board of Directors, and its organ-specific committees, with developing ethically sound continuous distribution allocation frameworks. It is intended to help ensure that the development of such frameworks is conducted in an ethically responsible manner. It does not prescribe specific policy solutions.

The OPTN Ethics Committee (hereafter, the Committee) highlights where areas of concern may lie and aims to assist organ-specific committees in closing potential gaps in equity, utility, and transparency and autonomy. While the outcomes and impacts of continuous distribution are presently unknown, it is imperative to commit to discussions around ideal outcomes and continually considering how they can be improved. This document hopes to contribute to the development of the best possible continuous distribution system and further discussions within the community regarding an ethical organ allocation framework. The white paper should be viewed broadly and considered during the development of each organ system's allocation framework.

Ethical Considerations

This section of the white paper identifies and generally describes the ethical questions that may be associated with development of a continuous distribution allocation framework and how all members of the transplantation community might be impacted. More specifically, the section identifies practical changes that might be expected to occur as a result of moving to a continuous distribution allocation system. The discussions are included here to provide the background information needed to contextualize the ethical considerations discussed later in the white paper. The OPTN Lung Transplantation Committee efforts to develop a continuous distribution allocation framework are farther along than those of other organ-specific committees, and as a result, are frequently referenced in this section. Although the OPTN Kidney Transplantation Committee and the OPTN Pancreas Committee are in the early stages of a joint project laying the groundwork for their own continuous distribution systems, the information provided in this section should be considered in the context of each organ-specific committees' work, as applicable.

Addressing Ethical Principles Associated with Organ Allocation

This white paper will address the ethical considerations associated with the development and implementation of a continuous distribution allocation framework. The analysis relies on the ethical principles of utility, equity, and transparency and autonomy. As described in the *Ethical Principles in the Allocation of Human Organs*, utility refers to the maximization of net benefit to the community and equity (described as 'justice' in the *Ethical Principles*) refers to the fair pattern of distribution of benefits.[9] The concept of autonomy is associated with the ethical principle of respect for persons, and holds that actions or practices tend to be right insofar as they respect individual's independent choices,

[9] OPTN Ethics Committee, *Ethical Principles in the Allocation of Human Organs*, June 2015, accessed May 13, 2021, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/.

as long as the choices do not impose harm on others.[10] Application of the principle of respect for autonomy must include consideration of the transparency of the processes and allocation rules decision-makers use.[11] The OPTN Ethics Committee undertakes this white paper in conjunction with other OPTN efforts addressing continuous distribution as an allocation framework.

The Final Rule requires the OPTN to develop allocation policies that are equitable and promote the efficient management of organ placement.[12] As previously discussed, adoption of a continuous distribution allocation framework is intended to improve the system's equity and make it more agile, thus improving its efficiency. This white paper examines the extent to which the ethical principles are addressed as part of the continuous distribution frameworks being developed by the OPTN's organ-specific committees. Ethical analyses of previous changes to allocation policy have suggested mixed results in terms of improving equity, efficiency, and respect for autonomy.[13,14,15]

The Committee would like the Board to consider issuing the white paper below as a guidance document and reference tool for organ specific OPTN committees to consider when developing continuous distribution as their organ allocation framework. The development of this new allocation framework impacts all members of the transplantation community and thus an ethical analysis of this framework should be accessible to all members of the transplantation community.

Practical Changes Expected with Implementing Continuous Distribution

In reviewing the work of other committees to develop organ-specific continuous distribution allocation systems, there appear to be recurring practical changes that fall within one of the categories below:

- Changes in calculating existing measurements
- Clarifying and re-prioritizing the weight of factors
- Addition of new measures

Some background on each of these changes is provided here to contextualize the ethical considerations discussed later in the white paper. While examples below may be specific to the OPTN Lung Committee's continuous distribution efforts, as they are farther along than other organ-specific committees, the following information should be considered in the context of each organ-specific committees' work, as applicable.

Changes in Calculating Existing Measurements

The current classification-based system places candidates into distinct classifications based upon their specific clinical criteria.[16] Candidates are sorted within those classifications, but cannot move between

[10] Ibid.
[11] Ibid.
[12] 42 C.F.R. § 121.8(a)
[13] Keren Ladin and Douglas W. Hanto, "Are geographic differences in transplantation inherently wrong?" *Current Opinion in Organs Transplantation* 22, no. 2 (April 2017): 174-178, https://doi.org/10.1097/MOT.0000000000000400.
[14] Sharon E. Klarman and Richard N. Formica, "The Broader Sharing of Deceased Donor Kidneys Is an Ethical and Legal Imperative," *Journal of the American Society of Nephrology* 31, no. 6 (June 2020): 1174-1176, https://doi.org/10.1681/ASN.2020020121.
[15] Joel T. Adler, Syed A. Husain, Kristen L. King, and Sumit Mohan, "Greater complexity and monitoring of the new Kidney Allocation System: Implications and unintended consequences of concentric circle kidney allocation on network complexity," *American Journal of Transplantation* (December 12, 2020), https://doi.org/10.1111/ajt.16441.
[16] OPTN Lung Transplantation Committee, *Update on the Continuous Distribution of Organs Project*, August 2020, accessed May 12, 2021, p.3, https://optn.transplant.hrsa.gov/media/3932/continuous_distribution_lungs_concept_paper_pc.pdf.

classifications. For example, most organ classification systems include geographic zones as factors, or measures of a candidate's distance from the donor hospital. Because current allocation systems utilize tiered approaches, which prioritize candidates within geographic zones before medical urgency or candidate biology, a candidate who is considered less sick than another candidate may still be prioritized on a match run by virtue of being in a zone closer to the donor hospital. No matter how much sicker the second candidate becomes than the first, the first candidate will remain at a higher priority level for obtaining an organ offer. Implementing a points-based allocation system permits other factors or variables to be accounted for when calculating each transplant candidate's score.[17]

In 2019, the OPTN Thoracic Organ Transplantation Committee detailed inequalities for candidates who reside on the edge of the hard boundaries within the existing classification-based system.[18] In the new points-based system, geography will remain a factor in allocation, but it will have a diminished role in terms of prioritizing candidates. Continuous distribution will emphasize the efficiency of organ matching and placements which require tradeoffs between medical priority, equity, and system efficiency.[19] The financial cost of transporting an organ will be taken into consideration when determining this value. With assistance from the Scientific Registry of Transplant Recipients (SRTR), the OPTN Lung Transplantation Committee has received two sets of modeling to determine how the changes in points attributed to geography will impact the overall Composite Allocation Score in order to ensure the outcome is impacted as intended.[20] Thus, in a points-based system geography will remain a factor but be recategorized as 'placement efficiency.' The weight of this attribute can vary from organ to organ and will be determined by its corresponding OPTN committee, while remaining consistent with the Final Rule and based in allocation requirements.

The associated costs of transplantation, such as the potential loss of an organ due to distance or ischemic time, the potential for slowing down the allocation process by offering organs to those unlikely to accept, or risks associated with flying to procure an organ, are all considered within the S-curve for proximity efficiency.[21] This rating scale is developed to account for additional inefficiencies that are possible with any organ procurement and transplantation. The OPTN Lung Transplantation Committee analyzed the efficiency costs associated with leaving the hospital, driving versus flying, and the point of infeasibility at which a transplant program will accept an offer on behalf of a candidate.[22]

Currently, highly sensitized candidates are listed higher on the match run in order to increase their access to transplantation. As with geography, sensitization will remain a consideration in continuous distribution but will be remodeled to fit more seamlessly with a points-based system. In the classification-based system, the Calculated Panel Reactive Antibody (CPRA) sliding scale is only used in kidney allocation but this model could be expanded and adapted to provide prioritization for highly sensitized candidates across other organ systems.[23,24] Within the development of a continuous distribution framework by the OPTN Lung Committee, literature has shown that CPRA can be a good

[17] OPTN Thoracic Organ Transplantation Committee, *Continuous Distribution of Lungs*, August 2019, accessed May 12, 2021, https://optn.transplant.hrsa.gov/media/3111/thoracic_publiccomment_201908.pdf.
[18] Ibid.
[19] Ibid.
[20] OPTN Lung, *Update*.
[21] OPTN Lung Transplantation Committee Meeting Summary, November 12, 2020, accessed May 12, 2020, https://optn.transplant.hrsa.gov/media/4238/20201112_lung_meeting-summary.pdf.
[22] Ibid.
[23] Ibid.
[24] OPTN Policy 8.4: *Kidney Allocation Points*.

predictor of the level of sensitization in thoracic candidates.[25] Considerations for CPRA and highly sensitized candidates would fall within the category of 'Candidate Biology' and the weight of this attribute can vary from organ to organ and will be determined by its corresponding OPTN Committee.

Blood type is a factor which includes both candidate and donor information and is important in every organ placement. As it stands, lung allocation classifies candidates as identical, compatible, intended incompatible, or incompatible, wherein incompatible matches are excluded from the match run and identical matches are preferred.[26] Through ongoing discussions and literature analysis, the OPTN Lung Transplantation Committee concluded the inclusion of blood type matching was to promote patient access and provide equity in the system. As a result, the OPTN Lung Transplantation Committee's continuous distribution framework will award differential point values for A, B, AB, and O patients. The value of these points will be based on data reflecting the quantity of available lung donors that is compatible with each blood type group.[27] In addition to the above mentioned factors, blood type was included in the SRTR modeling.[28] Accounting for blood type to mitigate biological disadvantages will be categorized within 'Candidate Biology' and the weight of this attribute can vary from organ to organ and will be determined by its corresponding OPTN Committee.

Changes in the value weights associated with the measurements

To assist the Lung Committee members in determining the weight of each attribute, a revealed preference analysis was employed. Such an analysis involves comparing mathematical trends to review how multiple decisions have been made. A revealed preference analysis takes the current, classification-based system and creates a baseline to measure any changes against. Results of the analysis found that placement efficiency, represented by nautical mile distance from the donor hospital, accounted for 81% of all the attributes combined. By contrast, waitlist urgency accounted for 7% and post-transplant survival accounted for only 3%.[29]

In October 2020, the Lung Committee members compared the results of the current policy against those identified through the Analytic Hierarchy Process (AHP) completed by the transplant community from August 1 through October 2, 2020, and the Lung Committee in August 2020.[30] According to the results of the community AHP exercise, pediatric access was the highest ranked factor (22.3%), followed by post-transplant survival (19.4%), waitlist urgency (17.9%), and candidate biology (17.8%). Placement efficiency accounted for only 9.8% of the community's weighting.[31] The Lung Committee's AHP exercise completed in August 2020 found waitlist urgency (27.7%), pediatric access (25.5%), and candidate biology (19.2%) as the highest weighted factors. Post-transplant survival (9.9%) was rated much lower by the Lung Committee than the community. After evaluating the previous results, the Lung Committee completed the AHP exercise again in October 2020. The five highest rated factors from the exercise were: pediatric access (31.6%), waitlist urgency (28.5%), candidate biology (17.5%), post-transplant survival (12.9%), and placement efficiency (6.3%).

[25] OPTN Lung, *Update.*
[26] OPTN Thoracic, *Continuous Distribution of Lungs*.
[27] OPTN Lung, *Update*.
[28] OPTN Lung, Meeting Summary, November 19, 2020.
[29] OPTN, *Continuous Distribution of Lungs: Summer 2020 Prioritization Exercise – Community Results*, October 15, 2020, https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf (accessed June 7, 2021).
[30] Ibid.
[31] Ibid.

Following the Lung Committee's finalizing the weights it will propose for continuous distribution, pediatric access, waitlist urgency, and post-transplant survival are prioritized much higher than they are under the current classification based system. It is also expected that placement efficiency will have a substantially lower priority.

Addition of New Measures

In addition to transforming components of factors used in current policy, the Lung Committee used their development process to identify new attributes for inclusion in the allocation system. In particular, the Lung Committee found opportunities to incorporate factors that can be described as addressing inequities in access to transplantation. The new factors consist of candidate height, whether a candidate is a prior living donor, pediatric status, and highly sensitized candidates. The Lung Committee considered other factors for inclusion, such as the likelihood of organ acceptance, the use of ex vivo perfusion, and HLA matching, but chose to exclude them during their current development effort.[32]

Some transplantation candidates' biological characteristics make it more difficult to match them with organs. For example, it may be difficult to match an organ with a candidate who is very short or very tall. A typical sized adult heart, for example, may be too large for an adult with a small stature. Conversely, a typical sized adult heart may be too small for a candidate who is above average in height. However, height is not addressed in the current classification-based system used to allocate lungs. As part of the Lung Committee's efforts to develop a continuous distribution allocation system, the Committee considered the medical literature suggesting that a candidate's height can influence access to transplantation.[33] As a result, the Lung Committee members agreed to include the use of priority points dependent on candidate height.

The Lung Committee also added new attributes for candidates who are prior living donors or pediatric candidates. Both attributes are included under the patient access factor. Although pediatric status is addressed through the medical urgency and post-transplant survival factors, the Lung Committee also created a separate pediatric priority attribute as part of the patient access factor.[34] The Committee decided that the rating scales for both prior living donors and pediatric age candidates would be binary—candidates get either all or none of the points. Under the proposed system, a candidate who is a prior living donor will receive a pre-determined amount of points, regardless of other considerations. The same is true for a candidate who meets the pediatric age criteria established by the Committee. Candidates who are neither a prior living donor or pediatric receive no points in those attributes.[35]

Using Desired Outcomes to Optimize a Continuous Distribution Framework

The Lung Committee has employed several different methodological approaches while developing a continuous distribution framework. As previously discussed, the Analytic Hierarchy Process was used to help the Lung Committee members consider the appropriate weighting of the factors. A revealed preference analysis was used to establish a baseline of weights according to existing lung policy. The

[32] OPTN Lung, *Update.*
[33] Jessica L. Sell, et al, "Short Stature and Access to Lung Transplantation in the United States: A Cohort Study," *American Journal of Respiratory and Critical Care Medicine* 193, no. 6 (2016): 681-688, https://doi.org/10.1164/rccm.201507-1279OC.
[34] OPTN Lung, *Update*.
[35] OPTN Lung, *Update*.

Committee also utilized a policy development framework composed of quantitative and analytical methods to optimize the chosen outcomes. Scientific literature addressing the topic shows that this approach successfully incorporates ethical considerations.

The "optimization" approach starts with decision-makers identifying the desired outcomes of a future system, as well as any potential constraints they wish to impose on the outcomes.[36] For example, a committee might identify minimizing waiting list mortality as the most desired outcome, but would like to achieve this while still maintaining the same placement efficiency and not increasing transplant rate disparities as a result of blood type. The proposed desired outcomes are then subjected to an analytics optimization process that determines the best policy solution. For continuous distribution, this involved identifying the optimal weights for each of the already established factors. Those weights were then used in simulation modeling to confirm the outcomes and check for unintended consequences.

In addition to identifying the best factor weights, the optimization process has several other advantages. The framework encourages stakeholders to have deeper and more meaningful discussions about what they wish to accomplish through the policy changes. It does this by very efficiently and quickly producing the optimized results. Stakeholders can then use the results to further enhance their desired outcomes. Using this approach, ethical considerations can be included at the outset of any policy development activity, and throughout the rest of the process.

Furthermore, it can be extremely difficult to determine what the outcomes might be prior to performing any analysis when trying to determine factor weights. In circumstances where there is a lack of information, it makes sense for the desired outcomes to guide the weighting of the factors, rather than the other way around. This can be most advantageous to ethicists for example, who may hold strong views about what should be the desired outcomes, but have less information about how to tangibly reach that outcome.

Another benefit is that tradeoffs between factors can be modeled at a very granular level. Stakeholders can view a full range of results whereas without optimization there may only be a few options to consider. This type of analysis is valuable in helping decision makers understand the relative impact that changes to a specific weight may have on certain variables. As a result, organ-specific committees can continue refining their proposed allocation frameworks in order to more accurately and objectively prioritize candidates, resulting in more equitable allocation of organs based on factors such as waiting list mortality and post-transplant outcomes.[37]

The Normative Justification for Adopting Continuous Distribution

What Does an Ideal System of Organ Allocation Look Like?

The Ideal Features of an Allocation System

To examine whether continuous distribution represents an improvement over the previous system of allocation, it is helpful first to consider what an ideal allocation system should do. For the upheaval associated with changing organ allocation to be worth the effort, its benefit ought to be clear. A system

[36] Ted Papalexopoulos and Nikos Trichakis, "Continuous Distribution: Tradeoffs through Optimization," presentation to OPTN Ethics Committee (April 28, 2021), https://optn.transplant.hrsa.gov/media/4624/20210428_ethics_meeting_summary.pdf.
[37] Dimitris Bertsimas, et al, "Development and validation of an optimized prediction of mortality for candidates awaiting liver transplantation," *American Journal of Transplant* 19, no. 4 (April 2019):1109-1118, https://doi.org/10.1111/ajt.15172.

of organ allocation should seek to achieve the greatest good for the greatest number of people, while reducing waste and promoting placement efficiency, thereby upholding the principle of *utility*. An organ transplantation system should be inclusive, and not leave vulnerable candidates at a further disadvantage, instead achieving the most sustainably equitable approach to organ allocation, thereby reflecting the principle of *equity*. Finally, the new system would ideally be easily understandable, increasing candidates' ability to participate in shared decision-making and facilitating access to a process which directly affects them, thereby promoting the principles of *transparency and autonomy.*

The ideal organ allocation system will furthermore successfully be able to accommodate all three of the ethical principles of utility, equity, and transparency (and autonomy), with a mechanism for making necessary adjustments on the occasions these principles come to stand in tension with one another. Thus, it would not adopt a monolithic, or built-in hierarchical, approach to dealing with attributes. For example, the ideal allocation system would not favor an outcome that only increases utility to the exclusion of other considerations. It should be fluid, comprehensive and flexible, attentive to both population-level needs and to the needs of particular individuals in special circumstances. An organ allocation system should on the one hand have enough power to be operative on a large scale, dealing with many relevant variables, while on the other have a mechanism for remaining aware of the needs and circumstances of a range of candidates, including disadvantaged individuals, pediatric candidates, prior living donors, candidates who live far from urban settings, and so forth.

It is therefore paramount that a new system of allocation be able to simultaneously accommodate many attributes at once, and not unduly preference or focus on any one particular attribute or measurement. This is challenging. Establishing the necessary and sufficient set of metrics and measurements which should be factored into the listing of patients, determining what constitutes a widely embraced set of best practices, and agreeing on uniform definitions of "successful transplant," all remain elusive. Yet, there is growing agreement within the transplant community on the need for a more comprehensive assessment of the many attributes which go into determining priority for patient listing.[38] To take an example, the current emphasis in many transplant centers on an attribute such as short-term post-transplant outcomes is neither able to look at the full picture captured by a large population, nor positioned to integrate into its method of listing candidates other "'patient-driven' allocation metrics such as waitlist mortality, turndown rates, and time to transplantation, as more meaningful metrics that incentivize utilization."[39] A healthy and functioning allocation system should be able to correct for the social disparities which, if left to inertia, would persist absent this extra attention, with the potential to unintentionally disadvantage some candidates.

That a system of allocation is, *de facto*, poised to be revised should be seen as an opportunity to construct a more comprehensive, equitable, and transparent model than the one which came before. According to our current, classification-based system, once a candidate is placed into a distinctive category based on clinical criteria within a particular geographical area, he or she cannot move to a

[38] "Current Opinions in Organ Allocation," *American Journal of Transplantation* 18, no. 11 (2018), 2625-34. https://doi.org/10.1111/ajt.15094.
[39] Ibid.

different category.[40,41,42] In this regard, geographic areas become rigid and distinct boundaries which preclude any particular candidate's being given greater consideration based on medical urgency or any other number of attributes. These edge cases can appear to treat similar patients dissimilarly, raising concerns of fairness, in addition to concerns about utility and autonomy. Moving past a classification-based system would likely constitute an overall improvement because at that point a whole host of variables could be considered simultaneously as relevant in determining listing. As technology's frontiers advance, and as it becomes easier to address concerns about ischemic time when procured organs are moved from one place to another, an allocation system can become less constrained to give primacy to any one factor such as a candidate's distance from the donor hospital where a transplantation will take place.

This considerably opens up the possibility of a more efficient and more equitable system of allocation. Specifically, it allows for the possibility of revisiting the full range of relevant measurements for listing, how they are to be weighted, and what determines how new measurements will be introduced. By recourse to a method of comprehensive *scoring*, and self-consciously constructing an algorithm for determining which will reflect the values we wish to see emphasized at any one point in time, we might give ourselves more tools than we previously had. This observation leaves open the question of *what* these measurements should be, *how* they should be weighted, and *whether* and *how* more measurements should be additionally considered at any point in time. The present claim is only that a way of allocating organs which is guided by specified desired outcomes is, on the whole, better than one where the measurements themselves determine an outcome, dispassionately and without enough attention either to the needs of a population as a whole or to the idiosyncratic needs of specific groups.

The Virtue of Transparency

Having addressed what an ideal allocation system should do, the next thing to do is consider the patient's perspective. Patients, and the public whose organ donations sustain the transplant system, are entitled to an allocation system which is clear, easy to understand, and empowers them in a context that is otherwise overwhelming. For instance, research has reported that candidate populations face excessive rates of unemployment and the need for support in activities of daily living.[43,44,45] this is relevant if only to point out the enormity of what patients in need of transplantation are already going through, increasing the burden on caretakers to make the transplantation process as easy for them as possible. Currently, patients face a sometimes difficult-to-understanding listing process where available

[40] OPTN Thoracic Organ Transplantation Committee, *Continuous Distribution of Lungs Concept Paper* (2018), p. 4, https://optn.transplant.hrsa.gov/media/3111/thoracic_publiccomment_201908.pdf (Accessed June 10, 2021). J.S. Snyder et al., "Organ distribution without geographic boundaries: A possible framework for organ allocation," Am J Transplant 18, no. 11 (Nov 2018), https://doi.org/10.1111/ajt.15115: Jon Snyder, "Systems without Geographic Boundaries" (paper present at the OPTN Ad Hoc Geography Committee meeting, March 26, 2018).

[41] Jon J. Snyder, et al, "Organ distribution without geographic boundaries: A possible framework for organ allocation," *American journal of transplantation* 18, no. 11 (2018): 2635-2640, https://doi.org/10.1111/ajt.15115:

[42] Jon Snyder, "Systems without Geographic Boundaries" (paper present at the OPTN Ad Hoc Geography Committee meeting, March 26, 2018).

[43] Fredrik Aberg, "From prolonging life to prolonging working life: Tackling unemployment among liver-transplant recipients," *World Journal of Gastroenterology* 22, no. 14 (2013): 3701-3711, https://doi.org/10.3748/wjg.v22.i14.3701.

[44] "Unemployment among dialysis patients is a complex issue," *Nephrology News & Issues,* January 6, 2016, https://www.healio.com/news/nephrology/20180227/unemployment-among-dialysis-patients-is-a-complex.

[45] Kevin F. Erickson, Bo Zhao, Vivian Ho, and Wolfgang C. Winkelmayer, "Employment among Patients Starting Dialysis in the United States," *Clinical Journal of the American Society of Nephrology* 13, no. 2 (2018): 265-273, https://doi.org/10.2215/CJN.06470617.

data is both limited and hard to understand and in which the criteria for evaluation used by transplantation programs can seem subjectively and inconsistently applied by the transplant programs.[46,47,48] Because of these challenging circumstances, it is all the more important that once matriculated through to the waitlist phase, the allocation process is one which can be easily understood and welcomes shared decision-making. With such high stakes, patients need to know they are entering this process on a level playing field.

Transparency and autonomy are inextricably connected. Transparency without the means to make meaningful health decisions may contribute to frustration and a feeling of helplessness while a rootless autonomy disjointed from situational clarity allows for uninformed action. Hence, an ideal system of allocation will acknowledge candidates' uphill battle to understand their position and to allow them to self-determine to the extent that self-determination is at all possible. Ideally, patients would be able to contribute to the activity of characterizing their medical profiles. The process would be sufficiently transparent to eliminate bias, aligning with candidate priorities. While it is unclear at the moment whether any proposed scoring system would be able to achieve these lofty objectives of patient participation, the perfect should not be the enemy of good and progress should be pursued; the process could at least include an effort to solicit candidate input at various junctures to assure that the goals the construction of the composite allocation score are intended to reflect are in keeping with the evolving concerns of patients over time, and in fact, the concerns of a wide variety of stakeholders. Such an allocation system could have a goal of being completely evidence-based where it would be clear to all onlookers that everyone awaiting an organ played by the same rules. Relevant attributes would be clearly understood, and there would be clear objectives for improving individual patient rankings in the case of each attribute. Moreover, candidate (and public) input would be integrated into composite score development and weighting.

It must be emphasized that these are ideals. It is a tall order to expect that any one modification to an allocation system could provide the impetus needed to provide optimal utility, perfectly equitable treatment, and maximal transparency and autonomy. But it is not too much to hope that the shift from one kind of allocation system to another would result in a significantly improved situation for candidates awaiting transplantation.

The Need for Incorporating Guardrails into Machine Learning for Healthcare Models

An allocation system should incorporate guardrails into Machine Learning for Healthcare (MLHC) models on which it may come to rely. It should be able to reflect the goals and values its creators have identified as important on behalf of all of the stakeholders and future candidates for whom it is meant to work. These desired outcomes, presumably able to be revised over time, should always be what is driving the justification for existing measurements, the manner in which we assign weights to these measurements, and the introduction of new measurements. An allocation system should not be seen as reducible to a super calculator, captive to its own computational functions. Rather, it should be able to incorporate new information and data points (e.g., with regard to biological attributes) as we learn of them in due course, reflecting adjusted desired outcomes as our deliberations over end-goal values play out.

[46] Melania Calestani, et al. "Patient Attitudes Towards Kidney Transplant Listing: Qualitative Findings from the ATTOM Study." Nephrology, dialysis, transplantation 29, no. 11 (2014): 2144–2150.
[47] Allison Tong, et al., "'Suspended in a Paradox'—patient Attitudes to Wait-listing for Kidney Transplantation: Systematic Review and Thematic Synthesis of Qualitative Studies." Transplant international 28, no. 7 (2015): 771–787.
[48] Cory R. Schaffhausen, et al., "Comparing Pretransplant and Posttransplant Outcomes When Choosing a Transplant Center: Focus Groups and a Randomized Survey." Transplantation 104, no. 1 (2020): 201–210.

Otherwise, we will merely have replaced one sort of classification system with a more complicated one, at a further level removed. One of the advantages of a scoring system is that it is has the potential to be driven by values, by "working backwards," determining measurements and weights according to an underlying ethics-focused and balanced account of the values we wish ultimately to preference at any one point in time.

The Normative Case for Continuous Distribution

Can continuous distribution do a better job than the current allocation system of approximating the ideals just described? The Ethics Committee takes the position that it can and now proceeds to make this case. We note, however, the significant caveat that many detailed theoretical and practical questions remain with regard to *how* continuous distribution will ultimately manage to be the comprehensive, optimizing, waste-reducing, equitable, and transparent reform which it has the potential to be. While we intend to make a vigorous case on its behalf, in the section that follows we set out to apply just as much vigor to presenting challenges which remain upon thinking about how to implement continuous distribution.

Moving Beyond Distinct Geographic Boundaries

To this end, in this section the Ethics Committee provides the normative justification for a shift from a classification to a points-based system. As explained above, "classifications" group similar patients together, where access is given to a class of individuals based on a few broad parameters, although the individuals themselves may have substantially different medical conditions (similar to vaccine distribution). On the other hand, ethical concerns related to the arbitrariness of "edge cases" could be alleviated by continuous distribution. For instance, a points-based system allows for all patients of comparable priority to be considered as eligible for transplantation at the same time. A points-based system is set up to distribute organs *continuously:* distribution and allocation is fluid and ongoing. Correspondingly, for example, as opposed to using geography in a manner which creates restrictive categories, geography in continuous distribution is more seamlessly integrated into allocation by determining how a recipient's distance from a donor aligns with the different requirements found in NOTA and the OPTN Final Rule: medical urgency, efficiency, outcomes, and patient access, factors which, when considered alongside one another, create a more open and adaptable distribution of resources.[49]

As described above, the composite scores patients receive in continuous distribution, once calculated, will demonstrate priorities for particular candidates. Patients' composite scores are by definition always in flux as more people become transplanted, go on and off the waitlist, and candidates' health statuses are re-evaluated. In a classification system, one who lives just outside a 250 nautical mile boundary could be precluded from a life-saving resource; such a policy appears arbitrary and unjust. Thus, by taking into account geographical feasibility but integrating this consideration with attributes constitutive of medical priority, the move to continuous distribution is positioned to better achieve a balance of equity in access, while optimizing utility.[50] The following sub-sections examine the relevant ethical concepts in isolation, one by one, to explain how the move from a classification system to a scoring system of allocation coherently aligns with each principle.

[49] OPTN Thoracic Organ Transplantation Committee, *Continuous Distribution of Lungs*, August 2019, accessed May 12, 2021, https://optn.transplant.hrsa.gov/media/3111/thoracic_publiccomment_201908.pdf.

[50] Jon J. Snyder et al., "Organ distribution without geographic boundaries: A possible framework for organ allocation," *American Journal of Transplantation* 18, no. 11 (2018): 2635-2640, https://doi.org/10.1111/ajt.15115.

Utility

With improved technology comes new possibilities for greater accuracy and precision in considering both patient-factors and patient-donor match factors. This allows not only for a reduction in arbitrariness in listing and prioritizing patients, but also for evidence-based improvement in some outcomes through recourse to mathematical optimization. Just as technology is able to allow for the safe movement of organs across greater distances, so does it also enable those developing an allocation system to better fulfill specified objectives of the principle of utility in a number of ways. The implementation of a composite allocation score allows for the appreciation of relevant patient medical attributes simultaneously.[51] This is critical both in terms of increasing the overall number of transplants that can be performed on an annual basis and in terms of preserving organs in the transplant process, that is, in terms of placement efficiency. Continuous distribution, which relies on the construction of the algorithm used to create a composite score *can* accommodate criteria as various as: medical urgency; donor/candidate compatibility (feasibility); candidate waiting time; graft survival; logistics and cost; in addition to any equity concerns which might subsequently be folded into their own metrics, such as social priority (pediatric cases and priority given to vulnerable groups).[52]

One way of understanding the value of continuous distribution is that it offers a way *optimally* to reflect the end-goals of the system. That is true whatever those end goals are and how they are weighed. This is to say, *if* the process starts with decision-makers identifying the desired outcomes, as well as any additional values-based considerations they want to import into the calculation leading to the composite score allocation, then it is possible to accommodate these many criteria optimally.[53]

Furthermore, if the scoring system is sophisticated enough, the weighting of these criteria can be further refined based on what we learn about specific organs case by case. A move towards a scoring system opens up room for a targeted approach to optimizing the pursuit of OPTN's obligations under the Final Rule, including: reducing the inherent differences in the ratio of donor supply and demand across the country; reducing travel time expected to have a clinically significant effect on ischemic time and organ quality; increasing organ utilization; and preserving organs.[54]

Finally, the move to a scoring system is one which positions operators of the allocation system, e.g., OPOs, to avail themselves of the most economical and intelligent decision-making tools when solving the many, and often distinctive, distribution and matching problems which a complex allocation system in a big population of stakeholders precipitates. By contrast, a classification system dependent on a unit of bounded areas constrains would-be problem solvers. In this respect, whatever the details in place are in terms of weighting and arriving at a composite allocation score, all other things being equal, a move to continuous distribution is supported by the principle of utility (and placement efficiency), for such a move facilitates the most complete, flexible, and resource-preserving approach to matching candidates to donors.

[51] Papalexopoulos "Continuous."
[52] Bertram L. Kasiske, Joshua Pyke, and Jon J. Snyder, "Continuous distribution as an organ allocation framework," *Current Opinion in Organ Transplantation* 25, no. 2 (April 2020): 115-121, https://doi.org/10.1097/MOT.0000000000000733.
[53] Papalexopoulos "Continuous."
[54] OPTN/UNOS Ad Hoc Geography Committee, *Frameworks for Organ Distribution*, December 2018, accessed May 28, 2021, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf.

Equity

A case can also be made for continuous distribution on the bases of egalitarian considerations and respect for persons. While geography is an allowable consideration under the provisions of the Final Rule[55], the removal of distinct geographic boundaries directly supports the principle of equity by ensuring that the accident of one's place of residence no longer prevents access to organs for transplantation. The elimination of distinct boundaries smooths access to organ transplantation across the United States, reducing geographic differences in access to transplant. The framework has the advantage of affording the allocation system the flexibility to take into account the idiosyncratic needs of each prospective recipient rather than utilizing a cruder method of treating patients as falling within a particular group and then assessing their eligibility according to a singular group characteristic.[56] Research findings reflect this advantage in light of the principle of equity accordingly:

> *Ascribing characteristics of broad geographic areas to individuals living in those areas is an ecological fallacy to be avoided. It is not appropriate to assign risks, or ease of access to organ transplant, to individuals within a community grouping based on geography or socioeconomic status because not everyone in the grouping shares those characteristics. A basic tenet of organ allocation in the United States is to allocate and distribute organs to individuals and not to groups or geographic regions or the transplant programs representing them. A continuous distribution system is optimally designed to do this and to avoid organ distribution based on geographic or other boundaries and arbitrary groupings.*[57]

As long as the framework is implemented accurately, a composite allocation score has the potential to act as a comprehensive and precise instrument of allocation, capable of appreciating the needs and claims of more candidates than the previous system could.

Success in this endeavor is dependent on the extent to which the composite score is sufficiently comprehensive and sensitive to the different circumstances surrounding all prospective candidates. For example, safeguards need to be established that prevent individuals in any way from gaming the process, as well as implement measures to prevent such individuals (or their advocates acting on their behalf) from obtaining transplants sooner than warranted by their actual disease severity; while such individuals may individually benefit when this occurs, the system, manipulated, overall can suffer.[58] By the same token, in order for the composite allocation score to be equitable, there needs to be room for critical correctives which can proactively be deployed to offset already existing disparities, otherwise ignored or insufficiently addressed in a mechanism that only considers how to optimize the weighting of biological attributes among a large population. These caveats noted, at least in principle, that the removal of distinct boundaries and the integration of geographical considerations (insofar as they are warranted by the OPTN Final Rule) into a scoring system that carefully considers a patient's medical profile represents an upgrade over the classification system, which is, as previously stated, at some level arbitrary. To be sure, the crafting of the composite allocation in the movement to continuous

[55] "[A]llocation policies…shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." 42 C.F.R. § 121.8(a)(8) (emphasis added).
[56] Brendan Parent and Arthur L. Caplan, "Fair is fair: we must re-allocate livers for transplant," *BMC Medical Ethics* 18, no. 26 (2017), https://doi.org/10.1186/s12910-017-0186-9.
[57] Kasiske, "Continuous."
[58] OPTN Ethics Committee, *Manipulation of the Organ Allocation System Waitlist Priority trough the Escalation of Medical Therapies,* June 2018, accessed May 29, 2021, https://optn.transplant.hrsa.gov/media/2500/ethics_whitepaper_201806.pdf.

distribution has the ability to be fluid and flexible enough to incorporate values which are likely to protect disadvantaged groups.

Finally, in terms of equity, the sponsoring committees will need to consider how access to transplantation is impacted by a move to continuous distribution. For example, the removal of distinct geographic boundaries corrects not just for the constraints built into a classification system as such, but also counteracts an approach that unduly emphasizes the priority of nearby neighbors over the needy everywhere. Stated differently, a framework of continuous distribution promotes inclusivity, overcoming the undue disqualification of consideration of recipients based solely on their distance from the transplant center of their would-be donor. Deceased and living donation, both, represent altruistic instances of giving the gift of life, wonderful exemplifications of other-regard. There is no reason that the injunction to "love the neighbor as thyself," appealing to many across a wide variety of religious and secular traditions, should not also come to include the "one far off," the stranger, not just the "near and dear."[59] While historically the concerns about the use of Donation Service Areas (DSA) as a unit of allocation were originally about efficiency, and there are no doubt reasons also to be concerned that attention to equity might direct us to pause before moving beyond any geographical areas, *theoretically* the notion of one, national and inclusive system is consistent with the ideal of "leaving no one behind." As technology increasingly allows for the preservation of the quality of donated deceased organs as they are transported over wider distances, the focus of concern might extend beyond specific areas, while still taking into consideration geographical proximity needs and characteristics. The move to continuous distribution thus smooths boundaries in such a way so as to allow for reasonable (i.e., non-arbitrary) geographic considerations, and allows for the accounting of more granular factors that if not considered could potentially misclassify or exclude patients.

Transparency and Autonomy

Once the move to a scoring system is complete, presumably candidates will be informed of all of the factors that go into arriving at a composite allocation score as well as the reasons for why some attributes are given priority over others. Ideally, every prospective stakeholder will have an opportunity to be heard and to be an active participant in the allocation process, at least in terms of contributing to the end goals the composite allocation score is meant to achieve. While there are complicating factors yet to be spelled out, a move to continuous distribution may in general be supported by the principles of transparency and autonomy. *Transparent* systems are free from obfuscation, deceit, and pretense, readily understood by the ones they impact, and free of complexities which block candidates from accessing critical information.[60] In this regard, transparent systems fuel a candidate's *autonomy*, i.e., one's ability to be freely self-directing and have a say in what happens to oneself in the future.

To candidates awaiting notification of an organ offer, a classification system which groups future recipients strictly in bounded areas for determining eligibility can come across as hard to understand and beyond their control. This, in turn, gives the perception that whether or not one has the freedom to avail oneself of a life-saving resource is a matter of sheer luck, independent of one's medical situation.

[59] Peter Singer, *The Expanding Circle: Ethics, Evolution, and Moral Progress* (Princeton, NJ: Princeton University Press, 1981).

[60] Definitions of "transparency" vary in sources from medical ethics. Some emphasize the notion of freedom from obfuscation and deceit, while others emphasize access to the relevant data, which, to be transparent, needs of be made clear and relatively free of complexity. In this white paper we take the view that both of these aspects of transparency are important. For a source that emphasizes both of these aspects, see: Maria Castelucci and Shelby Livingston, "Achieving Transparency in Healthcare," Modern Healthcare (September, 2017); https://www.modernhealthcare.com/reports/achieving-transparency-in-healthcare/#!/.

To some patients waiting to be added to the waitlist this reality can seem arbitrary, opaque, and frustrating. By contrast, a move to a scoring system has the potential to furnish candidates with the means to better understand all of the factors that go into arriving at a composite medical profile as well as the reasons for why some attributes are given priority over others. Ideally, everyone whom the allocation system affected would have an opportunity to be heard, in the design for the new continuous distribution framework: at the stage of building the calculator for the allocation score, and, once data starts to come in, at the subsequent stage of offering suggestions for how to refine this process to make it more equitable. By expanding and changing the priority given to the eligibility factors—and reducing the amount of occasions whereby one could be denied consideration for allocation simply because of one's blood type or where one lives—the new allocation system in continuous distribution will be less likely to run afoul of maintaining the public's trust, as it will be more likely than the one it is replacing to take into consideration the specific needs of all whom it affects.

It will also have an impact on the ability for candidates themselves to predict or understand their likelihood of organ transplantation. In principle, one of the potential advantages of moving to a framework of continuous distribution is that candidates who are now assigned a composite allocation score can be in a position to see more clearly than they did before where they stand in terms of their eligibility for being listed for a new organ.[61] This remains to be seen. In this respect, the shift represents for candidates a potential upgrade in terms of their own autonomous involvement in the transplantation process.

The move to a scoring system of allocation therefore has the potential to open up new options for future recipients. With the introduction of weighted attributes which will be factored into the composition allocation score, the new allocation system acquires the potential to be more *predictable*, where everyone affected knows where they stand from the outset. Furthermore, while the composite scores patients receive in continuous distribution will preference some candidates over others, these determinations are always in the process of being recalibrated as more people become transplanted and the circumstances surrounding candidates' specific healthcare trajectories change. The inherent attention to the *revisability* of composite scores in the new allocation process, in contrast to the finality presented by distinctive boundaries, on a collective level means legitimate and ongoing hope for everyone who is desperately awaiting an organ. Thus, both in terms of predictability and revisability, which also bear on the principles of equity and even efficiency, the move to continuous distribution significantly buttresses patient autonomy and makes the allocation system more transparent.

Finally, the move to a composite allocation score presents opportunities for patient involvement in the process of weighing in on end goals that the former classification system did not. Sorting out which attributes are ultimately emphasized in arriving at this score, as well as adjudicating their relative importance among one another, is in large part a function of procedural and distributive justice whereby a multitude of voices can be consulted in order to respect all the deserving parties who have a stake. In principle, involving all of these parties in this manner seems doable. If patients themselves are involved in the construction and subsequent revision of the process by which composite scores are developed, and their perspective is solicited on an ongoing basis, they are most likely to feel that there is an earnest regard for procuring their consent. The fluid nature of continuous distribution features opportunities to examine and revise the scoring system on a periodic basis, where hitherto neglected considerations may be given a fresh hearing. What counts and why in this process could be made to be open and available for all to scrutinize at any time, reducing the sense that one's fate was coerced or predetermined.

[61] Kasiske, "Continuous."

Challenges Which Persist, or May Be Exacerbated, in a Move to Continuous Distribution

This section presents a non-exhaustive list of various challenges which persist when implementing continuous distribution. These challenges can be grouped into five categories: (1) theoretical concerns (particularly as these relate to the construction of the composite allocation score); (2) concerns related to utility; (3) concerns related to equity; (4) concerns related to transparency and autonomy; and (5) pragmatic concerns which address foreseeable problems which are sure to arise upon implementation. In this white paper, our goal is merely to raise and briefly describe these concerns. Answering them is the work of future white papers and policies.

Previous sections of this white paper have demonstrated that a case can be made to support a move to continuous distribution as assessed according to the principles of utility (and placement efficiency), equity, and transparency and autonomy, but we have attempted to state this case hypothetically. Continuous distribution has the *potential* to represent a significant improvement beyond where we currently are, but it is crucial to interrogate the assumptions made in drawing such a conclusion. Will a move beyond a classification system be as fair to *all* candidates while resulting in more transplantations as the overview suggests? Will the process at which composite scores are determined welcome the participation of patients, be transparent and easily understood by them, making them more individually autonomous in the end?

While a scoring system could be a great boon judged in terms of the principle of utility, even the project of determining what are the appropriate *starting* set of attributes for arriving at a composite score in order to most accurately captures one's medical profile, is extremely complex. Similar to all algorithms, just in terms of predicting medical outcomes, estimates depend on factors included in the models and the quality of available data. This calculus may additionally vary from organ to organ. In terms of equity, as well, things become complicated quickly. To refer to an example raised by Ladin and Hanto, transplantation policies "do not function in a vacuum;" candidates from one geographical area are not all equally privileged, as a result of which some communities can afford less than others to divest themselves of the especially precious resources they do have.[62] To uphold the principle of equity, we need to ensure that transplantation policies do not inadvertently exacerbate already existing disparities. Finally, with regard to transparency and autonomy, there is a question about whether moving to individual composite scores will overwhelm candidates. Minimally, composite scores (and the individual attribute ratings which comprise it) require balancing at many levels and may lead to strange comparisons (optimal efficiency vs optimal equity, etc.) that are bewildering to sort through even for the most seasoned negotiator of an organ allocation system.

Pragmatic issues with implementing continuous distribution arise as well. In the concluding portion of this section, the white paper mentions some of the potential complexities associated with the development and implementation of continuous distribution, and sets out to describe, if not yet assess, the ethical and pragmatic consequences that may result from adding or removing certain eligibility factors, as well as re-prioritizing the importance of such factors. How will committees consider a potential surge of transportation of organs from one patient population to another? How will the

[62] Keren Ladin and Douglas W. Hanto, "Equitable Access Is Not a Secondary Goal of Organ Allocation," *American Journal of Transplantation* 17, no. 12 (June 2017), https://doi.org/10.1111/ajt.14387.

committees consider balancing the quality of organs that are offered nearby versus further away? We will also address the ethical considerations associated with expense and logistics. For example, how might equity and utility be impacted by changes in the costs associated with organ transplantation as part of a move to continuous distribution? In mentioning these complicating factors, the Committee's goal is to be realistic about the implementation of the new framework, seeking answers for some of the practical quandaries which are bound to arise even if the case that the move to continuous distribution is normatively justified and can successfully be made, and suggest what questions the sponsoring committees should ask during the development of continuous distribution.

Theoretical Concerns and the Composite Allocation Score

Fundamentally, shifting from a classification-based system to a continuous distribution system allows for the simultaneous consideration of multiple attributes, and an opportunity to reconsider the weighting of attributes in determining a final priority list. Although intuitively appealing, a points-based allocation framework faces a number of challenges, largely related to the development and implementation of the CAS. While shifting to a continuous distribution model is appealing for the reasons stated above, its promise is conditional on achieving optimal prioritization, engaging stakeholders appropriately, and continuously monitoring and nimbly responding to unwanted variation in outcomes. These are largely dependent on how attributes are defined, which attributes are included, how subsequent weighting priorities are determined, and the process for revising the CAS continuously to reflect the latest evidence-base and adhere to allocation priorities. Three theoretical concerns arise in considering a shift to continuous distribution, though it should be noted that some of these concerns may apply to any change to the organ allocation system.

The Perils of Path Dependency in Setting the Goals of Continuous Distribution

A key question that the transplant community must reconcile is whether the CAS should be developed to best align with the outcomes of recent pre-continuous distribution match runs (and as such, reflect current policy priorities), or whether it ought to start from a blank slate, and attempt to optimize the balance between principles of equity and efficiency. Starting from the current model, as the Lung Committee has, presents the advantage that the shift to continuous distribution does not disrupt current policy priorities, but rather allows for minor changes that increase efficiency while not harming or worsening equity across a number of domains, including: blood type, race, and pediatric status. It should be noted that the Lung Committee intends to positively impact prior living donors and sensitized candidates. The Kidney Committee intends to positively impact pediatrics and highly sensitized candidates. This reflects small, incremental improvement that, while desirable, may fall short of the promise and potential of organ allocation reform. In other words, such an application of continuous distribution may present marginal improvement, while requiring drastic changes to the organ allocation system and substantial upheaval on the part of many transplant programs. It does not necessarily transform the organ allocation system to one that is closer to ideal (see above): one more likely to truly achieve equitable access to transplantation while maintaining efficiency. Other organ committees have expressed interest in using continuous distribution to make allocation more efficient but maintaining a distribution closely resembling the current landscape.

What are the harms to starting with the current system and adapting continuous distribution to achieve similar distribution of outcomes as the present system or incrementally improve upon it? While a benefit may be that the shift to continuous distribution would not affect current policy priorities which have been widely adopted by the transplant community, path dependency also ensures that any existing

bias in organ allocation is carried into the new organ allocation system.[63,64,65] By specifying the same attributes, especially if the goal is to have continuous distribution closely mirror the distribution of organs achieved by the current system, the new allocation model may inadvertently smuggle in any existing bias stemming from structural factors, perpetuating unwanted disparities. Determining the weighting of each attribute in the CAS poses a significant challenge to the success of continuous distribution. Yet, how to achieve the optimal balance remains unclear. Prioritizing one factor or set of factors (e.g., utility) reduces the relative import of other categories, such as justice, which may improve outcomes such as graft survival, but at the cost of retaining unwanted disparities, for example.

While adjusting the CAS is possible, it will likely require phasing, and is subject to path dependency, making any future change more limited and incremental. Rebalancing the CAS may result in a distribution that is even less predictable in terms of impact on specific populations. This is especially true because continuous distribution projections are based on historical data, which include limited representation of underserved populations. This limits the accuracy of future projections and makes it difficult to anticipate consequences for those groups and should not be understated. While this is not an issue that is unique to CAS (or any allocation change for that matter) and these issues may arise from systemic factors, attention to underrepresented, or persistently disadvantaged populations is essential. The transplantation community ought to pay attention to how the CAS system changes distribution for the most vulnerable – who stands to gain and who stands to lose access to organs? Structural disadvantage, by race or other protected category (e.g., deprioritizing people with disabilities) would be an invidious and problematic result. This is not meant to imply that such disadvantage will be exacerbated by CAS; in fact, it may be alleviated by ethical guardrails. Still, ensuring that allocation systems do not perpetuate existing disadvantages, if any, must be a primary goal of any major change to system of organ allocation.[66]

As such, an intentional approach should be taken in developing the CAS. In developing the CAS and more broadly in considering continuous distribution, attention must be paid to understanding and responding to the mechanisms underlying structural, institutional, interpersonal, and internalized discrimination. In the context of racism, Purnell et al. explain:

> "*Structural racism refers to the mechanisms by which societies foster discrimination through systems of employment, housing, education, income, healthcare, and criminal justice that reinforce discriminatory beliefs, values, and distribution of resources. Within the context of transplantation, examples of structural racism include racial disparities in employment, wealth, and private health insurance; access to and utilization of primary healthcare and specialty care*

[63] David Wilsford, "Path Dependency, or Why History Makes It Difficult but Not Impossible to Reform Health Care Systems in a Big Way," *Journal of Public Policy* 14, no. 3 (November 2008): 251-283, https://doi.org/10.1017/S0143814X00007285.
[64] Paul Pierson, *Politics in Time: History, Institutions, and Social Analysis* (Princeton, NJ: Princeton University Press, 2004).
[65] M. Rosario Perello-Marin, Juan A. Marin-Garcia, and Javier Marcos-Cuevas, "Towards a path dependence approach to study management innovation," *Management Decision* 51, no. 5 (May 2013): 1037-1046, https://doi.org/10.1108/MD-08-2012-0605.
[66] The use of "existing disadvantages" is intended to reflect the limitations associated with the data collected and analyzed for use in the current organ allocation system. For instance, SRTR acknowledges data limitations associated with the simulated allocation models (SAM) created for each organ. The Liver Simulated Allocation Model (LSAM) User's Manual prepared in October 2019 acknowledges that "any bias or omissions in the input data may affect simulation results." The LSAM also discusses several specific limitations to consider when using the material and interpreting its results, including: reliance on historical data and standardized behavior. The user's manuals for other organ's Simulated allocation models also identify limitations. Scientific Registry of Transplant Recipients, "Liver Simulated Allocation Model User's Guide: Version 2019," pp. 34-35, https://www.srtr.org/media/1361/lsam-2019-User-Guide.pdf.

coordination; economic deprivation within racially segregated neighborhoods; and lack of widespread cultural-, linguistic-, and literacy-appropriate treatment decision support. Institutional racism, which refers to system-wide discrimination, either deliberately or indirectly, against specific groups of people, may manifest itself as suboptimal provider communication and education about transplant as a treatment option for Black patients, as well as differential rates of timely transplant referral and evaluation due to cultural assumptions or stereotypes about patient preferences for organ donation and transplantation. Internalized racism may be manifest itself as fears and concerns about medical mistreatment and bias, due to historical and current experiences of interpersonal racism experienced by Black patients."[67]

Thus far, discussion of continuous distribution has not sufficiently examined its potential impact on these multiplicative forms of racism and discrimination. Moreover, models have not sufficiently clarified potential proactive, anti-racist, anti-discriminatory approaches. Although continuous distribution allows for the simultaneous consideration of all factors, specifying thresholds (or ethical "guardrails") for many intersecting variables may ultimately diminish efficiency gains, and may be exceptionally complex, limiting transparency.

In light of existing disparities, many theories of justice would suggest that major changes to organ allocation, including shifting to continuous distribution, *should* represent a significant improvement upon current policy priorities for populations worse-off. The CAS should attempt to develop a comprehensive list of factors, consider the importance of each factor, or set of factors, a priori to ensure that they represent the optimal balance of ethical principles, as stated in NOTA,[68] not merely reflecting the balance achieved at present or a slight improvement.

The Importance of Diverse Expertise in Determining CAS

Given its central role to determining the distribution and prioritization of life-saving organs, much rests on the formation, structure, and process of refining the CAS. Whose expertise and perspective should determine the balance and inclusion of factors in the CAS? Thus far, the Lung Committee (and OPTN more broadly) have engaged largely the professional and scientific transplant community in the analytic hierarchy process. By soliciting input largely from scientific, clinical, and professional experts (also some highly engaged patients and donor families) findings informing the development of CAS (and continuous distribution more broadly) reflect a specific expertise, which although valuable, is not necessarily generalizable.

Veatch characterizes normative and empirical problems embedded in generalization of expertise in the following way:

"Generalization of expertise arises when, consciously or unconsciously, it is assumed that an individual with scientific expertise in a particular area also has expertise in the value judgments necessary to make-policy recommendations simply because he has scientific expertise. This assumption is very pervasive in decision making in scientific areas, but unwarranted. To reject this assumption does not imply that those with scientific expertise have no right or authority to

[67] Tanjala S. Purnell, Dinee C. Simpson, Clive O. Callender, and L. Ebony Boulware, "Dismantling structural racism as a root cause of racial disparities in COVID-19 and transplantation," *American Journal of Transplantation,* (February 2021), https://doi.org/10.1111/ajt.16543.

[68] 42 U.S.C. § 273 et. seq.

> *make policy recommendations. It does not even imply that some individuals with the scientific expertise might not also have expertise in the ethical and other value considerations which go into policy making. But such relationships must be demonstrated and such demonstrations are difficult to come by.*"[69]

The difficulty of generalizing expertise is one of conflating expertise in technical, scientific, or clinical knowledge and experience with knowledge of what is morally required or knowledge that stems from the lived experience in a particular domain. From polling the OPTN transplant community exclusively, problems with generalization of expertise in the context of continuous distribution are twofold: First, it conflates expertise in transplantation with evaluative expertise in setting ethical priorities for organ allocation. Second, it presupposes a level of diversity of perspectives and participation that may not currently be represented. This is partly an empirical question which future work should investigate more thoroughly.

An argument can be made that the scientific, clinical, and professional expertise of transplant experts is correlated with the moral and policy making expertise relevant to organ allocation policy. Transplant clinicians, professional stakeholders, patients, and donor families have extensive exposure to the inner workings of transplantation, which the general public does not. They have witnessed tragedy. They have invested years in training and in practice. They have experienced the stress of patients and families waiting desperately for life-saving organs, the disappointments of graft failures, the costs and risks associated with sustaining transplant centers. Such perspective is invaluable and critical in anticipating potential benefits and pitfalls of implementing new systems. Yet, such exposure does not necessarily afford one the moral expertise to determine how to balance organ allocation priorities. Intimate exposure to any field inherently changes one's perspective.[70] Even if the experiences of scientific experts were to increase sensitivity and their ability to sympathize with alternative courses of action, it would be impossible for such expertise to convey the spectrum of relevant perspectives. In this context, expertise as a transplant professional may decrease the likelihood that someone has experience as a transplant patient or a caregiver of a pediatric candidate, or as a person with disabilities, for example. Other important areas of expertise are known to be underrepresented in the transplant community, including expertise represented by Black and indigenous people of color.

Worth noting, in the current CAS system, although consultation is not sufficiently diverse, it may represent a marked improvement over prior systems of allocation in attempting to engage the transplant community. Still, these efforts have largely been focused on stakeholders represented within OPTN. Far broader engagement is needed to truly achieve diversity of perspectives.

Sometimes scientific or clinical expertise may inform a perspective that is divorced from the moral sensitivity needed for policy decisions. For example, Veatch notes that, "it also can be argued that long periods of experience with the same kind of complex problem could inure one to the personal feelings of those involved and leave one insensitive to what is uniquely morally required. Years of constant contact with suffering and illness may produce defense mechanisms for avoiding the serious personal dimensions of one's work."[71]

[69] Robert M. Veatch, "Generalization of expertise," *The Hastings Center Studies* 1, no. 2 (1973): 29-40.
[70] Peter A. Ubel, "Medical Facts versus Value Judgements – Toward Preference-Sensitive Guidelines," *The New England Journal of Medicine* 372, (2015): 2475-2477, https://doi.org/10.1056/NEJMp1504245
[71] Veatch, "Generalization," (1973).

As such, integrating community preferences into the development of CAS by incorporating community *values* as opposed to *technical skills,* is an important step. Here the import of inclusively defining the "transplant community", including the community of patients with organ failure or precursors to organ failure, and a subset of the public (perhaps with no affiliation to the transplant community), as they are stakeholders both as potential future patients and donors. Including diverse representation is crucial. Key to the success of such an effort is a system of checks and balances, ensuring that public preferences are fairly represented, and that they are checked by normative principles governing fair allocation of resources. For example, even if publicly held views at a time supported distributing organs according to social deservingness, or economic productivity, (criteria historically used outside in allocating scarce health resources), these notions would be rejected on the grounds that they violate key conceptions of justice: not treating people as a means to end; respect for persons; and facilitating discrimination according to protected categories. These comparisons are meant to be illustrative and are not the actual comparisons considered in the AHP. Several descriptions of AHP and the exercise were available on the OPTN website.[72]

Perhaps it makes most sense to first decide how much impact justice should have compared to utility. For example, should the system tolerate a CAS that reduces in any way the number of organs offered to Black people or sensitized patients? Should we specify that CAS should improve equity from existing standards? These questions are not merely empirical, depending on the changing views of the American population or transplant clinicians and professionals, who are currently the majority of respondents. Instead, a thoughtful, deliberative process is required to set in place limits constraining the degree to which these weights are either affected by past allocation or publicly held views, which may be (and are) subject to bias.

Examining the Process for Revising and Updating the New Composite Allocation Score in Light of New Data

Although precise procedures for developing and revising the CAS are beyond the scope of this paper, the Committee presents an approach to procedural justice that could be used to achieve consensus on how to operationalize attributes and balance them in the CAS. "Accountability For Reasonableness (A4R)" is an approach to procedural justice in which there need not be agreement upon principles of fairness or distributive justice priorities. Instead, in instances where reasonable people cannot agree on the hierarchy of principles governing resource allocation, the focus should turn to agreeing on a legitimate and fair process for deliberation and decision-making. By virtue of agreeing that the process is fair, stakeholders commit to agreeing that the outcome is also fair. A4R occupies a middle ground between "explicit" rationing, by requiring transparency about criteria; and "implicit" rationing, that do not require that principles or criteria are predetermined.[73,74] A4R has been used widely and in many countries for rationing of scarce health resources.[75]

[72] "Continuous Distribution," Organ Procurement and Transplantation Network, accessed June 13, 2021, https://optn.transplant.hrsa.gov/governance/key-initiatives/continuous-distribution/#AnalyticHierarchyProcessDefinition.
[73] Norman Daniels, "Accountability for reasonableness," *BMJ* 321, no. 7272 (November 2000): 1300–1301, https://doi.org/10.1136/bmj.321.7272.1300.
[74] Keren Ladin and Douglas W. Hanto, "Rationing Lung Transplants – Procedural Fairness in Allocation and Appeals," *The New England journal of medicine* 369, no. 7 (2013): 599-601.
[75] Katharina Kieslich and Peter Littlejohns, "Does Accountability for Reasonableness Work? A Protocol for a Mixed Methods Study Using an Audit Tool to Evaluate the Decision-Making of Clinical Commissioning Groups in England," *BMJ open* 5, no. 7 (2015): e007908–e007908.

A4R requires that the following criteria must be met to ensure procedural justice: First, the process must be public (fully transparent) about the grounds for its decisions. Second, the decision must rest on reasons that stakeholders can agree are relevant. Third, decisions should be revisable in light of new evidence and arguments. Finally, there should be assurance through enforcement that these conditions (publicity, relevance, and revisability) are met.

Fair procedures must be empirically feasible and adapted to facilitate the goals and inclusion of stakeholders involved and affected by decisions. In the case continuous distribution, key challenges to be worked out in the future include: (1) Establishing a fair process by identifying the junctures at which ethical decision-making occurs. (2) Stakeholders: Identifying and ensuring balanced participation of impacted stakeholders. Note that this requires use of best practices to reduce the power imbalance and ensure accessibility of information to all stakeholders. (3) Transparency: An important point to be examined is how to safeguard CAS from becoming so complex that it cannot be interrogated by modelers, scientists, and informed patients. Replicability and comparisons may become exceedingly difficult to examine under the new system. (4) Constraints on relevant reasons: Fair minded people who seek mutually justifiable grounds for cooperation must agree that the reasons, evidence, and rationales are relevant to meeting population health needs fairly, the shared goal of deliberation. For example, rationales must not reflect racist or bigoted preferences.

Fair process also requires opportunities to challenge and revise decisions in light of varying considerations that stakeholders may raise. This requires that, over time, the composition of stakeholders may evolve and change too, leading to different conclusions. When done well, deliberation is likely to yield decisions more sensitive to individual variations (or impacts on minority groups), provided that stakeholder involvement is sufficient (and not tokenistic).

However, this can only be done through a robust post implementation evaluation plan. Development of an analytic framework in line with allocation change ensures that there is not a lag in data collection or analysis and allows for an ongoing process to implement changes to balance unintended consequences to equity. Ethical monitoring can be done through developing regular review periods, to analyze data and implement changes in a systematic and routine manner, and doing so in a way that is accountable, transparent, and has respect for the public, individuals, and communities.[76]

While collection of data is essential, evaluation of the outcomes of interest requires data analysis to understand the effects of changes in allocation. This is in line with a directive in NOTA (1984) to "collect, analyze, and publish data concerning organ donation and transplants."[77] Development of an analytic framework in line with allocation change ensures that there is not a lag in data collection or analysis. Furthermore, specific timeframes (i.e., annually) should be established to ensure that changes made for the sake of more equitable distribution of organs is indeed more equitable, as well as monitor for unforeseen inequities. The ethical use of data and subsequent analysis should also follow the Federal Data Strategy – Data Ethics Framework set out in September 2020, which advocates for accountability, transparency and respect for the public, individuals, and communities.[78]

[77] 42 U.S.C. § 274.2(h).

[78] Federal Data Strategy, *Data Ethics Framework*, September 2020, accessed May 23, 2021, https://strategy-staging.data.gov/assets/docs/data-ethics-framework-action-14-draft-2020-sep-2.pdf.

While A4R makes it possible to educate all stakeholders about the substance of deliberation about fair decisions under resource constraints, it does not clarify how to do so and how to achieve balanced participation. When done well, A4R facilitates social learning and links healthcare rationing decisions to fundamental democratic deliberative approaches. This requires a great deal of skill, best practices, and oversight. A4R also does not clarify who should decide on the weighting of factors within CAS or how frequently should CAS weighting be revisited. While this paper does not answer these questions, it presents a robust ethical framework to guide the community in pursuing ethical solutions.

Concerns Pertaining to Utility

As defined by OPTN's *Ethical Principles in the Allocation of Human Organs*, the principle of utility as applied to organ allocation "specifies that allocation should maximize the expected net amount of overall good (that is, good adjusted for accompanying harms), thereby incorporating the principle of beneficence (do good) and the principle of non-maleficence (do no harm)."[79] Considering changes to an organ allocation framework requires weighing both positive and harmful consequences of different potential allocation schemes.

The positive consequences include "saving life, relieving suffering and debility, removing psychological impairment, and promoting well-being."[80] To quantify these positive consequences for rival allocation schemes OPTN looks to "[d]ata measuring predicted graft survival, predicted years of life added (both from time listed and time transplanted), and even more importantly, predicted quality adjusted life years" as relevant.[81] In terms of harmful consequences, the principle of utility counsels that OPTN consider "mortality, short term morbidities (post-operative surgical complications and acute organ dysfunction and/or rejection), and long term morbidities (side effects and complications from immunosuppressive medications, psychological impairment, and potential rejection of the organ)."[82] In its *Ethical Principles in the Allocation of Human Organs,* the OPTN has clarified that consideration of consequences need not be limited to "medical goods," but at the same time cautioned that in its application of the principle of utility "the social worth or value of individuals should not be considered, including social status, occupation, and so forth."[83] To clarify, while this does not "necessarily rule out the use of objective medical predictors of outcome (such as tissue-typing and panel reactive antibody levels) even if it is known that these factors are not randomly distributed among racial or gender groups," it does, however "rule out excluding individual members of a social group or giving them low priority simply because the group has statistically poorer outcomes."[84]

Importantly, "utility" need not be viewed as measuring a single item. OPTN's *Ethical Principles in the Allocation of Human Organs*, itself for example suggests that utility requires paying attention to both positive and negative consequences of an allocation system and even the positive systems have multiple components such as -- "saving life, relieving suffering and debility, removing psychological impairment, and promoting well-being."[85] These different facets will sometimes require trade-offs. That is true under the existing allocation scheme. What is important about continuous distribution is that it allows us to

[79] OPTN Ethics Committee. *Ethical Principles*.
[80] Ibid.
[81] Ibid.
[82] Ibid.
[83] Ibid.
[84] Ibid.
[85] Ibid.

see and adjust these trade-offs in a much more fine-tuned way rather than the blunter categorical form of the current system.

Moving from the current framework to one of continuous distribution is justified under the principle of utility if it improves upon the balance of positive and negative consequences for organ recipients overall, even if it exacerbates disparities between certain geographical areas or categories of patients in terms of those patients' access to organ transplantation. Moreover, the continuous distribution framework's goal of erasing "hard boundaries" is supported by the principle of utility. Utility justifies hard boundaries typically only on second-order administrability grounds, a kind of necessary evil. To the extent that a move to continuous distribution can improve on balance of good and bad consequences as compared to hard boundaries, it is ethically preferable under this principle.

Of course, when answering whether a particular change in organ allocation systems is warranted, as OPTN has recognized, the principle of utility does not stand alone. It is balanced by the principle of respect for persons and, as is particularly relevant here, the principle of justice. That is, OPTN has taken the position that "it is unacceptable for an allocation policy to strive single-mindedly to maximize aggregate medical good without any consideration of justice in distribution of the good, or conversely for a policy to be single-minded about promoting justice at the expense of the overall medical good."[86]

Concerns Pertaining to Equity

Many questions pertaining to the principle of equity are addressed elsewhere in this white paper. This section examines equity from the perspective of how data collection and the use of such information can impact the fair distribution of benefits. Additionally, the section asks how the implementation of a continuous distribution allocation framework might further disadvantage groups whose opportunities for transplantation are already fairly limited. Finally, recognizing that almost any change in the allocation of organs will result in some patients being better off, while others will have new and/or greater challenges, the section considers the extent to which concerns about such results should be considered when developing a new allocation system.

Considerations of Fairness Must Account for Choices and Quality of Information Used in Determining Candidate Priority

The transition to continuous distribution offers potential opportunities to better address equity and justice concerns within organ allocation. Important benefits include greater efficiency and the ability to prioritize particular contributors to the composite allocation score and outcomes to targets. Yet the system can only account for and prioritize data that is included. This means considerations for equity and justice must be focused on the choices and quality of variables along with what outcomes are prioritized. What processes will be established to determine the variables most likely to maximize equity in a continuous distribution system? Likewise, what impact does the timing of such determinations have on ensuring fairness throughout the system? Is it sufficient to identify the variables prior to establishing the allocation system? At the end? Is it possible to model the impact of different sets of data to identify which information best approximates the intended outcomes? For example, how different are the post-transplant outcomes for heart recipients when measured as graft survival or patient survival in predicting recipient survival?

[86] Ibid.

Thoughtful and intentional integration of equity and justice into the continuous distribution model offers opportunities to make huge strides in mitigating disparities in transplant access and wait times and potentially post-transplant outcomes. On the other hand, failure to integrate these factors risks denying the benefits of a more efficient system and further disadvantaging particular groups of patients. Recognition of the potential benefits or harms imposed by a continuous distribution model underscores the need to collect and incorporate meaningful and accurate data, to ensure that disparities in access to transplant may be minimized. To what extent might biases be incorporated into the allocation system as a result of who collects the data? This calls for both seeking this data and standardizing and mandating its collection so that the data collected from each member of the OPTN community is comparable. How does the allocation system ensure that there are fair processes in place to guide data collection and standardization? Initial models must be regularly reassessed in light of emerging higher quality data and the system regularly revised to promote improving equity and eliminate disparities in organ allocation. Additionally, how will the allocation framework be interrogated to ensure efforts to decrease disparities for a particular group do not do so by further disadvantaging other already disadvantaged groups?

In addition to integrating factors related to health equity as inputs in the model, there is a need to ensure that the prioritized post-transplant outcomes are clinically meaningful and reflect the values of clinicians and patients. How will the meaningful duration of patient and graft survival be identified for measuring? But also, how can the potential risk of a technical criterion fallacy be avoided when prioritizing any outcome other than patient survival? That is not a reason not to consider any other potential outcomes. However, it highlights the necessity to engage in the needed ethical deliberation about whether and how other outcomes such as quality of life, functional status, satisfaction, cognition, or employment ought to be considered.

Utilizing Data in a Meaningful Way

The premise behind the transition to a continuous distribution model for organ allocation is to dissolve hard boundaries and create a more complete and flexible approach to organ matching and organ allocation. However, without robust and quality data collection, monitoring, and utilization, the allocation framework runs the risk of creating unintended consequences in perpetuating or even worsening access disparities that already exist between rural and urban populations, racial/ethnic populations, pediatric populations, and low socioeconomic populations in transplant.

When weighing the attributes in creating a composite allocation score, how those weights are balanced against each attribute are values-based judgements, as opposed to data-based decisions. The specific weight of each attribute determines how much influence that attribute has toward a candidate's overall composite allocation score.[87] For example, the OPTN's *Update on the Continuous Distribution of Organs Project* states "many of the essential and controversial allocation policy decisions are those that are values laden questions."[88] The *Update* goes on to cite Veatch and Ross' discussion of the debate over a local or national allocation system, "[D]eciding whether to trade off efficiency to make the allocation more fair is fundamentally not a technical medical question. It is a question of the relative moral priority of efficiency and equity."[89]

[87] "Continuous Distribution – Lung," Organ Procurement and Transplantation Network, accessed June 16, 2021, https://optn.transplant.hrsa.gov/governance/key-initiatives/continuous-distribution/continuous-distribution-lung/
[88] OPTN Lung Committee, *Update on the Continuous Distribution of Organs Project*, p. 20, August 2020, https://optn.transplant.hrsa.gov/media/3932/continuous_distribution_lungs_concept_paper_pc.pdf (accessed June 16, 2021).
[89] Robert M. Veatch & Lainie F. Ross, Transplantation Ethics, (Washington, DC: Georgetown University Press, 2015) pp 377-78.

Identifying appropriate data points to be used in monitoring for further inequities and standardization of this data collection should be mandated for transplant centers and monitored closely throughout the transition to a continuous distribution model and beyond. This is critical to describe and measure disparities in transplant, but also to improve and revise the model of continuous distribution to eliminate these disparities.

In addition to including these factors how can the allocation system ensure that they are accurate and meaningful? The idea is that data collection should be standardized, but also that outcomes be organ specific and clinically meaningful. This will likely mean target graft and patient survival metrics should not be one year, but account for a much longer term. The duration will likely be specific to particular organs and may be longer than the timeframe currently measured by the OPTN and SRTR. To what extent will such a change introduce more uncertainty into the framework than a model focused on a well described and easier measured outcome such as one-year survival? And, how necessary is it that the model prioritize outcomes that are longer and more meaningful to patients and clinicians? As more routine outcome data is collected, this may offer an opportunity for revising the model to better promote desired outcomes of both efficiency and equity.

Known Data Gaps May Disadvantage Certain Populations

Lack of data or inadequate data about under-represented groups may reduce accuracy of modeling potentially affecting outcomes for these groups in ways that are difficult to anticipate. Current gaps which need to be considered and intentionally closed and disparities mitigated include 1) data on adolescent and young adult candidate listings and outcomes and 2) addressing racial and ethnic disparities in access to transplantation.

A vulnerable population within the transplant setting is the 17–25-year-old patient group who, based on their age, may have to undergo transition from the pediatric to adult settings.[90] They may be initially listed as a pediatric patient and transfer to adult setting prior to their transplantation or following it. There is currently limited data on outcomes of this population on the edge of age-related cut-offs in care. There is ample evidence that loss to follow up is significant in this age group.[91] Recognizing this, the OPTN put forth guidance in 2018 on pediatric transplant recipients transfer and transition urging data sharing between the two settings.[92] While moving to continuous distribution, how can access to transplantation in this population and allograft outcomes be improved so that they are treated similarly to other groups and that the harms they experience are not different from other populations?

There are known racial and ethnic disparities in access to transplantation across solid organs, in adult as well as pediatric populations and hence in this move to continuous distribution. What mechanism or entity can be constructed to guarantee fairness around reaching consensus on metrics to measure and

[90] OPTN Ethics Committee, *Ethical principles of pediatric organ allocation,* November 2014, accessed October 8, 2021, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/.
[91] Taylor A. Melanson, Karie Mersha, Rachel E. Patzer, and Roshan P. George, "Loss to Follow-up in Adolescent and Young Adult Renal Transplant Recipients, *Transplantation* 105, no. 6 (June 2021): 1326-1336, https://doi.org/10.1097/TP.0000000000003445.
[92] OPTN Pediatric Transplantation Committee, *Pediatric Transition and Transfer Guidance Document,* December 2018, accessed May 26, 2021, https://optn.transplant.hrsa.gov/governance/public-comment/pediatric-transition-and-transfer-guidance-document/.

monitor data? Moreover, how can such a mechanism be implemented to act on any perceived or identified disparities fairly and in a repeatable manner?[93,94,95,96]

Broader Sharing of Organs Increases Potential for Certain Populations to Face Reduced Access

Medical urgency is a component in the CAS for continuous distribution. A candidate's medical urgency will be captured through multiple attributes and ratings scales that are designed to address the most critical factors for waitlist and post-transplant survival. In addition to these factors, continuous distribution also accounts for how efficiently organs are allocated by considering the resources required to perform match runs, transport organs, and transplant organs. The Lung Committee focused on travel efficiency and proximity efficiency to help determine how lungs will be distributed. Still, by eliminating the current classification-based allocation system in favor of continuous distribution, the potential exists for improvements in placement efficiency to decrease access to transplantation among populations who previously benefited primarily by their proximity to the donor hospital. For example, how will the committee consider candidates in rural areas and more populated areas who may have the same medical urgency, but the composite allocation score of the candidate in the more populated area is enhanced as a result of better travel efficiency? How will the committee monitor the waitlist survival of such candidates to ensure they are not waiting so long as to make them un-transplantable in the future?

Allocation System Changes May Harm Groups Experiencing Limited Transplantation Opportunities

An objective of the OPTN Lung Committee in designing its Continuous Distribution of Lungs allocation framework was to align the attributes with the ethical principles of equity and utility. However, a move to any new allocation process has the potential for disadvantaged groups to become more disadvantaged. In discussing the effect of new policies, Ladin and Hanto explain "the effect of new [organ allocation] policies on already disadvantaged populations should not be neglected"[97] and that the developers of such policies have a responsibility to "not worsen existing disparities."[98] How can policy development be enhanced to ensure the appropriate mechanisms exist to prevent disadvantaged groups from potential greater harm? What feedback loops can be designed to measure the effects of allocation changes across groups, and also address such disparities in a timely manner?

Challenges Pertaining to Transparency and Autonomy

Despite the advantages of moving from a classification to a scoring system in terms preserving options for prospective candidates, there are features of a scoring system which will make navigating the

[93] Amit K. Mathur et al., "Racial and ethnic disparities in access to liver transplantation," *Liver Transplantation* 16, no. 9 (September 2010): 1033-1040, https://doi.org/10.1002/lt.22108.
[94] Sayeed K. Malek et al., "Racial and ethnic disparities in kidney transplantation," *Transplant International* 24, no. 5 (December 2010): 419-424, https://doi.org/10.1111/j.1432-2277.2010.01205.x.
[95] Alanna A. Morris, Evan P. Kransdorf, Bernice L. Coleman, and Monica Colvin, "Racial and ethnic disparities in outcomes after heart transplantation: A systematic review of contributing factors and future directions to close the outcomes gap," *The Journal of Heart and Lung Transplantation* 35, no. 8 (February 2016): 953-961, https://doi.org/10.1016/j.healun.2016.01.1231.
[96] Rachel E. Patzer et al., "Racial and ethnic disparities in pediatric renal allograft survival in the United States," *Kidney International* 87, no. 3 (March 2015): 584-592, https://doi.org/10.1038/ki.2014.345.
[97] Keren Ladin and Douglas W. Hanto, "Equitable Access Is Not a Secondary Goal of Organ Allocation," *American Journal of Transplantation* 17, no. 12 (June 2017), https://doi.org/10.1111/ajt.14387.
[98] Ibid.

process of organ transplantation more complicated and thus arguably less transparent from the future recipient's perspective, in turn also representing an obstacle to autonomy. With regard to the construction of a process leading to a composite score, questions will inevitably abound no matter how variables of attributes are ultimately weighted. Who has the most say in constructing the algorithm for scoring? How will we go about soliciting the input of as many candidates as possible as new data comes in and the scoring process is recalibrated? How will we ensure that the candidates involved are representative of the diversity within the candidate pool? And how flexible will the process of describing attributes themselves—which will have a sure bearing on one's eligibility—turn out to be in the end? If in actuality candidates are to have little to do with this process, one might wonder how much autonomy they are really gaining in a move to continuous distribution. If, on the other hand, describing a candidate's profile becomes part of a process of shared decision-making, there is suddenly quite a lot at stake in one's being able to adeptly and cleverly advocate for oneself. The new allowance for participation might unintentionally confront candidates directly as burden, stultifying, rather than enabling, their ability to act in their best interests.

There are also concerns with the realizability of the ideal of transparency to begin with. As Amartya Sen has pointed out, in actuality the viewpoint of the "impartial spectator" is not manageable and more likely reflects the perspective of the more powerful and privileged rather than the impoverished and disenfranchised.[99] By default, privilege is something that is imbalanced across strata of society and very difficult to correct for, thus making the ambition of a transparent and strictly egalitarian approach to allocation elusive.[100] Even if they are not "gaming the system," those with the most resources at their disposal will also likely be the ones best equipped to secure advocates most familiar with the composite score calculation, reducing the overall transparency of a system that might have been designed in good faith to increase.[101] In transforming the system of organ allocation, it is thus imperative to be aware of default imbalances in order to address them in advance and, in turn, achieve a process that is as fair and open as possible in terms of distributing resources.[102]

In the move to continuous distribution, moreover, we should consider the pressure all candidates might now feel to assemble clinical advocates to present their cases in a manner that is likely to result in their scoring higher. This might have psychologically paralyzing effect on candidates if, in the event that they are expected to participate in their advocacy, they are not easily and straightforwardly able to navigate the system which assigns them a rating. Just as patients battling illness can sometimes feel overwhelmed when they are given too many options at once which they do not fully understand, so could a process which went out of its way to include candidate input frustrate its own aims by making an already arduous ordeal more complex.[103,104] An outcome which would not be desirable is one in which the replacement of one system with another still left candidates feeling as if they were at the mercy of fate-determining forces beyond their control. This could lead to a kind of paradox whereby as boundaries loosened, giving hope and options to more patients, they did so at the expense of allowing for a clear set of expectations for candidates, ultimately undermining a principle of consent a new

[99] Amartya Sen, *The Idea of Justice* (Cambridge, MA: Belknap Press Harvard University Press, 2009).
[100] Keren Ladin and Douglas W. Hanto, "Are geographic differences in transplantation inherently wrong?" *Current Opinion in Organ Transplant* 22, no. 2 (April 2017): 174-178, https://doi.org/10.1097/MOT.0000000000000400.
[101] OPTN Ethics Committee, *Manipulation of the Organ Allocation System.*
[102] OPTN Ethics Committee, *Manipulation of the Organ Allocation System*.
[103] Yusrita Zolkefli, "Evaluating the Concept of Choice in Healthcare," *The Malaysian Journal of Medical Sciences* 24, no. 6 (December 2017): 92-96, https://doi.org/10.21315/mjms2017.24.6.11.
[104] Benjamin Davies, "Responsibility and the limits of patient choice," *Bioethics* 34, no. 5 (November 2019): 459-466, https://doi.org/10.1111/bioe.12693.

allocation system was otherwise meant to support. Complicating matters further, the introduction of the composite allocation score could lead to a situation in which it became more difficult to engage in comparisons between patients. The more measurements which go into determining listing, the more potential there is for scenarios which come across as confusing, and possibly which are seen as competitive.

What would be ideal is to adopt a process which managed both to move past distinct geographical boundaries, thereby opening up possibilities for all candidates, while not further handicapping anyone who might find a scoring system too bewildering to understand. This process would be able to consider several attributes and weight them according to a matrix of considerations, while still being inclusive of, and user-friendly for, all stakeholders affected by this scoring system. It is not yet clear, however, that the move to continuous distribution will be able to manage these ambitions.

Pragmatic Concerns

This section presents a survey of how pragmatic and implementation concerns associated with a move to continuous distribution might impact ideal outcomes. The actual assessment of these will be taken up in a second paper which will also be intended as an instructive resource for the OPTN and the sponsoring committees. Predicting implications of changes in allocation policy is difficult.[105] Continuous distribution is bound to increase complexity across the transplant system by disrupting existing relationships and patterns of organ sharing between transplant centers and organ procurement organizations, while confusing patients and resulting in uncertainty in the availability and prioritization of organs. Potential challenges include the following:

a. Addressing geographical and center-based changes in organ supply: Similar to short-term surges following previous organ allocation changes, some areas or populations that typically experience longer waits for organs may encounter greater supply and shorter waits, while those with historically shorter waiting times may experience reduced supply. To address these ethical quandaries, sponsoring committees should review donation and transplantation metrics to identify differences in how efficiency is addressed following implementation of continuous distribution. The findings could suggest allocation inefficiencies, such as transporting organs from an area only to have the same area import similar organs from elsewhere. Conversely, a data analysis could show that the committee achieved smarter distribution; whereby organs only travel long distances when truly needed and organs are transplanted close to the donor hospital to decrease travel efficiency-thereby achieving an ethical balance between equity and utility. In either event, sponsoring committees should review this data to determine if the appropriate ethical balance was achieved.

b. Changes and uncertainty for patients: Changes, positive or negative, have the potential to impact a patient's trust of the transplant system. From a patient's perspective, the move to continuous distribution raises considerations involving the principle of autonomy, and the transparency of processes and allocation rules to enable stakeholders to make informed decisions. Will patients approach multiple listing opportunities differently or donors consider living donations differently if there is uncertainty or difficulty in understanding how continuous distribution affects them individually? In addition to autonomy, efforts aimed at improving equity may become complicated

[105] Sharon E. Klarman and Richard N. Formica, "The Broader Sharing of Deceased Donor Kidneys Is an Ethical and Legal Imperative," *Journal of the American Society of Nephrology* 31, no. 6 (June 2020): 1174-1176, https://doi.org/10.1681/ASN.2020020121.

as individuals' identities are identified, reported, determined by others, classified, and contextually understood by many along the patients' process toward and through transplantation. It may be beneficial to gather this type of information in order to understand the ways these data could impact allocation and whether the appropriate ethical goals were achieved.

c. Changes in clinician behavior: Like patients, moving to continuous distribution may influence clinician decision making. Also, like patients, will clinicians have the appropriate information to make informed decisions? How might that information influence, or not influence, their acceptance practices? Some have suggested that continuous distribution will result in organs traveling greater distances than now. According to this line of argument, the greater distances produce longer ischemic times, and make the organs less viable. Others predict that "smarter" distribution will allocate more organs close to the donor hospital and only allocate organs long distances when there are significant benefits in doing so; and therefore, reduce the impact of ischemic time on organs. The sponsoring committees should evaluate potential changes in clinician behavior to ensure that continuous distribution meets its intended ethical balance between equity and utility.

d. Expense and logistics: Smarter distribution in continuous distribution, as opposed to broader distribution, is predicted to allocate more organs close to the donor hospital and only allocate organs long distances when there are significant benefits in doing so. However, the sponsoring committees should evaluate how the proposed changes might potentially impact utility throughout the entire allocation process. What will be the effect of shipping on organ acquisition costs and who will ultimately bear these cost changes? Other considerations include how a continuous distribution framework will impact decision making between imported organs with greater ischemic times and organs that travel less or little distance with considerably less ischemic time and the timing of acceptance decisions.

e. Problems with computing the composite allocation score: As described above, the composite allocation score quantifies how important each candidate attribute is in organ allocation, but there are multiple methods for determining these weights. From an equity perspective, will CAS mitigate existing disparities, merely replicating existing biases in a new system, or will its new approach find greater equity for existing disparities? From an autonomy perspective, how might the changes impact the amount of trust patients have for the system? Will the CAS confuse patients and increase uncertainty, or will it empower patients? In making large changes and relying on historical data, CAS increases uncertainty for certain populations who are underrepresented in current transplant data, rendering the impact on those populations even less clear. It will therefore be important for the sponsoring committees to evaluate the new framework continually for unintended consequences (such as undermining communitarian engagement of the public with transplant efforts, fall in organ donation rates, etc.). Finally, as the sponsoring committees evaluate the development of the CAS, they also have an opportunity to improve the process for ensuring the representation of and engagement of stakeholders.

Conclusion: Assessing the Overall Outlook in the Move to Continuous Distribution

On balance, notwithstanding the formidable challenges enumerated in this white paper which should be addressed as continuous distribution is adopted as the new allocation system, the move away from arbitrary units makes sense and is supportable. This move to a national plan, it is important to bear in

mind, remains distinct from the larger issue of national sharing of resources, and it will be important to make sure that vulnerable populations in the nation do not bear disproportionate consequences as a result. There is reason to be optimistic, however, that the move to a continuous distribution framework *can* ensure that the OPTN Board and the sponsoring committees consider the ethical principles of utility, equity, transparency, and autonomy to assist them with incorporating the appropriate correctives for disadvantaged or underserved populations within the larger whole. In this respect, justified on a case by case basis, it may be that the retention of some geographic considerations that are adaptable are appropriate and ethical. The hope is that a move to continuous distribution will allow for a more granular consideration of attributes in order to allow for the maximum amount of attention to individual patient circumstances. Indeed, a scoring system of allocation, as opposed to a classification system, has the potential to be more patient-centered and is consistent with the goal of improving accuracy and increased attention to each individual patient. Overall, therefore, there are strong grounds to conclude that the move to continuous distribution is ethically justified and something which will improve the overall welfare and well-being of patients.

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