Received: 2 July 2018 | Revised: 14 August 2018 | Accepted: 5 September 2018

DOI: 10.1111/ajt.15115

PERSONAL VIEWPOINT

AJT

Organ distribution without geographic boundaries: A possible framework for organ allocation

Jon J. Snyder[1,2] | Nicholas Salkowski[1] | Andrew Wey[1] | Joshua Pyke[1] | Ajay K. Israni[1,2,3,4] | Bertram L. Kasiske[1,2,3,4]

[1]Scientific Registry of Transplant Recipients, Chronic Disease Research Group, Hennepin Healthcare Research Institute, Minneapolis, MN, USA

[2]Division of Epidemiology and Community Health, School of Public Health, University of Minnesota, Minneapolis, MN, USA

[3]Department of Medicine, Hennepin Healthcare, Minneapolis, MN, USA

[4]University of Minnesota Medical School, Minneapolis, MN, USA

Correspondence
Jon J. Snyder, Scientific Registry of Transplant Recipients, Chronic Disease Research Group, Hennepin Healthcare Research Institute, Minneapolis, MN.
Email: jsnyder@cdrg.org

Funding information
Health Resources and Services Administration, Grant/Award Number: 250201500009C

The Final Rule mandates that organ allocation not be based on the transplant candidate's place of residence or listing, except as required by sound medical judgment and best use of donated organs, to avoid wasting organs and futile transplants, and to promote access and efficiency. Current Organ Procurement and Transplantation Network (OPTN) policies use donation service areas and OPTN regions to distribute and allocate organs for transplant. These policies have recently been called into question as not meeting the requirements of the Final Rule. Therefore, we propose using borderless allocation scores that combine medical priority scores with geographic feasibility scores. Medical priority scores are currently used in OPTN allocation policy, for example, the model for end-stage liver disease and the lung allocation score. Geographic feasibility scores can be developed to account for the effects of ischemia due to travel times, donor characteristics that modify the feasibility of traveling due to organ outcomes, and the costs of shipping organs over long distances. A borderless distribution and allocation system could address the goals of equity and utility, while fulfilling the mandates of the Final Rule and providing optimal use of a scare resource.

KEYWORDS
editorial/personal viewpoint, organ procurement and allocation, Organ Procurement and Transplantation Network (OPTN), Scientific Registry for Transplant Recipients (SRTR)

1 | INTRODUCTION

Organ allocation in the United States is governed by policies developed by the Organ Procurement and Transplantation Network (OPTN), which is operated by the United Network for Organ Sharing (UNOS) under contract with the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services (HHS). Current polices distribute organs near the donor before shipping over longer distances, with exceptions for patients with greater medical urgency.[1] Kidney and liver allocation policies generally use donation service areas (DSAs) and the broader OPTN regions before shipping organs to the rest of the country. DSAs are groupings of counties designated by the Centers for Medicare & Medicaid Services to be served by one of the 58 organ procurement organizations to facilitate organ donation within those counties.[2] The 11 OPTN regio ns are broader geographic areas designated by OPTN to administer OPTN operations.[3] Importantly, neither geographic entity was designed to optimize organ allocation or distribution.

Lung and heart allocation policies use concentric circles of increasing radius from the donor's location to prioritize candidates closer to the donor. DSAs, OPTN regions, and concentric circles all have defined geographic borders. Thus, two candidates in close geographic proximity may be given very different allocation priorities simply because one is located across a geographic border.

Abbreviations: DBD, donation after brain death; DCD, donation after circulatory death; DSA, donation service area; HHS, US Department of Health and Human Services; HRSA, Health Resources and Services Administration; MELD, model for end-stage liver disease; OPTN, Organ Procurement and Transplantation Network; PELD, pediatric end-stage liver disease; SRTR, Scientific Registry of Transplant Recipients; UNOS, United Network for Organ Sharing.

2 | REGULATORY FRAMEWORK

The National Organ Transplant Act (NOTA; PL 98-507) established OPTN in 1984 and the Final Rule established the regulatory framework for OPTN's structure and operations.[4,5] Section 121.8 of the Final Rule establishes the requirement that the OPTN Board of Directors develop equitable allocation of deceased donor organs:

§121.8 Allocation of organs

(a) Policy development. The Board of Directors … shall develop … policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

1. Shall be based on sound medical judgment;
2. Shall seek to achieve the best use of donated organs;
3. Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);
4. Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
5. Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

…

8. 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.

In addition, the Final Rule section 121.8(b) establishes four "performance goals" that include:

(3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency.

The Final Rule requires that organs be shared as broadly as feasible to candidates with the greatest medical need within the constraints justified under 121.8(a)(1)-(5). It implies that any limitation to broad sharing of organs must be justified by at least one reason given in clauses 1-5. Clauses 3 (programs' ability to decline an offer) and 4 (specific policies for each organ type) are not directly affected by broad sharing; clauses 1 (sound medical judgment), 2 (best use of donated organs), and 5 (avoid wasting organs and futile transplants, promote access and efficiency) remain to justify any limitation to national organ distribution.

3 | LEGAL CHALLENGES TO CURRENT ALLOCATION POLICIES

In November 2017, a lawsuit challenged use of DSAs to distribute lungs in the United States.[6] In response, OPTN revised its lung distribution policies, replacing DSAs with a 250-mile-radius circle extending from the donor hospital.[7] Following this emergency change to lung allocation policy, the OPTN Board of Directors created an Ad Hoc Committee on Geography, which established guiding principles for handling geographic distribution of organs for transplant, and proposed three possible frameworks to guide future development of policies that are less susceptible to legal challenge related to arbitrary and capricious geographic boundaries. The frameworks included (a) concentric circles (based on distance, population density, or some other metric), (b) mathematically optimized regions designed to maximize equity in access to transplant, and (c) a borderless distribution system based on a proximity or feasibility function advanced by the current authors.

At about the time the Ad Hoc Committee on Geography was finalizing its recommendations, a letter dated May 30, 2018, was sent to HHS by the legal firm that brought suit challenging lung distribution; on June 8, 2018, HHS sent a letter to OPTN directing review of its revised liver allocation policy and its use of DSAs and OPTN regions in allocating livers. On July 13, 2018, a suit was filed in US District Court Southern District of New York against HHS, OPTN, and UNOS, asking the court to halt implementation of the liver allocation policy passed in December 2017 and remove DSA and OPTN region from the policy in favor of zone-based distribution. On July 31, 2018, the HRSA Administrator, Dr Sigounas, directed the OPTN Board to adopt a liver allocation policy consistent with the Final Rule by its December 2018 board meeting.

Of the three frameworks advanced by the Geography Committee, concentric circles are used in existing policy (eg heart and lung allocation). Mathematically optimized regions were explored in detail during recent policy debates regarding liver allocation, but were not implemented.[8-11] Although the concept of a borderless system is not new,[12] we aim to describe it in detail to educate the community regarding how such a system could be developed.

4 | FEASIBILITY OF A BORDERLESS SYSTEM TO DISTRIBUTE ORGANS

The Final Rule requires an inherent compromise between medical priority and geographic feasibility, which can be operationalized by designing a system to prioritize allocation using: (a) a medical priority score, and (b) a geographic feasibility score.

4.1 | Medical priority score

Section 121.8(b)(2) requires priority based on "objective and measurable medical criteria" and motivates use of medical priority scores in organ allocation. OPTN policy uses medical priority scoring systems, including model for end-stage liver disease (MELD)/pediatric end-stage liver disease (PELD) scores for liver candidates, lung allocation scores for lung candidates, status groupings for heart candidates, and dialysis time and expected posttransplant survival for kidney candidates. Medical priority scores answer the question: If organ transport were not a constraint, how would we prioritize candidates to receive organ offers? Although medical priority scores are largely in place, additional work may be needed to convert all aspects of priority to a points system.

4.2 | Geographic feasibility score

The Final Rule stipulates that organs should be shared as broadly as feasible. However, logistical and practical constraints limit sharing all donor organs nationally. Ischemia time incurred during organ transport impairs outcomes after transplant. Additionally, greater costs are incurred when organs travel longer distances to reach patients with the highest medical priority scores. Organs may pass each other in route to meet small differences in medical priority. Finally, some donor organs may be more suitable for transport than others, based on organ type and susceptibility to ischemia from, for example, donation after circulatory death (DCD) versus donation after brain death (DBD) donors. The Final Rule allows limitations on broader sharing based on sound medical judgment to promote the best use of donated organs, avoid wasting organs and futile transplants, and promote access and efficiency. The geographic feasibility score can be designed to quantify "feasibility." Combining the two scores will allow each organ to reach the candidate with the highest medical priority score allowed by the constraints of the geographic feasibility score. The geographic feasibility score can be based on distance, travel time, costs, logistics, and donor factors.

5 | ALLOCATION BY COMBINING MEDICAL PRIORITY AND GEOGRAPHIC FEASIBILITY SCORES

A medical priority score and a geographic feasibility score can be combined to yield an allocation score to prioritize organ offers. For example, for adult liver candidates, the medical priority score is determined by MELD combined with exception points; candidates who most urgently need transplant are prioritized above MELD and exception candidates as Status 1A. This constitutes the basic framework of a medical priority score. The geographic feasibility score can then quantify the feasibility of distance and travel-related constraints. Simply stated, the geographic feasibility score will be a function that assigns higher points to candidates near the donor and lower points to candidates farther away, accounting for the implications of distance for the transplant's outcomes.

The process can be illustrated using the metaphor of a hill sloping away from the donor's location (Figure 1). Liver candidates, for example, are positioned on this hill at the location determined by distance and its constraints in a geographic feasibility score. Additionally, each candidate stands next to a flagpole. The flag's height is determined by the candidate's medical priority score; ie, candidates with higher allocation MELD scores or Status 1A have higher flags. Offers will be made first to the candidate with the highest flag relative to the donor, the second-highest flag next, and so forth. In this way a medical priority score and a geographic feasibility score can be combined mathematically to yield the allocation priority score. The specific weighting of the medical priority score against the geographic feasibility score will be determined based on the scale used for the medical priority score; eg, a 1-point difference in MELD is equivalent to an X-point difference in the geographic feasibility score.

The shape of the geographic feasibility score function, ie, the shape of the hill, is a mathematical representation of the value system that the transplant community espouses for allocating organs. Thus, the function can be shaped to define how much farther we are willing to ship an organ to a sicker patient. How much sicker must that patient be to justify shipping the organ that much farther?

The geographic feasibility score function could look like the function shown in Figure 2. This function has three zones: zone A is relatively near the donor, zone B is somewhere between "near" and "too far," and zone C is "likely too far."

5.1 | Zone A (nearest the donor)

A zone likely exists relatively close to the donor where travel is not the primary factor causing ischemic damage or increased costs, perhaps where organs are driven from the donor hospital to the candidate

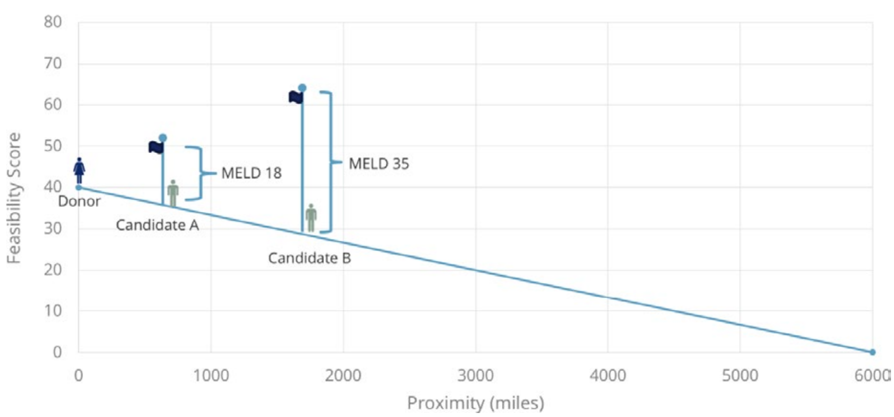

FIGURE 1 Conceptualizing a geographic feasibility score function as a hill sloping away from the donor's location. Candidates stand along the hill according to their distance from the donor. Each candidate stands next to a flag pole that is the height of the candidate's medical priority score (in this example, the MELD score for liver allocation). Using this oversimplified example, candidate B (located 1750 miles from the donor) would be prioritized over candidate A (located 700 miles from the donor), given a MELD score of 35, yielding a higher flag than candidate A's. The shape of the function could be changed to yield different results according the values of the transplant community. MELD, model for end-stage liver disease [Color figure can be viewed at wileyonlinelibrary.com]

hospital. The geographic feasibility score function may be flat in this zone and candidates would be prioritized solely based on the medical priority score. For example, if zone A is defined by candidates within 150 miles of the donor, and three transplant programs are within 150 miles of the donor hospital, then differences in transporting the organ to any of those hospitals are likely negligible with regard to the outcome of the transplant or costs. Hence, candidates at those three programs receive the same geographic feasibility score and would be prioritized based on their medical priority scores.

5.2 | Zone B (neither near nor too far)

In this zone, organs are likely flown from the donor hospital to the recipient hospital, and ischemic time and other logistical constraints reduce the feasibility of the transplant. The shape of the feasibility score function could be determined by numerous factors, eg, the relationship between ischemia time and patient outcomes such that the function becomes steeper at distances where the ischemic effect becomes more pronounced. The slope/shape of the function could also be influenced by donor factors; eg, high kidney donor profile index kidneys may be more susceptible to travel times. Regardless of the shape of the function, in the absence of vertical drops or "cliffs," there will be no geographic boundaries and candidates near each other with similar medical priority scores will have similar allocation priority.

5.3 | Zone C (likely too far)

The transplant community would agree that organs should generally not be shipped to this region due to concerns about patient outcomes and wasted organs. It may be denoted by a vertical drop in the feasibility function, or a "cliff" on the hill. The cliff would be tall enough to prioritize all candidates nearer to the donor before organs are offered to candidates past the cliff. A system with no cliffs would be truly borderless, but a cliff may be justified to quantify a zone of infeasibility.

The challenge of the geographic feasibility score is designing the shape of the function, ie, the shape of the hill, which need not be linear, but could be a smooth curve, or a combination. The strength of the concept is that any decision related to shaping the hill is exactly the justification required by the Final Rule. For example, the shape of the hill could be based on the association between ischemic time and transplant outcomes (Figure 3, top panel), ie, justified to avoid futile transplants and make the best use of donated organs. In addition, the slope of the hill could be modified based on donor factors, eg, steeper for DCD than for DBD donors (Figure 3, bottom panel). A steeper slope results in more priority for nearby candidates. Importantly, distance need not be the only factor considered in the geographic priority score function. The score could also be based on additional logistic factors, eg, travel time, estimated transportation costs, and donor characteristics. Finally, the relative importance of various factors can be modified over time as the field advances; eg, if the effect of ischemic time is mitigated by new technologies such as ex vivo lung perfusion, its contribution to the formula could be modified.

Of note, concentric circles in lung allocation policy are a special case of a geographic feasibility score. The policy uses circles with radii of 250, 500, 1000, 1500, and 2500 miles. In the hill metaphor, this is as a step function with cliffs at these distances from the donor (Figure 4). The cliffs are sufficiently high that all candidates before each cliff are prioritized ahead of all candidates beyond each cliff. Therefore, the three frameworks advanced by the Geography Committee can be conceptualized as two frameworks, because concentric circles are a special case of a feasibility score, one with boundaries defined by the circle boundaries.

One can also envision a system with "soft circles," ie, shorter cliffs such that sicker patients beyond the cliff can still receive offers ahead of less sick patients on the other side of the cliff. This is somewhat akin to proximity points offered within 150 miles of the donor as included in the liver policy passed by the OPTN Board in December 2017. Although perhaps more appealing than hard circle

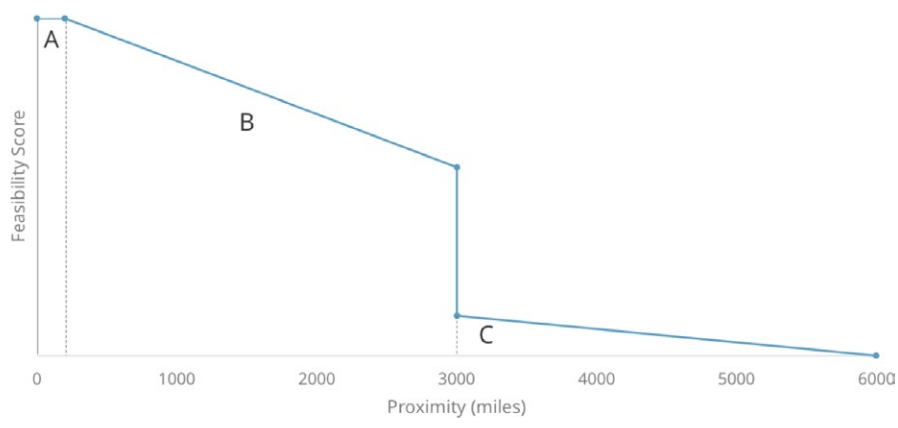

FIGURE 2 A conceptual framework for a geographic feasibility score function, showing three zones. In zone A (near the donor), distance and ischemic time are likely uncorrelated. Organs may be driven rather than flown. Because the function is flat in this zone, candidates are prioritized based solely on medical priority. In zone B (between near and too far), organs are likely flown. The function prioritizes patients nearer the donor with an increasing penalty for greater distance. Zone C (too far) is where we want to avoid shipping organs for fear of poor patient outcomes and wasting organs. This zone starts with a cliff of sufficient height that all candidates before the cliff are prioritized before any candidates after the cliff. This zone need not exist, but is worth considering for each organ type [Color figure can be viewed at wileyonlinelibrary.com]

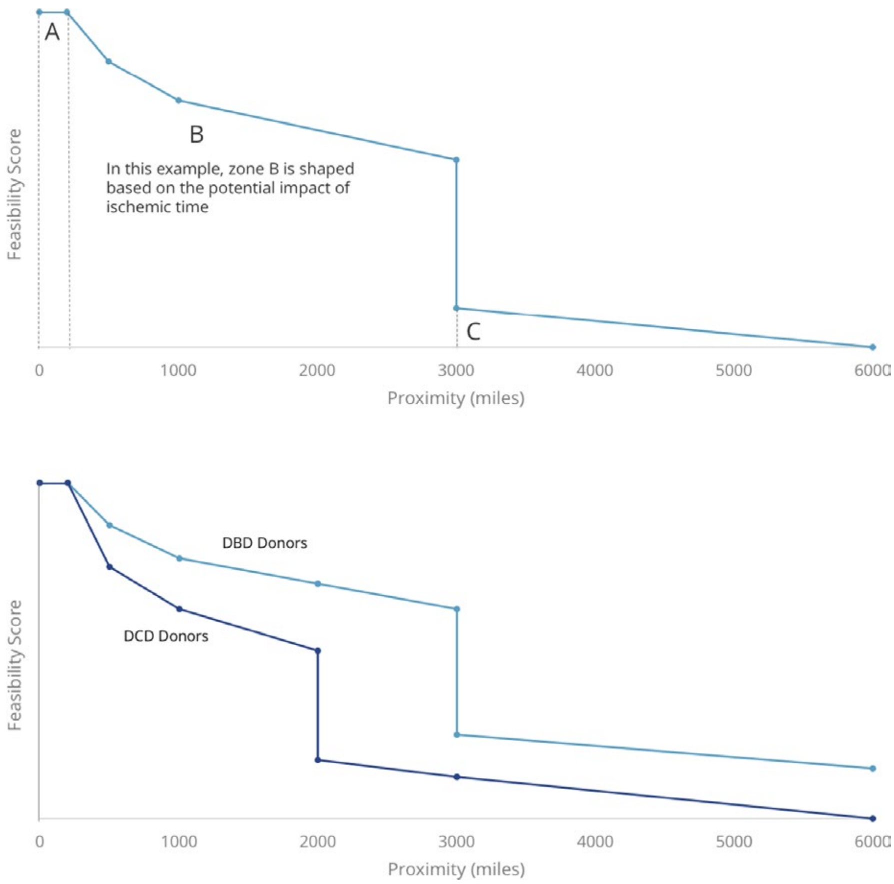

FIGURE 3 Top panel: An example of a curved function within zone B. The shape of the function could be based on the relationship between ischemic time and patient outcomes. Bottom panel: An example of different proximity functions based on donor characteristics. DBD donors may have a different feasibility function than DCD donors because DCD organs cannot be shipped over as great a distance. DBD, donation after brain death; DCD, donation after circulatory death [Color figure can be viewed at wileyonlinelibrary.com]

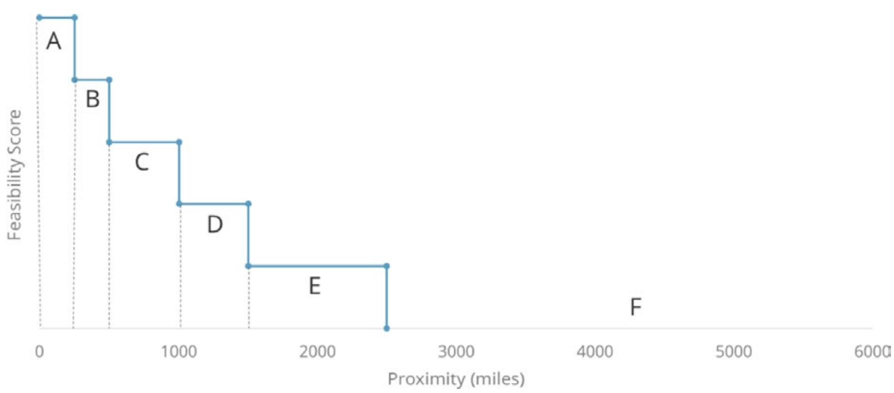

FIGURE 4 Current lung allocation zones expressed as a geographic feasibility function. Concentric circle boundaries in the policy are represented by vertical drops in the function at the circle boundaries of 250 (A), 500 (B), 1000 (C), 1500 (D), and 2500 (E) miles. Zone F is beyond 2500 miles [Color figure can be viewed at wileyonlinelibrary.com]

boundaries, a short cliff rather than a smooth function would require justification; ie, what medical or logistical situation at the location of the short cliff justifies a drastic change in the slope at that location?

The other framework advanced by the Geography Committee uses mathematically optimized distribution zones designed to equalize access to transplant across the country as measured by a disparity metric, as discussed next.

6 | PROMOTING EQUITY IN ACCESS

An allocation system combining a medical priority score and a geographic feasibility score is most likely to increase equity in access without sacrificing utility; ie, ship as far as feasible to the candidates with the greatest medical need. It will therefore fulfill the requirements of the Final Rule, including: “equitable allocation of cadaveric organs among potential recipients” (121.8[a]); “to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement” (121.8[a][5]), and “reducing the inter-transplant program variance to as small as can reasonably be achieved in any performance indicator” (121.8[b][4]).

The proposed system is most equitable to candidates on the waiting list, because it prioritizes the sickest candidates within the necessary constraints imposed by geographic feasibility. Equity is often conceptualized and measured at a group, not an individual, level, eg, candidates in California have less access to transplant than candidates in Georgia. This is often a difficult debate, because one must first agree on a metric to assess equity, eg, median time to transplant or transplant rate, and then decide which populations to compare to determine whether the system is equitable. When using a geographic feasibility score, if regional inequities were deemed unacceptable, the feasibility function may be poorly specified (are we shipping as far as feasible?) and we can modify the feasibility function to improve equity.

A framework defining mathematically optimized distribution zones differs fundamentally, because it attempts to minimize a disparity metric over groups of patients. This was how "neighborhoods" and "optimized regions" were defined for versions of the liver allocation policy considered by OPTN's Liver and Intestinal Transplantation Committee. Sharing districts were designed with the goal of reducing variation in DSA-level median MELD at transplant under constraints defined by the committee. This type of system seeks to achieve group equity, but given its necessary boundaries, it may result in bypassing candidates with greater medical need to ship organs to less urgent candidates farther away to achieve better balance between groups defined by the target metric. In contrast, the feasibility score framework starts from the standpoint of providing organs to the candidates with the greatest medical need within feasibility constraints justified under the Final Rule, without the need for geographic boundaries.

7 | SUMMARY

We describe an approach for developing organ allocation policies without defined geographic boundaries. Work is required to develop the feasibility score function for each organ type, eg, the ischemia-outcomes relationship, costs, relative weightings, etc, whereas medical priority scores are already largely in place. OPTN can use the feasibility score framework to define the shape of the function and where zones A, B, and C begin and end. These decisions can be informed by research into the projected travel times between each donor hospital and each transplant program, the effect of ischemic time on organ outcomes, the costs associated with shipping organs over long distances, etc. The OPTN Board of Directors is ultimately responsible for passing any changes to organ allocation policy. If the board is asked to defend these decisions, the research used to design the shape of the function can be cited. Furthermore, reducing organ allocation to two scores, a medical priority score and a geographic feasibility score, makes future changes to the policies conceptually simple by focusing the problem on one of the two scores. Finally, this framework clearly ties allocation policy development to the tenets set forth in the Final Rule since any decision leading to the development of the function will necessarily tie to paragraphs 121.8(a)(1)-(5) as required by the Final Rule.

ACKNOWLEDGMENTS

This work was supported wholly or in part by HRSA contract 250201500009C. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of HHS, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government. The authors wish to thank OPTN/UNOS leadership, the OPTN/UNOS Board of Directors and Executive Committee, and the members of OPTN's Ad Hoc Committee on Geography for valuable feedback in early discussions of the concepts put forth here; HRSA's Division of Transplantation for support in exploring this framework; and Chronic Disease Research Group colleague Nan Booth, MSW, MPH, ELS, for manuscript preparation and editing.

CONFLICTS OF INTEREST

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

REFERENCES

1. Organ Procurement and Transplantation Network. Policies. https://optn.transplant.hrsa.gov/governance/policies/. Accessed July 2, 2018.
2. Association for Organ Procurement Organizations. Donation Service Areas. www.aopo.org/donation-service-areas/. Accessed July 2, 2018.
3. Organ Procurement and Transplantation Network. Administrative Regions. www.transplantpro.org/community/regions/. Accessed July 2, 2018.
4. National Organ Transplant Act. https://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg2339.pdf. Accessed July 2, 2018.
5. Organ Procurement and Transplantation Network. Final Rule. www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5. Accessed July 2, 2018.
6. Holman vs. US Department of Health and Human Services. https://optn.transplant.hrsa.gov/media/2394/plaintiff_request_for_tro_20171119.pdf. Accessed July 2, 2018.
7. OPTN/UNOS. Modifications to the distribution of deceased donor lungs. https://optn.transplant.hrsa.gov/media/2400/thoracic_publiccomment_distribution_20180122.pdf. Accessed July 2, 2018.
8. Gentry SE, Chow E, Massie A, Segev DL. Gerrymandering for justice: redistricting US liver allocation. *Interfaces*. 2015;45(5):462-480.
9. OPTN/UNOS Liver and Intestinal Organ Transplantation Committee. Redesigning liver distribution to reduce variation in access to liver transplantation. https://optn.transplant.hrsa.gov/media/1269/liver_concepts_2014.pdf. Accessed July 2, 2018.
10. Gentry SE. Mathematical methods to reduce geographic disparities in organ availability. https://www.transplantpro.org/wp-content/uploads/sites/3/SRTR-Gentry-presentations-20150621.pdf. Accessed July 2, 2018.
11. Gentry SE, Massie AB, Cheek SW, et al. Addressing geographic disparities in liver transplantation through redistricting. *Am J Transplant*. 2013;13(8):2052-2058.
12. Burdick JF. A general approach to broader sharing in organ allocation. *Transplantation*. 2001;72(5):759-763.

How to cite this article: Snyder JJ, Salkowski N, Wey A, Pyke J, Israni AK, Kasiske BL. Organ distribution without geographic boundaries: A possible framework for organ allocation. *Am J Transplant*. 2018;18:2635–2640. https://doi.org/10.1111/ajt.15115