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PERSONAL VIEWPOINT

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Greater complexity and monitoring of the new Kidney Allocation System: Implications and unintended consequences of concentric circle kidney allocation on network complexity

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Abstract

The deceased donor kidney allocation system in the United States has undergone several rounds of iterative changes, but these changes were not explicitly designed to address the geographic variation in access to transplantation. The new allocation system, expected to start in December 2020, changes the definition of "local allocation" from the Donation Service Area to 250 nautical mile circles originating from the donor hospital. While other solid organs have adopted a similar approach, the larger number of both kidney transplant centers and transplant candidates is likely to have different consequences. Here, we discuss the incredible increase in complexity in allocation, discuss some of the likely intended and unintended consequences, and propose metrics to monitor the new system.

KEYWORDS
clinical research/practice, donors and donation: deceased, ethics and public policy, kidney transplantation/nephrology, organ acceptance, organ procurement, organ procurement and allocation, United Network for Organ Sharing (UNOS)

1 | INTRODUCTION

The deceased donor kidney allocation system in the United States has undergone several rounds of iterative changes.[1,2] The most recent substantial revision to deceased donor kidney allocation, the Kidney Allocation System (KAS) implemented in December 2014, made three major changes: (1) wait time started at dialysis initiation or at time of preemptive listing, whichever came earlier, (2) incorporation of estimates of both donor (kidney donor profile index [KDPI])[3] and recipient (estimated posttransplant survival [EPTS])[4] longevity, and (3) national priority for the most highly sensitized recipients. Implementation of KAS was followed by increased rates of transplantation for highly sensitized candidates[5] and an improvement in overall equity as measured by the transplant rates of waitlisted candidates across racial groups.[6,7]

These changes were not designed to address the geographic variation in access to transplantation, and so it is not surprising that geographic disparities persisted.[8] Variation in transplantation rates across the country has historically been attributed to differing local organ supply; however, marked variation in transplantation rates has been observed between centers within the same Donation Service Areas (DSAs).[9] These differences appear to be related to organ offer acceptance/decline patterns that worsen geographic disparities.[9,10] Organ offers are most frequently declined due to poor organ quality; however, other reasons for declining organ offers include anatomic abnormalities, long cold ischemia time, surgical damage, and

Abbreviations: DSA, donation service area; EPTS, estimated posttransplant survival; IQR, interquartile range; KAS, Kidney Allocation System; KDPI, Kidney Donor Profile Index; OPO, Organ Procurement Organization; OPTN, Organ Procurement and Transplantation Network; SRTR, Scientific Registry of Transplant Recipients.

recipient readiness.[11,12] Different centers may have different thresholds for declining offers that are influenced by perceptions of their relative local organ availability, and in turn the export or discard of locally declined organs creates additional subjective heterogeneity in access to transplantation.

Differential access to transplantation resulting from variation in local organ supply and center offer acceptance behavior is further exacerbated by the current allocation prioritization: kidneys recovered in each of the nation's 58 DSAs are preferentially allocated to “local” candidates waitlisted within that DSA with few exceptions.[2] Organs declined within a given DSA are subsequently offered within the donor hospital's OPTN region, and then allocated nationally if no regional transplant centers accept the organ for transplantation. These somewhat arbitrary DSA and regional borders have unintentionally had a direct, measurable impact on access to organ offers, influencing the time to transplant for patients and introduction of significant subjectivity into an otherwise objective allocation system.[13]

Changes in KAS addressed the social determinants of health and racial and ethnic disparities that were identified as important barriers to access to kidney transplantation,[14,15] while the proposed changes to the allocation policy seeks to eliminate the disparities that result from this stepwise approach to allocation by eliminating the current geographic boundaries to kidney allocation starting in December 2020. Distance between the intended recipient and the organ at the time of donation was allowed to remain a consideration—a practical recognition that increased distance and the associated organ preservation time has a detrimental impact on organ viability.[16] In the new policy, traditional DSA boundaries are replaced with a single 250 nautical mile circle centered around the donor hospital as the only geographical allocation border. While this approach is intended to decrease geographic disparities, there is likely an unintended detrimental impact on the operational efficiency associated with the resulting increased network complexity.

2 | A REMARKABLE INCREASE IN COMPLEXITY

Deceased donor kidney transplantation represents the largest of the solid organ transplants subsystems in the United States with the most transplant programs (237, compared to 144 liver, 141 heart, and 72 lung programs), the largest waitlist, and the highest annual volume of deceased and living donor transplants,[17] which will influence the impact of the new allocation system on the complexity of organ placement. With the 250 nautical mile radius of the donor hospital, the new allocation system radically changes the operational definition of “local” by increasing the volume of centers—many of whom lie outside the operational jurisdiction of the procuring organ procurement organization (OPO).

Using data from the Scientific Registry of Transplant Recipients (SRTR) August 2020 program-specific-reports and measuring 250 nm circles using geocoded transplant centers and donor hospitals, we estimate that the number of transplant centers considered “local” for a kidney will rise by a median of 17 centers (IQR 7–31), a 320% increase (Table 1). Notably, the median number of donor hospitals “local” to a transplant center will also increase from 41 to 194—a nearly fivefold increase (Table 1 and Figure 2). More concerning is the potential impact on organ allocation complexity; for example, kidneys procured at a given hospital currently have a median of 5 centers and a maximum of 15 centers as “local,” but those numbers increase to 23 and 73 centers, respectively.

These changes have immediate practice consequences, including that transplant centers will have more frequent interactions with multiple OPOs. Most centers work primarily with their single affiliated OPO under the current system, but now are going to be directly linked to donor hospitals that span as many as 18 different OPOs—and a median of nine OPOs (Table 1). The median number of “local” transplant centers that an OPO currently works with is 3 (IQR 2–5), but under the new system OPOs will be responsible for placing locally allocated kidneys at a median of 34 (20–55) different transplant centers.

This represents a dramatic increase in the number of transplant center–OPO relationships that will need to be established and strengthened to ensure that the allocation system can continue to efficiently place deceased donor organs. This is also likely to have a considerable impact on transplant center workflow, depending on how the organ offers are handled. Given the expectation that centers will be faced with an increased number of offers, there is likely to be a significant increase in the time spent evaluating and processing organ offers and pressure to revisit current workflows. For example, centers that have the surgeons evaluate offers directly may find this is no longer tenable given the necessary time commitments. Crossmatch considerations may also need to be revisited as do the challenges associated with increased logistical challenges.

The largest increases in the number of connections between OPOs and transplant centers will occur, not surprisingly, in regions of the country with greater population and hospital density (Figure 1) while those centers and OPOs in more rural or less densely populated parts of the country will experience smaller changes (Figure S1). In short, the number of increased connections and communication pathways for local kidneys alone is going to be substantial (Figure 1). Alternatively, while increasing complexity may make the system less efficient, there are data to suggest more connectivity (complexity) between OPOs and transplant centers may actually increase utilization.[18] This increase in connectivity between transplant centers and OPOs may ultimately lead to an increase in organ utilization once the challenges of the associated complexity of the system are overcome by revised workflows.

It seems likely that these changes will impact organ offer acceptance behavior at centers. Centers that were frequent importers (especially those using organs from more distant OPOs) may no longer do so if their local organ supply has increased, which may result in an increased risk of discard of nonlocally placed organs. Acceptance patterns at centers used to having only a few local centers on the

TABLE 1 Changes in local environment for centers, donor hospitals, and Organ Procurement Organizations under new allocation system

	DSA allocation				Concentric circle allocation			Absolute change (by centers or hospital)			Percent change (by centers or hospital)			
	n	Min	Max	Median	Min	Max	Median	Min	Max	Median	*n*	Min	Max	Median
Number of centers local to a donor hospital (min, max, median)	2071	1	15	5 (3–9)	0	73	23 (11–40)	−8	71	17 (7–31)	2071	100%	5700%	320 (156–683)%
Number of large centers local to a donor hospital (min, max, median)	2071	0	7	2 (1–4)	0	42	12 (6–19)	−5	41	9 (3–16)	2021	100%	4100%	300 (150–750)%
Number of centers with OAR > 1 local to a donor hospital	2071	0	7	2 (1–4)	0	40	11 (4–20)	−4	38	8 (2–17)	1959	100%	3400%	314 (100–700)%
Number of aggressive centers local to a donor hospital (min, max, median)	2071	0	9	2 (1–4)	0	37	11 (5–17)	−6	35	8 (3–15)	1689	100%	3100%	300 (105–700)%
Waitlisted patients that are local to donor hospitals (min, max, median)	2071	155	8423	1925 (876–3745)	0	26 553	9910 (4725–14 483)	3080	25 129	7367 (2501–12 793)	2071	100%	9573%	350 (129–809)%
Number of donor hospitals local to a transplant center (min max, median)	237	9	108	41 (27–75)	6	492	194 (151–324)	−50	455	149 (95–288)		−67%	3930%	365 (181–652)%
Number of donor hospitals local to a large transplant center	117	9	108	41 (27–75)	18	492	192 (155–326)	0	455	147 (96–407)		0%	3930%	414 (181–683)%
Number of donor hospitals local to centers with high probability of transplant (min, max, median)	95	9	108	35 (24–53)	18	492	183 (129–304)	50	455	146 (95–248)		−67%	3930%	424 (198–756)%
Number of donor hospitals local to transplant centers with OAR >1	118	9	108	37 (24–73)	9	459	213 (144–330)	18	404	183 (96–304)		−67%	3930%	421 (189–769)%
Number of OPOs local to transplant centers (min max, median)	237	1	1	1 (1–1)	1	18	9 (5–12)	0	17	8 (4–11)		0%	1700%	800 (400–1100)%

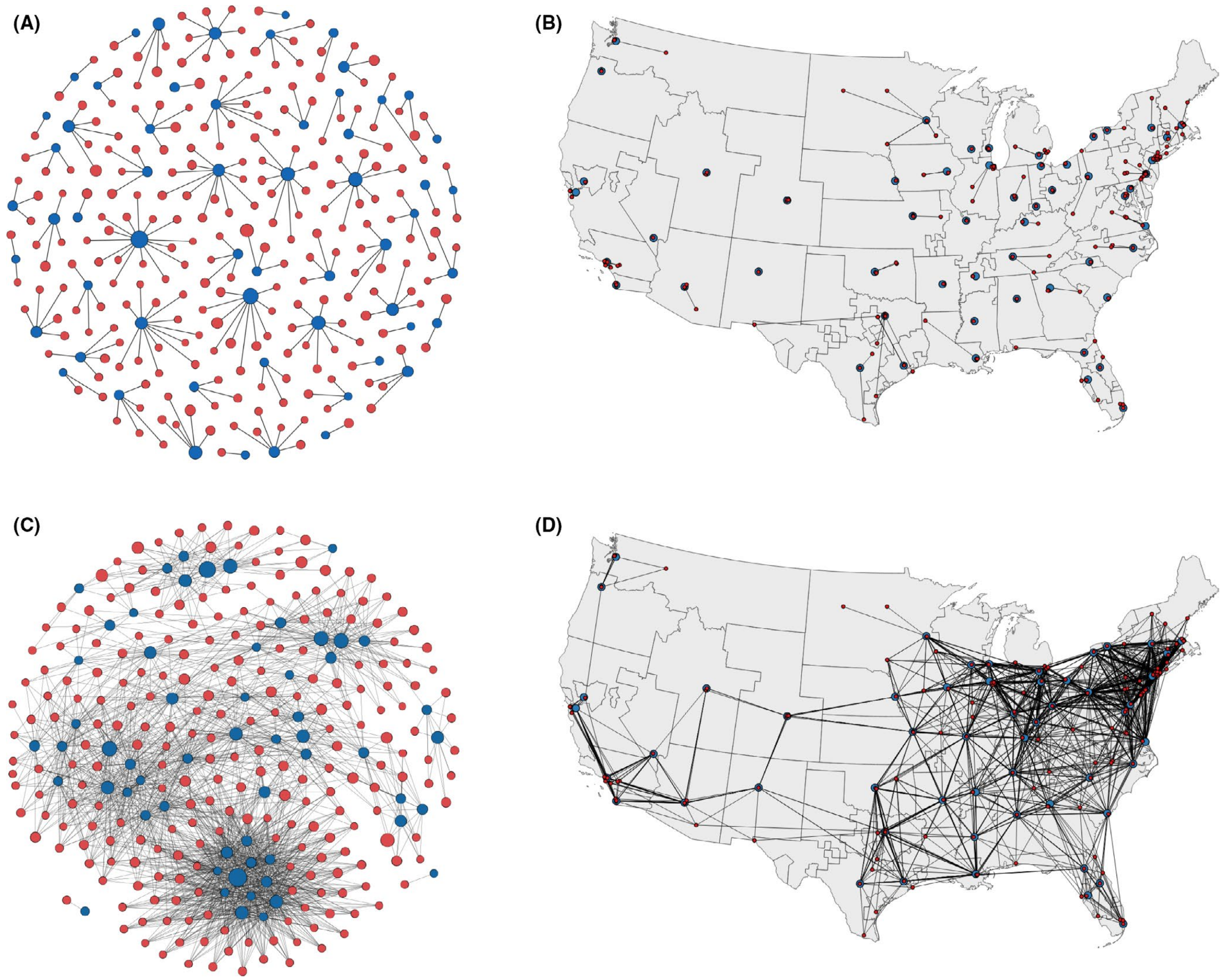

FIGURE 1 Connectivity diagram (A, C) between Organ Procurement Organizations (blue) and kidney transplant centers (red) under the current Donation Service Area-based system (A) and the new 250 nm allocation circles (C). The same connections are presented on a map for the current system (B) and the new system (D)

match run may also change when they must contend with longer travel times, longer cold times, and more competition. The unintended consequence may also be more declined organ offers—a phenomenon that may also be accompanied by a greater use of the "provisional accept" designation, increasing the potential for confusion and discard.

While this scenario currently occurs for imported organs, the frequent introduction of more than one OPO creates the need for more handoffs and the opportunity for communication error. With nearly 20% of deceased donor kidneys being discarded annually, and the high number of organ turn downs that appear to be unrelated to organ quality, there is already concern about organ utilization and the negative impact of the system design.[9,12,19,20] This process benefits from strong relationships between individual OPOs and transplant centers. In particular, transplant centers will have to work with more OPOs that service the increased number of donor hospitals that will now be considered to be "local" within the 250 nautical mile circles. These increased connections may adversely impact the strength of these relationships, at least at the outset, resulting in the unintended consequence of either increased discards or placement of kidneys lower on the match run, thereby exacerbating the subjectivity that is already adversely impacting the allocation of organs, access to transplantation, and patient outcomes.[9,21]

Although the circles are of a fixed radius from the donor hospitals, travel logistics and travel options can be quite variable resulting in markedly different travel times from a given donor hospital to different transplant centers at similar distances due to factors such as geography, road and traffic patterns, proximity to airports, and terrain. While logistical challenges exist in our current system as well, there is likely to be a steep learning curves as OPOs identify these challenges and their potential solutions. This is likely to also be associated with increased costs given the expectation that the average distance traveled will also increase. Tissue typing and physical crossmatching requirements will add to the logistical complexity, with an increasing number of centers at which patients near the top of the match run are listed. This complexity is likely to be

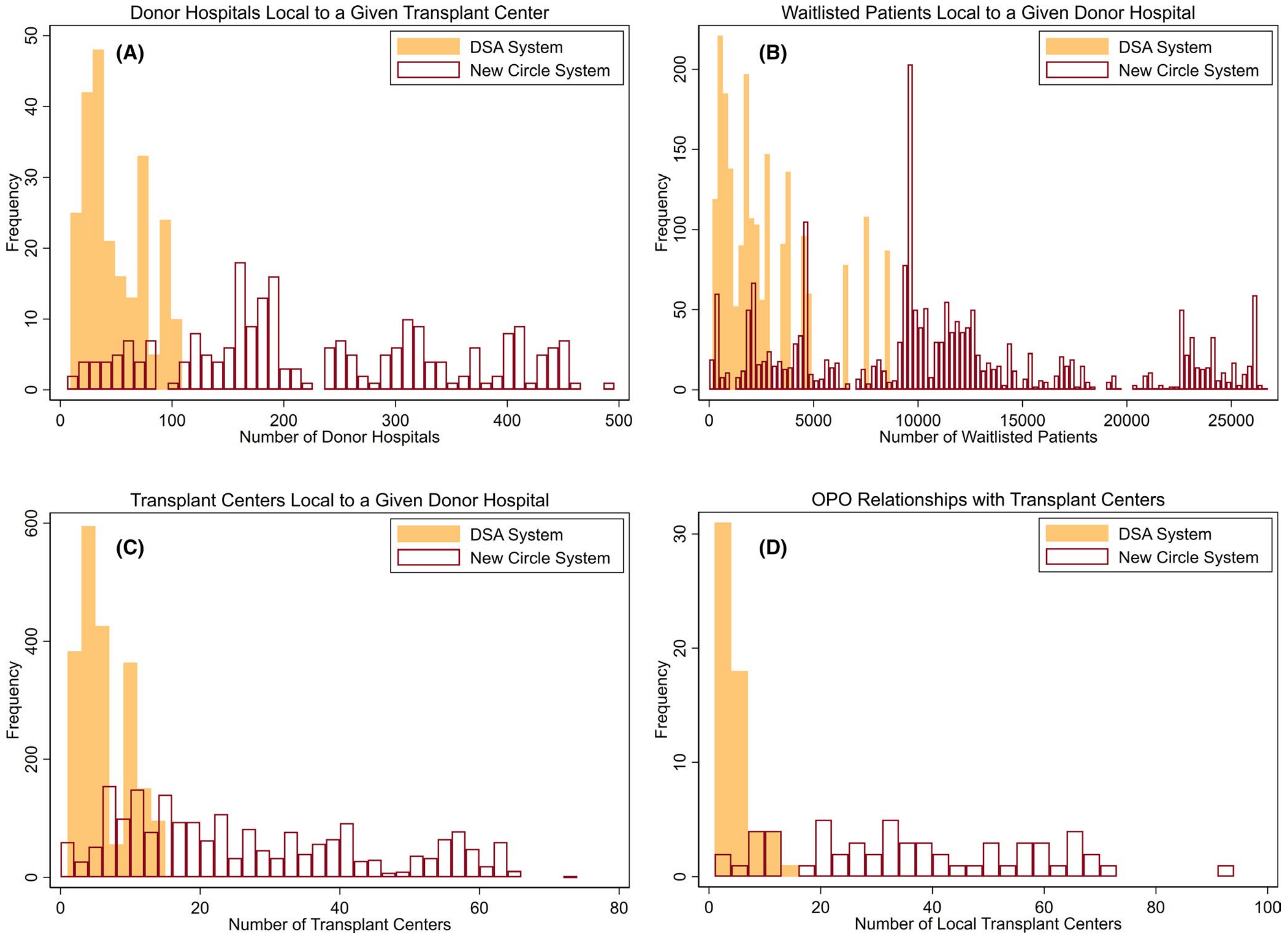

FIGURE 2 Histograms of increase in complexity under 250 nm system from the perspective donor hospitals local to a transplant center (A), waitlisted patients local to a donor hospital (B), transplant centers local to a donor hospital (C), and OPO relationships with transplant centers (D)

accompanied by increased costs for both OPOs and transplant centers but may have the unintended consequences of having centers more willing to consider a virtual crossmatch instead. The impact of these shifts for sensitized patients remains to be seen—and should be proactively monitored.

We also note that the number of donor hospitals that have a "local" transplant center with an offer acceptance ratio >1, as reported in the August 2020 SRTR program-specific-reports, will increase from a median of 2 to 11 centers. This increased competition within the 250 nm radius may result in fewer organs placed outside of the circle, which in turn could result in decrements in the total time traveled, cold ischemia time accrued, and the need to use the national allocation process. The new system may also increase organ utilization rates and force less aggressive centers to reconsider their offer acceptance thresholds to benefit their patients.

3 | PATIENT-LEVEL IMPACT

The patient-level repercussions of the impact of broader organ sharing on deceased donor kidney utilization may differ based on where the patient is located. Under the current system, "aggressive" transplant centers may be more likely to utilize marginal organs out of necessity due to an intense local organ shortage. After a shift to the circle system, many aggressive centers may have increased access to higher quality local organ offers for candidates listed at their centers. However, if this benefit to certain local candidates is accompanied by a decrease in net utilization, we may expect that overall waiting times and access to transplantation may not improve but rather worsen. While the relative paucity of organs will persist overall, the willingness of the transplant center to accept an organ is not clearly associated with local competition or organ availability.[22-25] There is considerable variation in the willingness to accept organs that contributes to the varied probability of transplantation,[21] which is also reflected in the willingness to use less-than-ideal kidneys that appears unrelated to organ availability or local competition.[22]

Given the established benefit of earlier transplantation with marginal kidneys compared to waiting for higher quality organs, any potential adverse impact such as rising kidney discard rates must be identified early. The proposed changes should result in reductions in the currently observed geographic disparities in access to transplantation, by creating broader sharing across larger geographic areas. The median number of patients that would appear in a "local" match run for a kidney from a given donor hospital will increase from 1925 under the current system to 9910 under the circle system (Table 1, Figure 2).

Whether the impact of the increased competition will be even across centers remains to be seen. An increase in opportunities for local placement of the organ due to an increase in competition for these organs[22,23,25] should lower geographic disparities. However, the number of large transplant centers, defined as performing at least 50 deceased donor kidney transplants per year, local to each donor hospital will increase from 2 (IQR 1–4) to 12 (IQR 6–19), while the number of aggressive local centers will increase from 2 (1–4) to 11 (5–17) (Table 1). The increased organ pool for transplant centers may disproportionately benefit more aggressive centers or centers with more resources to efficiently manage the resulting increased complexity. Differential impacts on transplant centers, even if driven by center philosophy, may widen the disparities in the probability of transplantation for patients between centers—or the existing spread may be attenuated by an overall increase in organ utilization.

4 | MONITORING THE NEW SYSTEM

Given the wide range of outcomes in the system, and the differences between the kidney allocation system and other organs, pending changes in the kidney allocation system may result in considerable differences from those that we have seen with the other solid organ transplant systems. The implementation of a robust monitoring system is warranted to ensure rapid identification and response to unintended consequences resulting from the proposed changes (Table 2).

These monitored areas must include organ offer acceptance patterns, organ recovery and utilization rates, and wait times both for the transplant center and broader geographic areas. In addition, attention to process measures including organ procurement (or nonprocurement)[26] rates, changes in cold ischemia times, provisional yes, number of declined offers, and early posttransplant complications (e.g., delayed graft function, primary non function) will be important. Larger centers commonly have more resources and the ability to be more aggressive; the effects of this on medium- and smaller-sized transplant centers is harder to predict. Similarly, there are likely to be differences in the impact experienced in more dense regions of the country compared to the less densely population regions of the country which further underscores the need for prospective monitoring.

As a needed improvement, improved transit logistics for tracking organ movement and determining more precise arrival times of these organs is an important imperative that the OPTN should invest in as the complexity of the allocation system increases. Improved tracking will have the added advantages of potentially creating more accountability for travel times and the creation of process measures that would help lower cold ischemia times.

Finally, patient behavior changes may result as well. For example, significant reduction in multilisting by patients would represent a recognition by patients that this practice no longer represents a large advantage. The distance required to travel to another transplant center to gain benefit from multilisting will likely decrease for most transplant candidates. Although centers in close geographic proximity will likely have a similar donor pool (e.g., multiple hospitals in close proximity in cities like Boston and New York), transplant centers in less dense parts of the country will have markedly different organ availability over a shorter distance (in the Midwest and South, for example). As a result, candidates may benefit from multilisting within current DSA borders under the new system. Perhaps more importantly, the perceived absence of a perceived benefit from listing at multiple centers within the boundaries of a single DSA will disappear and may encourage more multilisting. Changes in multilisting patterns (which are also influenced by center aggressiveness as well as nearby transplant center wait times)[9,22] and pursuit of living donation (as a result of differing allocation and perceptions of access) may identify differences that may otherwise go unrecognized in the absence of a robust process measurement plan.

TABLE 2 Potential measures for the ongoing assessment of the deceased donor kidney allocation system

Transplant center measures	Process measures	Patient behaviors
Organ offer acceptance patterns	Organ nonprocurement rates	Multilisting patterns
Organ utilization rates	Cold ischemia time	Pursuit of living donors
Wait times at transplant centers	Overuse of "provisional yes"	
Acceptance of multilisting patients	Early posttransplant complications	
Center aggressiveness	Discard rates	
	Geographic disparities	

Importantly, these monitoring paradigms need not—and should not—create new transplant center metrics, but rather should be comprised of measures that will ensure that the changes in the allocation system will benefit the patients as intended by lowering geographic disparities without making other undesirable features of our current system worse. Transparency about any observed changes is also crucial given the possibility that centers will be differentially impacted.

5 | CONCLUSIONS

Equity in kidney transplantation remains a lofty goal, and the change to concentric circle allocation of deceased donor kidneys is a key step toward that goal. Diminishing geographical disparities is a likely outcome of the proposed change. However, marked increases in the complexity of the allocation system from the perspective of donor hospitals, OPOs, and transplant centers should be expected, along with the potential for unintended consequences. Early evaluation of the impact of the changes are needed, beyond an assessment of the impact on geographic disparities, to ensure that the changes do not inadvertently incentivize or change behavior/processes and exacerbate other imbalances. Close monitoring may also create opportunities from the unintended consequences, not unlike a learning health-care system, that might benefit our patients and inform future iterative changes. In short, monitoring these changes should be an imperative as we remain focused on benefiting our patients.

DISCLOSURE

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

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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