



September 24, 2024

Jim Kim, MD
Chair
Organ Procurement and Transplantation Network
Kidney Transplantation Committee
Keck School of Medicine of USC
1520 San Pablo St. Health Sciences Campus
Los Angeles, CA 90033

Re: Continuous Distribution of Kidneys Update, Summer 2024

Dear Dr. Kim,

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to provide comment regarding the Organ Procurement and Transplantation Network (OPTN) request for feedback on “Continuous Distribution of Kidneys Update, Summer 2024.”

Maximizing patients’ access to kidney transplant—and ensuring that access is equitably available to all patients—is of utmost priority for ASN. Addressing the growing non-use rates as well as the increase in allocations out of sequence are crucial components of achieving that goal, and the society appreciates the OPTN, the OPTN Kidney and Pancreas Committees, and the Expeditious Task Force’s attention to these issues. ASN agrees that the current allocation system is not optimal but has reservations about the advancement of continuous distribution based on timing and issues with Kidney Allocation System (KAS) 250.

ASN recognizes that the OPTN Kidney and Pancreas Committees in particular have put several years of work into envisioning a future system of continuous distribution, a points-based framework that assigns a composite allocation score that considers all of a candidate's characteristics, replacing the current classification-based framework, which draws hard boundaries between classifications that exist in the current allocation system.

The society understands that this summer 2024 update builds on these prior efforts and a vision to move towards continuous distribution but questions why advancing continuous distribution is a focus at this moment in time when so many other components of the transplant system are in flux and when KAS 250 has presented such extensive challenges. Since OPTN initially resolved to pursue continuous distribution, seismic shifts have occurred in the field of transplantation—some planned by policymakers, others unforeseen changes or unintended consequences—that ASN believes warrant reconsideration of the pursuit of continuous distribution.

In this letter, ASN outlines its broader concerns regarding the momentum towards continuous distribution and offers input on select aspects of the specific requests for feedback.

Multiple Ongoing Initiatives

ASN supported the September 2023 announcement that the originally anticipated timeline for progression to continuous distribution for kidney and pancreas was being revised, coinciding with the establishment of the OPTN Expeditious Task Force. Since that time, the number of changes and initiatives—both led by the Expeditious Task Force and originating from other OPTN or HHS efforts—has grown. Particularly because these changes may substantially affect organ allocation and organ use practice patterns, preparing to shift the allocation system framework to continuous distribution in parallel raises questions about the timeliness of the effort.

As one example, while ASN has expressed reservations regarding the expedited placement variance proposed in February 2024, the society nonetheless observes that the vision for the variance—to test and ultimately codify workarounds to the current allocation system—could profoundly change how organs are allocated and used nationwide.¹ Given that the community will be awaiting the outcomes and learning from the variance (and working through the OPTN policy process to integrate any protocols deemed successful to the allocation system) it seems potentially discordant to be pursuing major changes to the allocation framework in parallel.

Additionally, the Centers for Medicare and Medicaid Innovation (CMMI) Increasing Access to Organ Transplantation (IOTA) model has been proposed to take effect next year and aims to test incentives for greater organ acceptance and use over the subsequent six years. Major changes to the allocation framework in parallel could potentially hinder CMMI's ability to determine the success of the model.

ASN highlights that numerous advancements in infrastructure and technology would first need to be achieved to make continuous distribution, as currently envisioned, function. The HRSA Modernization Initiative, implementing the Securing the U.S. OPTN Act, enacted in 2023, includes considerable emphasis on improving the underlying information technology as well as data availability and quality within the transplant system. One significant barrier to optimal organ allocation ASN hopes to see addressed under the auspices of the Modernization Initiative is the timely sharing of crucial CMS patient data with HRSA, including regarding data on patient death or return to dialysis that is crucial for organ allocation and other critical policy and regulatory decisions. Any future changes to the allocation framework could and should benefit substantially from access to this information as well as other IT modernizations.

Challenges Under KAS250

ASN observes that recent experience with the current kidney allocation framework, which aimed to move towards a system of continuous distribution using a 250 nautical mile cutoff, has included several challenges. KAS250 has introduced operational inefficiencies that have overwhelmed many transplant programs. These inefficiencies are directly linked to the rise in discards and in some analyses been shown to be as disruptive as the initial surge of COVID in March 2020.^{2,3} Prior to KAS 250, approximately 6-7 million offers were made annually, whereas

¹ ASN public comments: "Proposed Expedited Placement Variance." February 2024. <https://www.asn-online.org/policy/webdocs/24.2.4ExpeditedVarianceComments.pdf>

² Yu, M. et al. Use of Offer Bypass Filters under the Circular Kidney Allocation System. *Kidney360*, May 2024. DOI: 10.34067/KID.0000000000000423

³ Cron, D. et al. Increased volume of organ offers and decreased efficiency of kidney placement under circle-based kidney allocation. *Am J Transplant*, 2023 Aug. DOI: 10.1016/j.ajt.2023.05.005

under KAS 250 the number of offers is now approaching 30 million—an unsustainable volume of offers for transplant programs to process. In 2022, it required an average of 150 offers to place a single kidney, and the majority of the approximately 30 million offers made in 2022 were made for kidneys that ultimately went unused.⁴ ASN notes, however, that there is no way for transplant centers to identify the offers for organs that will be discarded, and thus they need to consider all offers received – offer volume continues to rise despite efforts to implement organ filters (organ offer filters are voluntary tools transplant programs use to bypass receiving organ offers they would not accept).⁵ In recent years, the U.S. transplant system has seen unprecedented numbers of organs discarded and organs allocated out of sequence (nearly one in three kidneys are currently placed out of sequence).⁶ The OPTN Medical and Professional Standards Committee (MPSC) itself notes that it expects the number of allocations out of sequence it reviews to continue to increase.⁷ The increase in out of sequence allocations and evidence of open offers⁸ that have led to significant list diving or other allocation violations is concerning and ought to inform any further iterations of allocation policy.

There are other concerning trends that appear largely attributable to KAS250. For example, the percentage of kidneys accepted by the top-listed recipient has significantly decreased, from 24% in 2019 to a little more than 12% in 2022. These worsening statistics suggest that the system is not functioning optimally. In short, we have moved from an allocation system that used a hub-and-spoke approach to a model with many-to-many relationships, creating a dramatic increase in complexity, with far more centers being represented in the top 50 patients to whom an organ is offered.⁹

The society also observes that while KAS250 was purportedly implemented with the goal of lowering geographic inequities, differences in organ supply relative to the waitlist were identified but never shown to be the primary driver of the variation in transplantation rates.¹⁰ Rather, it would appear that the large disparities in the probability of transplantation for those fortunate few who did make it to the waitlist was primarily determined by the organ offer acceptance of their centers.¹¹ In other words, center behavior likely played a larger role in determining likelihood of transplantation than organ availability within a given geography. It is also notable that under KAS 250, cold ischemic time even for kidneys transplanted within the *original*

⁴ Yu M., et al. Deaths on the Waitlist Following Declined Offers Represent Missed Opportunities for Patients AJT, Volume 24, Issue 6, Supplement 1.

⁵ Yu, M. et al. Use of Offer Bypass Filters under the Circular Kidney Allocation System. *Kidney360*, May 2024. DOI: 10.34067/KID.0000000000000423

⁶ King K. et al. Deceased donor kidneys allocated out of sequence by organ procurement organizations. *Am J Transplant*. 2022;22:1372–1381

⁷ OPTN Membership and Professional Standards Committee Report to the Board of Directors. June 12, 2024. https://optn.transplant.hrsa.gov/media/iwradpt5/20240612_mpsc_report-to-the-board.pdf

⁸ ASN notes that the term “open offers” refers to offers that an OPO makes to one center exclusively, allowing that center to select the patient it would like to offer the kidney to (irrespective of where they would have been in the match run) once the kidney is offered to the center out of sequence (functionally, more of a “closed” offer than an “open” offer).

⁹ Adler J., et al. Greater complexity and monitoring of the new Kidney Allocation System: Implications and unintended consequences of concentric circle kidney allocation on network complexity. *Am J Transplantation*. December 2020. DOI: 10.1111/ajt.16441

¹⁰ King K. et al. Geographic Variation in the Availability of Deceased Donor Kidneys per Wait-Listed Candidate in the United States. *Kidney Int Rep*. Nov. 2019. doi: 10.1016/j.ekir.2019.08.018

¹¹ King K. et al. Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *JASN*. Dec. 2020. doi: 10.1681/ASN.2020030335

geographic boundaries of the procuring OPO has increased, again pointing to operational inefficiencies affecting even organs that travel only a short distance.¹²

Furthermore, as the number of offers made to centers has grown substantially under KAS250, even programs that have instituted nuanced organ offer filters have struggled to keep pace with the volume, creating operational challenges and indirectly contributing to systemic inefficiencies—in part due the inadequacy of the available filters. Programs struggling to keep pace under KAS250 raises concerns about whether the system would be capable of handling an even greater increase in offers under a 650 nautical mile radius for distribution and whether the number of kidneys placed out of sequence would continue to grow even more—further obviating the concept of the match run itself. Moreover, it is unclear whether a larger nautical mile radius (and accompanying burden for transplant centers) would offer meaningful benefit in terms of organ utilization. As the number of organ offers has ballooned, utilization rates have not improved.

In light of these challenges, it is worthwhile to ask:

- What is the fundamental goal of further advancement towards continuous distribution?
- What evidence does the committee have currently to suggest that the current allocation system is stable or benefiting patients in a way that makes further advancement towards continuous distribution advisable?

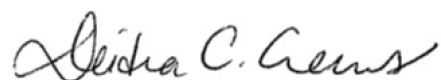
Based on the available data, ASN is not convinced that moving forward with continued distribution is advisable or timely. ASN recommends the Committee assess these questions and pause the continued momentum toward continuous distribution. Again, the society supports improving the existing allocation algorithm but is not convinced that pursuing the continuous distribution allocation framework is the right approach.

Pediatric population implications

Should the committee and OPTN continue to pursue continuous distribution, ASN urges particular focus on ensuring that the new allocation framework continues to meet the needs of the pediatric patient population. For example, a system that shifts towards a 650 nautical mile radius (and increased cold ischemic time and/or delayed graft function) may not be adequate for children.

In sum, ASN appreciates the opportunity to make recommendations about continuous distribution and hopes this feedback is useful as the committee and OPTN consider next steps. Please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org with any questions or to discuss this letter in more detail.

Sincerely,



Deidra C. Crews, MD, ScM, FASN
President

¹² Early Effect of the Circular Model of Kidney Allocation in the United States. Puttarajappa CM et al. JASN. January 2023. DOI: 10.1681/ASN.2022040471