

October 16, 2024

Clifford D. Miles, MD
Chair
Membership and Professional Standards Committee
Organ Procurement and Transplantation Network
4315 Emile St.
Omaha, NE 68105

Submitted electronically

Re: OPTN Special Comment Period: Update Criteria for Post-Transplant Graft Survival Metrics

Dear Dr. Miles,

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 are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the Organ Procurement and Transplantation Network (OPTN) Special Comment Period: Update Criteria for Post-Transplant Graft Survival Metrics.

Maximizing patients' access to kidney transplantation—and ensuring that access is equitably available to all patients—is of utmost priority for ASN. The society stands ready to work with OPTN, including the OPTN Membership and Professional Standards Committee and Expeditious Task Force, to achieve this goal, and appreciates this proposal as a positive step in that direction. Overall, ASN supports the MPSC's recommendation to change the flagging threshold for 90-day graft survival and 1-year conditional on 90-day graft survival for adult transplant recipients.

Transplantation is the optimal therapy for most people with kidney failure, yet too few people on the more than 90,000-person long kidney waitlist get a chance to receive a kidney, with an average of 12 people per day dying on the waitlist. Meanwhile, the organ nonuse rate continues to grow, eclipsing 25% nonuse in 2022 and climbing to nearly 30% nonuse today.^{i,ii} The United States has the highest nonuse rate in the world, and data suggest that many procured kidneys that currently go unused would have benefitted a recipient if transplanted.ⁱⁱⁱ Indeed, the great majority of transplanted kidneys offer patients quality of life and survival benefits as compared to dialysis, and patients who receive a kidney transplant at even the lowest-ranked programs have better outcomes than those who remain on dialysis.^{iv,v}

ASN believes that our transplant system has the potential to successfully utilize many more of these more than 8,500 unused kidneys to benefit patients, though certain policy changes are needed to hasten achievement of that goal. The reasons for nonuse are multifactorial, but the September 2024 proposal from the MPSC to change the flagging threshold for graft survival metrics for adult transplant recipients may be an important step in the right direction. Indeed, in its February 2024 feedback to the Expeditious Task Force, ASN suggested “changing transplant center performance evaluation and public reporting practices that create more latitude for programs to accept marginal kidneys” to decrease nonuse. and the society appreciates that this

proposal moves the OPTN in that direction.

As MPSC noted, “the perception that programs consider the potential of future MPSC review when determining whether to accept more complex organs or perform more complex transplants could pose a barrier” to increasing transplant rates or decreasing wait time and patient mortality on the waitlist. ASN agrees that concerns about flagging have contributed to risk-averse behavior and, for some patients awaiting a kidney transplant, missed opportunities to receive the optimal therapy. Accordingly, ASN supports MPSC’s proposal to revise the current adult graft survival metrics and make them less stringent. The society hopes that this change will allow some programs presently making conservative patient or organ offer acceptance decisions due to concern about an MPSC flag will feel they have the latitude to say “yes” to more kidneys (particularly more complex kidneys) and to more patients who could benefit from a transplant.

Specifically, MPSC recommended changing the flagging threshold from a 50% probability that the transplant program’s hazard ratio is greater than 1.75 to a 50% probability that the transplant program’s hazard ratio is greater than 2.25. Data presented in the proposal show that the number of programs flagged under the alternate proposal would drop to just 14, versus the 42 flagged under current thresholds using January 2024 Program-Specific Report data. As MPSC noted in its proposal, most programs that receive flags go on to be cleared. ASN supports raising the flagging thresholds as recommended.

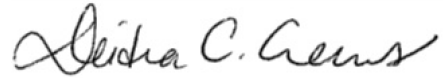
ASN agrees with MPSC’s rationale not to change the thresholds for flagging for pediatric programs, particularly given that the low volume of pediatric transplant programs can make it difficult to discern statistically meaningful outliers, and the paramount importance of safety in this patient population. ASN also understands that MPSC considered raising the threshold on the offer acceptance metric from the current 50% probability that the rate ratio is 0.30 to 0.35, or higher. ASN agrees that it makes sense not to pursue this change because MPSC has less experience reviewing programs flagged based on the adult offer acceptance rate ratio as compared to the two graft survival metrics.

As the new thresholds take effect for the 90-day graft survival and 1-year conditional on 90-day graft survival for adult transplant recipients, ASN urges MPSC, together with the Scientific Registry of Transplant Recipients, to continue to closely monitor patient outcomes to identify any unforeseen trends emerging that suggest unintended consequences.

Lastly, ASN suggests that as a complementary step to changing the graft survival flagging thresholds, MPSC revisit instituting a composite score for its four existing performance metrics (graft survival metrics, organ offer acceptance, and waitlist mortality). With this approach (which would require the establishment of different thresholds) flagging would occur if centers were performing poorly across multiple measures, reducing the emphasis on any one isolated metric.

ASN is committed to creating a world without kidney diseases, including by continuing to drive improvements in transplantation and maximizing access to this critical therapy for all Americans who could benefit. To discuss these recommendations further, or if ASN can provide any additional information, please contact ASN Strategic Policy Advisor to the Executive Vice President Rachel Meyer at rmeyer@asn-online.org.

Sincerely,



Deidra C. Crews, MD, ScM, FASN
President

ⁱ Mohan S, et al. Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy. *Kidney International*. 2023.

ⁱⁱ SRTR. Non-Use Rate: Kidney. Donation and Transplantation System Explorer.
<https://www.srtr.org/tools/donation-and-transplant-system-explorer/>

ⁱⁱⁱ Husain S, et al Characteristics and Performance of Unilateral Kidney Transplants from Deceased Donors. *CJASN*. Vol 13. January 2018.

^{iv} Tonelli M., et al. Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *Kidney International*. 2011.

^v Schold, J. et al. Association between Kidney Transplant Center Performance and the Survival Benefit of Transplantation Versus Dialysis. *CJASN*. October 2014.