



September 30, 2021

Mr. Ian R. Jamieson, Chair  
Membership and Professional Standards Committee  
Organ Procurement and Transplantation Network  
Health Resources and Services Administration  
U.S. Department of Health & Human

**Re: Enhance Transplant Program Performance Monitoring System**

Dear Mr. Jamieson:

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 comment on the Organ Procurement and Transplantation Network's (OPTN) recommendations developed by the OPTN Membership and Professional Standards Committee.

Transplantation is the best available therapy for many individuals with kidney failure. However, Black Americans, Latinx Americans, Native Americans, and Native Hawaiian/Pacific Islander face disparities in nearly every step of transplant care. Black Americans are less likely than white Americans to be identified as transplant candidates, referred for evaluation, placed on the kidney transplant waitlist, receive kidney transplants especially pre-emptive transplants, and/or receive living donor kidney transplants, while also being more likely to receive lower quality kidneys, have organ offers declined for them and have poorer transplant graft survival.

Many factors contribute to these inequities that are within the control of federal policy makers. In recognition of the OPTN's role in setting standards, monitoring, and promoting high quality care in the transplant arena, ASN feels the organization has an important role in working with policymakers to address these inequities. Factors where OPTN's leadership influence federal policy include:

- Addressing transparency of confusing federal oversight structures of organ procurement, allocation, and transplantation
- Eliminating policies that engender risk aversion and transplant center evaluation measures that are misaligned with patient interests
- Removing patient evaluation criteria to gatekeep transplant access that have a limited association with patient outcomes (especially compared to patient

outcomes on other kidney replacement therapies), such as income, race, requirement of dual insurance, substance use, and obesity.

The new MPSC proposal has several measures of quality, and, while we recognize the need for quality measures to drive improvements in transplant, the current proposal raises significant concern as outlined below.

### **Waitlist Mortality Ratio**

The national waitlist is already shrinking as a direct result of fewer additions and an increasing number of waitlisted candidates being removed. As a result, the proportion of patients with end stage kidney disease that are on the waitlist is at the lowest level in over two decades suggesting that the waitlist is no longer a reflection of the need for transplantation in this population. This measure will only further disincentivize waitlisting of candidates and will further obscure transplant center practices with regard to the referral, evaluation, and selection for waitlisting.

Also, given that kidney transplant centers are not primarily responsible for the care of patients while they are on the waitlist, their ability to institute or change clinical practices that would influence the mortality of waitlisted candidates is limited. This proposal raises further questions about the relevance of this measure as a measure of the quality of care being provided by transplant centers.

### **Offer Acceptance Ratio**

While we agree that this is an important measure that is highly variable across transplant centers and appears to have a direct impact on the probability of transplantation for candidates at that center, the implications of continuing to exclude bypass offers from the denominator needs to be better understood as does the benefit of excluding those organs that are discarded. In addition, this measure should be made easily accessible to patients along with information on how their center practices are likely to impact their ability to get a transplant. Alternatively, the rate at which transplantable organs are declined for some patients but are used successfully at other transplant centers may achieve the same goal while also creating a clear and unambiguous feedback loop to transplant centers about the organ offer evaluation processes.

### **90-Day graft survival**

It is not clear that the relatively few events in this category are likely to allow for meaningful analysis or interpretation. The development of quality measures should focus either processes of care or outcome measures where there is an opportunity for clinically relevant improvement. Given that it is unlikely that 90-day survival rates can be lowered any further in a systematic manner and that adverse events are relatively rare events that preclude the identification of systemic problems by this measure.

## **Conditional 1-year graft survival**

With the withdrawal of one year graft outcomes by CMS as a quality measure and the concurrence of Health Resources & Services Administration (HRSA) that longer term measures are preferred by patients, this measure would be at odds with these trends. Currently, the differences in the 1-year survival rates between transplant centers are small and not clinically meaningful. In addition, patients do not perceive this as a meaningful measure of quality of care, the ability of centers to make clinically significant improvements in their 1-year survival rates undercuts the value of this as a meaningful quality measure.

## **Aspirational/Experimental Metrics**

Measures of quality of care should be objective, reliable, valid, valued by patients, provide insights where there is clinically significant variation across centers, and account for variations in the clinical acuity being encountered. Quality measures should provide actionable insights and be designed in a manner that the processes being assessed are under the influence of transplant centers. This is the only way to ensure that they have the ability to influence the quality measure and allow it to reflect changes in clinical practice.

Measures should be designed to drive improvements in processes of care that result in improved patient outcomes that are meaningful to both the health care system (i.e., reduced mortality, reduced graft failure) and to patients (i.e., improved patient activation, improved adherence, improved quality of life). New measures of quality should also be evaluated for the risk of unintended consequences especially those that adversely impact access to transplantation.

Access to transplantation is important to both patients and the health system and improved access to transplantation is a prerequisite to reducing disparities and increasing transplantation rates. As a result, measurement of process measures (such as the proportion of referrals that start evaluation or the time spent in evaluation) or outcome measures (such as the proportion of referred individuals who are eventually waitlisted) would be important ways that access to transplantation could be objectively measured with a focus on processes that are exclusively under the purview of the transplantation.

Novel metrics are likely to require additional data capture. These additional data may be necessary because the process or outcome of interest is not currently being captured in the OPTN registry. An example of this would be data elements about the pretransplant evaluation process are not currently part of the OPTN registry. Data elements necessary for a more robust risk adjustment may also be necessary to reflect current clinical care complexities and to ensure that there is confidence in the community that the measures are reflective of the variations in patient population across centers.

## **Alignment of metrics and other policies**

Subjecting transplant centers to different quality metrics that are not aligned or using different methodologies/ thresholds has been recognized as being part of the historical challenge in the transplant community. The resulting chaos contributed to the decision to withdraw CMS measures. Needing to track and respond to different quality measures that are not aligned creates logistical challenges for smaller programs. Such a situation will also result in the creation of competing priorities at transplant centers that would undermine the primary mission of increase transplants. Similarly, new payment models and the development of interventions such as the kidney transplant learning collaborative should be designed to align with one another. It is unclear if there was an attempt to ensure that that new metrics align with the recently implemented mandatory ESRD Treatment Choices (ETC) model and with the proposed voluntary, value-based payment model: the Kidney Care Choices (KCC) model.

As you are aware, the ongoing "Task 5" effort, by HRSA and the Scientific Registry of Transplant Recipients (SRTR), to identify and implement new proposed metrics is ongoing. This proposal from the MPSC appears to be distinct and separate from those efforts. As a result, these proposals seem both premature and create a situation that will limit what the Task 5 effort can propose or risks being distinct and misaligned from their final recommendations.

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 ASN members thank the Biden-Harris Administration for its commitment to providing a robust, transparent approach to transplantation critical to improving kidney care for all patients. To discuss this letter further, please contact David White, ASN Regulatory and Quality Officer, at [dwhite@asn-online.org](mailto:dwhite@asn-online.org) or (202) 640-4635.

Sincerely,

A handwritten signature in cursive script, appearing to read "Susan Quaggin".

Susan E. Quaggin, MD, FASN  
President