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Suma Nair, PhD
Associate Administrator
Health Resources and Services Administration
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5600 Fishers Lane
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Re: Process Data for Organ Procurement and Transplantation Network, OMB no. 0906-xxxx-New

Dear Administrator Johnson and Associate Administrator Nair,

The National Kidney Foundation is grateful for the opportunity to provide feedback on the information collection request (ICR), *Process Data for Organ Procurement and Transplantation Network*, recently issued by the Health Resources and Services Administration (HRSA). We support the initiative to expand and standardize organ procurement and transplantation network (OPTN) data collection to include essential process data from organ procurement organizations (OPO) using the ventilated patient form, as well as referral and evaluation information gathered from transplant centers using the prewaitlist data form.

According to the World Health Organization (WHO), reliable data are vital for understanding the state of healthcare, and “analyzing these data points can help guide policy decisions, funding, and research agendas to address gaps in health care service provision better and meet the most urgent needs.”¹ The organ shortage and the prevalent and preventable health inequities in kidney transplantation in the United States are indeed an urgent public health crisis that demands strategic data collection, transparent reporting, intentional research, and effective interventions.

The ventilated patient form and prewaitlist forms are necessary to conduct in-depth analyses to identify best practices and implement targeted interventions that optimize quality improvement in the organ donation and transplantation processes. Additionally, the insights gained from these comprehensive data, as noted above by WHO, will provide valuable information to the Department of Health and Human Services (HHS) agencies that oversee and regulate the organ donation and transplantation system to better inform policy development, ensuring that any resolution in practices is evidence-based and aligned with the needs of patients and communities.

NKF acknowledges the valid concerns surrounding the administrative burden associated with the proposed new data collection forms. We strongly encourage HRSA to investigate the potential for incorporating automation into OPO and transplant center processes to the extent feasible while safeguarding personal health information (examples: referral from donor hospitals to its designated

¹ <https://www.who.int/activities/understanding-global-health-through-data-collection>



OPO, referrals from dialysis centers to transplant centers, use of application program interfaces (APIs) to communicate between providers, OPOs, transplant centers, etc.). By leveraging technological advancements, such as APIs and system integration, the OPTN can significantly minimize the need for manual data entry. This automation could enhance efficiency, reduce the possibility of human error, and promote data integrity. Implementing these technologies would enable OPOs and transplant centers to focus more on strategic initiatives, clinical innovations, and patient services.

We firmly believe that administrative burden should not deter the implementation of the ventilated patient and prewaitlist data forms. HRSA must weigh the potential benefits of enhanced and standardized data collection, which could lead to improved insights to enhance the overall performance of the transplant ecosystem. Therefore, we advocate for a balanced approach that addresses these concerns while still pursuing the necessary advancements in data collection practices that would continue to aid in the modernization of the OPTN.

Lastly, if prioritizing comprehensive data collection with the goal of enhancing efficiency and performance is perceived as problematic, this could be an opportune moment to reimagine the workforce infrastructure of organ procurement organizations and transplant centers. HRSA might consider actively collaborating with leading health systems to identify best practices and implement strategies that would streamline operations and boost the overall performance of their transplant service lines. Engaging in these efforts could involve analyzing current workflows, integrating advanced technologies, and sharing best practices among institutions to ensure that all aspects of the transplant process work together harmoniously, ultimately leading to better patient outcomes and increased organ utilization.

Ventilated Patient Form

OPOs play a crucial role within the transplant ecosystem. They are the sole entities entrusted with the responsibility of recovering organs from deceased donors for transplantation. This vital function entails coordinating with hospitals and families of deceased individuals to facilitate the donation process and ensure that organs are recovered, preserved, and allocated to those in need safely, activities for which they must be held accountable.

Compelling statistics illuminate the need to enhance the organ donation process. On average, 12 individuals on the national kidney transplant waiting list die each day, highlighting a significant disparity between the demand for deceased donor kidneys and the current supply. This concern about the mortality rate underscores the necessity for reform, which data must inform.

Improved data collection through the ventilated patient form will support the closure of gaps in the ability to understand gaps in OPO processes. Missed and untimely organ referral rates and suboptimal approaches for organ donation are not transparently reported for analysis to the transplant

community.² With more than 103,000 individuals currently waiting for a life-saving organ transplant, donor hospitals must recognize every potential opportunity for organ donation by not overlooking organ referrals. Further, every potential donor family must receive a compassionate and respectful approach when considering organ donation. Every missed opportunity can mean the difference between life and death for patients on the national transplant waitlist.

Collecting comprehensive OPO data aligns with the HRSA OPTN Modernization Initiative to improve transparency, performance, and efficiency of the U.S. transplant system and the Centers for Medicare and Medicaid Services (CMS) OPO Final Rule to improve OPO performance. Data collection and reporting are opaque, and to resolve this, data must be publicly available. Currently, the deceased donor registry data are only accessible to the United Network for Organ Sharing (UNOS) and its approved users.³ With variable practice and performance among OPOs,⁴ Systematic collection and analysis of these data could provide researchers, organ donation, and procurement professionals with the necessary information to implement quality improvement opportunities. Quality improvement could maximize organ donation rates and streamline OPO processes, subsequently leading to an increase in transplantation.

Prewaitlist Data Forms

Kidney transplantation is widely regarded as the best treatment for kidney failure, as it markedly improves quality of life and is associated with lower long-term costs compared to continuous dialysis.⁵ However, despite its many advantages, access to this life-saving treatment remains difficult for individuals from socially and economically disenfranchised communities. Comprehensive data analyses are critical to examining the disparities in access to kidney transplantation, especially since minimal efforts have been made to address these gaps effectively.⁶

NKF has consistently championed the promotion of health equity in kidney transplantation. Various non-medical factors restrict access to kidney transplantation, including but not limited to systemic issues like race, socioeconomic status, insufficient knowledge of transplantation, lack of or underinsurance, and disparate referral practices.⁷ These factors are often out of the patient's control. One particularly critical issue was the use of racialized kidney function tests, which contributed to the

² Doby, B. L., Boyarsky, B. J., Gentry, S., & Segev, D. L. (2019). Improving OPO performance through national data availability. *American Journal of Transplantation*, 19(10), 2675-2677. <https://doi.org/10.1111/ajt.15508>

³ https://auth.unos.org/Login?redirect_uri=https%3A%2F%2Fportal.unos.org

⁴ Lynch, R. J., Doby, B. L., Goldberg, D. S., Lee, K. J., Cimeno, A., & Karp, S. J. (2022). Procurement characteristics of high- and low-performing OPOs as seen in OPTN/SRTR data. *American Journal of Transplantation*, 22(2), 455-463. <https://doi.org/10.1111/ajt.16832>

⁵ Patzer RE, Pastan SO. Policies to promote timely referral for kidney transplantation. *Semin Dial*. 2020 Jan;33(1):58-67. doi: 10.1111/sdi.12860. PMID: 31957930.

⁶ Park, C., Jones, MM., Kaplan, S. et al. A scoping review of inequities in access to organ transplant in the United States. *Int J Equity Health* 21, 22 (2022). <https://doi.org/10.1186/s12939-021-01616-x>

⁷ Harding JL, Perez A, Snow K, et al. Non-medical barriers in access to early steps of kidney transplantation in the United States - A scoping review. *Transplantation Reviews (Orlando, Fla.)*. 2021 Dec;35(4):100654. DOI: 10.1016/j.tre.2021.100654. PMID: 34597944; PMCID: PMC8532168.

postponement of transplant referrals. This practice has had detrimental effects, harming thousands of Black kidney patients who face unjust delays in receiving potentially life-saving treatments.⁸

The OPTN's establishment of the policy requiring transplant centers to use race-neutral kidney function tests underscores the ongoing necessity to rigorously investigate the underlying causes of transplant disparities and implement effective remediation strategies. HRSA and members of the OPTN must maintain efforts to understand these disparities fully and work towards a more equitable transplantation system for all individuals in need.

The majority, if not all, of the data in the pre-waitlist data forms is collected by transplant centers. It is crucial to establish a standardized approach to ensure that all patients seeking transplantation receive equitable access to necessary services. To achieve this, we emphasize the importance of transparently documenting key details such as the date of patient referral, the current status of that referral, and the specific reasons for any closure of a referral. This data is vital not only for understanding individual patient journeys but also for identifying broader trends and disparities related to access to transplantation. Therefore, we strongly encourage HRSA to exercise its regulatory authority to mandate the collection of this critical data. By doing so, HRSA can enhance our understanding of transplant access disparities and work towards solutions that promote equity among all patients.

We recognize that patients encounter several challenges, not only in obtaining referrals to a transplant program but also in successfully navigating the evaluation phase. Concerns regarding financial and social support, anxieties related to transplantation, and the level of trust patients have in their care teams may hinder their initiation or completion of the evaluation process.⁹ We have also heard anecdotal stories from our patient advocates, who say losing wages due to the extensive evaluation process has been an obstacle.

To effectively address disparities in the transplant evaluation process, it is crucial to gather comprehensive information regarding potential transplant candidates. This includes determining whether candidates are actively employed and generating income, as financial stability can influence their eligibility and access to healthcare resources. Additionally, we need to track whether a patient progressed to the selection committee stage and, if so, the outcomes of that review. Specifically, it is important to document whether the committee approved or declined the candidate for transplantation and to provide a clear rationale for any declines. Understanding these factors will enable us to identify and rectify inequalities present throughout the transplant evaluation process, ultimately leading to fairer access to life-saving treatments. Lastly, there is currently no standardized

⁸ Boulware LE, Purnell TS, Mohottige D. Systemic Kidney Transplant Inequities for Black Individuals: Examining the Contribution of Racialized Kidney Function Estimating Equations. *JAMA Netw Open*. 2021;4(1):e2034630. doi:10.1001/jamanetworkopen.2020.34630

⁹ Dageforde, Leigh Anne^{1,2}; Box, Amanda^{3,4}; Feurer, Irene D.^{1,2,5}; Cavanaugh, Kerri L.⁴. Understanding Patient Barriers to Kidney Transplant Evaluation. *Transplantation* 99(7):p 1463-1469, July 2015. | DOI: 10.1097/TP.0000000000000543



definition of transplant referral. We believe defining transplant referral for regulatory purposes will improve transplant referral data collection to enhance access to kidney transplantation.

NKF supports implementing the pre-waitlist data forms as a strategy to examine and alleviate inequitable access to the national kidney transplant waitlist. This initiative is crucial for promoting a more equitable healthcare framework for all individuals impacted by kidney disease.

Note about the demographic data collection section on the ventilated patient and prewaitlist data forms: We understand this is the national standardized demographics data form as defined by the Office of Management and Budget Office (OMB). NKF advocates for more inclusive demographic data options to fortify data integrity. For example, there is currently no option available for individuals of mixed race. Both West Indian and Haitian are listed as Black race subcategories, but Haitians are indeed West Indian. Additionally, providing language options is essential, as language barriers can hinder non-English speaking patients or donor families from effectively engaging with the organ donation and transplant system, potentially hindering access to transplantation or the ability to consent to organ donation.

The National Kidney Foundation (NKF) firmly believes in advocating for a high-performing, patient-centered, transparent organ donation and transplant system that ensures everyone has the same access to the life-saving therapy of kidney transplantation; patients deserve this. We believe interventions should be evidence-based, and that requires collecting and reporting comprehensive data. NKF stands ready to support HRSA and OPTN members in ensuring this endeavor is executed successfully. Please contact Morgan Reid, Senior Director, Transplant Policy and Strategy, at Morgan.Reid@kidney.org with any questions.

Sincerely,

Kevin Longino
CEO and Transplant Patient

Kirk Campbell MD
President