E-STAR

The Early Steps to Transplant Access
Registry Executive Management Team
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January 3, 2025

Carole Johnson
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically

RE: Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New

Dear Administrator Johnson,

On behalf of the Early Steps to Transplant Access Registry (E-STAR) Executive Management Team, we appreciate the opportunity to respond to the Health Resources and Services Administration (HRSA) Department of Health and Human Services (HHS) request for public comment on the necessity and recommendations on HRSA's intention to collect information on pre-waitlisting transplant care events.[1,2] This letter is limited to comments on the pre-waitlisting data collection and does not address ventilated death data collection elements. The E-STAR team is a multi-disciplinary team with a decade of experience engaging in collaborative research and quality improvement efforts to identify and reduce barriers to kidney transplantation for end-stage kidney disease patients and reduce disparities in access to transplantation. Although much of our work has been concentrated in the Southeastern U.S., it has been recognized nationally as an innovative effort to achieve equity, access, and transparency in the kidney transplant process. For numerous decades, our team has produced leading research on mechanisms of transplant access and equity, drawing insights from a novel registry database we have constructed over the last 15 years, the Early Steps to Transplant Access Registry (E-STAR), which captures information on measures of referral and evaluation start (pre-waitlisting care processes), as well as waitlisting and transplant receipt. Thus, we offer comments informed by extensive experience working with such data and leveraging them to advance the goals that we share with HRSA of expanding transplant access and equity through quality improvement initiatives and pragmatic trials. Our public comment serves to emphasize the necessity and utility of this data collection and makes several recommendations to improve these efforts to strengthen equity, access, and transparency in the transplantation process.

Briefly, our organization is supportive of the collection of pre-waitlisting data, and we have several points in this letter and suggestions for improvement.

1. HRSA should consider the inclusion of standardized social risk factors or social drivers of health (SDOH) data collection at the time of referral and evaluation start and suggest HRSA consider working with the Gravity Project to ensure alignment.
2. The collection of Social Security Numbers, not just Medical Record Numbers, will be critical to linking these data across other data sources to identify patients with organ failure.

3. Transplant centers have substantial shortages in the nephrology workforce, and pre-transplant processes can be time- and labor-intensive and may require hiring additional staff. These challenges must be addressed by ensuring that transplant centers can cover these costs.
4. Preliminary data from >35 transplant centers across the country have demonstrated that at least some of these data elements are feasible to collect, but there may need to be a phase-in or period of voluntary data collection (e.g., first year) to ensure programs have enough time to conduct appropriate data quality work to ensure the data are valid and feasible to obtain. E-STAR processes and lessons learned may be helpful for HRSA in implementation of data collection.
5. We recommend using more advanced IT processes to automate the submission of these data, such as software for automated referrals, and/or use of Application Programming Interfaces to collect these data, and/or submission of these data elements as a "batch submission" on a frequent (e.g., quarterly) basis, rather than adding new forms at different time points to collect for each patient at the time of the transplant phase.
6. Standardized definitions for each step in the kidney transplant process (e.g., evaluation start vs completion) and sequential data collection are needed to ensure consistency and data accuracy across centers.

Calls for national data collection have persisted for decades, and the proposed initiative represents an important opportunity to enhance transparency and advance equity in access to transplantation. The disease burden of end-stage kidney disease in the U.S. is substantial,[3] yet access is limited and variable.[3-6] The cost-effectiveness of transplant[4-6] underscores the need for increased efforts to improve access; however, the lack of these data hinders the ability to critically understand why only some patients are referred, evaluated, or selected for listing. Our team has long advocated for national data collection on the early steps in the transplant process, including transplant referral and evaluation start and completion. In the absence of such data and motivated by shared goals with the Southeastern Kidney Transplant Coalition,[7] we have spent over a decade building the only multi-regional database capturing referral and evaluation data. Using E-STAR, established in 2012, we found substantial dialysis facility-level variability in referral and evaluation start in Georgia (range: 0% to 75%)[8] and later in the Southeast (range: 0% to 90%)[9]. E-STAR, now encompassing data from 37 transplant centers across New York, New England, the Southeast, and the Ohio River Valley, reveals significant transplant center-level variation in referral and evaluation start overall (referral range: 2% to 52%; evaluation start range: 17% to 98%) and by region.[10] E-STAR demonstrates the feasibility and value of collecting comprehensive pre-waitlisting data to inform HRSA initiatives, intervene on factors causing differential access, and inform patient program selection. **We echo decades of calls and emphasize the overarching need for the collection of data on pre-waitlisting steps (e.g., referral for transplantation and start and completion of the transplant evaluation process) nationally to improve transparency in access and equity in transplantation.** Such transparency also enables and strengthens research and quality improvement efforts that advance and ensure the performance of the HRSA in alignment with its mission to "improve health outcomes and achieve health equity through access to quality services, a skilled health workforce, and innovative, high-value programs."[11]

HRSA's announcement of national data collection (2024) reflects growing recognition of its importance, supported by decades of advocacy from researchers, clinicians, patients, and national organizations. In 2021, the Centers for Medicare and Medicaid Services (CMS) Technical Expert Panel (TEP)[12] emphasized

the need for national data on referral as a more proximal step under the influence of clinicians caring for dialysis patients.[13] Similarly, on the transplant program side, the SRTR Consensus Conference (2022), United Network for Organ Sharing (UNOS), and the **2022 National Academies of Science, Engineering, and Medicine (NASEM) report called for the collection of pre-waitlisting data to adequately understand barriers in access and create a more equitable, cost-effective, transparent, and efficient system for the procurement, allocation, and distribution of deceased donor organs.**[14] This report emphasized the "need to create new performance metrics for transplant centers…to include a focus on equity in access to transplant referral and evaluation, as well as equity in access to transplant."[15] The OPTN Modernization Initiative (2023) and the organization of the Organ Transplantation Affinity Group to reduce variation in pre-transplant and referral practices, represent critical steps forward. Further, updates to include referral information within the CMS-2728 form (effective June 2024) will enhance data collection but exclude individuals pre-emptively referred for transplant evaluation – that is, referred before initiating dialysis treatment (conventional non-transplant therapy for patients with end-stage kidney disease) – whose transplant care and outcomes are generally better than those who begin dialysis before transplant.[16]

Further, these data will support the expansion of research and quality improvement activities to build understanding and describe inequities as well as to develop and effectively implement interventions to improve patient care and care systems. Our team believes that national pre-waitlisting data will allow for improved quality metrics better aligned to create a more equitable system, addressing current limitations caused by current metrics commonly focused on transplant rates and short-term post-transplant outcomes. Such data can inform interventions and tools focused on equity as we have done with E-STAR, where feedback reports and educational intervention doubled referral rates and reduced racial disparities in the Reducing Disparities in Access to Kidney Transplant (RaDIANT) Community randomized control trial.[17] Synergies exist with efforts to incorporate social determinants of health (SDOH) data, as highlighted in a recent report on SDOH and waitlisting outcomes.[18] Social factors are key drivers of early transplant access, particularly for disadvantaged communities. HRSA and OPTN should consider including the collection of social risk factor data in this initiative, collaborating with the Gravity Project to align SDOH-related data documentation. Additionally, linking pre-waitlisting data with existing datasets on individuals with organ failure (e.g., End Stage Renal Disease Quality Reporting System and United States Renal Data System data) is essential for understanding and addressing barriers and disparities in access to referral. To achieve this, HRSA and OPTN must collect Social Security Numbers (SSNs), the standard identifier needed for accurate data integration across systems.

Lastly, it is essential to accurately estimate the burden and hesitations experienced by transplant centers due to concerns about resource limitations and lack of transparency regarding the specific requirements for data collection. Efforts to explore efficient data collection techniques should be prioritized. While we strongly support the proposed initiative, we must express concern about the increased time burden on transplant centers, particularly given the rise in low-quality referrals and ongoing staffing limitations. To mitigate these challenges, the CMS cost report should be updated to reflect workforce adjustments, and data collection should occur through quarterly batch submissions with a phased approach. Sequential data collection on referral and evaluation, coupled with linking to existing databases for pre-waitlist mortality data, is essential to ensure data quality, accurate tracking of patient outcomes, and generating unbiased metrics before transplant. Further, the OPTN should include time for pilot testing, necessary revisions, and a period of voluntary submission to prepare centers for the substantial effort

required for these submissions. HRSA and OPTN should consider engaging voluntary E-STAR participants to pilot test this initiative, leveraging their experience to refine processes, ensure data quality, and optimize implementation. Exploring Application Programming Interface (API)-based data sharing mechanisms can further streamline submissions, reduce burdens, and enhance data quality, with funding included in the OPTN modernization initiative. Utilizing our collaboration with E-STAR centers, a survey on the collection of the data elements proposed in the national data collection and not currently collected within our registry highlights mixed transplant center perspectives. Notably, all agreed that reporting evaluation status (active vs. closed) was feasible, while one center agreed that it was feasible to report on only one element (evaluation status) not currently captured in E-STAR. Although preliminary, these findings strengthen our recommendations for increased staffing and streamlined processes to prepare centers for the proposed data collection.

In summary, the Early Steps to Transplant Access Registry Executive Team supports the collection of pre-waitlisting referral and evaluation-related data and its potential positive impact on access to transplantation for the more than 500,000 patients on dialysis in the United States. However, we urge careful consideration of several key factors, as outlined in this public comment, before implementing this mandatory data collection. Thank you for raising these critical issues for our country's organ donors, kidney disease patients, and transplant recipients. We greatly appreciate the opportunity to contribute to this Request for Information and we thank you for your consideration of our response. Please let us know if we can be helpful in sharing any other processes, lessons learned, or details from our >10 year experience collecting pre-waitlisting data from transplant centers.

Sincerely,

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