Transplants.org

01.02.25

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

Dear Health Resources and Services Administration,

The organ donation and transplant community applauds HRSA's commitment to strengthen the role of data in the Organ Procurement and Transplantation Network (OPTN).

HRSA's proposed data collection changes for pre-waitlist transplant patients and potential organ donors demonstrate an essential first step to improve the OPTN's data management, and we at Transplants.org appreciate your recommendations.

Transplants.org is a patient-founded, patient-centric 501(c)(3) nonprofit improving outcomes and access for transplant patients through education, support, research, and advocacy. Built upon fundamentals of collaboration, technology, and data, our team includes a former President of the OPTN, a former CTO and former CISO of the U.S. Department of Health and Human Services, and executives from notable technology and healthcare organizations — all united by a common mission: to improve the lives of solid organ and stem cell transplant patients.

We support all efforts to enhance transplant data including its collection, quality, breadth, and accessibility. Ultimately, data is essential to drive research and accelerate innovation that can identify and democratize best-in-class standards that result in optimal outcomes and increased equity for all transplant patients. It is critical that the OPTN collects granular, accurate data for every transplant patient, from pre-waitlist through their final days, as well as every potential donor to further expand donor organ availability.

While the proposed HRSA initiative is an important first step, we hope it represents what is only the first of many in an ongoing journey for the OPTN. The path forward must include a series of sustained actions as recommended below to ensure we best honor the generosity of organ donors and donor families with exceptional outcomes for every transplant patient — recognizing the true success of these improvements is measured in human lives.

Automate Data Collection to Increase Data Breadth

The OPTN should embrace automated data collection through real-time integrations with Electronic Health Record (EHR) providers, such as Epic, Oracle Cerner, and iTransplant. This approach will eliminate the need for innumerable web-based, manual-entry forms and flat file exports, both enhancing data accuracy and breadth while simultaneously reducing burden on clinicians and administrative staff.

A unified, integrated data management system would enable:

- EHR-agnostic integration to eliminate duplicative data collection efforts
- More granular and accurate data variables across patient cohorts, conditions, and demographics
- Near real-time data updates to minimize delays in decision-making and analysis
- Reduced costs and human input to free up resources for care and analysis

This transplant data management system should also inherently feature built-in data governance and privacy-enhancing technologies for appropriate security, permissions, and data identification.

Create an Open-Source Transplant Data Standard

Much of today's transplant data is not standardized across the ecosystem, which impedes interoperability between stakeholders and limits the ability to aggregate, connect, and analyze data effectively.

The U.S. transplant landscape should create and universally adopt an open-source data standard that builds upon existing data standards, such as ICD, LOINC, SNOMED, and CLIF, while bridging the gap in transplant-specific terminology and protocols. An open-source transplant data standard would provide a unified framework that supports cooperation across all stakeholders, ensuring that data is not only consistent but also adequately mapped between transplant centers, organ procurement organizations (OPOs), human leukocyte antigen laboratories (HLAs), and other key participants.

This effort would unlock opportunities for richer data insights, greater research collaboration, and ultimately more individualized and effective care for transplant patients.

Leverage Longitudinal Data for Big Picture Understanding

The true power of longitudinal data is that it provides a complete picture of a transplant patient's journey, beginning prior to their transplant evaluation and waiting for a donor organ to surgery to the ongoing care (and likely complications) for years to come. This holistic dataset can identify patterns, better assess outcomes, and guide clinical decision-making. It also helps capture critical nuances of transplant recipients' quality of life, which is as important as survival rates.

A comprehensive longitudinal dataset that tracks key clinical and non-clinical variables — such as pre-transplant evaluations, surgical procedures, rejection episodes, immunosuppressant adjustments, post-transplant biopsies, and secondary conditions — will empower the ecosystem to identify and democratize best practices and improve outcomes for all patients.

Additionally, by integrating data from wearables, patient reported-surveys, and cohort registries, we can further deepen our understanding of transplant patients' long-term health outcomes. This approach moves us beyond the narrow 3-year post-transplant timeline that is often the focus of current data tracking. Instead, we need to capture the full patient journey, which includes their ability to return to normalcy and their quality of life after transplant.

Understanding the transplant process in its entirety — beyond the life-saving surgery itself — will provide actionable insights for clinicians, researchers, and policymakers. This will allow us to refine care protocols, better manage complications, and tailor treatments to individual needs, ultimately ensuring that transplant recipients can lead healthier, more fulfilling lives.

Strengthen Ecosystem-Wide Data Collaboration

Additionally, today’s siloed data approach fails to connect longitudinal data that encapsulates the complete patient journey from end-stage organ disease diagnosis through lifelong post-transplant care.

Current OPTN member data participants are essentially limited to transplant centers, OPOs, and HLA labs, erroneously excluding many critical stakeholders within the ecosystem. As a result, key players such as organ preservation companies, DNA rejection testing labs, transportation and logistics services, dialysis providers, and other organizations are shut out of the data collaboration process, leaving each stakeholder to undertake an independent data strategy with universally underwhelming results.

The OPTN’s historical approach to data management — marked by fragmented, incomplete data and siloed access — has needlessly limited progress and stunted the ability to leverage modern technologies like artificial intelligence (AI).

Data transparency, accessibility, and accountability must be foundational principles for our ecosystem’s future improvements. A more collaborative data approach will also promote innovation across the ecosystem. By including more stakeholders in the data-sharing process, we can ensure that all parties — regardless of size or influence— have the ability to contribute insights and improvements to the nation’s transplant system.

Increase Data Accessibility and Reduce Latency

Data in the transplant ecosystem often suffers from gross latency — being delayed for months, quarters, or even years before it can be analyzed and used to inform decision-making. This delay impedes real-time clinical decisions and limits the ability to make timely interventions for transplant patients.

HRSA must set clear expectations for real-time data collection that empowers the ecosystem with actionable insights. In addition, adopting a no-cost, open-data policy for approved researchers would foster innovation across the sector. By making high-quality, de-identified and anonymized data immediately accessible to academic researchers, third-party developers, and other innovators, we can accelerate the development of new tools and technologies that improve transplant outcomes and patient care.

Furthermore, we need to eliminate the technical barriers that make it difficult to access historical data for retrospective analysis. Often, as the ecosystem continues to evolve, valuable historical data becomes harder to retrieve and utilize. A shift to modern, real-time systems will not only reduce this latency but also make it easier to extrapolate usable insights from past data.

Use Data to Answer Patients' Questions

For too long, transplant candidates and recipients have asked fundamental questions related to their care that improved data could better help clinicians and researchers adequately answer, such as:

- Am I good candidate for transplant?
- What's the best organ offer for me?
- What's the life expectancy for an organ transplant recipient?
- Which immunosuppressants and dosages will work best for me to avoid rejection?
- What are my chances of needing another transplant?
- Will I develop cancer or experience other complications?
- What are other lifestyle restrictions will I experience?

Unfortunately, the answers to these questions are often poorly answered with no central data repository to conduct research, leaving many candidates and recipients to turn to social media for information. We can and should do better for this special community.

Find a Better, Data-Centric Path Forward

As a patient-founded and patient-centric nonprofit, Transplants.org remains committed to working with HRSA, the OPTN Board of Directors, the OPTN Members, and other stakeholders to propel the nation's transplant system to deliver faster, more equitable, and better outcomes for all transplant patients.

Thank you again for your leadership and your commitment to improving the lives of transplant patients.

With gratitude,

Tristan Mace (Heart Recipient, '21)
Co-Founder & Executive Chairman
Transplants.org