

October 1, 2024

The Honorable Morgan Griffith
Subcommittee on Oversight and Investigations
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

Delivered Electronically

Dear Chairman Griffith,

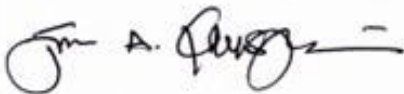
The American Society of Transplantation (AST) is the leading organization uniting the U.S. transplant community and is comprised of more than 5,000 professionals dedicated to advancing the field of transplantation and improving patient care. Our Society is staunchly supportive of the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative. To this end, we have identified several existing challenges and how we, as a community, might be able to address these concerns. In the position paper that follows, we have summarized approaches to improve donor organ utilization, improve allocation of complex and hard-to-place organs, and a means to enhance patient involvement in transplant decision making.

Our society is encouraged by efforts HRSA has undertaken to revamp the system, however we are concerned about the transition from a single contractor to now 15 contractors. For this to be successful and best serve patients, oversight and communication with the stakeholders - patients and the transplant professionals that serve them - will be crucial. The AST stands behind these modernization efforts and will work with the new contractors and the newly elected OPTN Board to lend our experience and expertise where needed. A newly elected OPTN Board selected by the transplant community will ensure trust and proficiency of the OPTN with patients and transplant providers. The OPTN has saved countless lives and will exceed these numbers as we move forward together (OPTN and Community) to ensure continued success of the OPTN.

Although there were recent serious allegations made by witnesses at the September 11th congressional hearing, we do not feel these are representative of the vast majority of transplant practice or the culture of the existing OPTN. Certainly, these allegations need to be investigated and appropriate actions taken if confirmed. Current allegations notwithstanding, the overall tenor of the OPTN has been supportive and constructive regarding regulatory oversight of organ procurement organizations and transplant programs. These valuable attributes need to continue as we move forward with the modernization efforts.

The AST looks forward to our continued working relationship with Congress and HRSA in support of the OPTN Modernization Initiative.

Respectfully,



Jon Kobashigawa MD
President, American Society of Transplantation

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ORGAN PROCUREMENT & TRANSPLANTATION NETWORK (OPTN) MODERNIZATION

The American Society of Transplantation (AST) is the premiere organization uniting the transplant community and is comprised of more than 5,000 professionals dedicated to advancing the field of transplantation and improving patient care.

While the US organ donation and transplantation system is the best in the world and continues to increase the number and quality of transplants performed (46,632 living and deceased donor organ transplants in 2023, an 8.7 percent increase over 2022 and a 12.7 percent increase over 2021¹), the AST recognizes the need for continuing improvements to the system and supports the optimization of the Organ Procurement & Transplantation Network, also known as OPTN Modernization.

While renovations of this system could be disruptive, collaboration is critical to successful implementation of much needed change. The AST is committed to working tirelessly to unite our stakeholders and ensure that the precious gifts of our donors are transparently, equitably, and efficiently transplanted in the right patient at the right time, and are cared for to optimize the longevity of the transplanted organ.

Existing Challenges in the Organ Procurement and Distribution System

The core challenge faced by the U.S. organ transplantation system is one of high demand and limited organ availability. Achieving optimal efficiency and equity at the system level requires strong coordination among the federal agencies, the 15 contractors assigned by HRSA to administer the OPTN, health systems, health care providers, and other entities in the transplantation ecosystem. Despite best efforts, system-based challenges remain that prevent effective collaboration. These challenges can result in conflicting policies that may contribute to increased organ non-utilization.

Understanding Organ Non-utilization

The AST understands that non-utilization of donated organs that are deemed transplantable is unacceptable, implying that as a community we are not valuing the gift of our donors and their loved ones. However, the factors contributing to organ non-utilization are multifarious and imprecise. The AST seeks to better understand the barriers to providing cohesive and durable solutions while aligning the incentives and metrics of our organ procurement organizations (OPOs) and transplant centers. Is organ non-utilization really the most critical problem today or is it a byproduct of numerous sequential changes, including the Kidney Allocation System (KAS) in 2014, KAS 250 in 2021, Continuous Distribution of Lungs in 2023, Conditions of Coverage by the Centers of Medicare and Medicaid Services (CMS), and regulatory oversight that challenge a complex system? Importantly, do we view or even have the appropriate data to analyze the problem? The AST is committed to using best available evidence and science to improve utilization and address these challenges and believes the following actionable items need to be addressed to achieve this goal:

¹ Organ Procurement and Transplantation Network. Continued Increase in Organ Donation Drives New Records in 2023; New Milestones Exceeded. <https://optn.transplant.hrsa.gov/news/continued-increase-in-organ-donation-drives-new-records-in-2023-new-milestones-exceeded/>. Accessed September 23, 2024.

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- Establish clear definitions of what organs are transplantable and identify who determines these criteria
- Determine the actual proportion of non-utilized transplantable organs with meaningful potential to extend life
- Create greater accessibility of current data on rates of organ non-utilization
- Establish improved transparency and communication of graft quality data among OPOs and transplant centers
- Increase accounting of donor risk factors to better inform transplant center graft and recipient selection to optimize odds of successful transplantation and survival benefit to patients
- Improve understanding of the proportion of organs that are currently procured that should be transplanted to benefit patients
- Identify reasons for donor organ decline due to concerns for regulatory oversight and how it impacts donor acceptance

Use of Hard-to-Place or Complex Organs

The AST recognizes that not all organs are easily transplantable and there are more complex organs that require different pathways for allocation. Over the past two years our community has seen a marked increase in complex organs and the non-utilization rates of these organs are high. More research is needed to understand which patients would benefit most from increased availability of such organs, including survival benefit, quality of life, and readmission rates. Evaluation of such metrics could provide a better, data-driven approach to guide transplant centers in appropriate recipient selection to maximize benefit for their patients.

Expedited Placement

Expedited placement was created for use in emergency scenarios to rescue organs that are at risk for non-utilization. Figure 1 below shows the proportion of accepted offers via expedited placement for all organs from January 2019 – July 2024, illustrating that this practice has increased significantly over the past four years prompting concerns that this OPO practice may jeopardize equity. The AST believes that while placing organs efficiently is laudable, an alternative organ allocation system or “rescue pathway” for complex or hard-to-place organs needs to be standardized in a transparent, codified system rather than a grassroots level to prevent subversion of the actual organ allocation systems.

Proportion of Accepted Offers via Expedited Placement

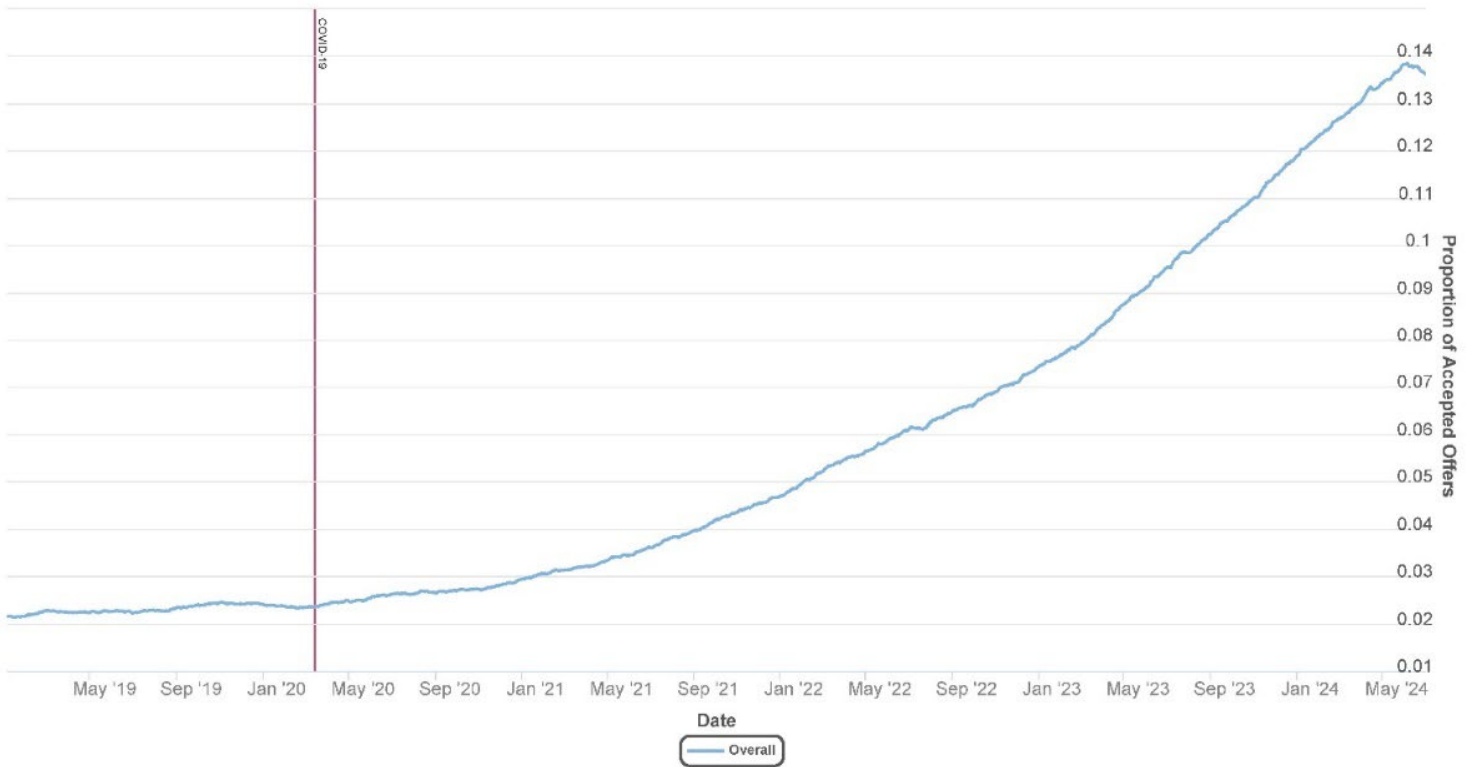


Figure 1- Proportion of accepted offers via expedited placement for all organs from January 2019 – July 2024 ²

Patient Involvement in Transplant Decision Making

The AST has a strong foundation of engaging patients in the transplant journey and strongly supports shared decision making. Given the complexity of the organ donation process, the organ utilization decision, and the need to maintain efficacy and efficiency in organ placement, the AST recommends an inclusive study engaging our patient community. The goal is to determine what information is most valuable to patients and how it can best be shared. This would be coupled with improvements and alignment in our organ utilization metrics in order to provide accurate and meaningful information to our patients. The AST remains supportive of current efforts and data collection on how patients access care throughout their disease progression to better understand the spectrum of end-stage organ disease, in addition to the transplant event.

Summary

As the leading voice for the transplant community, AST reaffirms that we have the best organ donation and transplant system in the world, but improvements are necessary to make a timely transplant available to all patients in need.

As we embark on much needed improvements in our transplant system, we should strive for a system where the goals of regulators, transplant centers, OPOs, and all stakeholders are aligned in doing what is best for our donors and recipients in need. There is no quick fix. Rather, by taking intentional steps, we will serve our community well in working towards an efficient and aligned system.

² Scientific Registry of Transplant Recipients. Donation and Transplant System Explorer. <https://www.srtr.org/tools/donation-and-transplant-system-explorer/>. Accessed September 26, 2024.