OPTN Update

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The National Organ Transplant Act (NOTA) passed in 1984 established the Organ Procurement and Transplant Network (OPTN) and authorized Congress to appropriate funds through HRSA to a contractor to operate the network[i]. The United Network for Organ Sharing is a not-for-profit organization that was awarded the first HRSA contract. UNOS held the OPTN contract continuously up until 2023.

UNOS/OPTN developed all the policies and procedures, developed the organ sharing algorithms, prioritization policies and developed and copyrighted the software to run the allocation programs. UNOS also made its fiduciary Board the OPTN Board.

NOTA authorized the OPTN to have oversight for the quality of transplantation at the programs and for the OPOs. UNOS has been in a difficult position because it did not have statutory authority to fully regulate programs and OPOs. UNOS could not directly close programs or OPOs for quality reasons.

There were always complaints about how UNOS ran the OPTN. And there was plenty to criticize, not all of which was under UNOS' control. Access to waiting lists is very disparate around the country as is quality of care at transplant centers. We see this in our performance model rankings every year. It is interesting to note that these issues are not unique to transplantation, access to specialty care in general is a big problem nationally. The quality of care varies significantly as does the cost. In contrast to most medical care where therapeutic resources are relatively abundant (in the US at least), transplantation is unique because transplantation requires donor organ availability which is far more constrained and inconsistent. For example, organ acceptance rates vary widely by center (see example data below). Organ discard rates vary and are higher than they should be. And OPO efficiency is different geographically (see map below). Too many patients are dying on wait lists with disproportionate numbers from disadvantaged populations. All these variables are only partially or not directly related to OPTN/UNOS policy but create inequities that are contributing to the dissatisfaction with the OPTN and UNOS. To assess and make recommendations about these issues, Congress commissioned the National Academy of Medicine to study the state of the OPTN in 2022 and the NAM issued a report titled, Realizing the Promise of Equity in the Organ Transplantation System. The recommendations in this report are:

- Develop national performance goals for the U.S. organ transplantation system (Recommendation 1).
- Improve the OPTN policy-making process (Recommendation 2).

- Achieve equity in the U.S. transplantation system in the next 5 years (Recommendation 3).
- Accelerate finalizing continuous distribution allocation frameworks for all organs (Recommendation 4).
- Eliminate predialysis waiting time points from the kidney allocation system (Recommendation 5).
- Study opportunities to improve equity and use of organs in allocation systems (Recommendation 6).
- Increase equity in organ allocation algorithms (Recommendation 7).
- Modernize the information technology infrastructure and data collection for deceased donor organ procurement, allocation, and distribution (Recommendation 8).
- Make it easier for transplant centers to say "yes" to organ offers (Recommendation 9).
- Increase transparency and accountability for organ offer declines and prioritize patient engagement in decisions regarding organ offers (Recommendation 10).
- Require the establishment and use of a donor care unit for each organ procurement organization (Recommendation 11).
- Create a dashboard of standardized metrics to track performance and evaluate results in the U.S. organ transplantation system (Recommendation 12).
- Embed continuous quality improvement efforts across the fabric of the U.S. organ transplantation system (Recommendation 13).
- Align reimbursement and programs with desired behaviors and outcomes (Recommendation 14).

Some developments before and after the NAM report.

- **Required Enhanced OPTN Security and Performance –** In September of 2021, after a cybersecurity data breach, HRSA required the current OPTN contractor to take a series of actions to improve security and performance, including to increase security of the OPTN IT system, and improve the use of secure processes for system access and information exchange.
- **Sought Expert and Community Input on Ways to Improve Transparency, Accountability, and Performance in OPTN Operations** – In April of 2022, HRSA published a formal Request for Information (RFI) on ways to improve patient and donor engagement, strengthen accountability throughout the system, and best leverage modern technology to support this lifesaving work. HRSA received responses from patient advocates, technology experts, OPTN members and other stakeholders. Responses focused on the need to modernize the OPTN system technology without compromising patient safety.
- **Convened a Conference with Patients and Families to Strengthen Performance Measures** – In July 2022, HRSA created a forum for patients, families, and interested stakeholders to share their concerns and recommend future metrics for the transplantation system that support informed decision making for patients with organ failure, their families, and their health care teams. The Scientific Registry of Transplant Recipients is in the process of developing new metrics based on the conference feedback and recommendations.

6.30.2025

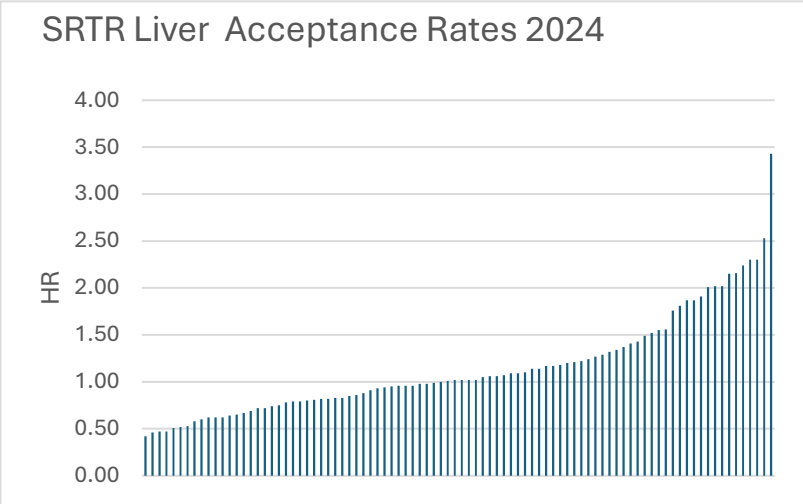
- **Formally Engaged Technology Partners to Improve OPTN IT Systems** – In July 2022, HRSA initiated ongoing engagement with the United States Digital Service (USDS)—which is dedicated to improving government services through technology modernization and data science—to leverage their expertise and advice as HRSA implements the OPTN Modernization Initiative.
- **Ongoing Collaboration with the Centers for Medicare & Medicaid Services (CMS) and other HHS Agencies –** HRSA continues to collaborate with CMS and other HHS agencies on actions related to improving federal oversight, alignment and support of the organ donation and transplantation system.

Based on all of this, President Biden signed the bill introducing more competition to US organ transplant network contracting practices on Sep 25, 2023. https://www.congress.gov/bill/98th-congress/senate-bill/2048

The result of this is that HRSA awarded new contracts in these 6 areas in 2023.

- **Arbor Research Collaborative for Health** will be working on patient safety and policy compliance systems and processes.
- **General Dynamic Information Technology** will look at ways for HRSA to improve the OPTN organ matching IT system.
- **Maximus Federal** will work to increase transparency and public engagement in OPTN policymaking processes, such as around committee activity.
- **Deloitte** will improve internal and patient-facing OPTN communications.
- **Guidehouse Digital** will work on improving OPTN's budget development and management systems and processes.
- **Building HRSA Capacity:** HRSA is also building its capacity to support the modernization initiative, including engaging a Program Management Support contractor.

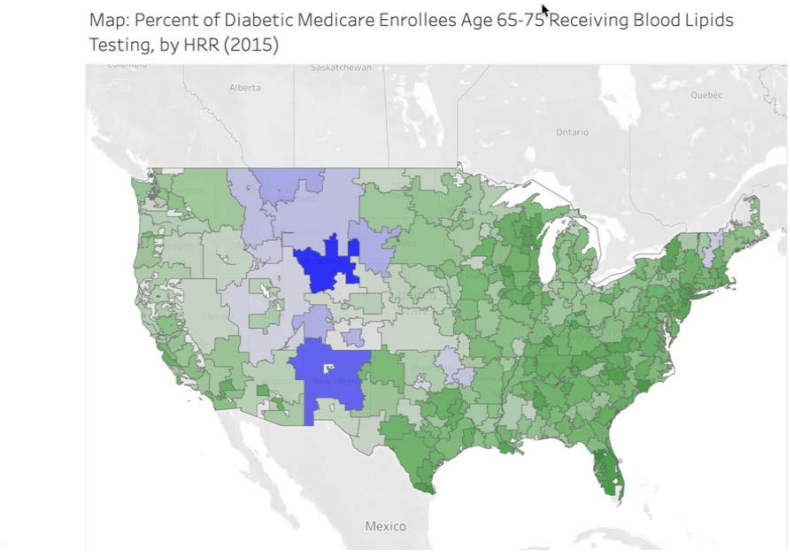
Nonetheless, taking up the original charge given to the NAM, few, maybe none, of the above government actions will address the inequities that the NAM was commissioned to study.



As we know from our performance model work, organ acceptance rates vary significantly across programs (see graph). That's why we include this metric. But this behavior is not really under purview of the OPTN. The OPTN cannot adjudicate medical practice, and, just like deciding to embark on a

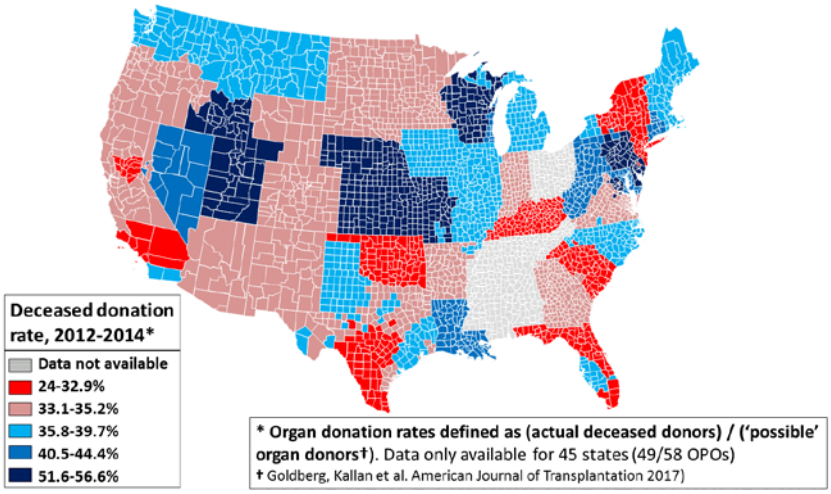
medical treatment of a given disease, accepting an organ is a medical decision between the doctor and the patient, and legally is not the decision of a governmental entity.

It is interesting to note that all medical care has tremendous variation in access to, and choices of, treatment for care. However, because there is a national database with federal oversight and politics because of the oversight, transplantation is in the spotlight.



This map is just one sample from the Dartmouth Atlas that report's on variation in costs and quality of care across the country. (https://www.dartmouthatlas.org/)

Figure 3: Organ donation rates per donor service area using administrative data based on the denominator of 'potential donors



Another source of inequity is the wide variation in the number of potential donors and OPO's proficiency in converting a potential donor to an actual donor. (See map). The current expansion of distribution acuity circles that expand the area over which donor organs are distributed to transplant centers increases the costs due to increase travel costs but does not necessarily erase these differences in donor organ availability.

There is much more to solving the inequities than the current multiple contracts suggest. One recent article concluded, "Although patient interest in transplantation plays a role, other potential drivers include patients' preferences, knowledge of transplantation, challenges navigating the

referral and selection processes, communication and trust between patients and clinicians, and structural and personal bias. Very little work has been done to identify and mitigate disparities at this stage in the process and should be the focus of future research to elucidate potential approaches for intervention". Int J Equity Health. 2022 Feb 12;21:22.

More recently, the DOGE driven HRSA layoffs present an additional challenge to the ongoing turmoil around federal oversight of transplantation. For example, the National Kidney Foundation's statement on mass staff terminations at HSS, February 18, 2025, says, "While it is certainly appropriate to try to identify inefficiencies in government, the terminations across HHS will negatively affect the lives of kidney patients in the United States. NKF is deeply concerned about these actions, which appear to be haphazard and indiscriminate. Among the more alarming cuts we've learned are: A significant number of employees at HRSA's Division of Transplantation who have been working on modernizing the transplant system. Mass layoffs stand in direct opposition to the goals of transplant system reform to improve efficiency, transparency, and the ability of the government to respond to the needs of people who rely on the system. Chaotic terminations of the employees charged with implementing reforms will ensure the status quo persists."

And now, the two Senators who launched these reforms are raising the alarm.

HEALTH CARE

Wyden, Sanders: Federal layoffs threaten organ transplant system modernization

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How might all this affect INTERLINK, its clients, facilities and its future in the transplant business.

1. The underlying system is strong and well-established. Programs will continue to do transplants because demand remains high. So, payers will continue to want informed contracts with facilities to serve their members.
2. The current chaos will not change the underlying foundation. I doubt much will change in the next few years until these new OPTN contractors get to work. And even then, I am not sure how much they will change the system for the better. This new arrangement may increase the risk that patients and/or donors will fall through the cracks. Imagine if our air traffic control system has 6 contractors running the system!
3. Clients will likely look for even more information to reassure them and help them to navigate an already complicated system made even more challenging by the federal actions outlined above.
4. Implementation of some of the NAM recommendations or others, could increase transplant costs overall. It remains to be seen however, if implementation of anything will

be possible given the multiple contractors now involved and the staff cutbacks at HRSA. Nonetheless, if one or some are implemented in the next few years some potential impacts are outlined here:

a. INTERLINK will need to closely monitor the SRTR's development of new measures based on patient and family input from the conference in July 2022. We will not want to be out of synch with these metrics with our performance model.
b. **Accelerate finalizing continuous distribution allocation frameworks for all organs (Recommendation 4).** More continuous distribution means more travel time for organs which means more cost in organ acquisition.
c. **Modernize the information technology infrastructure and data collection for deceased donor organ procurement, allocation, and distribution (Recommendation 8).** Sooner or later, this will end up becoming an expense on the OPTN's budget. The vast majority of the OPTN is funded by waiting list registration fees that programs pay ($1028 in 2024) to register each patient on the waiting list. As OPTN expenses increase, some of these will be passed on to centers via these fees, unless HRSA provides more funds than they have in the past. This is unlikely in the current environment.
d. **Make it easier for transplant centers to say "yes" to organ offers (Recommendation 9).** This may decrease waiting time, and increase organ acceptance rates, both of which would be good outcomes for patients and potentially reduce costs. However, this is a vague recommendation and I am not sure how or if the OPTN will make it "easier", because as outlined above the OPTN cannot dictate medical practice.
e. **Require the establishment and use of a donor care unit for each organ procurement organization (Recommendation 11).** This could potentially reduce deceased donation costs. There is some evidence that donor care units can reduce donation costs. Gauthier JM, Doyle MBM, Chapman WC, et al. Economic evaluation of the specialized donor care facility for thoracic organ donor management. *J Thorac Dis*. 2020;12(10):5709-5717.
f. **Align reimbursement and programs with desired behaviors and outcomes (Recommendation 14).** This recommendation did include suggestions for payment reform to give centers more incentives to use higher risk organs that will ultimately function well but usually require longer hospitalizations to manage the immediate post-transplant period of marginal organ function. The single fact that DRGs are based on recipient diagnoses (CCs and MCC) and do not account for donor risk factors will need to be solved.

Conclusion:

"Those who have knowledge don't predict. Those who predict, don't have knowledge"
Lao Tzu, ancient Chinese philosopher.

6.30.2025

The best guess is that the modernization efforts by the federal government are not likely to have a significant effect on changing the fundamental dynamics of the transplant system. Costs of care will likely increase due to more longer distance organ sharing but could be mitigated somewhat if more OPOs develop donor service centers. It will be interesting to see if the SRTR metric reform begins to look more like INTERLINK's performance model. In that case, INTERLINK will be way ahead of the curve. Most likely, there will be more confusion andless certainty on the regulatory side, and clients and programs will need more support than ever.

6.30.2025