



Actions to strengthen the U.S. organ donation and transplant system

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Introduction

United Network for Organ Sharing (UNOS) is proposing reforms that will improve the U.S. organ donation and transplant system. We have also outlined changes to the Organ Procurement and Transplantation Network (OPTN) contract that we believe will hold all parts of the system accountable to better serve the patients who rely on us every day.

Below, we have detailed:

- actions we are taking now and will take soon, as they are currently within UNOS' capabilities and/or within the authority of the current OPTN contract
- tasks UNOS recommends are added to and funded within future OPTN contracts

The following actions and recommendations are intended to reflect the needs of the broader donation and transplant community.

Increase direct service, tools, and resources to patients, donors, caregivers, and their families

The current contract obligates the OPTN contractor to provide web-based patient education materials on the OPTN website, which provide information about how organ allocation works, what to expect during the transplant process, the wait list, resources by organ, and more.

UNOS currently enhances these offerings with expanded resources.

UNOS will undertake/propose the following action:

- Require the OPTN offer more expansive consumer empowerment tools to enable patients to make choices regarding their care, and education and resources for patients, donors, caregivers, parents, and their families.
- Develop with the patient community consumer choice tools that include information to assist patients in finding appropriate care for their needs, timely updates about new patient benefits or care programs, emerging medical innovations, or other information to help patients navigate through the donation and transplant process.
- Including these enhanced offerings as part of OPTN contract would ensure the OPTN serves as a centralized resource to patients and their loved ones during their journey.

Improve equity in access to the transplant healthcare system

The OPTN is currently charged with developing and maintaining equitable organ allocation policies that apply to waitlisted patients, but true access to transplant — not just the waitlist — cannot be measured without understanding the national disease burden. We must take action to seek broader equity in access to transplant health care. The OPTN has been able to continually monitor and adjust organ allocation policies to improve equity in access among these waitlisted patients. The OPTN maintains an Equity in Access Dashboard to enable public research and review of these ongoing efforts and publishes organ allocation policy monitoring reports for the public, which include data on key equity indicators.^{1,2,3}

UNOS will undertake/propose the following action:

- Seek authorization for the OPTN to collect data to identify barriers to equitable access to the waitlist and quantify the national disease burden. While the increases in transplant rates for minority patients are important, more data collection on patients *before* they are added to the waitlist is needed to eliminate inequities in access to the transplant waitlist.^{4,5,6,7}
- Data to be collected include characteristics of patients with end-stage organ failure and those subsequently referred to transplant hospitals, including elements such as clinical characteristics, socio-economic information, and patient demographics (age, race, address, etc.). This kind of data could assist in improving policy to increase equity for the broader end stage organ failure population.

Enable the OPTN to collect donor potential data directly from hospitals to drive more improvement in organ procurement organizations and diversify the pool of donors

UNOS will undertake/propose the following action:

- Seek authorization for the OPTN to collect or receive data on ICU deaths for patients under age 70 for faster and more accurate monitoring of organ procurement organization (OPO) performance. As the OPTN begins to develop new OPO performance metrics, access to hospital death data would provide the OPTN the ability to offer near real-time and targeted performance review and corresponding action plans for underperforming OPOs, based on an understanding of the true number of potential donors. The OPTN could also offer enhanced collaboratives and education based on the increased visibility these data would provide. The OPTN supports use of these data for regulatory purposes as well.
- The OPTN will continue to advocate for a national investment in the automation of donor referral.⁸ Such a solution would provide a streamlined, independently reported data source on donor potential and has the potential to reduce the burden on already stressed Intensive Care Unit (ICU) clinical staff by reducing manual data entry — the way many donor referrals are largely made today. In addition, it would ensure every potential donor is referred every time. Every hospital with the ability to ventilate patients would need to participate, a requirement that is beyond the authority of UNOS or the OPTN. Automated donor referral would be a significant innovation. Our nation has the technology to automate this important step, but it will not occur without a national commitment.^{9,10,11}

Increase transparency in OPO, hospital, and system performance by making more comparative performance data available publicly

UNOS will undertake/propose the following action:

UNOS will publish three key reports on the web that are currently available only to professionals, adjusting them for improved accessibility for a broader public audience:

- *Interactive OPO organ recovery and usage maps* (by May 30, 2023): These maps will display both OPO and hospital-level recovery and transplant information based on donor characteristics selected by the user, as well as an organ usage map that displays which programs are transplanting the organs from those same donors.
- *OPO System and Process Measures Dashboard* (by Sept. 30, 2023): This interactive dashboard provides a variety of OPO data, enabling the public and professionals to compare OPO performance on key measures such as donors recovered, conversion rate, and authorization rate.¹²
- *OPTN Metrics Dashboard update* (by Dec. 31, 2023): Currently, this interactive dashboard allows the public to explore U.S. donation and transplant trends at the national and regional levels. The updated version will add the ability to explore data by individual OPO and transplant hospital. It also will add statistics relating to the non-utilization of organs recovered for transplant and offered to a center, as well as reported reasons for discard of organs recovered for transplant.¹³

The OPTN will convert policy monitoring reports to public dashboards for all organ allocation policies following implementation of the continuous distribution framework, beginning with lung allocation.¹⁴ The new policy monitoring dashboards will continue to report data on key equity in allocation measures but will also be able to monitor the impact of policy changes based on the geography of where transplant hospitals are located and if they are in rural or urban areas.

Reduce risk of organ delay, damage, or loss in transport

Addressing concerns about organ tracking and transportation requires a system-wide, multi-pronged approach. UNOS has taken action as a private entity in developing and launching its own organ tracking solution, currently in use by 16 OPOs.¹⁵ However, both the federal government and the OPTN must require, develop and enact a solution for national, system-wide tracking and efficient air transit. UNOS is currently seeking support from Secretary Buttigieg to change Federal Aviation Administration regulations to reduce the risk of delay and loss for organs traveling by commercial air.¹⁶

UNOS will undertake/propose the following action:

Advocate for changes in the next OPTN contract that require the OPTN to:

- Mandate the use of physical trackers for unaccompanied deceased donor organs recovered for transplant.
- Develop a centralized organ tracking system.
- Publicly report on data related to tracking.
- Review all cases in which an organ is lost.

Maintain safe, modern, and reliable OPTN IT systems and infrastructure

There has been significant discussion concerning UNOS' IT systems. UNOS has requested that the USDS conduct an in-person assessment of UNOS' IT infrastructure.¹⁷ To date, we have not received a response. UNOS has also engaged an independent consulting firm to assess our technology and modernization efforts against industry best practices and the U.S. Digital Services Playbook standards. Additionally, UNOS is updating its systems' user interface to make it easier for donation and transplant professionals to make and evaluate offers. We are leveraging internal and external experts in human-centered design, as well as engaging members of the community throughout the design process.

UNOS will undertake/propose the following action:

- Continue developing new security standards with the OPTN Network Operations Oversight Committee (NOOC) and HRSA, aimed at ensuring that OPO, hospital, and histocompatibility laboratory systems and environments comply with the National Institute of Standards in Technology (NIST) or an equivalent standard, complete training, and pass routine audits. This proposal is available for public comment through March 15, 2023.¹⁸

Enhance OPTN Membership and Professional Standards Committee (MPSC) oversight and increase transparency in the process

Oversight of the system has been an ongoing topic of discussion and clarification. UNOS has contacted CMS leadership to initiate formal coordination between UNOS and the OPTN, HRSA and CMS. Through this coordination, communication will be improved so that both CMS and UNOS can appropriately and swiftly act to ensure that quality of care and patient safety is enhanced, as well as to make the system more accountable overall.

UNOS will undertake/propose the following action:

- UNOS will create a new public page on the OPTN website to increase transparency on MPSC performance improvement and compliance review activities. Work is targeted to begin in Q1 2023, pending HRSA approval.
- The OPTN will issue timely patient safety and improvement communications gleaned from current case reviews to inform the public, help members avoid safety events, and comply with OPTN obligations. Currently, HRSA must approve each communication.
- The OPTN MPSC will next begin the process of enhancing its OPO performance measures to better hold OPOs accountable for their performance in 2023.

Advocate for increased coordination in system oversight by requiring CMS, HRSA, and the OPTN to:

- Share information on a consistent basis regarding performance trends, improvement, and compliance efforts.
- Establish consistent protocols for escalating cases and conducting joint investigations between UNOS, CMS, and HRSA, especially as it relates to incidents, complaints, and

trends in OPO and transplant program performance. Real-time data will assist in ongoing reviews of OPOs and transplant hospitals.

- Provide OPO and transplant programs education to improve understanding of both OPTN performance metrics and CMS regulations. This would require working with CMS to provide accurate and coordinated information and would assist OPOs and transplant programs in understanding the full scope of OPTN policies and CMS regulations.

Make the OPTN an organization independent of the OPTN contractor

Governance of the OPTN has been an area of ongoing attention. UNOS has requested HRSA engagement since May 2021 to create an independent OPTN board of directors distinct from the OPTN contractor's board of directors. UNOS shared a proposal with HRSA to change the governance structure that includes creation of a new, nonprofit corporate entity to be the OPTN as specified in NOTA.

Recently, UNOS proposed an amendment to the existing OPTN contract to HRSA to accomplish a fully compliant restructuring with separate boards of directors by the end of the current OPTN contract, on Sept. 29, 2023. Partnership with HRSA is essential to the successful development of any OPTN governance restructuring plan.¹⁹

UNOS will undertake/propose the following action:

- Advocate for the addition of a provision to the future OPTN contract to empower the OPTN to communicate with patients and professionals expediently. As a network of donation and transplant clinicians, professionals, and patients, it is incumbent upon the OPTN to provide timely information related to emergent public health crises, patient safety concerns, time sensitive policy changes, and more. To effectively keep OPTN members and the public informed, such a contract modification would allow for more nimble and flexible communication with professionals and the public.

Conclusion

All stakeholders, including UNOS, share a common mission: Get as many usable transplant organs as possible to patients who need them, fairly, equitably, and efficiently. We must hold all parts of the system accountable for making sure that this happens. It is important that the next contract hold the OPTN to providing the highest level of service to patients and the greatest level of transparency to the public who has charged it with this lifesaving work.

Notes

- ¹ OPTN Equity in Access dashboard. <https://optn.transplant.hrsa.gov/data/visual-dashboards/equity-in-access/>.
- ² “OPTN resource pages by organ.” <https://optn.transplant.hrsa.gov/professionals/by-organ/>.
- ³ “One year monitoring report shows increase in kidney transplant following policy changes.” <https://optn.transplant.hrsa.gov/news/one-year-monitoring-report-shows-increase-in-kidney-transplants-following-policy-changes/>. 1 July 2022.
- ⁴ Ashby, V. B., J. D. Kalbfleisch, R. A. Wolfe, M. J. Lin, F. K. Port, and A. B. Leichtman. “Geographic Variability in Access to Primary Kidney Transplantation in the United States, 1996-2005.” *American Journal of Transplantation* 7, no. s1 (2007): 1412–23. <https://doi.org/10.1111/j.1600-6143.2007.01785.x>.
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- ⁹ Niles, Patricia; Hewlett, Jonathan; Piano, John; Liu, Wade. Automated electronic referrals are changing donation. *Transplantation: September 2020 - Volume 104 - Issue S3 - p S259* doi: 10.1097/01.tp.0000699788.52410.58
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- ¹¹ “Cleveland Clinic, Lifebanc and Transplant Connect Develop Automated Donor Referral Process.” 30 April 2021.
<https://newsroom.clevelandclinic.org/2021/04/30/cleveland-clinic-lifebanc-and-transplant-connect-develop-automated-donor-referral-process/>. Accessed 20 Jan. 2021.
- ¹² New OPO System and Process Measures Dashboard now available.
<https://unos.org/news/opo-system-and-process-measures-dashboard/>
- ¹³ OPTN Metrics Dashboard. <https://optn.transplant.hrsa.gov/data/visual-dashboards/optn-metrics/>.
- ¹⁴ “Continuous distribution: Creating a more fair and patient-focused system for organ allocation.” <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/>
- ¹⁵ “7,000 organs tracked with UNOS organ tracking service.”
<https://unos.org/news/in-focus/7000-organs-tracked-with-unos-organ-tracking-service/>. 14 Dec. 2022.
- ¹⁶ UNOS letter to Secretary Buttigieg. <https://unos.org/wp-content/uploads/UNOS-leadership-requests-meeting-with-DOT-HRSA-FAA-and-TSA.pdf>. 8 Dec. 2022.
- ¹⁷ “UNOS letter to USDS.” <https://unos.org/wp-content/uploads/UNOSGR-2023-01-04-UNOS-leadership-requests-meeting-with-US-Digital-Service.pdf>. 4 Jan. 2023.
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