

## **The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System Senate Finance Committee Health Subcommittee Hearing**

**July 20, 2023**

### **Statement for the Record Submitted by:**

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The United Network for Organ Sharing (UNOS) appreciates the opportunity to submit a statement for the record on the Senate Finance Committee’s Health Subcommittee hearing titled “The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System,” held on July 20, 2023.

UNOS is the mission-driven, non-profit organization that serves as the nation’s organ donation and transplant system—the Organ Procurement and Transplantation Network (OPTN)—under contract with and oversight by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS). We are committed to working with policymakers to help ensure that the United States continues to be the leader in successful organ donation and transplant.

UNOS has heard calls from policymakers and stakeholders urging reforms to the organ donation and transplant system and is embracing change. In support of a more competitive bidding process, UNOS welcomes HRSA’s modernization initiative<sup>1</sup> and does not oppose the Securing the U.S. Organ Procurement and Transplantation Network Act.<sup>2</sup> As the current OPTN contractor, UNOS is committed to being an invaluable partner to HRSA as reforms are implemented.

In keeping with UNOS’ goal of seeking to improve the system, under the new leadership of Maureen McBride, Ph.D., UNOS released an Action Agenda<sup>3</sup> in January 2023, which is a set of collaborative reforms that will strengthen the system and address concerns shared by Members of Congress and other stakeholders. The Action Agenda also aligns with the reforms that HRSA announced in March, including a focus on quality improvement, data transparency, governance and technology. Every aspect of the agenda is focused on serving patients, and these reforms will help to bolster and streamline the nation’s system.

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<sup>1</sup> UNOS Statement Supporting Improvements to the National System, March 22, 2023, <https://unos.org/news/unos-welcomes-competitive-bidding-process-for-next-optn-contract/>.

<sup>2</sup> UNOS Position on the Securing the U.S. Organ Procurement and Transplantation Network Act, June 30, 2023, <https://unos.org/wp-content/uploads/UNOS-letter-securing-US-Organ-Transplantation-Network-Act-063023.pdf>.

<sup>3</sup> UNOS Actions to Strengthen the U.S. Organ Donation and Transplant System, Jan. 30, 2023, <https://unos.org/wp-content/uploads/Actions-to-strengthen-the-US-organ-donation-and-transplant-system-30-Jan-2023.pdf>.

UNOS is actively identifying areas for improvement so that we can adopt changes that strengthen the system to better serve the patients who rely on us every day. Being transparent about systemic challenges is critical because addressing these areas will require action and collaboration from the entire organ donation and transplant community as well as policymakers.

Consistent with its Action Agenda, UNOS is working to drive change in key areas including: (1) increasing direct services, tools and resources to patients, donors, caregivers and their families to more easily navigate the transplant journey, which could provide information to candidates about their status on the waitlist; (2) reducing the organ non-use rate (non-use refers to organs recovered for transplant but ultimately not transplanted); (3) improving equity in access to the transplant healthcare system; (4) ensuring access to OPTN data; (5) maintaining safe, modern, and reliable information technology (IT) systems and infrastructure; (6) reforming the OPTN Membership and Professional Standards Committee (MPSC) processes; and (7) restoring trust in the organ donation and transplant system by establishing an independent OPTN board of directors.

#### **I. Increasing Patient Resources to Navigate the Transplant Journey**

A key component of the Action Agenda is patient empowerment through additional services, tools and resources for patients, donors, caregivers and their families. Our aim is to help patients and their families navigate their transplant journey, which can be complex and burdensome, especially to those already struggling with a difficult diagnosis, ongoing illness and other sources of stress. HRSA has the opportunity, as it undertakes OPTN modernization, to ensure patients have the information they need, including about their status on the waitlist, in an accessible format.

Given the importance of ensuring a patient-centered organ donation and transplant system, UNOS is advocating that HRSA require the OPTN to offer more expansive consumer empowerment tools to enable patients to make choices regarding their care, as well as education and resources for patients, donors, caregivers, parents, and their families. The next contract should require, in collaboration with the patient community, the development of 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, and a candidate's status on the waitlist to help patients navigate through the donation and transplant process. Including these enhanced offerings as part of the OPTN Contract would ensure that the OPTN serves as a centralized resource to patients and their loved ones during their journey.

Patients have shared concerns about the lack of clear and readily accessible information regarding their status on the waitlist. Transplant hospitals, which know their patients best, make the decision about whether to temporarily inactivate a transplant candidate, meaning that the candidate will not receive organ offers while in that status. Neither UNOS nor the OPTN are involved in any decision to inactivate or reactivate an individual candidate. UNOS does not communicate with patients about their placement or status on the waitlist. The transplant hospital is responsible for all phases of the patient's treatment and serves as the first and most authoritative source of information for patients and their caregivers.

At the direction of a transplant program or by individual choice, a candidate may have an inactive status on the waitlist for a variety of reasons. In many cases, a transplant team changes a candidate's

status to inactive due to medical factors that would decrease the likelihood of a successful transplant. For example, a patient may develop a medical condition, such as cancer, that requires treatment before that person is healthy enough to receive a transplant. Other reasons that a transplant hospital may make a candidate inactive include lack of health insurance, non-compliance with required transplant medical evaluations, or that the candidate is waiting for a living donor. Transplant hospitals have the ability to modify a candidate's waiting list status from active to inactive, and they must also report to the OPTN a reason for inactivation. Data regarding the number of candidates who are active or inactive are publicly available on the OPTN website.

## **II. Reducing the Organ Non-Use Rate**

Any organ not ultimately transplanted represents a profound loss, both for the selfless donor's family and the patient waiting. Between 2011 and 2020, the annual non-use rate for kidneys was between 18 and 20 percent. Liver non-use since 2011 has been between 8 and 10 percent. The non-use rate for kidneys increased following a change in kidney allocation policy and was approximately 25 percent as of March 2022.

The number of deceased-donor organs recovered has increased annually over the past decade. As the medical criteria for deceased organ donation continue to broaden, increasing numbers of organs come from older donors and people who died of circulatory death. The increase in the number of medically complex donor organs that are recovered and offered to transplant hospitals corresponds to an increase in the non-use of organs but also the number of transplants performed and lives saved.

Livers and kidneys are viable outside of the body longer than hearts and lungs, so an organ may be recovered before a recipient is identified or biopsy results of the donor are known, both in the interest of the patients in need and to best honor deceased donors. The primary issue for non-use reported to the OPTN is that the waitlist has been exhausted, meaning that all transplant hospitals declined the organ for their patients. Sometimes, post-recovery biopsy findings may determine that an organ is not suitable for transplant. As a result, livers and kidneys that were initially recovered for transplant but were ultimately determined to not be medically suitable are likely to have a higher rate of non-use.

UNOS, working in collaboration with members of the organ donation and transplant community, is pursuing a variety of innovative strategies to improve organ acceptance rates at hospitals, make it easier to say "yes" to organ offers, and save more lives. The OPTN and UNOS are working to improve acceptance through kidney offer filters, predictive analytics, an offer acceptance collaborative, transplant hospital performance metrics, and improvements in the efficiency of transportation of organs by commercial air. Additionally, the OPTN Board is establishing a task force to identify additional ways the community can work together to reduce the non-use rate.

### *Kidney Offer Filters*

The kidney offer filters tool creates a more efficient offer process and reduces the risk of non-use. The tool enables transplant hospitals to avoid receiving offers that they would not accept. For example, a hospital may have a filter that would prevent it from receiving offers for any donor over a specified age or other medical criteria. The OPTN recommends filters to hospitals based on offers

that they have historically received but never accepted, and hospitals may design their own filters as well. With these filters enabled, offers can then reach programs more willing to accept them sooner. The tool also shows hospitals data on offers that were filtered from their program but transplanted at other programs, allowing them to review and adjust their own acceptance practices and filters. More than half of kidney transplant programs have elected to use the tool. The OPTN Board adopted a policy in June 2023 that would automatically turn on offer filters in all adult kidney transplant programs with the ability for them to modify or opt out of the offer filters.

### *Predictive Analytics*

In 2023, the OPTN launched the predictive analytics tool, which is available to all adult kidney programs, with the aim of increasing organ use rates by providing information about the impact that accepting or declining an offer could have on a patient. At the time of an organ offer, the tool uses statistical models to display: (1) the time-to-next offer, which predicts the length of time the candidate could wait for another high-quality organ offer; and (2) a mortality prediction, which offers a visualization of the candidate's likelihood of survival over the next three years without a transplant. During a pilot test, participating programs showed a 2.9 percentage point increase in offer acceptance compared to the previous period, while programs in the control group did not show an increase.

### *Offer Acceptance Collaborative*

Earlier this year, UNOS brought together 83 transplant hospitals to participate in the OPTN Offer Acceptance Collaborative. The 6-month project, launched on January 31, 2023, supports OPTN members as they work together to improve offer acceptance practices and processes at their respective transplant programs. The transplant community and other stakeholders have access to recorded sessions from the kickoff conference as well as webinars hosted throughout the collaborative.

### *Transplant Hospital Performance Metrics*

In December 2021, the OPTN Board of Directors approved new metrics for monitoring the performance of transplant programs. The OPTN began to evaluate transplant programs' offer acceptance rates in July 2023. The collection of these data will help inform future initiatives to reduce non-use.

### *Efficient Transportation of Organs*

The current OPTN Contract does not include a task for facilitating, tracking, or collecting data on the transportation of organs. However, our Action Agenda includes recommendations to improve the efficiency of the transportation of organs. UNOS supports provisions in the Federal Aviation Administration (FAA) reauthorization legislation that would enable the transportation of donated organs, primarily kidneys and livers, in the passenger cabin instead of in the cargo hold of an airplane. Transporting organs through cargo involves more logistical challenges including restricted schedules, gaps in handling, and less flexibility. Cargo does not lend itself to the nature of organ transplant, where organs are viable outside of the body for a limited amount of time and must be transported at all hours of the day and night.

Additionally, UNOS developed a travel application to make it easier for organ procurement organizations (OPOs) to select the most efficient option to transport organs on commercial flights. It aggregates real-time flight schedules, driving directions, and critical logistics data like cargo hours to give users a comprehensive understanding of an organ's projected travel time and path. The tool is being pilot tested by a limited number of OPOs. It is expected to be available to all OPOs later this year.

### **III. Improving Equity in Access to the Transplant Healthcare System**

UNOS is striving for increased equity in access to transplant through the continuous distribution allocation framework and changes to the estimated glomerular filtration rate (eGFR) equation and soon to the kidney donor profile index (KDPI) score. Previously, transplant hospitals sometimes used a race-inclusive calculation of eGFR to estimate a candidate's level of kidney function. The KDPI is used to evaluate every kidney offered for transplant from a deceased donor. It estimates how long a kidney from that donor may function after a transplant. UNOS is also seeking authorization for the OPTN to collect pre-waitlist data to understand the burden of end-stage organ failure, including the prevalence, incidence, and mortality, and barriers that patients face to being included on the waitlist.

#### *Continuous Distribution Allocation Framework*

As established by federal law, explicated in what is known as the OPTN Final Rule<sup>4</sup>, the OPTN has an obligation to design policies to achieve equitable organ allocation by distributing organs over as broad a geographic area as possible and with the sickest patients being served first regardless of location. In 2010, the Secretary's Advisory Committee on Organ Transplantation (ACOT) explicitly recommended that the OPTN develop evidence-based allocation policies not determined by arbitrary administrative boundaries such as donation service areas (DSAs), OPTN regions or state borders. Where people live and receive treatment does not determine the severity of their illness nor priority for a lifesaving organ.

Continuous distribution is a new organ allocation framework aimed at making the national system even more equitable and the organ allocation policymaking process more accessible. This new approach will ensure more meaningful engagement with patients and the public about the values that should guide organ allocation in the United States.

As a result of HRSA's July 2018 directive that the OPTN remove the use of DSAs in organ allocation policies, the OPTN approved allocation policies that consider distance between donor and recipient for liver and kidney transplants as a bridge to the continuous distribution allocation framework. The liver acuity circles allocation policy ensures that the sickest patients and children are getting transplants more quickly than ever before. The kidney allocation policy has resulted in a 29 percent increase in overall transplant rates and improved equity in access to transplants for key populations including Black candidates, Hispanic candidates, Asian candidates, highly-sensitized candidates, and pediatric candidates.<sup>5</sup>

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<sup>4</sup> 42 C.F.R. 121

<sup>5</sup> OPTN Kidney Transplantation, Eliminate Use of DSA and Region from Kidney Allocation Two Year Post-Implementation Monitoring Report, June 22, 2023,

In December 2018, the OPTN Board of Directors approved the continuous distribution framework for future policy development. Continuous distribution will consider all patient factors together to determine the order of an organ offer, and no single factor will decide an organ match. The score will consider factors like patient medical urgency, outcomes and biology, in balance with the efficient management of organ placement, providing the sickest patients with even better access to lifesaving organs. The goal is to increase fairness by removing all the hard boundaries that are part of the classification-based system.

All organ systems are transitioning to the continuous distribution model. The framework was first implemented on March 9, 2023, for lung. In July, the OPTN published its three-month lung allocation policy monitoring report<sup>6</sup> presenting data describing the U.S. transplant system before and after the allocation policy change. The report showed an overall decrease in waitlist removals due to death or too sick to transplant.

#### *Elimination of Inclusion of Race in eGFR Equation*

In December 2022, the OPTN Board approved a process to improve transplant equity by backdating the waiting times of Black kidney transplant candidates who were disadvantaged by previous use of a race-inclusive calculation to estimate their level of kidney function. The Board action requires all kidney transplant programs, starting January 5, 2023, and within one year, to identify those Black kidney candidates whose current qualifying date was based on the program's use of a race-inclusive eGFR calculation, and to determine whether a race-neutral eGFR calculation shows the candidate should have qualified sooner to start gaining waiting time for a transplant. Programs must then apply to the OPTN for a waiting time modification for such candidates.

As of July 31, 2023, UNOS, as the OPTN contractor, has completed 7,733 waiting time modifications for kidney transplant candidates who qualify, submitted by 116 of the 230 kidney transplant programs.

#### *Elimination of Race in KDPI Score*

During its June 2023 meeting, the OPTN Executive Committee approved a new project sponsored by the Minority Affairs Committee to revise the KDPI score to eliminate the consideration of race and exposure to the hepatitis C virus (HCV). The KDPI is used to evaluate every kidney offered for transplant from a deceased donor and estimate how long a kidney from that donor may function after a transplant. An OPTN working group that includes key stakeholders from the kidney community has been established to identify how to revise the KDPI calculation without race and HCV. UNOS has been working with the Scientific Registry of Transplant Recipients (SRTR) to develop a simulated allocation model to evaluate the effects of potential changes to the KDPI score formula.

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[https://optn.transplant.hrsa.gov/media/4mhfm3og/eliminate\\_use\\_of\\_dsa\\_and\\_region\\_from\\_kidney\\_allocation\\_two\\_year\\_post\\_implementation\\_monitoring\\_report\\_2yr.pdf](https://optn.transplant.hrsa.gov/media/4mhfm3og/eliminate_use_of_dsa_and_region_from_kidney_allocation_two_year_post_implementation_monitoring_report_2yr.pdf).

<sup>6</sup> OPTN Lung Transplantation Committee, Lung Continuous Distribution Three Month Monitoring Report, July 13, 2023,

[https://optn.transplant.hrsa.gov/media/fzhh1e5r/data\\_report\\_lung\\_committee\\_cd\\_07\\_13\\_2023.pdf](https://optn.transplant.hrsa.gov/media/fzhh1e5r/data_report_lung_committee_cd_07_13_2023.pdf).

The OPTN will issue a proposed revision to the KDPI score for public feedback during the OPTN Winter 2024 comment period.

#### *Collection of Pre-Waitlist Data*

The OPTN is currently charged with developing and maintaining equitable organ allocation policies that apply to waitlisted patients. The OPTN has been able to continually monitor and adjust organ allocation policies to improve equity in access to transplants among waitlisted patients. The OPTN maintains an Equity in Access dashboard<sup>7</sup> to enable public research and review of these ongoing efforts and publishes organ allocation policy monitoring reports for the public. These resources include data on key equity indicators such as race and ethnicity, rural vs. urban, insurance type, and education level.

True access to transplant, however, not just the waitlist, cannot be measured without understanding the national disease burden. UNOS calls for government action to seek broader equity in access to transplant health care. UNOS seeks authorization for the OPTN to collect data to identify barriers to equitable access to the waitlist and quantify the national disease burden. More data collection on patients before they are added to the waitlist is necessary to eliminate inequities in access to the transplant waitlist. Such data are important to understanding patient, population, and transplant program-level factors that may contribute to inequities in waitlist and transplant access, which could drive research, quality improvement, and other initiatives for OPTN members to address these inequities.

#### **IV. Ensuring Access to OPTN Data**

UNOS is committed to data transparency and accessibility. As the OPTN contractor, UNOS is required by the OPTN Final Rule to provide data for research and analysis of the performance of the OPTN or individual transplant programs. UNOS and the OPTN are similarly required by the OPTN Final Rule and the OPTN Contract to provide to the Secretary of HHS or their designees any OPTN data or information that the Secretary requests.

UNOS responds to formal requests for OPTN data from the public and OPTN members. Like OPTN members and the public, UNOS must similarly submit formal requests to obtain OPTN data for the work it performs outside of its support for the OPTN. In 2022, UNOS received more than 1,400 formal requests for OPTN data. Anyone can submit a data request through the OPTN website<sup>8</sup> and OPTN members can request data through UNet<sup>SM</sup>, UNOS' IT system. OPTN members may request data they have previously submitted to the OPTN at any time, and the OPTN will provide that data to the OPTN member without charge. Information can be provided in datasets, so that requesters can perform their own analysis, or in static reports.

Pursuant to the OPTN Final Rule and the OPTN Contract, patient-identified data requests require that the requester submit a signed data use agreement (DUA), a plan to secure the data, a research

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<sup>7</sup> Equity in Access to Transplant Dashboard, <https://insights.unos.org/equity-in-access/>.

<sup>8</sup> Organ Procurement & Transplant Network, Request Data, <https://optn.transplant.hrsa.gov/data/request-data/>.

plan, and documented approval by an Institutional Review Board (IRB). Requests for patient-identified data must be approved by HRSA before UNOS can release the information to the requester. UNOS also has an obligation as the steward of OPTN data under the OPTN Contract to secure all OPTN data, and therefore all OPTN data requests are subject to restriction on how OPTN data can be stored and used.

Our goal is for the organ donation and transplant community to leverage data for performance improvement. To that end, UNOS has expanded our online self-service tools, enhanced and built new public-facing dashboards, and has a data analytics department to assist with inquiries.

#### **V. Maintaining Safe, Modern, and Reliable IT Systems and Infrastructure**

UNet has been the focus of significant discussion, especially in the wake of reports from the National Academies of Sciences, Engineering, and Medicine (NASEM) and the United States Digital Service (USDS) last year. UNet is the system that helps match donor organs to candidates on the transplant waitlist. In January, UNOS engaged an independent consulting firm to assess our technology and modernization efforts against industry best practices and the USDS Digital Services Playbook. This assessment is in progress. Security, reliability, and modernization have deservedly received much attention. UNOS has also focused many of our improvement efforts on the IT system and security.

##### *UNet Improvements*

UNOS is making improvements to UNet, including steadily moving the platform into the cloud, as recommended by our own experts as well as by NASEM and USDS. The OPTN's predictive analytics tool, which enables all adult kidney transplant programs to evaluate organ offers through predictive analytics data, was born in the cloud. Other functions of UNet are being transitioned to Microsoft Azure and should be in the cloud next spring. This work will not complete our modernization, but it is an important step in what is and should be continuous momentum for improvement. And it will make our system even more secure. As we work, UNOS is building to the highest industry and federal government security standards.

##### *Cybersecurity Defenses*

HHS Office of Inspector General (OIG) contractors recently conducted rigorous penetration tests of UNOS' IT security and have told us we already have established strong defenses against cyberattacks that exceed what most similar organizations have in place. Nonetheless, we continue to press for ongoing improvement in this quickly evolving environment.

##### *Network Reliability*

In February, the IT system experienced a 51-minute outage. However, during the last 15 years, the network has been up and running 99.9 percent of the time, consistent with the target service level agreement (SLA). By that measure, reliability is good, and getting better, but we believe we can make additional improvements.



UNOS shares policymakers' concern about patient safety, and UNOS can confirm that during the February service outage, there were no reported negative effects on any donor or recipient activity taking place within the entire organ donation and transplant network. UNOS staff conducted prompt outreach to all OPTN members who contacted us during the outage and confirmed that all donor and recipient functions being performed within UNet before the interruption were completed successfully once service was restored. We understand that no transplants were put in jeopardy despite the outage.

As we have shared with HRSA and staff for Chair Ron Wyden (D-OR) and Sen. Chuck Grassley (R-IA), UNOS has taken and will continue to take actions to safeguard against future system disruptions. Most significantly, UNOS implemented additional monitoring and alerts to ensure visibility of all database conditions that could lead to a system failure and has accelerated plans to transition the UNet database into one of the Azure public cloud database platforms.

#### **VI. Reforming MPSC Member Compliance Investigations Processes**

In response to concerns that investigations examining compliance with OPTN membership requirements were not forwarded to the OPTN MPSC for review, the MPSC implemented improvements in October 2022 to increase transparency.

Specifically, the MPSC established a new process to review all investigative activity assessing member compliance with OPTN requirements and policies. Previously, the MPSC reviewed reports when investigations revealed potential noncompliance with OPTN obligations. Staff would consult with MPSC members during the investigation, particularly for guidance on clinical matters pertaining to medical judgement and patient safety; however, the full Committee did not receive information about investigative activity that was not identified as a potential noncompliance or safety issue.

This process has been reformed to provide the MPSC with greater information and to aid in its decision making and compliance function. Now, the MPSC will regularly receive information including but not limited to:

- The number of reports submitted;
- The method of receipt, such as the Improving Patient Safety Portal, Member Reporting Line, and referrals from Patient Services;
- Whether the reporter was an OPO, transplant program, histocompatibility laboratory, patient or donor family member, or anonymous;
- Whether the report was a self-report or about another organization;
- The number of reports that are still pending review, referred to the MPSC for action, or are not forwarded for an MPSC action; and
- For cases not referred to the MPSC for formal action, the MPSC will receive a brief summary of the nature of the reports and investigative findings that led to staff's determination not to forward for MPSC review.

Staff have implemented revised processes and documentation so that cases are not formally closed until the MPSC has received the information described above about a case. When the MPSC learns of issues that are outside of OPTN purview, it informs our HRSA colleagues.

## **VII. Restoring Trust in the System by Establishing an Independent OPTN Board of Directors**

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.

On July 14, 2023, in response to a contract task added by HRSA on May 12, 2023, UNOS submitted an in-depth plan to HRSA for creating an independent OPTN board. This would clearly establish an OPTN board with distinct priorities, providing greater role clarity and ensuring trust in the national system. UNOS recommended to HRSA that this separation will require the formation of an OPTN corporate entity as required by the National Organ Transplant Act (NOTA), affirming its establishment as a private, non-profit entity among other steps.

To ensure seamless continuity, according to this plan, the separation will occur prior to or coinciding with the end of the current OPTN Contract. UNOS is committed to working with HRSA to ensure the successful and timely implementation of any OPTN governance restructuring plan under the current OPTN Contract to ensure the OPTN board is independent from the governance of any OPTN contractor.

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UNOS appreciates the engagement of Congress, HRSA, and the Centers for Medicare & Medicaid Services (CMS) on these complex issues. All stakeholders, including UNOS, share a common mission: Identify, allocate and transplant as many suitable organs as safely, equitably and efficiently as possible. We must hold all parts of the system accountable for making sure that this happens. UNOS extends our gratitude to Chair Wyden and the other Senators on the Senate Finance Committee who have worked with UNOS. We look forward to your ongoing collaboration to improve the system for the benefit of patients, donors, and their families.