

STATEMENT OF THE NATIONAL KIDNEY FOUNDATION

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SUBMITTED TO THE SENATE COMMITTEE ON FINANCE

HEARING ON "A SYSTEM IN NEED OF REPAIR: ADDRESSING ORGANIZATIONAL FAILURES OF THE U.S.'S ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK"

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August 5, 2022

The National Kidney Foundation (NKF) respectfully submits our statement for the record on behalf of the 37 million individuals in the United States, 1 in 7 adults, estimated to have chronic kidney disease (CKD).¹ The prevalence of kidney failure is expected to increase dramatically, possibly exceeding one million people who may need access to the transplant waitlist by 2030.² There are not enough deceased or living donor organs to meet current or future needs creating a public health emergency that needs immediate attention. Although 24,669 people received a kidney transplant in 2021, far too many are still waiting. Many never access the transplant waitlist or learn that a transplant is an option. There are 100,000 individuals on the transplant waitlist, and more than 90,000 are waiting for a kidney.

NKF is fiercely committed to holding the transplant system accountable for the ethical stewardship of organs as a precious, life-saving resource. NKF's transplant policy agenda seeks to implement policy changes, payment reforms, legislative solutions, quality measurement, and oversight activities that:

- Maximize the number of kidneys procured and transplanted;
- Minimize the number of kidneys discarded;
- Enhance the transplant process to become more transparent and patient-centric; and
- Drive continuous performance improvement across the transplant system.

The United Network for Organ Sharing (UNOS) has been the sole contractor of the Organ Procurement and Transplantation Network (OPTN) contract--without competition--since 1986. In its nearly 40 years of providing oversight of the organ donation and transplant system, UNOS has witnessed the continuous growth of the waitlist, which comprises almost 100,000 organ failure patients currently waiting for a kidney transplant.³ UNOS is acutely aware that supply is not meeting demand. The OPTN goals should include transparency, equity, and efficacy of organ donation and transplantation practices.

A vital responsibility of UNOS is to provide oversight to the nation's organ procurement organizations (OPO). As revealed in recent congressional investigations, life-threatening inefficiencies and inequities in the transplant system are directly related to OPO underperformance. OPOs are the only transplant stakeholders with the privilege and responsibility of recovering deceased organs for transplant. The lack of oversight is a catastrophic disservice to patients. Transplant centers and OPOs are left to their own devices and tools to sort out logistics of organ and patient transportation leading to inefficiency, wasted expense and directly leading to increased discards.

We have made many recommendations to the Centers for Medicare and Medicaid Services (CMS), Health Resources & Services Administration (HRSA), Organ Procurement and Transplantation Network (OPTN), and Scientific Registry for Transplant Recipients (SRTR) on strategies to improve the organ donation and transplant

¹ Centers for Disease Control and Prevention. *Chronic Kidney Disease in the United States, 2021*. Centers for Disease Control and Prevention; 2021.

² McCullough KP, Morgenstern H, Saran R, Herman WH, Robinson BM. Projecting ESRD Incidence and Prevalence in the United States through 2030. *J Am Soc Nephrol*. 2019 Jan;30(1):127-135. DOI: 10.1681/ASN.2018050531. Epub 2018 Dec 17. PMID: 30559143; PMCID: PMC6317596.

³ [National data - OPTN \(hrsa.gov\)](https://www.hrsa.gov/national-data)

system, which are summarized below.

1. Improving Organ Procurement and Increasing Organ Donation

Immediate data transparency: OPOs collect organ donation data that is currently inaccessible to the public. As an entity whose sole purpose is to serve the public, it is a disservice to patients needing transplantation, organ donors, and donor families who make the selfless decision to donate their loved one's organs. The following metrics (at a minimum), currently captured by all OPOs, should be made publicly available for quality assurance, performance improvement, and stratified by gender, race, ethnicity, age, zip code for health equity purposes:

- Number of organ referrals
- Number of braindead donors
- Number of donation after cardiac (DCD) donors
- Missed organ referrals
- Conversion rate
- Approach rate
- Consent rate
- Percentage of first-person consent

Regulatory consequences for OPOs failing to respond timely to donor hospitals to evaluate potential organ donors: When donor hospitals make a referral for a patient who is not automatically clinically ruled out as an organ donor, the OPTN contractor should require OPOs to make every effort to elicit a timely onsite response for an evaluation.

Regulatory consequences for missed organ referrals: Donor hospitals should face repercussions for missed referrals of potential organ donors. When a hospital fails to notify an OPO of a potential organ donor, critically ill patients continue to wait for a life-saving organ transplant. Further, families lose the opportunity to continue the legacy of their loved ones through the selfless gift of organ donation, and the wishes of the person who has designated their desire to donate their organs are unfairly forfeited.

Staffing to reflect the DSA (Donor Service Area) community: The OPTN contractor must call for OPOs to recruit, hire, and train staff representing the diverse racial, ethnic, and cultural communities they serve. Diversity, equity, and inclusion should be reflected across all departments within the OPO, including executive leadership, OPO professional staff, the clinical teams that interface with donor hospitals, and the teams that work with potential donor families.

Transportation: Organ transportation delays and inefficiencies have life-threatening consequences for waiting patients. It is unacceptable that donated organs are discarded due to transportation pitfalls after donors and donor families have made the selfless decision to donate organs. Examining challenges in the transportation system and identifying policies, best practices, and strategies to mitigate cold ischemia time that results in organ discards is imperative.⁴

Consent training: Reducing disparities and ensuring that each donor and their families are respectfully considered and supported during the donation process must be a standard upheld by all OPOs.⁵ OPO staff must be adequately trained and equipped to approach families of all races, ethnicities, socioeconomic backgrounds, and religious beliefs for organ donation. OPOs should be held accountable for instituting donor family communication best practices,

⁴ Cooper M, Formica R, Friedewald J, et al. Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Clin Transplant*. 2019;33(1):e13419. doi:10.1111/ctr.13419

⁵ Guadagnoli, E., McNamara, P., Evanisko, M. J., Beasley, C., Callender, C. O., & Poretsky, A. (1999). The influence of race on approaching families for organ donation and their decision to donate. *American journal of public health, 89*(2), 244–247. <https://doi.org/10.2105/ajph.89.2.244>

especially around recognizing and eliminating implicit bias, ensuring racial equity, and delivering trauma-informed care.

Donor management and Patient Safety: The OPTN contractor must assess and improve the clinical knowledge of OPO staff to maximize organ recruitment and transplantation. This includes perfusing organs and donation outcomes after cardiac death (DCD) and braindead (BD) donors and organs. Patient safety during organ recovery and transplantation must never be compromised, and documentation of adverse events should undoubtedly be documented, reported, and reviewed to determine the cause and need for remedy.

2. Reducing Deceased Donor Kidney Discards

In partnership with CMS, HRSA, and other stakeholders, the OPTN contractor should implement regulatory changes, payment policy adjustments, and quality improvement initiatives to incentivize OPO and transplant center practices that could reduce discards as recommended by NKF's 2017 Discard Consensus Conference.⁶ Such recommendations include:

- Begin the organ allocation process earlier in the donor evaluation phase.
- Improve communication between OPO and transplant surgeons--The Kidney Allocation System relies on an electronic communication platform, DonorNet, that limits verbal communication between the OPO and transplant center. The exclusive use of DonorNet without collaborative conversations between the OPO and transplant center contributes to decreased organ utilization.
- Accelerate virtual crossmatching and send early prospective crossmatch samples.
- Require frequent QAPI meetings with OPOs and transplant centers to review and analyze data and investigate root causes for low organ transplant rates.
- Secure "local backups" to mitigate the possibility of a kidney discard.
- Increased patient-centricity around organ offers may reduce kidney discards.
- The OPTN contractor should consider creating an algorithm that recommends which patient group receives specific organ offers (ex., determine which patient group would benefit most from a particular organ offer to mitigate "list diving" and reduce organ discards)

Risk aversion in the transplant system is a significant contributor to kidney discard and devastating for patients depending on a life-saving kidney transplant. NKF has urged CMS to develop new reimbursement mechanisms that incentivize transplant centers to list high-risk patients, accept less-than-perfect organs for transplant, and adopt innovative therapies and technologies. New transplant center performance measures should be designed to reduce risk-aversion.

Patients have an essential role in improving risk aversion and reducing discards by making their wishes clear to their care teams. Patients are often less risk-averse than their surgeons and centers. As they spend more time on the waitlist, they may accept an imperfect organ that still confers clinical value compared to dialysis. Transplant centers, nephrologists, and dialysis facilities must regularly consult patients to assess and refine their transplant goals. Increasing utilization is closely linked to reimbursement, transparency, and improved organ acceptance practices. However, it begins with a patient-centered approach to understanding the waitlisted patient's goals and preferences. Transplant programs should also promote shared decision-making with inactive waitlist patients.

Place urgent attention on the role of organ transportation in organ discards: Changes in the allocation system have resulted in more organs being transported across the nation than ever before. Dependence on commercial flights presents several challenges for transplantation that contribute to avoidable discards. Organ recovery usually occurs in the late hours when donor hospital operating rooms are less busy and when there are fewer commercial flights. Every hour a recovered organ waits to be transplanted, cold ischemia time (CIT) increases, decreasing the likelihood of transplantation. Federal regulations no longer allow organs to fly in the cockpit with the pilot, only as

⁶ Cooper M, Formica R, Friedewald J, et al. Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Clin Transplant*. 2019;33(1):e13419. doi:10.1111/ctr.13419

cargo, which exacerbates CIT. Kidneys with too much CIT are discarded and represent a potential life lost on the waitlist. Deceased kidneys are a scarce resource; inefficiencies in air travel should never be a reason for organ discard.

3. Making the Transplant Process and Experience More Transparent and Patient-Centered

Patients on the waitlist receive many organ offers; however, the transplant center often declines organ offers on behalf of their patients without their knowledge or consent. Increasing organ utilization is closely linked to reimbursement, transparency, and improved organ acceptance practices. However, it begins with a patient-centered approach to understanding the waitlisted patient's goals and preferences. Transplant programs should never lose sight of promoting shared decision-making with patients. Patient-centricity should be a priority for every regulatory agency that oversees the organ donation and transplant system, as patients should always have the option to be active participants in shared-decision making with their healthcare team.

There is a need for organ donation and transplant stakeholders to implement additional patient-centric process measures, including bi-annual reports to patients on organs offered and declined on their behalf and annual conversations between patients and their care team regarding patient preferences and tolerances for accepting or rejecting imperfect organs. In addition, if, through this process of shared decision-making, transplant programs and candidates discover either donor or recipient characteristics that would result in universal organ decline, we encourage transplant programs to utilize the organ filters now better optimized to minimize allocation of unacceptable offers resulting in increased cold ischemia time and slowing identification of the appropriate recipient and potential organ discard.

4. Improving System Performance

Harmonizing Regulatory Agency Oversight: NKF supports policies that remove silos, improve operations, drive system-level performance, and increase equity. CMS, UNOS, HRSA, SRTR, and the Joint Commission share oversight of the organ donation and transplantation system. This fragmented oversight contributes to communication, process, and alignment gaps. NKF advocates for one HHS-level office that would provide overall management of the transplant ecosystem to mitigate deficiencies that result from a lack of cohesion and accountability. It is of the utmost importance that performance standards among the regulatory agencies that oversee organ donation and transplantation are aligned in both process and implementation. Misaligned measures only muddle behavior rather than direct it towards shared goals.

Modernizing the technology infrastructure: NKF supports two separate contracts for the Information Technology (IT) Infrastructure and one for other OPTN priorities. The current IT architecture is outdated and fraught with inefficiencies that impair organ donation and transplantation, such as OPO and transplant center communication, waitlist management, and organ allocation. Patients face life-threatening consequences because the UNOS technology is not sophisticated enough for efficient organ distribution. For example, nearly one in five kidneys is offered to a deceased person still on the waitlist because the transplant center is unaware that the patient has died, and deceased candidates receive a median of 4 organ offers before being removed from the waitlist.⁷

The OPTN contractor should not own any technology associated with the organ donation and transplantation process. Separating the two contracts allows OPTN to leverage significant improvements in information technology and mitigate the risk of disruption to the donation and transplant process.

Mandating Transparency: Data transparency of organ donor hospitals, OPOs, and transplant centers must be prioritized to improve organ allocation processes. The lack of data transparency creates significant barriers to care

⁷ Husain SA, Winterhalter FS, Mohan S. Kidney transplant offers to deceased candidates. Am J Transplant. 2018 Nov;18(11):2836-2837.

and inequities for the entire population that could benefit from transplantation. Data collected from OPOs and transplant centers are outdated, inadequately audited, incomplete, and self-reported, making it impossible to develop modern quality measures, specifically for steps in the pre-transplant process. Patients need real-time data, or as close to real-time as possible, to make informed decisions about transplantation. The current delay in data does not accurately portray the current state of organ donation and transplantation.

NKF was deeply troubled by OPTN's announcement about adding 35,000 verified deaths to the standard analytical files. This adjustment illustrates the failure of the current system to capture data from a range of sources and cross-reference it to ensure maximum efficiency. Further, OPTN's announcement lacked urgency or even recognition of the gravity of data inconsistencies and their implications for transplantation-related research. This incident reinforces the critical need for transparency and the need to separate the IT contract from other OPTN requirements to ensure that patients and the system benefit from the cutting-edge technologies that can eliminate these inconsistencies and inefficiencies. HRSA must also determine how death data is collected and verified with the OPTN contractor and CMS to mitigate an error of this magnitude in the future.

Enhanced Waitlist Management: The transplant waitlist is poorly maintained because of inconsistent communication between transplant centers, dialysis facilities, and patients or caregivers due to the current antiquated IT architecture. Patients on the waitlist are frequently unaware of their waitlist status—active or inactive – and receive little or no information from the transplant centers. This absence of communication among patients, their dialysis facilities, and transplant centers represents a failure of the OPTN to improve communication between various stakeholders in transplantation, resulting in inefficient allocation and the perpetuation of silos of care.

Health Equity: Prejudice and implicit bias are common elements of OPO practice. Beliefs that people of color will not donate perpetuate patterns where hospitals are less likely to refer prospective donors to the OPO. In studies, Black/African American families have declined donation because of insufficient time to process and discuss important issues and a lack of sensitivity and empathy during the approach process.⁸ Research has also found that OPOs are more likely to approach White families over Black/African American families.⁹ NKF strongly opposes race-based adjustments to the OPO metrics and suggests that OPOs adopt best practices to overcome bias and prejudice on the ability of families to donate their loved one's organs. For example, hiring staff that represents the communities they serve and implementing frequent training on cultural sensitivity, diversity, and inclusion to improve conversations with non-White populations about donation.

A kidney transplant is the optimal treatment for end-stage renal disease. Still, Black/African American people are disadvantaged at every step of the transplant process and have poorer graft outcomes.¹⁰ Organ failure patients desperately need an equitable transplant ecosystem. Justice, fairness, equity, and transparency are values our organ donation and transplant system need, and patients deserve. Federal agencies that oversee the organ donation and transplant system must uphold these values to influence public confidence in our organ donation and transplant system. Regardless of demographic characteristics or socioeconomic status, every person should have the right to access the national transplant waitlist.

5. Amplifying the Patient Voice

⁸ Siminoff LA, Alolod GP, Gardiner HM, Hasz RD, Mulvania PA, Wilson-Genderson M. A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation. *J Racial Ethn Health Disparities*. 2021;8(2):485-493. doi:10.1007/s40615-020-00806-7

⁹ Guadagnoli E, McNamara P, Evanisko MJ, Beasley C, Callender CO, Poretsky A. The influence of race on approaching families for organ donation and their decision to donate. *Am J Public Health*. 1999;89(2):244-247. doi:10.2105/AJPH.89.2.244

¹⁰ Norton JM, Moxey-Mims MM, Eggers PW, et al. Social Determinants of Racial Disparities in CKD. *J Am Soc Nephrol*. 2016;27(9):2576-2595. doi:10.1681/ASN.2016010027

As a patient advocacy organization, NKF is proud to uplift the voices of the patients we have the honor to represent. Improvement of the organ donation and transplantation system should not occur without patients learning what they need and want for the success of their transplant journey. When presented with the opportunity to comment on how to improve the current transplant system, we received the following responses from patients:

Improve communication – "Ensure that transplant centers have adequate resources and staff to support their patients with consistent and effective communication. Patients deserve to know when they are listed for transplant and the actions they can take to maintain optimal health on the waitlist. Centers must alert patients of their waitlist status when they become listed and made inactive or delisted. Physicians, Advanced Practice Providers, Nurses, Transplant Coordinators, Social Workers, and other transplant center staff that interface with patients should adequately and compassionately share the reasons for an inactive status with patients and why they have been delisted."

Include the Patient as Part of the Care Team – "Clear and timely communication between the transplant team and patients can promote shared decision-making should be afforded to each patient. Transplant centers have complained about patient compliance; if transplant centers want improved cooperation from patients, they should prioritize shared decision-making."

Promote Cultural Sensitivity – "Clinical and non-clinical transplant center staff must practice cultural sensitivity and inclusivity to decrease patients' risk of falling through the cracks due to language barriers and cultural misunderstandings. Transplant centers need appropriate communication strategies and mechanisms to relay messages with non-English speaking patients to prevent patient isolation and poor outcomes."

Address Patients' Mental and Emotional Well-being – "Organ failure is scary. Dialysis creates added stress and anxiety. Dialysis patients face various challenges—healthcare complications, lethargy (too tired to participate in common daily activities), lack of social support, and depression, to name a few. Patients experience a general fear when faced with organ failure and the prospect of their mortality. Organ donation and transplant surgery are overwhelming to think about. Transplant centers could assuage these feelings by communicating with their patients in as close to real-time as possible about what to expect during the process (not just once, but reminders throughout would be helpful)."

Conclusion

The National Kidney Foundation has been fighting kidney disease for over 55 years and works tirelessly to improve outcomes for kidney patients and patients at-risk by emphasizing prevention, early detection, and CKD management to slow or stop the progression of kidney disease. We are also committed to increasing access to kidney transplantation and improving patient choice of high-quality, patient-centered options to treat kidney failure. Kidney care is fraught with disparities. We will continue to advocate for policies that prevent barriers, biases, and prejudices that prevent all patients from receiving the care they rightly deserve.

We welcome any questions about our recommendations and to improve the American organ donation and transplant system. Please contact Morgan Reid, Director of Transplant Policy and Strategy (morgan.reid@kidney.org), or Lauren Drew, Director of Congressional Relations (lauren.drew@kidney.org).

Thank you for your consideration.