



August 14, 2021

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Co-Chair, Ad Hoc Committee on Transplantation
National Academies of Science, Engineering, and Medicine
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Kizer and Committee Members,

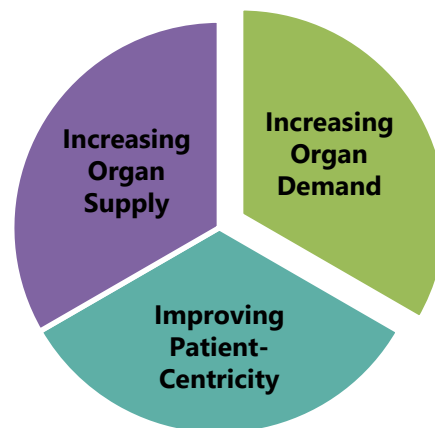
On July 15, 2021, Kevin Longino, Chief Executive Officer of the National Kidney Foundation (NKF) and transplant recipient, provided remarks to a meeting of the ad hoc committee conducting the study, *A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution*. We are following up on Kevin's remarks with the following written testimony.

The U.S. transplant system performs incredible feats every day, including not just maintaining but exceeding previous years' number of kidney transplants during the COVID-19 pandemic. It must also be said that our transplant system is far from optimized. Twelve kidney patients die on the waitlist each day while 9 kidneys are discarded. Twenty people each day are removed from the waitlist, and tens of thousands of kidney patients will not even learn that transplant is an option for them. Kidney care is one of the starkest examples of race and class disparities in all of health care.

Historically, improving the transplant system has focused on increasing the organ supply. This is appropriate given the dramatic disparity in the need for organs and their availability. However, NKF approaches the issue of kidney transplantation more holistically and we encourage the committee to do the same. Improving our transplant system also requires focusing on, paradoxically, increasing demand for transplant by bringing more people into the system, and improving the patient-centricity and patient experience of transplant.

I. Increasing the Organ Supply

Figure 1. Approaches to improving transplantation in the United States



Approximately 3500 kidneys are discarded annually.¹ It is too simple to suggest that each one of these kidneys could be transplanted into one of the nearly 5000 people in the U.S. who die waiting for a kidney transplant, but certainly many of these less-than-perfect kidneys still have significant value to patients when compared to their quality of life and survival on dialysis. In May 2017, NKF convened a group of 75 multidisciplinary experts on transplantation to discuss the high rate of organ discard at the Consensus Conference to Decrease Kidney Discards. The paper that resulted from that conference outlined a set of actionable steps to improve utilization and reduce discards including creating an expedited placement pathway for kidneys at high risk of discard, increasing the Medicare payment for kidney transplants to cover the increased costs of transplanting these kidneys, creating accountabilities for transplant centers to improve their acceptance practices, and increasing the capacity of transplant centers to bear risk associated with the transplant of less-than-perfect organs.² We elaborate on each of these proposals below:

Adopt Expedited Placement

On March 15, 2021, the Organ Procurement and Transplant Network (OPTN) adopted new policies for kidneys that place the distance between donor and recipient at the center of allocation. The first unit of allocation is now the 250 Nautical Mile (NM) circle around the donor hospital, with recipients nearer to the donor hospital receiving more points. The other variables used to calculate the rank list of candidates to whom the kidney should be offered, known as a match run (waiting time, donor/recipient immunologic compatibility, prior living donor, survival benefit, and pediatric status) were unchanged by the March 2021 policy. Thus, current allocation policy does not account for a procured kidney's risk of discard.

When a kidney is procured for transplant, the United Network for Organ Sharing (UNOS) Organ Center generates the match run. Every center on the match run then has the opportunity to consider the organ for a waiting patient. As the match run process proceeds, the kidney accumulates more time out of the body decreasing its quality and increasing its risk for discard. As it pertains to kidney discards, there is a tension in kidney allocation between the needs of the few and the needs of the many. Transplant surgeons value the opportunity to consider every possible kidney for their patient, even when it is statistically unlikely that center will ever accept a kidney of certain quality for its patient. As a result, the median number of declines before a kidney is accepted is seven.³ This practice does not serve waitlisted patients when a kidney that might have been accepted with less cold time eventually reaches a center that would have taken it earlier in allocation but now cannot do so due to the deteriorated quality of the kidney. The experts convened for the Consensus Conference to Decrease Kidney Discards wrote, "[c]enters always refusing high-risk organs

¹ doi:10.1001/jamainternmed.2019.2322

² <https://onlinelibrary.wiley.com/doi/10.1111/ctr.13419>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5544513/>

slow allocation and should not receive these offers to ensure use of organs at risk of discard.⁴ In 2019, UNOS initiated the Kidney Accelerated Placement Project (KAPP), a pilot program designed to shunt hard-to-place kidneys having reached national allocation to centers with a demonstrated history of using them. The pilot failed due to the COVID-19 pandemic and because the kidneys were not expedited from first offer, rather they were only directed to centers after accumulating many hours of out the body going through standard allocation. **UNOS must adopt an expedited placement policy for kidneys at high risk of discard. The kidneys must be expedited from first offer.** The issue of kidney discards has been well recorded and the community's support for expedited placement has been documented in the literature since 2018. Expedited placement should not be continuously tested in pilots but should be designed for success and permanently adopted into OPTN policy.

Increase Medicare Payment

As of January 1, 2021, under the Inpatient Prospective Payment System (IPPS), Medicare reimburses transplant centers three flat rates for kidney transplants in the following categories: DRG 652 (Kidney Transplant), MS-DRG, MS-DRG 650 (Kidney Transplant with Hemodialysis with Major Complication or Comorbidity) and MS-DRG 651 (Kidney Transplant with Hemodialysis without Major Complication or Comorbidity).⁵ Historically, Medicare only paid one flat rate for all kidney transplants.

In 2020, the Centers for Medicare and Medicaid Services (CMS) acknowledged that kidney transplants requiring hemodialysis are more costly and proposed to increase the Medicare reimbursement for these transplants. While CMS' proposal somewhat improved the payment structure, it continues to act as a disincentive for transplant centers to accept and transplant kidneys at high risk of discard, which generally require higher acuity care after the procedure and thus are more expensive for the center to use.

Unfortunately, the IPPS is bound by budget neutrality, meaning that a higher Medicare reimbursement for more complicated transplants adversely impacts the reimbursement for non-complicated transplants. The new payment structure also fails to account for other drivers of high-cost transplants, such as high levels of donor specific antibodies, cardiac care and monitoring in older transplant recipients, and the use of expensive, but highly effective biologic agents to reduce the risk of rejection. **It is imperative that Congress and CMS develop solutions to appropriately fund kidney transplant relative to Medicare spending on dialysis, which exceeds \$35 billion annually.**⁶

⁴ Ibid.

⁵ <https://www.govinfo.gov/content/pkg/FR-2020-09-18/pdf/2020-19637.pdf>

⁶ https://www.usrds.org/media/1734/v2_c09_esrd_costs_18_usrds.pdf



The need for increased Medicare reimbursement of kidney transplant has been amplified by the new kidney allocation policies described above. As kidneys are allocated more broadly, they spend more time “on ice” and the cost of the procedure and hospital stay increases commensurately. Notably, transplant centers have more flexibility to accept less-than-perfect kidneys for commercially insured patients because the reimbursement is more likely to make the center “whole.” Medicare patients, who are not working and may be disadvantaged in other ways, may wait on dialysis until a lower cost organ to transplant becomes available.

Improving Acceptance Practices

Transplant centers can filter out offers for waitlisted candidates by specifying what types of kidneys the surgeon will accept for her or his patient. In theory, organ filters improve the efficiency of allocation by bypassing centers that will not use a kidney of a certain quality. In reality, there is no accountability for what a center says it will accept versus what the center actually accepts. Currently, transplant centers are not accountable for behaviors that contribute to discards, such as the disingenuous use of organ offer filters or turning down an organ on behalf of a patient without the individual’s knowledge or consent. NKF is a steadfast proponent of measuring transplant center performance against a standardized organ offer-acceptance rate.

The UNOS Membership Professional Standards Committee (MPSC) has released for public comment a proposal to improve transplant center performance monitoring that includes a metric of organ offer acceptance.⁷ The metric, however, is only intended for the MPSC’s use in performing its oversight responsibility and will not be used to rate or rank programs. While a metric of organ offer-acceptance rate is likely not suitable for regulatory use by CMS, given the importance of this behavior for improving the organ supply and the numerous disincentives, many of which we describe here, that preclude greater organ offer acceptance currently, **it is imperative that UNOS collect, report, and leverage organ offer-acceptance rates for continuous improvement.**

The MPSC proposal also has no bearing on transparency, a close cousin in concept to accountability. Organ offer practices are opaque to patients, the vast majority of whom have no idea that patients receive an average of 17 offers before receiving a transplant, and that patients who die on the waitlist receive a median of 16 offers over a 2-year period.⁸ It is not hyperbole to say that patients who hear these statistics are horrified and begin to lose trust in the system. Relatively simple solutions could improve on the problem. **The Scientific Registry of Transplant Recipients (SRTR) should produce reports quarterly on the**

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https://optn.transplant.hrsa.gov/media/4777/transplant_program_performance_monitoring_public_comment_aug2021.pdf

⁸ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2749266>

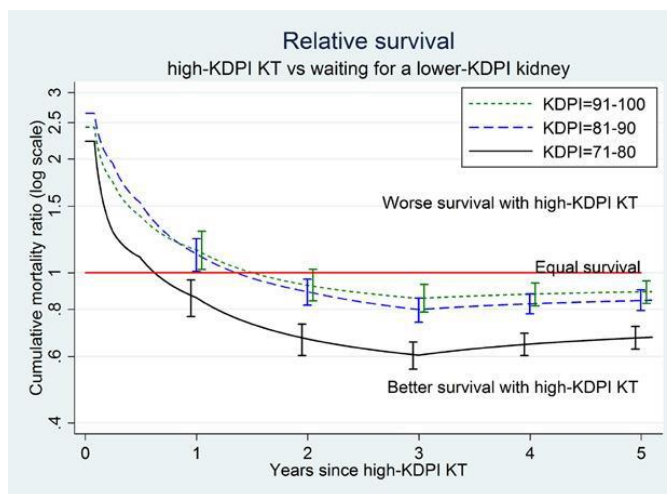
number of organs declined by the center to be shared with the waitlisted patient.

Improve Risk Tolerance

One-year post-transplant patient and graft survival has been the core outcome measure for transplant programs, required by CMS and used by the MPSC to flag transplant programs. CMS has moved away from the outcome measure, recognizing that the measure contributes to transplant program risk aversion. The MPSC metrics proposal, *Enhance Transplant Program Performance Monitoring System*, recommend preserving a version of one-year post-transplant patient and graft survival that is conditional on survival during the perioperative period.

NKF is tentatively supportive of the measure, understanding that outcome measures are relevant to patient safety and program quality overall. We have also recommended to the MPSC that the transplant system move towards tracking and reporting 5-year outcomes compared with anticipated survival if the individual remained on dialysis. This recommendation includes a seemingly contradictory idea. Patients who pursue a transplant expect that they and their transplant will last longer than one year. A longer outcome period may actually discourage the transplant of higher KDPI organs or riskier donors. **To address this concern, we strenuously recommend that outcomes be measured relative to survival on dialysis.** While high KDPI kidneys are associated with a shorter expected posttransplant kidney survival, acceptance of these organs increases access to kidney transplant and therefore reduces mortality for appropriate patients compared to individuals who remain on dialysis (Figure 2).

Figure 2



Broadly speaking, transplant centers are risk averse. Undoubtedly, the potential that a



program will be flagged for safety concerns within a year post transplant contributes to a risk averse culture, though more nebulous factors like the mindsets of transplant physicians also play a role.

NKF also supports the development and implementation of a measure of shared decision-making on organ acceptance. Generally speaking, patients are less risk averse than their surgeons and centers. As they spend more time on the waitlist, they may be willing to accept a less-than-perfect organ that still confers clinical value when compared to dialysis. Patients thus have an essential role in improving risk aversion by making their wishes clear to their care teams. **Tools to measure shared decision-making and accountabilities to encourage it are needed.** Shared decision-making is not a one-time activity. Patients' tolerance for risk can vary throughout their time on this list and must be continuously assessed. Notably, reducing risk aversion is closely linked to reimbursement, transparency, and improved organ acceptance practices. A patient-centered approach begins with an ongoing understanding of the waitlisted patient's goals and preferences after which transparency and greater organ acceptance should naturally follow.

Reduce Barriers to Living Donation

Living donors have an essential role in closing the gap between the demand for deceased donor kidneys and their supply. Given the value of a living donor kidney to a recipient and the health system overall, we are not doing everything possible to eliminate barriers to living donation. As a threshold matter, living donors should be made whole in terms of unreimbursed expenses associated with donation. The National Living Donor Assistance Program (NLDAC) reimburses eligible donors for travel expenses, lost wages, and dependent care expenses.

The program is limited by income eligibility requirements for recipients and donors, capped at 350% of HHS Poverty Guidelines. **As a preliminary step, NKF recommends raising the income eligibility threshold to 500% of Poverty Guidelines. Broadly speaking, the NLDAC program should be reformed to decouple the ability of the donor to receive assistance from the recipient's income. In addition, states should implement tax credits that encourage employers to institute living donation policies, including wage protection and paid time off. Such policies will reduce the need for living donors to rely on third-party organizations for financial support.**

Ensuring that living donors have access to life, long-term, and disability insurance without discrimination based on donor status and are protected under the Family and Medical Leave Act of 1993 (FMLA) are key components of eliminating barriers to living donation. NKF has secured 20 state laws that protect living donors and is leading the passage of the federal Living Donor Protection Act. **All living donors should have the security and certainty**

provided by this legislation.

Transplant centers, nephrologists and dialysis facilities can do more to empower patients to search for a living donor. Clinicians and dialysis providers balk at additional responsibility for kidney transplantation because they are constrained in their ability to increase access to transplant by gaps in the organ supply. This is reasonable but fails to account for the role of the care team in providing education about living donation. NKF's flagship program, The Big Ask, The Big Give (BABG) helps patients ask their community to consider being a donor. A preemptive transplant from a living donor, a transplant that a patient receives before beginning dialysis, is the closest treatment to a cure for kidney disease however less than 3% of ESKD patients receive one. **Empowering and educational programs like BABG should become part of routine kidney care so that patients begin their search for a living donor as soon as possible.**

Encourage Innovation

Across kidney care, reimbursement for innovative drugs and technologies have been limited in uptake by capitated payment structures. Transplant is no exception. **New technologies such as normothermic and hypothermic machine perfusion, in situ perfusion for donors after cardiac death and ex-vivo organ interventions to improve organ quality and reduce discard should be tested in demonstration projects to determine their superiority to existing technologies.** Demonstration projects may also be a suitable forum for testing novel payment arrangements to incorporate these innovative approaches into the transplant system.

II. Increasing Organ Demand

Despite transplant being optimal treatment modality for an expanding group of ESKD patients, there are relatively few incentives to encourage it on the demand side. Value-based purchasing programs for nephrologists, i.e., the Merit-Based Incentive Payment System (MIPS), and dialysis facilities, i.e., the Quality Incentive Program (QIP) do little to incentivize transplantation. Dialysis facilities are required by CMS regulations at § 494.90(d) to educate dialysis patients about transplantation and the Quality Incentive Program ties 2% of Medicare reimbursement to dialysis facility performance on a set of quality measures, one of which is Percent of Prevalent Patients Waitlisted (PPPW).

Despite these efforts, patient access to the waitlist has not increased in two decades and has actually fallen in socially vulnerable populations,⁹ making it a health equity issue. Access to the waitlist also represents the possibility of transplantation if not a guarantee. In addition, when patients are brought into the transplant system, they often receive more support in finding a living donor and participating

⁹ <https://jasn.asnjournals.org/content/32/4/913>



in kidney paired donation (KPD). It is simply a disservice to patients to claim that because organ supply cannot meet demand that patients should not be educated on and encouraged to pursue kidney transplantation and that incentives that encourage these behaviors among providers and clinicians are purposeless. It is no fault of patients' that we have not done everything possible to maximize the organ supply.

Consistent, high-quality transplant education is badly needed. Dialysis facilities claim that they do not have the expertise to provide comprehensive transplant education, whereas nephrologists and transplant centers often note that there is little extra time to provide these services. The result is that patients approaching dialysis or on dialysis are not told that transplant is an option for them. Even among patients who wish to pursue a transplant, misconceptions abound, with dialysis patients reporting that they have already been listed at a center when they have not or are active on the waitlist when they are not.

III. Improving Patient-Centricity

Patients care not only about their ability to access a transplant and the outcome of that transplant, but also about the efficiency and effectiveness of the process itself. Donor and recipient evaluations can be streamlined to make the best use of patients' time, referrals can be followed up on more promptly, time from referral to evaluation shortened, education on living donation enhanced and communication with and management of waitlisted patients improved. Patients who have received transplants often point to these process inefficiencies as aspects of care that they would like to see improved. Because the OPTN contract has no oversight over the pre-waitlisting steps to transplant, there is little to no data collection on or oversight over these early steps to transplant anywhere in the U.S. government. The lack of these data makes it nearly impossible to encourage patient-centered process improvements in kidney transplant programs. Transparency, shared decision-making, improved acceptance practices, improved transplant education, and greater support for living donors as described above are also elements of patient-centricity in kidney transplantation that must be implemented.

We greatly appreciate the committee's attention to these written remarks. We would welcome the opportunity to speak with the committee or committee staff to elaborate on the recommendations herein. Please contact Miriam Godwin, Health Policy Director, at miriam.godwin@kidney.org.

Sincerely,



NATIONAL KIDNEY
FOUNDATION®

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