The Advancing American Kidney Health (AAKH) Executive Order: Promise and Caveats for Expanding Access to Kidney Transplantation

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More than 700,000 persons in the United States suffer with kidney failure but the vast majority will not have an opportunity to receive a kidney transplant, even though transplantation provides superior quality of life and survival compared to chronic dialysis. In 2019, there were 16,534 deceased donor and 6,867 living donor kidney transplants, while nearly 95,000 patients remain on the kidney transplant waiting list. Remarkably, two important transplant strategies, compatible living donor kidney transplantation (LDKT) and transplantation with high-quality deceased donor organs, not only provide clinical benefit but are also cost saving to the healthcare system.\(^1\) Higher-risk kidney transplant options (i.e., with lower-quality deceased donor organs or blood type incompatible LKDT) are more expensive but remain cost-effective, providing superior cost per quality-adjusted life year ratios than dialysis.\(^1\) Although a minority of patients with kidney failure have comorbidities that preclude safe transplantation, many others that are not currently wait-listed would likely pursue and benefit from transplantation if it were more accessible, without the prolonged waiting that often correlates with health deterioration on dialysis and may render a patient “too sick for transplant”.

The federal government is deeply invested in the care of patients with kidney disease, and the establishment of disease-specific Medicare entitlement in 1972 expanded dialysis access across age groups and comorbidity profiles to an extent not possible in some other countries. In concert, Medicare spending for kidney failure care has grown exponentially, to \(~\$91,000\) annually for the care of each hemodialysis patient and \$76,000 for the care of each peritoneal dialysis patient, resulting in total spending of \$36 billion in 2016.\(^2\) By comparison, average annual spending for transplant recipients is \~\$38,000.\(^2\) Moreover, current overall adjusted mortality per 1000 patient-years rates is 166 for hemodialysis patients and 154 for peritoneal dialysis patients, compared to only 29 for transplant recipients.\(^2\) Delivery of transplant education at dialysis centers correlates with listing rates,\(^3\) but the quality of transplant education provided by dialysis centers under the Centers for Medicare and Medicaid Services (CMS) education mandate is variable and inconsistent.\(^4\) Thus, current clinical practices favor the common use of the higher cost/lower benefit modality (in-center hemodialysis) which does not serve the best interests of patients and has tenuous economic sustainability.

To address these issues, the federal government, in July 2019, launched a historic initiative to shift practice towards increased use of home dialysis and transplantation through the ‘Advancing American Kidney Health’ (AAKH) Executive Order.\(^5\) The AAKH blueprint is centered on 3 broad goals: 1) reducing the risk of kidney failure; 2) improving access to and quality of person-centered treatment options; and 3) increasing access to kidney transplants, with the latter two directly tied to expanding transplantation. The goal of improving patient-centered care will be benchmarked against a target for 80% of patients who
initiate renal replacement therapy in 2025 and do so by receiving dialysis in the home or undergoing a transplant. While ambitious, initiatives to foster reaching this metric were promptly drafted, including new reimbursement models designed for testing by the Center for Medicare & Medicaid Innovation. A nationally randomized, mandatory ESRD Treatment Choices Model includes payment adjustments favoring home versus in-center dialysis, while a voluntary model incorporates a Kidney Transplant Bonus (KTB) of up to $15,000 when patient is transplanted and sustains at least 3 years of allograft function. The KTB is designed to incentivize early consideration of transplant in treatment modality planning. The models will empirically assess the impact of payment restructuring over the next 3 years (with possible 1- to 2-year extensions), but in advance of these data, revising reimbursement incentives appears to be one rational strategy to help transform practice patterns.

While early education and appropriate referrals are important strategies to mitigate disparities in transplant access, referral alone cannot increase transplantation without an expanded organ supply. Goal 3 of the AAKH Executive Order targets doubling the number of kidneys available for transplant by 2030. Currently, approximately 20% of procured kidneys are not utilized for transplant, and recent studies have suggested substantial untapped potential for deceased donor kidney transplantation (DDKT) in the United States compared to countries such as France, primarily from broader use of organs from older donors with more comorbidity. To this end, in December 2019, U.S. Department of Health and Human Services (HHS), through CMS and the Health Resources and Services Administration (HRSA), proposed new rules to support increasing both DDKT and LDKT. In the former, the focus is on the Organ Procurement Organizations (OPO), the not-for-profit companies that are responsible for evaluation and procurement of deceased donor organs. Their performance will be evaluated based on new metrics that include defining donation and transplantation rates based on national death records rather than self-reported data, benchmarking performance against the donation and transplantation rates of the current top 25% of OPOs, with consequences for sustained underperformance including risks of decertification.

Importantly, OPOs do not act in isolation, and efforts to successfully expand organ procurement and placement requires well-coordinated partnership of OPOs with donor hospitals and transplant centers. Organs from Public Health Services (PHS) infection risk donors, donors with known viral infections such as Hepatitis C, and lower predicted survival (as reflected in higher Kidney Donor Profile Indices) can provide survival benefit over dialysis, although at higher risk than transplant from “ideal” donors. However, transplant centers face significant performance scrutiny, commonly resulting in a risk-averse culture, with less high-risk organ utilization. Thus, while CMS recently removed the strict performance metrics for one-year allograft and patient survival from the Conditions of Participation for
transplant program reapproval, transplant centers must continue to publicly report their post-transplant outcomes and are ranked and assessed for Centers of Excellence designations for private insurance contracting. Furthermore, there are other financial disincentives to expanded organ acceptance, as transplantation of clinically higher-risk organs increases the cost of transplantation without compensatory increases in Medicare reimbursement. Importantly, from the patient outcomes perspective, clinical utility of higher-risk organs can vary with recipient characteristics, and expanded organ use requires nuanced understanding of which patients may benefit from these organs and efforts to promptly direct to appropriate recipients. Finally, as organ allocation policies are being actively revised to distribute organ offers over broader geographic boundaries, it will be critical to monitor how broader geographic sharing impacts utilization and outcomes of higher-risk organs, which may be particularly vulnerable to injury from longer cold ischemia times during transport.

Expanding living donation, the other key strategy in expanding donor supply, has significant barriers, including financial disincentives to donors. Although donation-related medical expenses are paid by the recipient’s insurance or Medicare, living donors incur both direct and indirect costs in the donation process that are not reimbursed, such as travel, lost time from work, and dependent care. In one U.S. study, 92% of living kidney donors incurred direct costs (median $433, range $6 to $10,240) and more than one-third reported lost wages in the first year following donation (median $2,712, range $546 to $19,728). A single-center, retrospective survey of living donors who were working for compensation at the time of donation found that increased length of time to return to work was a significant predictor of financial burden. Living kidney donation declined after 2005 and remained below 2005 levels until 2019, with the onset of the decline correlating with the economic recession, and most dramatic declines in men among all but the highest income quartile. Financial barriers may also contribute to racial disparities in LDKT access, which have increased over time. As a result, in December 2019, HRSA issued a proposed rule to support LKDT by removing financial disincentives to living donation; specifically expanding the scope of reimbursable expenses for living donors to include lost wages, and childcare and eldercare expenses for those donors who lack other forms of financial support, administered through the National Living Donor Assistance Center (NLDAC).

While the HRSA proposed rule as an important step to improve financial neutrality for living donors, even more can be done. Based on provisions of the Organ Donation and Recovery Improvement Act (ODRIA) of 2004 authorizing federal reimbursement of non-medical expenses as a payer of last resort, awarding of travel and lodging grants to living donors requires income testing of the intended recipient. Means testing of the recipient is problematic in the case of non-directed donors, who offer their gift
without an identified recipient, and is also likely a barrier for non-related directed donors without a close established relationship with their recipient (e.g., donors who learn of a need through social networking, and may wish to be evaluated anonymously). Revision of recipient means testing in the NLDAC program to help mitigate financial barriers for all potential donors, regardless of their relationship to the intended recipient, could be a key step forward to increasing LDKT.

Another barrier to living donation is the medical leave time required for recovery which has reportedly caused some donors to lose their jobs. Proposed legislation such as the ‘Living Donor Protection Act’ is designed to prevent insurance discrimination based on serving as an organ donor and to protect the right to use Family Medical Leave Act to recover from donation surgery, and provides another opportunity to advance LDKT. With slow progress on a federal bill in recent years, a number of states have introduced state-level LDPAs. CMS could also consider provision of lifetime Medicare insurance as a financial and clinical safeguard.

The 2019 AAKH Executive Order brings great promise for expanding access to transplantation by dissolving silos created by current patient education and referral practices, incentivizing optimal procurement and placement of deceased donor organs, and removing barriers to LKDT. However, there are caveats that warrant ongoing attention (Figure). We hope AAKH is starting point to unify collaborative efforts across policy makers, transplant and general nephrology providers, and OPOs in a shared goal of making access to kidney transplantation – the clinically and economically superior treatment for kidney failure – a near-term reality for all patients in need.
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Author Contributions
Krista Lentine: Conceptualization; Writing - review and editing  
Roslyn Mannon: Conceptualization; Visualization; Writing - original draft; Writing - review and editing

Disclosures

Krista Lentine is a member of the American Society of Nephrology Quality Committee and Roslyn Mannon is a member of the American Society of Nephrology Policy and Advocacy Committee.
Figure. Opportunities and challenges for expanding kidney transplant access through the AAKH Executive Order. AAKH, Advancing American Kidney Health; DDKT, deceased donor kidney transplantation; EO, Executive Order; KTB, Kidney Transplant Bonus; LDKT, living donor kidney transplantation; NLDAC, National Living Donor Assistance Center; OPO, Organ Procurement Organization

**Opportunities & Challenges for Expanding Kidney Transplant Access through the AAKH Executive Order**

**Focus**

- **Breakdown Silos in Current Practice**
  - Test Medicare payment adjustments
    - Favor home vs in-center dialysis
    - KTB for clinicians when their patient is transplanted and sustains at least 3 years of allograft function

- **Increase DDKT**
  - Revise metrics of OPO performance
    - Define donation & transplantation rates based on national death records rather than self-reported data
    - Benchmark performance against the current top 25% of OPOs
    - Enforce consequences for sustained under-performance, including risk of decertification

- **Increase LDKT**
  - Reduce financial disincentives to living donation
    - Expand the scope of reimbursable expenses through NLDAC to include lost wages, childcare & eldercare expenses for those who lack other forms of financial support

**EO Action**

- **Cautions & Opportunities for Further Action**
  - Ensure that treatment choices are patient-centered
  - Transplant centers must adapt & scale for potential large increase in referrals
  - KTB rewards primary nephrologist but not the transplant center that provides most consistent care for the initial 3 years

  - OPOs do not act in isolation – organ procurement & placement require collaboration with donor hospitals & transplant centers (OPO metrics are effectively system metrics)
  - High-stakes benchmarking against peers may discourage collaboration & sharing best practices across OPOs

  - Requirement for recipient ‘means testing’ is a barrier to supporting donors without a close relationship to the intended recipient
  - Broader efforts to achieve financial neutrality are warranted (e.g. protection from insurance discrimination)
  - Expansion of living donation should be coupled with donor safety protections (e.g. long-term follow-up & healthcare access)
REFERENCES


