IMPACTS OF VASCULAR ACCESSES ON PAYERS AND PROVIDERS IN THE USA

AUTHORS: Fan Zichen, Kashyap Milindh, Oyeniyi Oluwagbebemi, Wang Andi

Executive Summary

Vascular accesses (VA) are critical to performing hemodialysis treatment. Although needles are used to access the bloodstream, they cause complications that severely threaten vascular access, requiring urgent and costly interventions. This translates to increased cost of care for payers and significant loss of revenue for dialysis providers. They also limit patient transitions to home hemodialysis.

The clinical impacts of vascular access on patients have been thoroughly explored, particularly in understanding the incidence of complications and hospitalizations, and the performance evaluations for various interventions required to sustain a patent vascular access. However, not much emphasis has been given to the impact of vascular accesses and their attending complications on dialysis providers and payers, particularly concerning financial and operational efficiencies. This paper aims to reveal how the VA impacts providers and payers in the US.

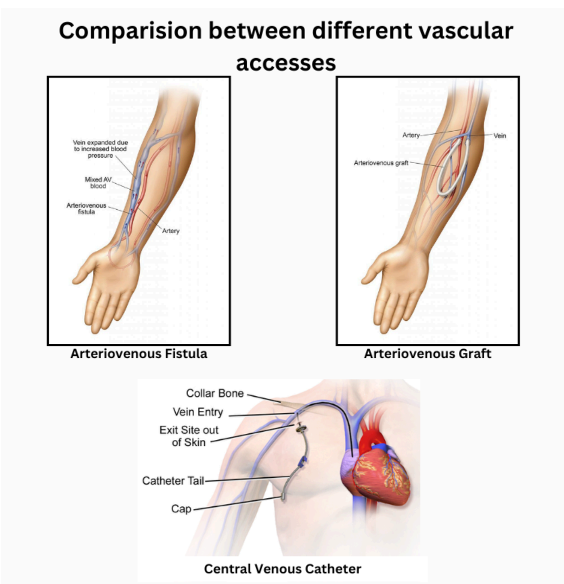
Using both collected and deduced empirical data, we show a thorough analysis of today's industry standards, the financial implications of existing vascular access to stakeholders like the Center for Medicare and Medicaid Services (CMS) and Large Dialysis Organizations (LDO), the operational impacts on dialysis providers and their staff at various decision-making tiers, and the role of macro-level initiatives and externalities on the outcomes in dialysis. Furthermore, the paper also offers insightful recommendations, advocating the role of technological innovations in vascular access devices, collaboration among industry stakeholders, and a focus on policies that drive better health outcomes and lower costs in the long term.

Our comprehensive exploration sets the stage for a transformative shift in US renal care, advocating for improved vascular access management as a cornerstone of better patient care, operational efficiency by dialysis providers, and cost-sustainable chronic care delivery. Ultimately, this paper contributes to the conversation of value-based care in dialysis from the perspective of payers and providers.

US Vascular Access Trends Reveal Troubling Insights

Vascular accesses (VA) are critical to hemodialysis treatment, with their usage reflecting trends in patient management. There are three primary vascular access options for initiating hemodialysis. They include the arteriovenous fistula (AVF), arteriovenous graft (AVG), and central venous catheters (CVC). The AV fistula is the often recommended choice due to its lower infection rate,[1] with 62.6% of hemodialysis patients utilizing this access type.[4] However, not all patients are ideal candidates for fistula access, necessitating the use of an AV graft.

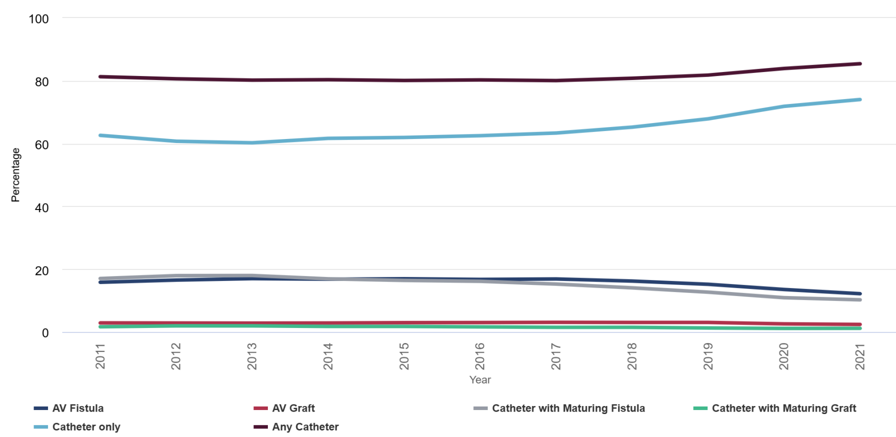
Unlike fistulas, AV grafts use a synthetic tube to connect an artery to a vein and typically last for two to three years before needing to be explanted due to complications related to stenosis and thrombosis,[50] which progressively limit blood flow within the access vessel. Approximately 16.7% of US patients use AV grafts,[4] especially if they have thin veins and require more urgent hemodialysis than is obtainable with a fistula. AV fistulas and grafts have pros and cons and require routine evaluations by vein experts and nephrologists to make an informed decision.



The third access type, the central venous catheters (CVCs) accounts for 21% of the prevalent hemodialysis patient population.[4] A catheter is inserted into a large vein or artery in the neck or chest and is used for short-term access, pending the maturation of the fistula or graft access. This insertion provides immediate bloodstream access but is associated with a high incidence of complications, including catheter-related bloodstream infections (CRBSIs) at 27.77%,[23] thromboses at 14%-18%,[24] and central vein stenosis at 13%,[25, 5] which leads to high risks for patients' survival with CVCs.

Recently, the utilization of catheters at hemodialysis initiation has escalated, with 85.4%[37] of patients starting treatment via catheters in 2021 – a 4.6% increase since 2018 (Figure 1).

This increase is primarily due to the impact of the COVID-19 pandemic, where some ESRD patients required urgent dialysis treatments. This CVC uptake is concerning, especially given its association with high–complication risks,[29] including infection, thrombosis, and torsion. Catheter-related infections (CRI) are associated with increased length of hospital stay, from 2.4 to 5.7 days, as well as increased patient mortality.[32] CRI is responsible for 15 - 36% of all hemodialysis patients deaths and 20% of total hospitalizations.[33]



Data Source: 2023 United States Renal Data System Annual Data Report

The decline in the use of arteriovenous fistulas (AVFs) and maturing fistulas is also notable. From 2013 to 2021, the use of AVFs decreased from 17.0% to 12.2%, while the combined usage of catheters and maturing fistulas reduced from 18.0% to 10.2%. This shift towards temporary access types like central venous catheters (CVCs) raises concerns about potential increases in complications such as infections, which are more common with CVCs.

Their safety and efficacy profiles heavily influence the industry standards for vascular access. AVFs are preferred for their longevity and overall lower complication rates, making them the preferred standard. Arteriovenous grafts (AVGs) are utilized when AVFs are not viable, offering quicker access despite a seemingly higher risk of complications. In a related study,[24] a comparison of vascular access types revealed that although patients with arteriovenous fistulas (AVFs) and arteriovenous grafts (AVGs) had similar annual rates of CVC exchange and angioplasty (an intervention to restore blood flow to the access), those with AVFs experienced significantly fewer thrombectomies - 52% for AVGs compared to 35% for AVFs. This difference emphasizes the importance of selecting the optimal vascular access type based on expected clinical outcomes and complication rates. CVCs, while necessary for immediate access, are to be used temporarily until a more permanent solution like an AVF or AVG can be established.

Regional and provider variations in vascular access utilization rates also exist, with urban centers and specialized clinics typically reporting higher rates of AVF usage due to better-skilled staff and adherence to best practices. On the other hand, rural areas appear to have a higher reliance on CVCs, reflecting a scarcity of both skilled staff and access to specialized care. This disparity in care access and patient outcomes is due to factors, including a lack of patient education about the benefits of different access types, limited accessibility to dialysis centers or vascular access centers for necessary interventions, and the relative ease of management for dialysis clinic staff. Additionally, the use of CVCs is widespread in the early days or weeks of dialysis when patients require an urgent start and their permanent access is not yet sufficiently mature.

These utilization trends highlight the challenges and need for improved strategies in vascular access management to not only enhance outcomes for hemodialysis patients and minimize the disruptions and cost of care suffered by dialysis payers and providers.

Poking the Industry Standard

Based on the low quality of evidence, the 2019 Kidney Disease Outcomes Quality Initiative (KDOQI) vascular access guidelines conditionally recommend that a functional AVF should be preferred to an AVG in incident HD patients due to fewer long-term vascular access events associated with unassisted AVF use[57]. However, ongoing investigations show that AVFs might not always be the best option for dialysis patients.

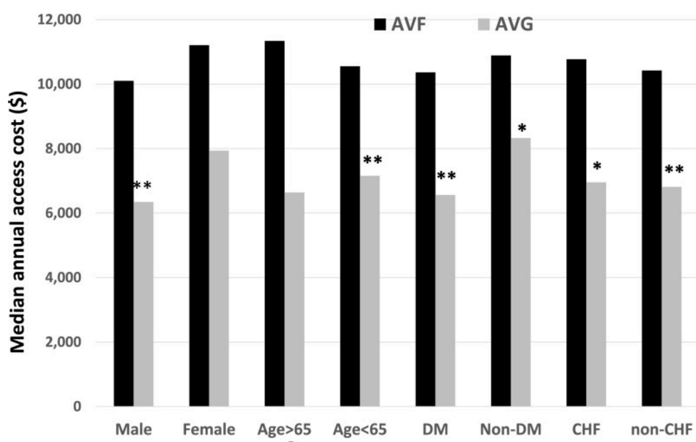
Although the AVF is considered to be safer because it utilizes the patient's body tissue, they are unpredictable in their maturation after surgery. In data collected from 535 patients, the median time to maturation was 115 days, with age and chronic disease influencing the maturation time,[7] but AVFs required more frequent interventions before maturation.[8] The frequency of new AVFs requiring assisted maturation can range from 27% to 58%,[8] and the median frequency rate of an AVF requiring intervention before successful cannulation was 50.5% versus 17.7% for AVG.[9] In comparison, the median time for AVGs to be successfully used without prior intervention was 1 month, and 2 months with an intervention; whereas AVFs required 3 months without any assisted maturation, and 4 months with assisted maturation. Therefore, AVFs require more interventions than AVGs in the initial few months after the access creation.

Cost of access-related procedures in patients with an initial AVG, a successful AVF, or a failed AVF

Parameter	AVG	AVF-S	AVF-F	*P* Value AVF-S versus AVG	*P* Value AVF-F versus AVF-S
No. of patients	113	190	105		
Percutaneous procedures, median $/yr [IQR]	2438 [444–4593]	1438 [0–3527]	2892 [1277–5518]	<0.01	<0.001
Surgical access procedures, median $/yr [IQR]	2819 [1411–4274]	4675 [2277–8234]	5501 [2948–10,281]	<0.001	0.03
Hospitalization for CRB, median $/yr [IQR]	0 [0–7171]	0 [0–2020]	5693 [1908–16,361]	0.06	<0.001
Total access-related cost, median $/yr [IQR]	6810 [3718–13,651]	8146 [4014–14,397]	16,652 [9938–33,053]	0.46	<0.001

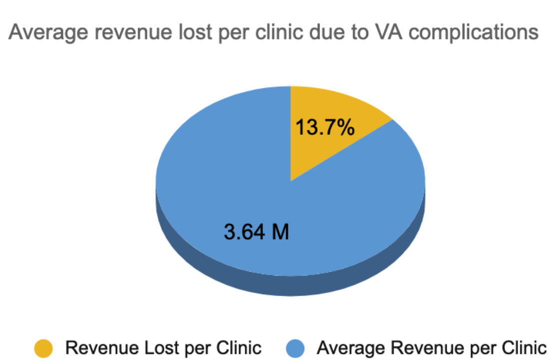
AVF-S, successful arteriovenous fistula; AVF-F, failed arteriovenous fistula.

While the 2019 KDOQI guidelines note that AVFs generally incur lower costs for implantation and maintenance compared to AVGs,[11] recent studies reveal that AVFs' extended maturation period might lead to higher overall expenses.[10] These costs arise from the need for more frequent interventions to assist maturation and the temporary use of central venous catheters. The table on the left shows the median total annual cost related to AVF access was $3,832 more than for AVGs.[10] Applying this amount to the incidence of hemodialysis patients in the US in 2020, cited as 15,446 and 2,958 for AVF and AVG (14.1% vs. 2.7%) respectively,[4] the median total annual access-related cost is $83 million for AVF and $3 million for AVG, resulting in a significant AVF-driven cost gap of $80 million.



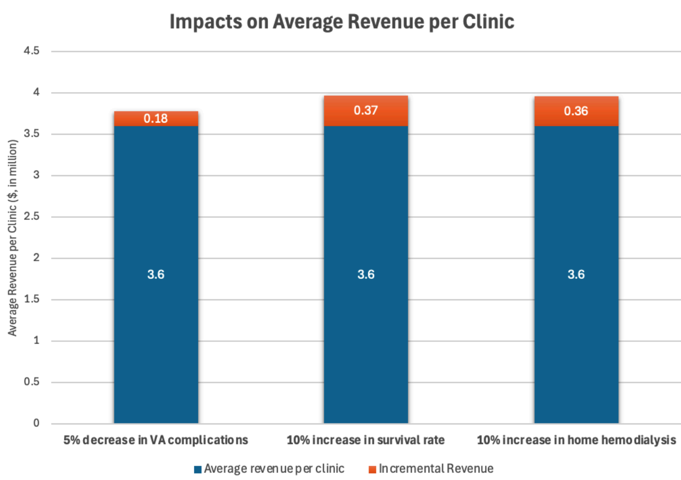
Furthermore, the cost of technique failure across the access types is higher in AVFs than in AVGs. AVF has a primary failure rate of 20% to 60%.[35] The figure on the left, shows that the annual cost is higher in patients who initially receive an AVF rather than an AVG in multiple patient sub-groups. A failed AVF can cost twice as much as a successful one ($16,452 vs. $8,146),[10] With a failed AVF access, the total additional access-related cost can range from $231 million to $693 million, whereas the cost for AVG is $449 million in the same patient population (by deduction). They are effectively demonstrating AVG as a fraction of overall AVF costs.

Beyond Blood Flow: Vascular Accesses Impact Dialysis Providers' Financial and Operational Efficiency

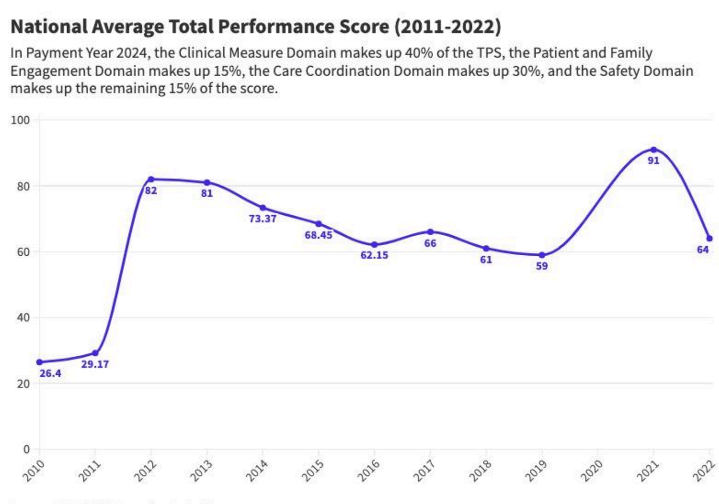


Vascular access (VA) complications profoundly affect dialysis clinics' operational and financial performance. 12.6% of hemodialysis sessions are missed due to these complications,[20] resulting in an annual revenue loss of approximately $3.77 billion across 7,609 clinics in the US, and an average revenue loss of $0.5 million per clinic (13.7% loss). An empirical analysis shows how a 5%

reduction in VA complications could increase annual revenue per clinic by $181,965, a 36.4% jump in savings relative to existing losses. We also determined that enhancing patient survival rates by 10% could lead to a corresponding percentage increase in annual revenue, adding another $0.37 million per clinic each year. Additionally, a clinic would gain another 0.36 million by a 10% increase in home hemodialysis patients.



In the clinic, operational inefficiencies arise as frequent VA complications disrupt treatment schedules and increase the workload on already strained clinical staff, leading to higher operational costs, a reduction in staff productivity, and a deterioration in the quality of patient care. For instance, outpatient dialysis clinics typically aim for an above 90% chair utilization ratio.[54] Several variables affect this, including staff availability, complications during treatment, and transition times between treatments. Existing protocols for safely managing vascular accesses at the point of care result in an average transition time of up to 30 minutes.[54] An improved vascular access device that facilitates faster treatment transition times and reduces the frequency of incidences during treatment, will increase staff productivity hours (SPH) and chair utilization. Also, at a staff-to-patient ratio of 1:12 for nurses and 1:4 for patient care technicians, a high frequency of VA complications such as infiltration and hemorrhaging exacerbates what is an already stressful job. The national shortage of skilled dialysis nurses does not help either. Reducing VA complications will help clinics improve operational efficiency, maintain higher chair utilization and staff productivity, and enhance overall patient care.



The CMS Quality Incentive Program (QIP) evaluates dialysis clinics based on their Total Performance Scores (TPS), derived from multiple metrics including clinical, safety, and reporting measures. Clinics scoring below 60 on the QIP scale face up to 2%[59] reduction in reimbursement per payment year.[51] For an industry with ever-tightening margins within the existing reimbursement models, this penalty is too costly for some unprofitable clinics. While the QIP is designed to promote higher standards of patient care and treatment outcomes, the national average TPS, as depicted in the graph, hovers around 64. This suggests that while most clinics are avoiding penalties, they are not necessarily making significant improvements in the quality of care they provide.

It is also critical to note the increasing focus on home hemodialysis (HHD) and the urgency to remove traditionally limiting barriers including safe and proper handling of vascular accesses. Over 90% of treatments happen at an outpatient dialysis clinic.[37] However, the need for expanding home dialysis options is increasing due to government interest in delivering better care at lower costs, rising incidences of professional burnout in dialysis nurses caused by staffing shortages,[26] and the reeling impacts of a recent pandemic.

In 2019, Executive Order 13879 launched the Advancing American Kidney Health initiative[26] with multiple objectives including a significant increase in home dialysis patients. A new home dialysis bill, HR-8075 was introduced in April 2024 to expand home dialysis education and cover training costs.[55] Furthermore, the COVID-19 pandemic cast a spotlight on the deadly contagion risk faced by dialysis patients in the absence of private, at-home care. These trends are accelerating the expansion of home dialysis options to patients by large dialysis organizations.[12,42]

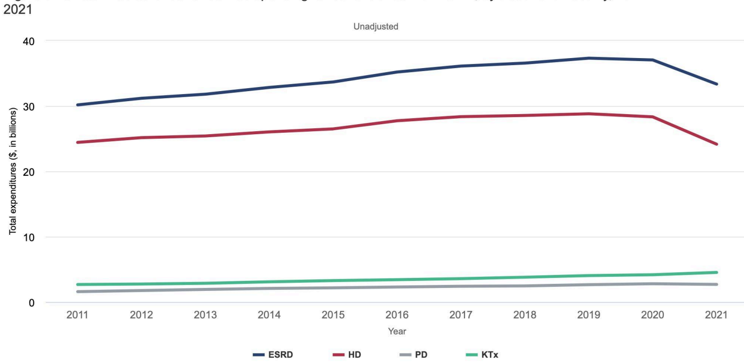
However, the transition to home-based dialysis is significantly hindered by staff training, patients' education, knowledge of HHD options, safety concerns of self-cannulation, and general fear of needles. For instance, safe self-cannulation for home hemodialysis takes up to 6 weeks of training and practice. Justifiable patient fears such as the pain from needle cannulation, the fear of self-cannulation, and the risk of delayed response to dialysis emergencies that often involve massive hemorrhaging, complicate this transition from clinic to home. In a related study,[38] participants described cannulation experiences that were physically and psychologically traumatic, and the traumatic cannulation experiences influenced some participants to choose hemodialysis via catheters, despite the known infection risks.[38] Moreover, the high barriers such as financial budget to training staff and care partners for effective home hemodialysis disincentivize the adoption of this alternative treatment modality, despite its convenience and long-term cost-effectiveness.

Thus, as the demand for both at-home and in-center treatment increases, vascular accesses must be safe, less susceptible to complications, and easy to access. Achieving this is essential for delivering improved patient care, lowering the barriers to greater home dialysis adoption, and improving staff efficiency in the dialysis clinic.

For Payers, the Impacts of Vascular Accesses are Significant

The financial implications of vascular access (VA) complications are significant for payers like the government (through the Center for Medicare and Medicaid Services (CMS)), private insurers, and non-profits such as the National Kidney Foundation (NKF) through its health insurance premium program for income-qualifying patients.

Figure 9.10 Total Medicare fee-for-service spending for beneficiaries with ESRD, by treatment modality, 2011-2021



Data Source: 2023 United States Renal Data System Annual Data Report

From 2011 to 2020, inflation-unadjusted Medicare spending on ~~both ESRD and~~ HD beneficiaries grew in lockstep by 16% to $28.3 billion and only recently began a slight drop in 2021,[37] which is primarily due to the switch from Medicare fee-for-service to Medicare Advantage.[58] Vascular access-related costs accounted for as much as $531 million of the medicare spending on dialysis in 2020,[31] which is 1.77% of the total medicare expenditure on HD. As the table on the left shows, ~~how~~ the average annual costs of percutaneous procedures ($2,726), surgical access procedures ($3,838), and hospitalizations for catheter-related bloodstream infections ($26,709) stack up to the average cost related to maintaining vascular access for dialysis.[8]

Median annual vascular access-related costs in patients with an initial AVF, an initial AVG, or no access surgery

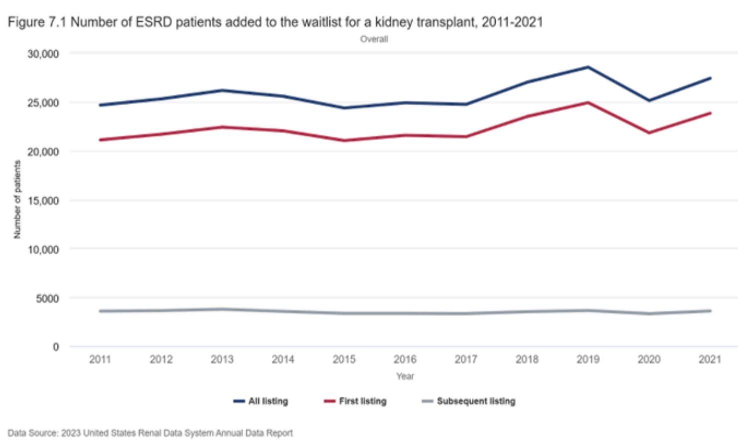
Parameter	AVF	AVG	CVC	*P* Value, AVG versus AVF	*P* Value, CVC versus AVF
No. of patients	295	113	71		
Percutaneous procedures, median $/yr [IQR]	1879 [371–4290]	2438 [444–4593]	3860 [1586–7759]	0.28	<0.001
Surgical access procedures, median $/yr [IQR]	4857 [2523–8835]	2819 [1411–4274]	–	<0.001	–
Hospitalization for CRB, median $/yr [IQR]	0 [0–6345]	0 [0–7171]	26,709 [9746–56,794]	0.13	<0.001
Total access-related cost, median $/yr [IQR]	10,642 [5406–19,878]	6810 [3718–13,651]	28,709 [11,793–66,917]	0.001	<0.001

Additionally, emergency-room dialysis visits pose a significant financial burden to CMS, alongside disrupting ongoing treatment regimens for patients. A study examining the impact of emergency room dialysis on hospital costs revealed that 214 patients accounted for 15,682 emergency-only hemodialysis visits.[39] At an average cost per visit of $1,363, this translated to a total cost of $10.7 million annually.[39]

In summary, efficient prevention and treatment of vascular access-related complications will produce meaningful cost savings for payers in the healthcare system. And, in acknowledging the critical role of vascular accesses to overall dialysis outcomes, tangible improvements in VA complication rates would reduce spending and lower the burden on the health system.

The Dialysis Macro Landscape Directs Player Participation

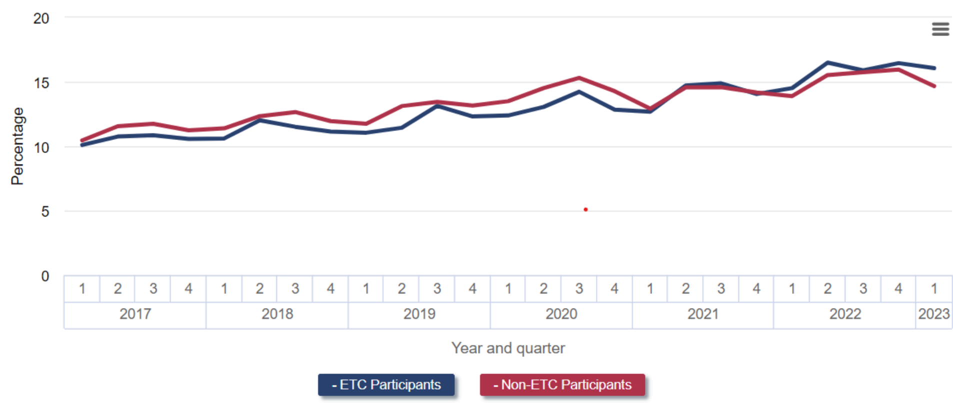
In July 2019, Executive Order 13879[41] - Advancing American Kidney Health (AAKH), was introduced with the objectives of reducing the incidence of End Stage Renal Disease (ESRD) by 25% by 2030, increasing the adoption of home dialysis and kidney transplants to 80% of new ESRD patients, and double the number of kidneys available for transplant by 2030.[2] These goals will not only improve patients' health outcome but also reduce costs for CMS, private payers, and dialysis providers.



~~However, despite the AAKH,~~ The current home hemodialysis (HHD) uptake among prevalent ESRD patients is at 2.3%[4], and this number is well below the target of 80% from the AAKH goal.[2] There is a significant gap in reaching the executive order's goals. The current development for facilitating home-based dialysis includes technologies like portable machines, and payment models to encourage more home dialysis. ~~Also, the average kidney transplantation waiting time is long, and the chance for successful kidney transplant outcome goes down each year as the patient remains on dialysis treatment.[56]~~ Although portable dialysis systems are a welcome innovation, which facilitates home hemodialysis, having reliable vascular access solutions remains the prerequisite for enjoying the convenience.

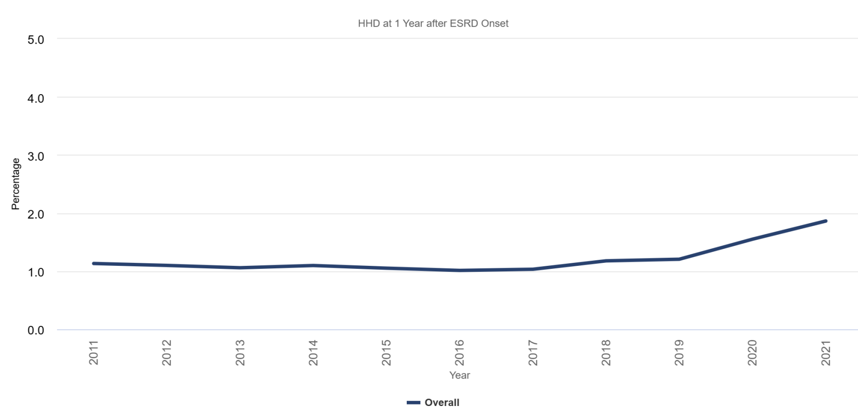
Reimbursement models significantly affect the landscape of innovation and clinical practice. The AAKH initiative introduced the mandatory ESRD Treatment Choices (ETC) model, which evaluated facilities based on home dialysis and kidney transplant rates, adjusting payments accordingly. ~~The ETC model required dialysis facilities to retrain employees and invest more in home dialysis programs, leading to higher costs and opposition from large organizations.~~ ~~In 2022, CMS made three changes to the ETC model, including additional beneficiary protection, adjustments to the Performance Payment Adjustment model, and a revised performance scoring methodology.~~ In 2022, CMS made three changes to the ETC model, focusing on innovating payment models to incentivize a specific outcome—home dialysis. These changes include enhanced beneficiary protections, modifications to the Performance Payment Adjustment model, and an updated performance scoring methodology.

Figure 2.2 Utilization of home dialysis in adult incident dialysis patients by provider assignment into the ESRD Treatment Choices payment model, January 2017 to March 2023



As a result, home dialysis adoption increased, with 16% of patients in ETC markets using home dialysis in 2022 and Q1 2023, 1% higher than non-ETC markets.

The Comprehensive ESRD Care (CEC) model, implemented from October 2015 to March 2021, involved 33 ESRD seamless care organizations (ESCOs) and aimed to enhance collaboration among healthcare providers. This initiative improved patient outcomes and lowered costs for Medicare beneficiaries with ESRD by reducing hospitalizations, post-acute care usage, and central venous catheter use.



Data Source: 2023 United States Renal Data System Annual Data Report

From 2011 to 2019, the percentage of patients performing home hemodialysis at 1 year after ESRD onset was relatively stable, ranging from 1.0% to 1.2%.[37] However, the percentage increased sharply from 1.2% in 2019 to 1.9% in 2021.[37] The marked increase in HHD adoption one year post-ESRD diagnosis suggests a gradual shift in treatment modality which aligns with the goals of AAKH.

~~Additionally, the overall performance of the AAKH on kidney transplantation suggests progress, and there is more work to be done to meet the initiative's ambitious targets. The yearly number of patients added to the kidney transplant waitlist has remained relatively flat at about 24,000 to 26,000 per year.[37] Until the implementation of the AAKH initiative in 2020, when the overall number of patients added to the waitlist grew by 9% to 27,413.[37] Despite the challenges posed by the COVID-19 pandemic, the AAKH initiative has positively influenced kidney transplantation. The slight rebound in the number of patients added to the waitlist after 2020 indicates a post-pandemic recovery and renewed focus on transplantation efforts.~~

The AAKH initiative has positively influenced kidney transplantation, despite the challenges posed by the COVID-19 pandemic. Since its implementation in 2020, there has been a 9% increase in the number of patients added to the kidney transplant waitlist, growing to 27,413. This rebound indicates a post-pandemic recovery and renewed focus on transplantation efforts. While the yearly number of patients added to the waitlist had remained relatively flat at about 24,000 to 26,000 per year before 2020, the overall performance of the AAKH suggests progress. However, there is still more work to be done to meet the initiative's ambitious targets.

Over the years, there have been new technologies developed for… dialysis. Innovations in vascular access would round out the suite of solutions that resolve these often painful and inconvenient aspects of the dialysis experience. Portable dialysis machines have provided flexibility and freedom in the location of dialysis treatment. Bioengineered blood vessels were developed as a vascular replacement and are now in a clinical trial and could overcome the risks and complications in vascular accesses for dialysis treatment.[45] Research on a Wearable Artificial Kidney (WAK) offers a portable dialysis solution, aiming to enhance patient mobility and improve quality of life for those with end-stage renal disease.[52] Also, there are nephrologists who have been working on a man-made artificial kidney[44] which will be a waterless and dialysate-free technology to create the first implantable artificial kidney, to offer alternative solutions to traditional dialysis. Along with these external innovations in both dialysis reimbursement and technology, focusing on safer and more reliable vascular access will reduce the negative impacts and costs of complications and treatment disruption during dialysis.

Recommendations for Fixing Vascular Access Challenges in Dialysis Treatment

Acknowledging the critical role of vascular access in a successful dialysis treatment, it is important to prioritize its improved performance, as well as its safe and reliable operation. This white paper proposes several integrated approaches to addressing the challenges of vascular access complications and their financial and operational effects on dialysis providers and payers.

Firstly, there is a dire need for innovation in vascular access that promotes access patency, minimizes the risk of clot formation, and reduces the incidence of infections. Success in these areas will deliver better patient outcomes, and improve the dialysis experience both in-center and at-home. Such advancements are essential for patient safety and the overall success of dialysis therapy.

Secondly, Improving vascular access technology will address both operational and financial inefficiencies for dialysis providers. We already addressed how a reduction in VA complications and its associated emergencies, will ease the workload on dialysis clinic staff, and minimize the stress and burnout. This also enhances job satisfaction and retention at the dialysis providers, a competitive advantage for savvy managers.
The financial incentives for dialysis providers are critical. Given the role of VA-related complications in contributing to operational inefficiencies and revenue leaks within the provider business model, prioritizing appropriate vascular access solutions will yield immediate and long-term clinical and accounting benefits.

Thirdly, collaboration between key stakeholders— large dialysis providers, payers, and technology companies— should be positively incentivized. At the end of 2023, CMS finalized its proposal to make payments when practitioners train caregivers to support patients with certain diseases or illnesses in carrying out a treatment plan.[47] This added rule implemented by CMS would financially compensate care partners for their training time and is a progressive step towards easing the barriers to adopting home hemodialysis. By pooling resources and expertise, these entities can drive significant advancements in vascular access technology. This collective approach ensures that technological innovations align with the clinical needs and financial frameworks of the healthcare system.

The alignment of CMS' payment models with the overall quality of care provided to dialysis patients is very commendable and should be sustained. Models such as the CEC (Comprehensive ESRD Care), the ETC (ESRD Treatment Choices), and the CKCC (Chronic Kidney Care Choices) aim to improve overall patient health outcomes and reduce cost. The models ~~Since the models prioritize the quality of care delivered in their performance metrics, they~~ align incentives for all parties in the dialysis ecosystem - delivering better dialysis outcomes at reasonable costs.

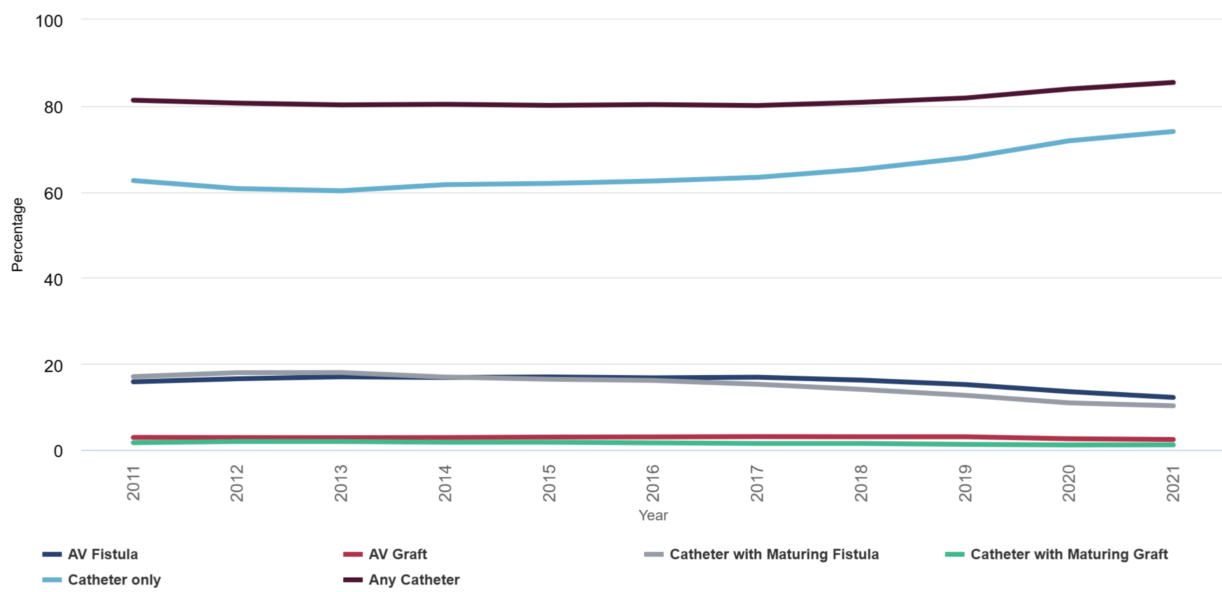
Conclusion: Injecting Efficiency and Savings Patients, Payers and Providers

By prioritizing improvements in vascular access through technological innovations and industry-wide collaboration, the US healthcare system can see significant financial benefits, both for providers and payers. Reduced complication rates from improved vascular access devices will translate to fewer hospitalizations, fewer emergency room visits, and surgical interventions. This translates to substantial cost savings for both CMS and private insurers. Dialysis clinics will also experience a financial boost through increased operational efficiency and reduced revenue loss from missed treatments due to complications.

More importantly, patients will experience tremendous improvement in their health and quality of life because reliable vascular access with fewer complications allows for more consistent and effective dialysis treatment. Importantly, central venous catheters (CVCs), while offering immediate access to hemodialysis, should be discouraged due to their high risk of infection and complications. Arteriovenous fistulas (AVFs) are considered the gold standard of vascular accesses, but can their unpredictable maturation can prove to be very costly for all involved parties. Arteriovenous grafts (AVGs) bridge this gap by providing reliable access sooner than AVFs and offer lesser complication rates when compared to CVCs. Although AVGs have their limitations in terms of lifespan, they represent the optimal balance between rapid access and long-term patency for hemodialysis patients**.**

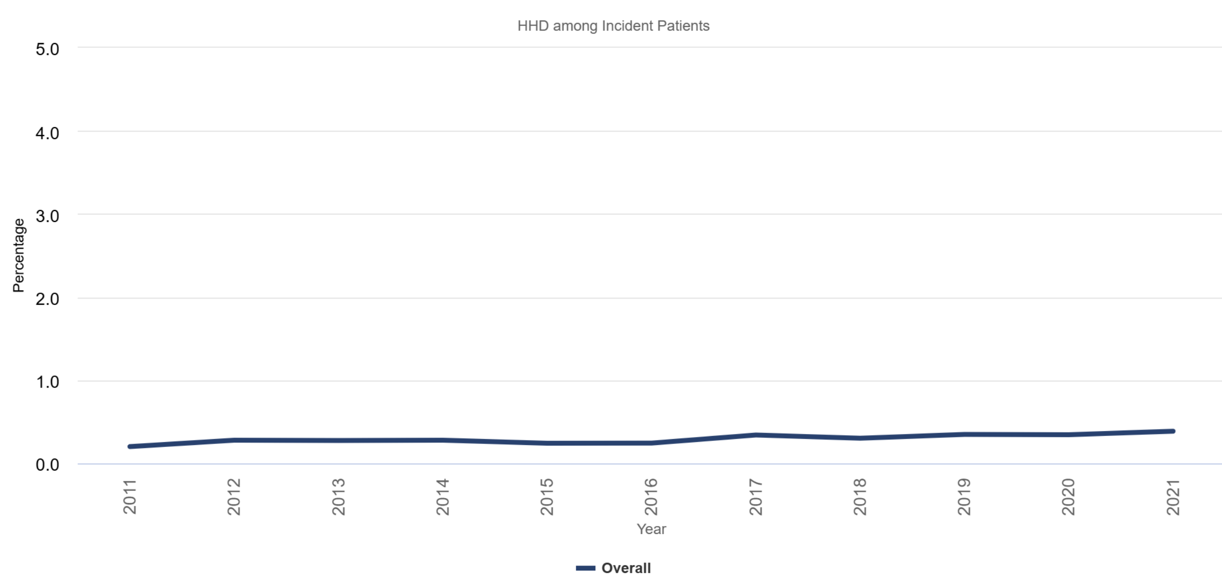
By focusing on advancements in AVG technology along with other vascular access innovations, and ensuring their financial sustainability within the healthcare system, we can achieve a future where dialysis patient populations can benefit from having safe and optimal vascular accesses. This will lead to a more cost-effective and patient-centered approach to dialysis care, mutually benefiting payers and providers.

Figure 1. Vascular access use at HD initiation, 2011-2021



Data Source: 2023 United States Renal Data System Annual Data Report

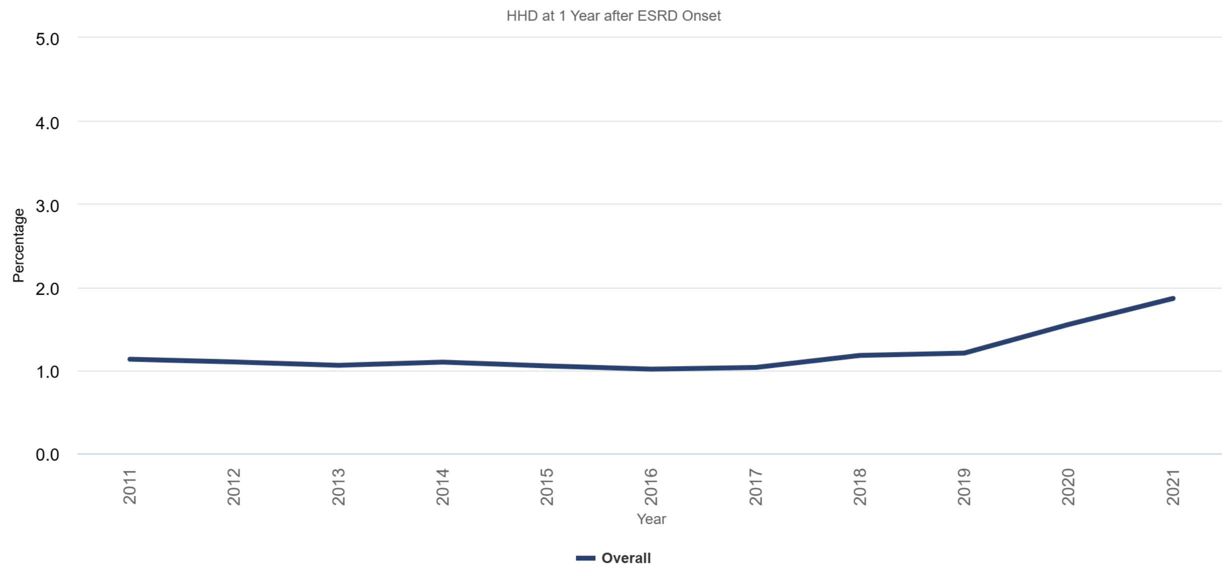
Figure 2.1A Utilization of HD — Home Hemodialysis among incident patients



Data Source: 2023 United States Renal Data System Annual Data Report

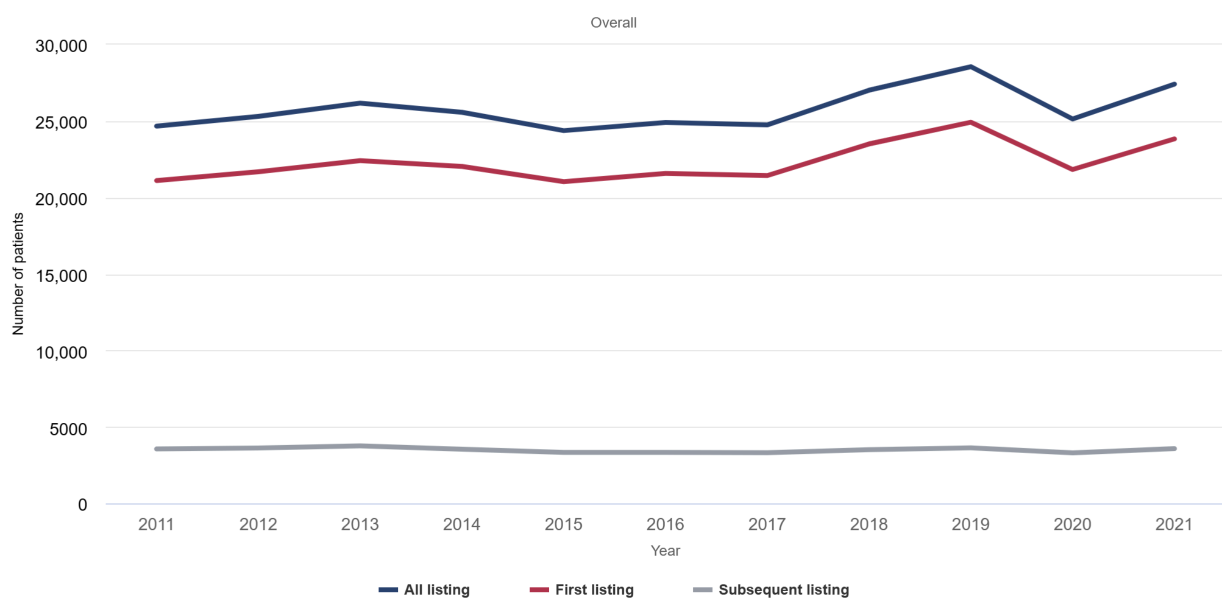
Fan Z., Kashyap M., Oyeniyi O., Wang A. Impact of Vascular Accesses on Payers and Providers in the USA. 2024

Figure 2.1B Utilization of HD — Home Hemodialysis at 1 Year after ESRD Onset



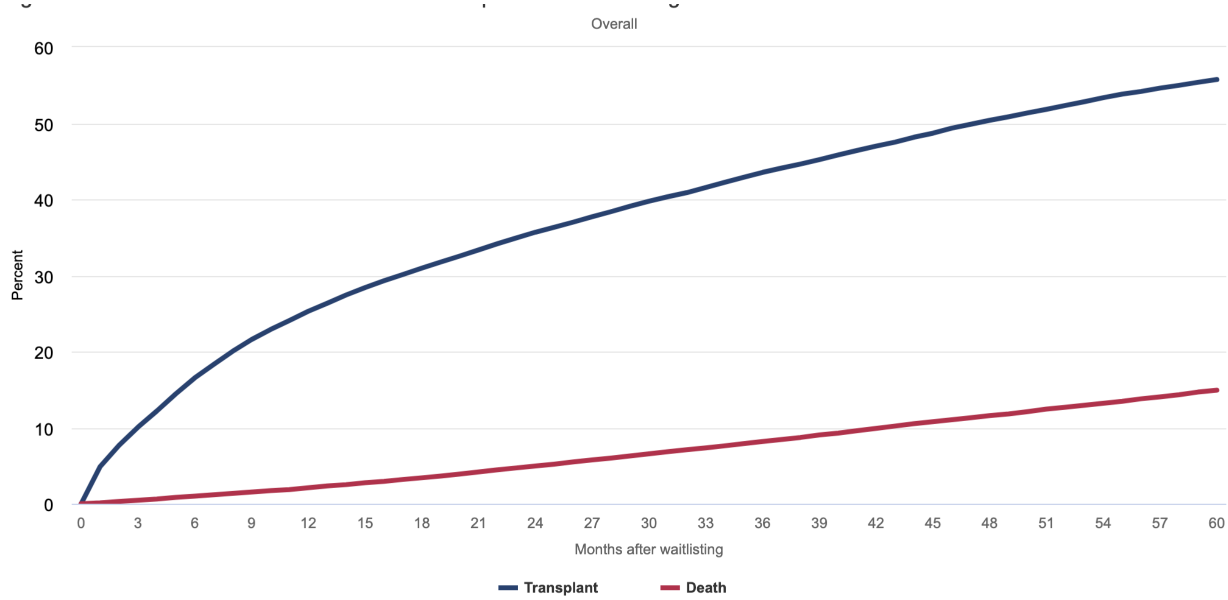
Data Source: 2023 United States Renal Data System Annual Data Report

Figure 2.2A Number of ESRD patients added to the waitlist for a kidney transplant, 2011-2021



Data Source: 2023 United States Renal Data System Annual Data Report

Figure 2.2B Cumulative incidence of death or transplant after waitlisting in 2015



Data Source: 2022 United States Renal Data System Annual Data Report

Table 2. Median annual vascular access-related costs

Median annual vascular access-related costs in patients with an initial AVF, an initial AVG, or no access surgery

Parameter	AVF	AVG	CVC	*P* Value, AVG versus AVF	*P* Value, CVC versus AVF
No. of patients	295	113	71		
Percutaneous procedures, median $/yr [IQR]	1879 [371–4290]	2438 [444–4593]	3860 [1586–7759]	0.28	<0.001
Surgical access procedures, median $/yr [IQR]	4857 [2523–8835]	2819 [1411–4274]	–	<0.001	–
Hospitalization for CRB, median $/yr [IQR]	0 [0–6345]	0 [0–7171]	26,709 [9746–56,794]	0.13	<0.001
Total access-related cost, median $/yr [IQR]	10,642 [5406–19,878]	6810 [3718–13,651]	28,709 [11,793–66,917]	0.001	<0.001

CRB: catheter-related bacteremias

Table 3. Cost of access-related procedures

Cost of access-related procedures in patients with an initial AVG, a successful AVF, or a failed AVF

Parameter	AVG	AVF-S	AVF-F	*P* Value AVF-S versus AVG	*P* Value AVF-F versus AVF-S
No. of patients	113	190	105		
Percutaneous procedures, median $/yr [IQR]	2438 [444–4593]	1438 [0–3527]	2892 [1277–5518]	<0.01	<0.001
Surgical access procedures, median $/yr [IQR]	2819 [1411–4274]	4675 [2277–8234]	5501 [2948–10,281]	<0.001	0.03
Hospitalization for CRB, median $/yr [IQR]	0 [0–7171]	0 [0–2020]	5693 [1908–16,361]	0.06	<0.001
Total access-related cost, median $/yr [IQR]	6810 [3718–13,651]	8146 [4014–14,397]	16,652 [9938–33,053]	0.46	<0.001

AVF-S, successful arteriovenous fistula; AVF-F, failed arteriovenous fistula.

References

1. Vachharajani TJ, Taliercio JJ, Anvari E. New Devices and Technologies for Hemodialysis Vascular Access: A Review. American Journal of Kidney Diseases. 2021;78(1):116-124. doi:10.1053/j.ajkd.2020.11.027
2. Nesbitt H. American Society of Nephrology: Advocacy & Public Policy - view documents. ASN News. Accessed May 16, 2024. https://www.asn-online.org/policy/webdocs/page.aspx?code=220#:~:text=Advancing%20American%20Kidney%20Health%20Initiative%20%2D%2D%20A%20Primer&text=President%20Trump%20signed%20an%20Executive,%2C%20treatment%2C%20and%20preventative%20care.
3. Lin E, Ginsburg PB, Chertow GM, Berns JS. The "Advancing American Kidney Health" Executive Order: Challenges and Opportunities for the Large Dialysis Organizations. *Am J Kidney Dis*. 2020;76(5):731-734. doi:10.1053/j.ajkd.2020.07.007
4. "Annual Data Report." National Institute of Diabetes and Digestive and Kidney Diseases, U.S. Department of Health and Human Services, usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/4-vascular-access. Accessed 30 Apr. 2024.
5. Sohail MA, Vachharajani TJ, Anvari E. Central venous catheters for hemodialysis—the myth and the evidence. Kidney International Reports. 2021;6(12):2958-2968. doi:10.1016/j.ekir.2021.09.009
6. Ng LJ, Chen F, Pisoni RL, et al. Hospitalization risks related to vascular access type among incident US hemodialysis patients. Nephrology Dialysis Transplantation. 2011;26(11):3659-3666. doi:10.1093/ndt/gfr063
7. Huber TS, Berceli SA, Scali ST, et al. Arteriovenous fistula maturation, functional patency, and intervention rates. JAMA Surgery. 2021;156(12):1111. doi:10.1001/jamasurg.2021.4527
8. Allon M. Vascular Access for Hemodialysis patients. Clinical Journal of the American Society of Nephrology. 2019;14(6):954-961. doi:10.2215/cjn.00490119
9. Harms JC, Rangarajan S, Young CJ, Barker-Finkel J, Allon M. Outcomes of arteriovenous fistulas and grafts with or without intervention before successful use. Journal of Vascular Surgery. 2016;64(1):155-162. doi:10.1016/j.jvs.2016.02.033
10. Al-Balas A, Lee T, Young CJ, Kepes JA, Barker-Finkel J, Allon M. The Clinical and Economic Effect of Vascular Access Selection in Patients Initiating Hemodialysis with a Catheter. J Am Soc Nephrol. 2017;28(12):3679-3687. doi:10.1681/ASN.2016060707

11. Vascular Access 2006 Work Group. "Clinical practice guidelines for vascular access." American journal of kidney diseases : the official journal of the National Kidney Foundation vol. 48 Suppl 1 (2006): S176-247. doi:10.1053/j.ajkd.2006.04.029
12. Davita Inc. 4th quarter 2022 results. DaVita Investor. Accessed May 15, 2024. https://investors.davita.com/2023-02-22-DaVita-Inc-4th-Quarter-2022-Results#:~:text=Consolidated%20revenues%20were%20%242.917%20billion,months%20ended%20December%2031%2C%202022.
13. Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) Kidney Care Choices (KCC) Model. cms. 2023. Accessed May 16, 2024. https://www.cms.gov/priorities/innovation/media/document/kcc-py23-rfa.
14. ESRD Quality Incentive Program. CMS.gov. Accessed May 15, 2024. https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incentive-program.
15. Comprehensive esrd care model. CMS.gov. Accessed May 15, 2024. https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-esrd-care.
16. CEC PY5 annual EVAL report findings at a glance. www.cms.gov. December 2020. Accessed May 15, 2024. https://innovation.cms.gov/data-and-reports/2022/cec-annrpt-py5-fg.
17. KCC Model Participants Lists_final, www.cms.gov/files/document/kcc-model-participants-cy2024.pdf. Accessed 30 Apr. 2024.
18. Hippen BE, Reed AI, Ketchersid T, Maddux FW. Implications of the advancing American Kidney Health Initiative for Kidney Transplant Centers. American Journal of Transplantation. 2020;20(5):1244-1250. doi:10.1111/ajt.15619
19. Natori Y, Anjan S, Simkins J, et al. Successful lung transplantation in COVID-19 PCR positive patients: A single-center experience. The Journal of heart and lung transplantation : the official publication of the International Society for Heart Transplantation. October 2023. Accessed May 15, 2024. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10232938/.
20. Wahood W, Takahashi E, Rajan D, Misra S. National Trends in Complications of Vascular Access for Hemodialysis and Analysis of Racial Disparities Among Patients With End-Stage Renal Disease in the Inpatient Setting. Kidney Int Rep. 2023 Mar 20;8(6):1162-1169. doi: 10.1016/j.ekir.2023.03.001. PMID: 37284686; PMCID: PMC10239770.

21. Al-Balas A, Lee T, Young CJ, Kepes JA, Barker-Finkel J, Allon M. The clinical and economic effect of vascular access selection in patients initiating hemodialysis with a catheter. *Journal of the American Society of Nephrology*. 2017;28(12):3679-3687. doi:10.1681/asn.2016060707
22. 2023 Annual Report. DaVita Investor. Accessed May 15, 2024. https://investors.davita.com/financial-reports.
23. Patil VC, Patil HV, Ramteerthkar MN, Kulkarni RD. Central venous catheter-related bloodstream infections in the intensive care unit. *Indian Journal of Critical Care Medicine*. 2011;15(4):213-223. doi:10.4103/0972-5229.92074
24. Wall C, Moore J, Thachil J. Catheter-related thrombosis: A practical approach. *Journal of the Intensive Care Society*. 2015;17(2):160-167. doi:10.1177/1751143715618683
25. Al-Balas A, Almehmi A, Varma R, Al-Balas H, Allon M. De novo central vein stenosis in hemodialysis patients following initial tunneled central vein catheter placement. *Kidney360*. 2022;3(1):99-102. doi:10.34067/kid.0005202021
26. 2022 USRDS Annual Data Report. National Institute of Diabetes and Digestive and Kidney Diseases. Accessed May 15, 2024. https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities
27. 2018 USRDS Annual Data Report. National Institute of Diabetes and Digestive and Kidney Diseases. Accessed May 14, 2024. https://usrds-adr.niddk.nih.gov/2018
28. Böhlke M, Uliano G, Barcellos FC. Hemodialysis catheter-related infection: Prophylaxis, diagnosis and treatment. *The Journal of Vascular Access*. 2015;16(5):347-355. doi:10.5301/jva.5000368.
29. Tavanaee Sani A, Eslami Nowkande AR, Ghorbany H. Central Venous Catheter Related Infection among Patients on Hemodialysis. *Medical Journal of Mashhad University of Medical Sciences*. 2012;55(2):110-115. doi:10.22038/MJMS.2012.5298
30. Oliver MJ, Callery SM, Thorpe KE, Schwab SJ, Churchill DN. Risk of bacteremia from temporary hemodialysis catheters by site of insertion and duration of use: A prospective study. *Kidney International*. 2000;58(6):2543-2545. doi:10.1046/j.1523-1755.2000.00439.x
31. Stewart F, Kistler K, Du Y, Singh RR, Dean BB, Kong SX. Exploring kidney dialysis costs in the United States: A scoping review. *Journal of Medical Economics*. 2024;27(1):618-625. doi:10.1080/13696998.2024.2342210
32. Hemmati H, Safayiasl A, Badrangbuye S, KazemnezhadLeyli E, Pour-safar MZJ. Central venous catheter infections in hemodialysis patients. *J Guilan Univ Med Sci*. 2018;27(105):20–7.

33. Sahli F, Feidjel R, Laalaoui R. Hemodialysis catheter-related infection: Rates, risk factors and pathogens. *Journal of Infection and Public Health*. 2017;10(4):403-408. doi:10.1016/j.jiph.2016.06.008
34. Oliver MJ. The science of fistula maturation. *Journal of the American Society of Nephrology*. 2018;29(11):2607-2609. doi:10.1681/asn.2018090922
35. Venkat Ramanan S, Prabhu RA, Rao IR, et al. Outcomes and predictors of failure of arteriovenous fistulae for Hemodialysis. *International Urology and Nephrology*. 2021;54(1):185-192. doi:10.1007/s11255-021-02908-5
36. Fissell RB, Fuller DS, Morgenstern H, et al. Hemodialysis patient preference for type of vascular access: Variation and predictors across countries in the Dopps. *The Journal of Vascular Access*. 2013;14(3):264-272. doi:10.5301/jva.5000140
37. 2023 USRDS Annual Data Report. National Institute of Diabetes and Digestive and Kidney Diseases. Accessed May 15, 2024. https://usrds-adr.niddk.nih.gov/2023
38. Duncanson EL, Chur-Hansen A, Le Leu RK, et al. Dialysis needle-related distress: Patient perspectives on identification, prevention, and management. *Kidney International Reports*. 2023;8(12):2625-2634. doi:10.1016/j.ekir.2023.09.011
39. Shafqat F, Das S, Wheatley M, et al. The impact of "emergency-only" hemodialysis on hospital cost and Resource Utilization. *Western Journal of Emergency Medicine*. 2023;24(2):206-209. doi:10.5811/westjem.2022.11.58360
40. 2022 USRDS Annual Data Report. National Institute of Diabetes and Digestive and Kidney Diseases. Accessed May 15, 2024. https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/7-transplantation
41. Executive Order 13879—Advancing American Kidney Health. www.govinfo.gov. 2019. Accessed May 15, 2024. https://www.govinfo.gov/content/pkg/DCPD-201900464/pdf/DCPD-201900464.pdf.
42. Shaping a sustainable tomorrow. Fresenius Medical Care. 2022. Accessed May 15, 2024. file:///Users/zichenfan/Downloads/FME_Annual_Report_2022_EN.pdf.
43. DaVita Kidney Care Expands Use of NxStage Home Hemodialysis Machines from Fresenius Medical Care. DaVita. March 2021. Accessed May 2024. https://investors.davita.com/2021-03-23-DaVita-Kidney-Care-Expands-Use-of-NxStage-Home-Hemodialysis-Machines-from-Fresenius-Medical-Carehttps://investors.davita.com/2021-03-23-DaVita-Kidney-Care-Expands-Use-of-NxStage-Home-Hemodialysis-Machines-from-Fresenius-Medical-Care.
44. Uclahealth. Game-changing artificial kidney, now in development, offers hope for dialysis-free life. UCLA Health. November 15, 2021. Accessed May 18, 2024. https://www.uclahealth.org/news/article/game-changing-artificial-kidney-now-in-development-offers-hope-for-dialysis-free-life.

45. Platform-Technology. HUMACYTE. December 10, 2023. Accessed May 19, 2024. https://humacyte.com/platform-technology/.
46. ESRD treatment choices (ETC) model. CMS.gov. Accessed May 23, 2024. https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model.
47. Office of the Federal Register, National Archives and Records Administration. *Federal Register. 89*(29):9776-9784; 2024.
48. KCP ETC proposed Rule letter Sept 2019 final. www.annanurse.org. September 15, 2019. Accessed May 23, 2024. https://www.annanurse.org/download/reference/health/activities/9_15_19.pdf.
49. Farrington C, Lee TC. The new age of vascular access: Choosing the right access for the right reason in older hemodialysis patients. *American Journal of Kidney Diseases*. 2020;76(4):457-459. doi:10.1053/j.ajkd.2020.03.024
50. Frequently asked questions about dialysis access surgery. BIDMC of Boston. Accessed June 1, 2024. https://www.bidmc.org/centers-and-departments/transplant-institute/dialysis-access-center/frequently-asked-questions-about-dialysis-access-surgery#:~:text=The%20long%20loop%20gives%20the,but%20can%20often%20last%20longer.
51. ESRD Quality Incentive Program (QIP). PQDC. Accessed June 3, 2024. https://data.cms.gov/provider-data/topics/dialysis-facilities/esrd-quality-incentive-program.
52. Wearable Artificial Kidney (W.A.K.). English. Accessed June 6, 2024. https://drgura.com/contents/wearable-artificial-kidney.php.
53. Cridlig J, Kessler M, Cao-Huu T. Arteriovenous fistula or catheter: Creating an optimal vascular access for Hemodialysis. *Hemodialysis*. Published online February 27, 2013. doi:10.5772/52242
54. 'Self-reported interview with dialysis clinic operators' (2024).
55. The NKF urges passage of New Home Dialysis Bill. National Kidney Foundation. April 22, 2024. Accessed July 14, 2024. https://www.kidney.org/news/national-kidney-foundation-urges-passage-new-home-dialysis-bill.
56. Esther L Ellis. Multiple listing for a kidney transplant. Duke Health. Accessed July 15, 2024. https://www.dukehealth.org/blog/multiple-listing-kidney-transplant.
57. Lok CE, Huber TS, Lee T, et al. Kdoqi Clinical Practice Guideline for Vascular Access: 2019 update. *American Journal of Kidney Diseases*. 2020;75(4). doi:10.1053/j.ajkd.2019.12.001
58. Nguyen KH, Oh EG, Meyers DJ, Kim D, Mehrotra R, Trivedi AN. Medicare advantage enrollment among beneficiaries with end-stage renal disease in the first year of the 21st Century Cures Act. JAMA. 2023;329(10):810. doi:10.1001/jama.2023.1426

59. https://www.cms.gov/files/document/py-2026-esrd-qip-fact-sheet-12142023.pdf#:~:text=URL%3A%20https%3A%2F%2Fwww.cms.gov%2Ffiles%2Fdocument%2Fpy