IMPACTS OF DIALYSIS VASCULAR ACCESSES ON U.S PAYERS AND PROVIDERS

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Executive Summary

The vascular access (VA) is a critical component of hemodialysis treatment, yet it remains a significant source of morbidity, cost, and operational challenges within the US healthcare system. VA complications, such as infections and thrombosis, lead to increased hospitalizations, emergency room visits, and dialysis treatment interruptions. These adverse events impose substantial financial burdens on healthcare providers, including dialysis clinics and payers like the Center for Medicare and Medicaid Services (CMS).

Despite the well-documented clinical impact of VA complications on patients, the financial and operational consequences for providers and payers have been less thoroughly explored. This white paper addresses this gap by examining the economic implications of VA on the dialysis industry and identifying opportunities for improvement.

This white paper is targeted at decision-makers within dialysis clinics and healthcare organizations, as well as payers and policymakers. Our goal is to equip these stakeholders with actionable insights to improve VA care, reduce costs, and enhance patient outcomes. By analyzing industry standards, financial data, and operational challenges, we demonstrate how suboptimal VA management impacts dialysis providers, payers, and ultimately, patients. We highlight the importance of transitioning from central venous catheters (CVCs) to more durable options like arteriovenous fistulas (AVFs) and arteriovenous grafts (AVGs), emphasizing the latter as a balanced choice between rapid access and long-term patency.

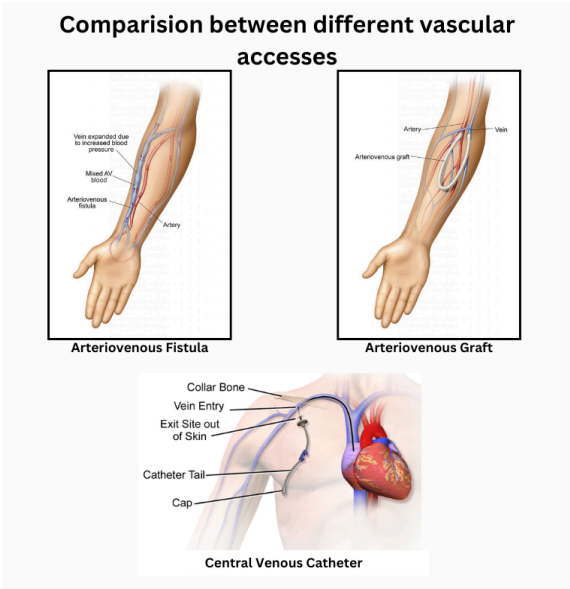
This paper advocates for a multifaceted approach to improving VA care, including technological advancements, industry collaboration, and policy changes. By prioritizing these initiatives, the US healthcare system can achieve significant cost savings, enhance patient outcomes, and optimize dialysis care delivery. Ultimately, this work

contributes to the broader goal of value-based care in dialysis by demonstrating the critical role of VA management in achieving better health outcomes and lower costs.

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.

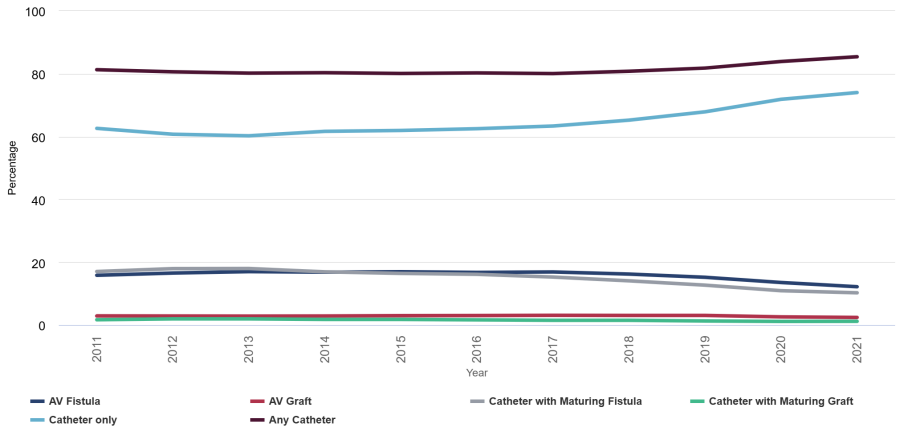
Unlike fistulas, AV grafts use a synthetic tube to connect an artery to a vein and typically last for two to three years before needing to be explanted due to complications related to stenosis and thrombosis,[31] which progressively limit blood flow within the access vessel. Approximately 16.7% of US 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%,[15] thromboses at 14%-18%,[16] and central vein stenosis at 13%,[17, 5] which leads to high risks for patients' survival with CVCs.

Recently, the utilization of catheters at hemodialysis initiation has escalated, with 85.4%[4] of patients starting treatment via catheters in 2021 – a 4.6% increase since 2018.

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,[19] 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.[21] CRI is responsible for 15 - 36% of all hemodialysis patients deaths and 20% of total hospitalizations.[22]



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,[16] 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[36]. 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

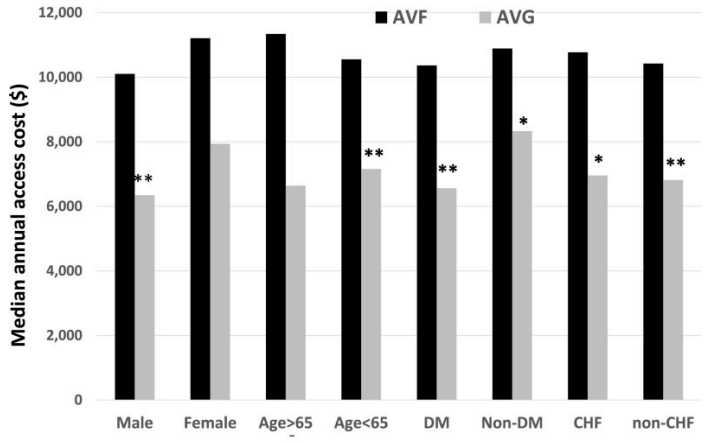
Cost of access-related procedures in patients with an initial AVG, a successful AVF, or a failed AVF

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.

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.

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.

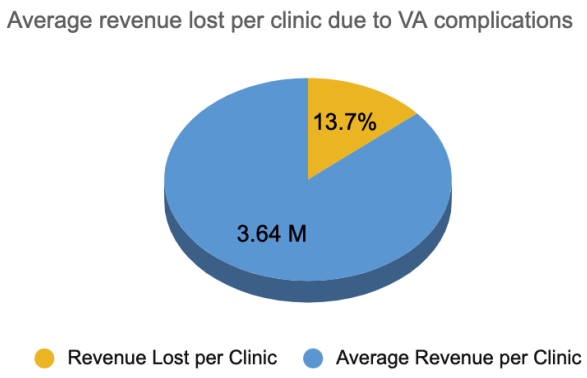


Furthermore, the cost of technique failure across the access types is higher in AVFs than in AVGs. AVF has a primary failure rate of 20% to 60%.[23] The figure on the left, shows that the annual cost is higher in patients who initially receive an AVF rather than an AVG in multiple patient sub-groups. 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.

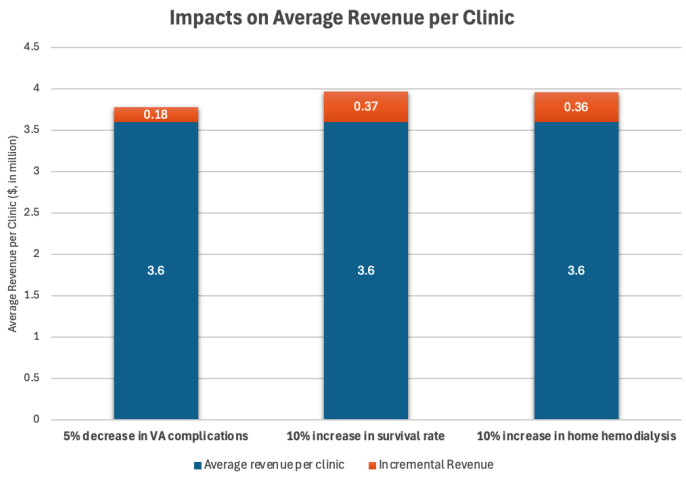
Beyond Blood Flow: Vascular Accesses Impact Dialysis Providers' Financial and Operational Efficiency

Vascular access (VA) complications profoundly affect dialysis clinics' operational and financial performance. 12.6% of hemodialysis sessions are missed due to these complications,[14] 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.[34] 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.[34] 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 a 2% reduction in reimbursement per payment year.[32] For an industry with ever-tightening

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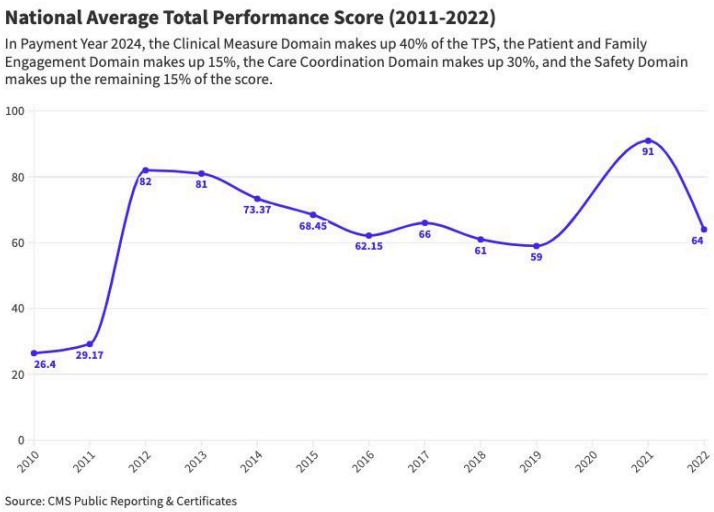
margins within the existing reimbursement models, this penalty is too costly for some unprofitable clinics. While the QIP is designed to promote higher standards of patient care and treatment outcomes, the national average TPS, as depicted in the graph, hovers around 64. This suggests that while most 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.[54] 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,[18] and the reeling impacts of a recent pandemic.

In 2019, Executive Order 13879 launched the Advancing American Kidney Health initiative 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.[35] 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, 27]

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,[24] 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.[24] Moreover, the high barriers such as

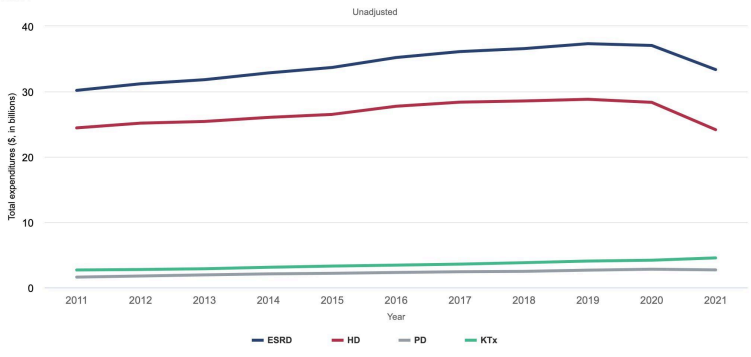
financial budget to training staff and care partners for effective home hemodialysis disincentivize the adoption of this alternative treatment modality, despite its convenience and long-term cost-effectiveness.

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 HD beneficiaries grew in lockstep by 16% to $28.3 billion and only recently began a slight drop in 2021,[3] which is primarily due to the switch from Medicare fee-for-service to Medicare Advantage.[37] Vascular access-related costs accounted for as much as $531 million of the medicare spending on dialysis in 2020,[20] which is 1.77% of the total medicare expenditure on HD. Per the table indicating VA-related costs in patients with initial accesses, the average annual costs of percutaneous procedures ($2,726), surgical access procedures ($3,838), and hospitalizations for catheter-related bloodstream

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

infections ($26,709) stack up to the average cost related to maintaining vascular access for dialysis.[8]

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 and $10.7 million in annual costs.[25]

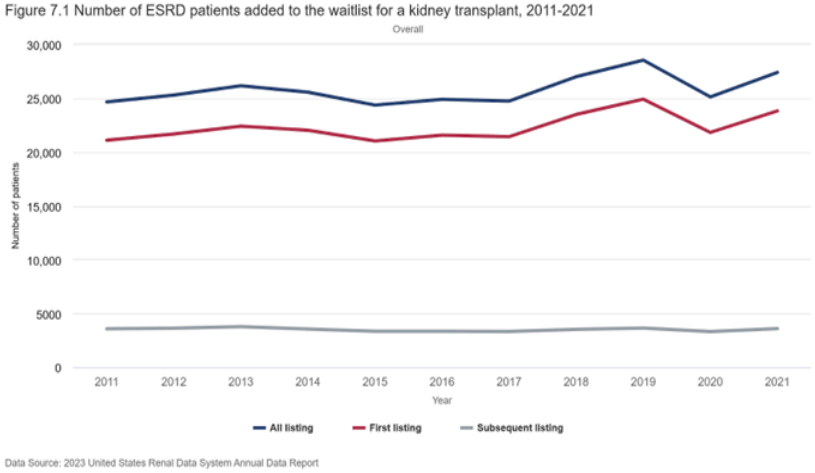
More recently, value-based care (VBC) arrangements are seeing increased attention for their ability to simultaneously improve patient outcomes and reduce costs. Payers such as Humana contract with dialysis providers like Evergreen Nephrology, Strive Health, DaVita, and Fresenius,[38] to incentivize clinical and financial outcomes in the management of dialysis patients. The ESRD Treatment Choices (ETC) and Kidney Care Choices (KCC) model are the CMS' play for VBC and also incentivize the use and surveillance of the preferred vascular accesses.[39] For some payers, this has translated to a 5% decrease in hospital admissions and a 12% reduction in the medical expense ratio for VBC-based arrangements.[38]

In summary, efficient prevention, monitoring, 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 cost burden on the health system.

The Dialysis Macro Landscape Directs Player Participation

In July 2019, Executive Order 13879[26] - Advancing American Kidney Health (AAKH), was introduced with the objectives of reducing the incidence of End Stage Renal Disease (ESRD) by 25% by 2030,[26] increasing the adoption of home dialysis and kidney transplants to 80% of new ESRD patients,[26] 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.

Figure 7.1 Number of ESRD patients added to the waitlist for a kidney transplant, 2011-2021



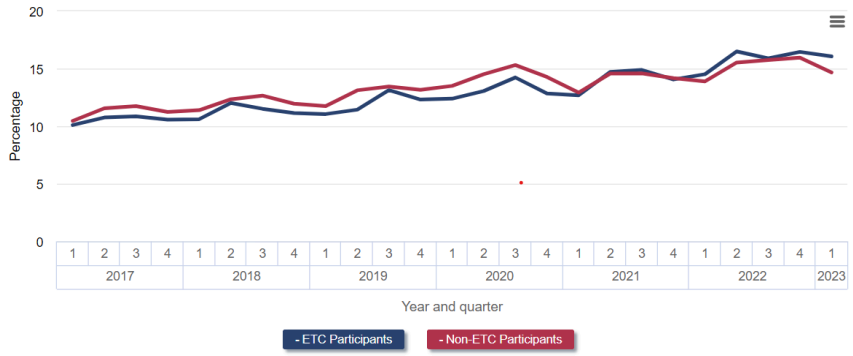
Data Source: 2023 United States Renal Data System Annual Data Report

:cesses on Payers and Providers
in the USA: 2021

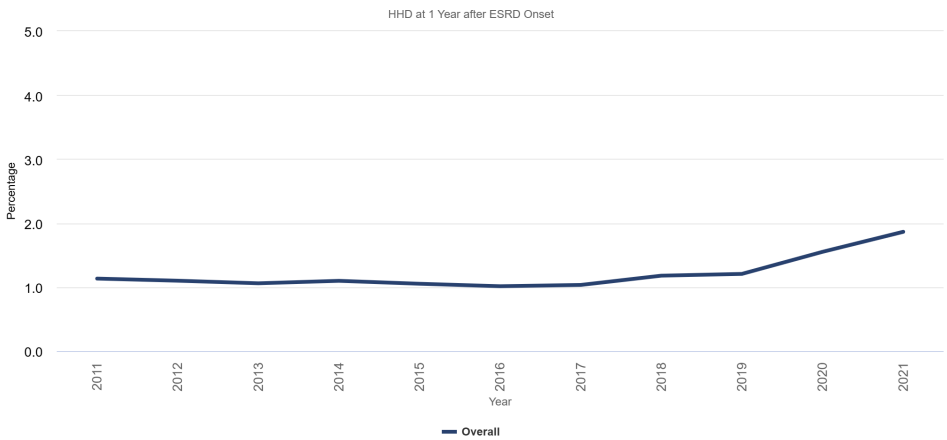
Despite the AAKH, current home hemodialysis (HHD) uptake among prevalent ESRD patients is at 2.3%[4], well below the target of 80% from the AAKH goal.[2] There is a significant gap in reaching the executive order's goals. Contemporary development for advancing home-based dialysis include technologies like portable machines, and payment models that incentivize home dialysis. Although portable dialysis systems are a welcome innovation, for facilitating dialysis in more convenient settings, having reliable vascular access solutions remains the prerequisite for enjoying the convenience.

Reimbursement models influence the landscape of innovation and clinical practice. In 2022, CMS introduced the mandatory ESRD Treatment Choices (ETC) model,[40] to incentivize provider facilities based on home dialysis and kidney transplant rates, using adjusted payments as penalties or bonuses. Consequently, home dialysis adoption in ETC markets quickly outpaced non-ETC markets in 2022 and early 2023.[6]

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



Implemented from October 2015 to March 2021, the Comprehensive ESRD Care (CEC) model 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%.[6] However, the percentage increased sharply from 1.2% in 2019 to 1.9% in 2021,[6] suggesting a gentle shift in treatment modalities, including vascular access choices and care practices that align with AAKH goals. Its continued impact is further reflected in the increased number of patients added to the kidney transplant waitlis.[13]

In addition to the new technologies being developed for ESRD care. Innovations would round out the suite of solutions that resolve these oftenpainful and inconvenient aspects of the dialysis experience. While portable dialysis machines have provided flexibility and freedom in the location of dialysis treatment, bioengineered blood vessels are developed as a vascular replacement to address the risks and complications recorded during dialysis.[29] Ongoing 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.[33] Also, there are nephrologists investigating the possibility of artificial kidney[28] that utilize a waterless and dialysate-free technology to proffer alternatives to traditional dialysis methods. Together with these innovations, safer and more reliable vascular accesses will drive better clinical outcomes and reduce complications and costs of 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.[30] 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 costs. The models align incentives for all parties in the dialysis ecosystem - delivering better dialysis outcomes at reasonable costs.

Conclusion: Injecting Clinical Efficiency and Cost Savings for Payers and Providers

Vascular access (VA) complications pose a significant burden on both dialysis providers and payers. Dialysis clinics experience substantial revenue losses due to missed treatments caused by VA-related issues, increased operational costs associated with managing complications and staff overtime, along with a severe restriction on patients eligible for home-based care. These challenges contribute to reduced profitability and hinder the ability of clinics to invest in necessary resources, such as staff training and advanced technology. By addressing VA complications, dialysis providers can improve operational efficiency, increase revenue, and enhance patient care.

For payers, VA complications are major cost drivers, including increased spending on hospitalizations, emergency department visits, and medications. These costs erode the financial viability of value-based care models, which aim to improve patient outcomes while reducing expenditures. By reducing VA complications, payers can achieve significant cost savings and support the success of value-based care initiatives.

To address these challenges, a comprehensive approach is necessary. Prioritizing technological innovation in VA devices can lead to improved patency, reduced complications, and enhanced patient experience. Fostering collaboration among dialysis providers, payers, and technology companies is essential to accelerate the development and implementation of new solutions. Additionally, supportive policies that incentivize the use of optimal VA practices and promote the adoption of home dialysis are crucial.

By implementing these strategies, the healthcare industry can significantly improve the management of vascular access, leading to enhanced patient outcomes, reduced costs, and improved operational efficiency for dialysis providers and payers. Ultimately, these efforts will contribute to a more sustainable and patient-centered dialysis care delivery system.

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