Petition to the State Health Coordinating Council
Regarding Special Need Single Specialty ASC for Vascular Access
for HSA-VI
2024 State Medical Facilities Plan

July 26, 2023

Petitioner:		*Contact:*	
Name:	Carolina Vascular Care, PLLC	**Name:**	Karn Gupta, MD
		E-mail:	kgupta@carolinavascularcare.com
Address:	45 Guardian Court Suite 100 Rocky Mount, NC 27804	**Phone:**	919-754-0303

STATEMENT OF REQUESTED ADJUSTMENT

Carolina Vascular Care, PLLC requests the following change to the *2024 State Medical Facilities Plan* (*SMFP*), Chapter 6 to address a special need for two more specialty ambulatory surgical centers dedicated to vascular access in HSA VI:

> *There is a special need in* HSA VI *for two operating rooms that can only be located in an ambulatory surgical center dedicated to vascular access procedures, and no ambulatory surgical center may have more than one such room.*

REASONS FOR THE PROPOSED ADJUSTMENT

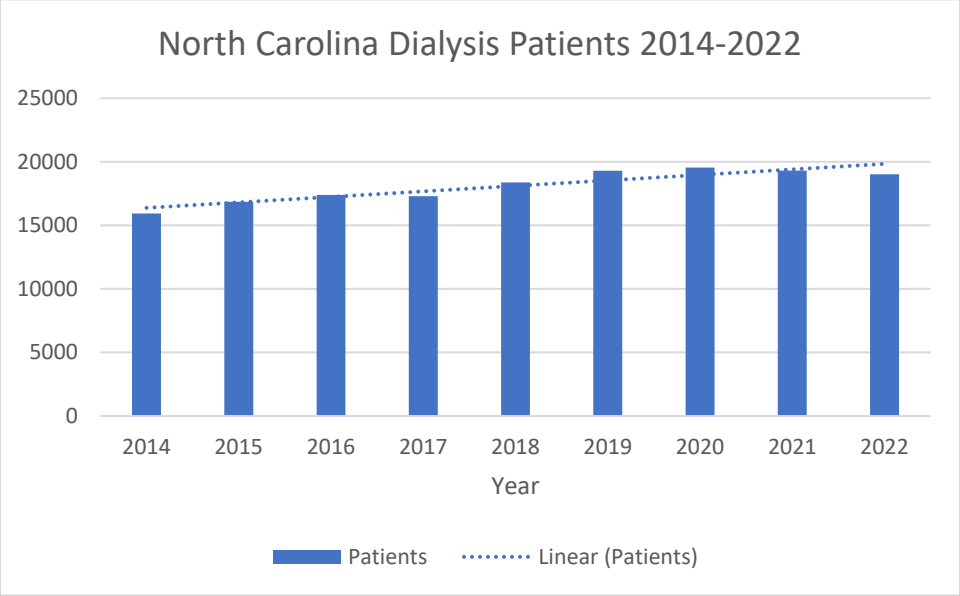
Overview

End stage renal dialysis care involves frequent maintenance of the access point for the dialysis procedure. The access point is unnatural, and the natural body reaction is to close it down. Maintenance involves an outpatient procedure to keep the access open. Very few nephrologists in this state have training and experience to do these procedures. Today, the procedures are efficient and cost-effective when done in a vascular access ambulatory surgery center. One vascular access specialty operating room included in the 2023 SMFP is helpful, but not enough for HSA VI. The vast geography and high population of dialysis patients in this HSA make one vascular access operating room insufficient.

Importance of Vascular Access in Dialysis Care

Approximately 1 in 7 US adults have some level of chronic kidney disease ("CKD") (Chronic Kidney Disease in the United States, 2021). This often progresses to complete kidney failure – i.e., End Stage Renal Disease ("ESRD") (CKD Related Health Problems, 2021). According to data in the NCHSR Dialysis Patient Origin reports, approximately 19,000 North Carolina residents were receiving renal dialysis in 2022 and their numbers were steadily increasing (NCHSR, 2022), as depicted in Figure 1 (the slight drop in patients in 2021 and 2022 are from CKD patients who passed away during COVID). The underlying causes, including hypertension and diabetes, are still as prevalent as ever in North Carolina. New cases of CKD are reappearing, and the number of patients will trend upwards again.

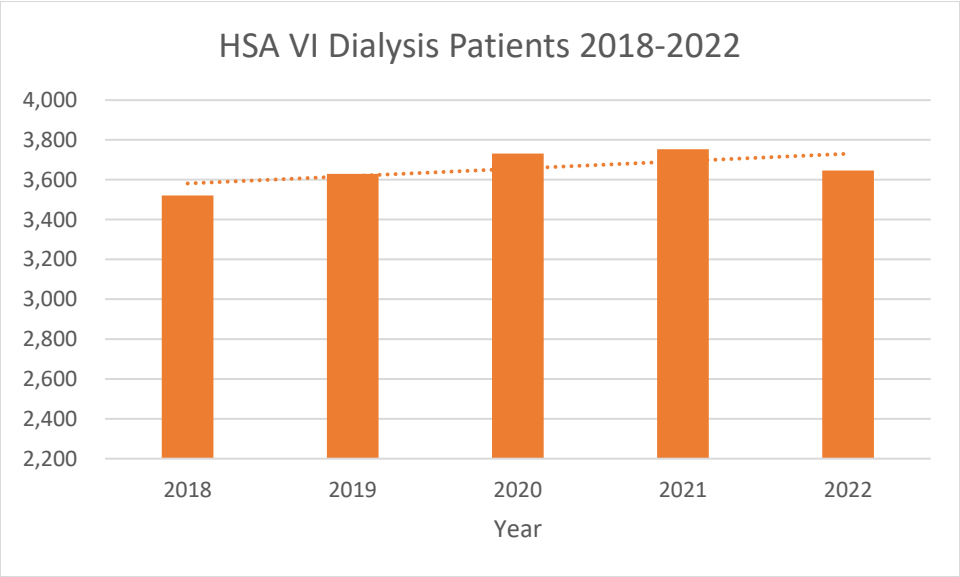
Figure 1 – North Carolina Dialysis Patients, 2014-2022



Source: (NCHSR, 2022)

HSA VI patterns follow the state, as illustrated in Figure 2.

Figure 2 – HSA VI Dialysis Patients, 2018-2022



Source: (NCHSR, 2022)

To survive, people who are on renal dialysis must have either regular, three-times weekly dialysis or a kidney transplant. They require hemodialysis every other day to filter their blood through a machine that removes waste products. Connection to the machine requires the person to have a vascular access point. Vascular access, including an arteriovenous ("AV") fistula, graft, or dialysis catheter, provides direct access to the individual's circulatory system, so the dialysis machine can remove, filter, and return clean blood back to the person. While indispensable to hemodialysis treatment, because they are artificial and are subject to unnatural high blood flows during the dialysis treatment, even the best vascular access points have high dysfunction rates (Grapsa, 2012).

If the access point becomes dysfunctional, patients are susceptible to clotting, infection, and venous injury. Therefore, dialysis access point management and treatment of vascular access complications are critical to an ESRD patient's successful treatment program. If the access point is compromised, ESRD patients cannot receive dialysis. They need immediate repair; because, without dialysis they risk hospitalization, serious complications, and death (World Kidney Day).

Vascular Access Clinical Options

Vascular accesses are surgically created vein and artery blood shunts that fall into three categories (see Attachment A):

- Catheters
- Arteriovenous (AV) Grafts or
- Arteriovenous (AV) Fistulas

Catheters and AV Grafts are synthetic shunts, whereas AV fistulas are constructed from the patient's own veins and arteries. Catheters are typically the first access a dialysis patient will receive because catheters allow immediate access, whereas AV grafts and AV fistulas require anywhere from two to three months post-surgery to mature into functioning accesses. Despite the maturation period, AV grafts and AV fistulas are preferable to catheters because catheters have the highest infection rates among the three. All vascular accesses are susceptible to dysfunction. As a result, the average dialysis patient requires two to four access interventions per year to maintain a well-functioning access (Lok, 2019) (Wong SPY, 2022).

For ESRD patients on hemodialysis, vascular access is a lifeline – but one that requires regular attention. Without a functioning vascular access, patients cannot receive hemodialysis; a dialysis delay of even two days can lead to life-threatening complications and eventually death.

Vascular Access Procedural Options

Today, three settings offer vascular access procedures: hospitals (HOPD), ambulatory surgery centers (ASC) and physician offices. The physician office is often referred to as an Office Based Laboratory ("OBL") and is classified as an "Extension of Practice." There are different payment rate schedules for each setting. Medicare and Medicaid set the framework and third-party insurance programs follow. ASCs and OBLs are significantly more cost effective than the HOPD alternatives.

No health care facility in HSA VI offers vascular access procedures in an ambulatory surgical setting. There are only two (ASC or HOPD) multi-specialty ASCs in the 29 counties of HSA VI. Neither do vascular access procedures. None of the hospitals in HSA VI provide outpatient vascular access care. Currently, Vascular Access care is only available at three OBLs in Rocky Mount, Greenville, and New Bern.

HSA VI has enough renal dialysis patients to support three vascular access care ambulatory surgery centers. The following paragraphs will provide more information.

SMFP Operating Room Methodology and Vascular Access Centers

In North Carolina, apart from GI endoscopy centers, an ASC license requires at least one operating room. Changes in the CON statute enacted in 2020 will allow North Carolina counties with populations of 125,000 or more to be exempt from ASC CONs. This will only affect Pitt and Onslow counties in this HSA. The other counties are too small to qualify.

The number of operating rooms needed is determined by the SHCC, using a standard methodology. The Proposed 2024 SMFP shows no need for more operating rooms. The 2023 SMFP provides two opportunities for a new vascular access operating room. Pitt County has three general operating rooms; and HSA VI has an opportunity for one vascular access OR. The Pitt County batch was due June 15; two applicants applied for all three rooms. One requested a multispecialty ASC that would not include vascular access. The other requested a specialty ASC that would include vascular access. Pitt County CON decisions will occur by November 2023.

In HSA VI, CON applicants cannot submit for dedicated vascular access rooms until October 15, 2023. By the time that decision occurs in March 2024, the SHCC will have finished work on the 2024 SMFP, and the three existing OBLs will compete for the one available ASC.

There is no other option for dialysis patients in the 29 counties of HSA VI to maintain their vascular access in a freestanding outpatient setting (See Table 6C 2024 SMFP) (NC Dept of Health and Human Services, Division of Health Service Regulation, 2023).

There is a scenario in which HSA VI gains two vascular access centers. One from the Pitt County batch that was due June 15 and one from the HSA VI opportunity. But this scenario is not guaranteed and could result in only one vascular access ASC.

HSA VI has the Largest Number of Dialysis Patients in North Carolina

HSA VI has more renal dialysis patients than any other North Carolina HSA. In 2022, HSA VI had 3,646 ESRD patients – almost 20 percent of North Carolina's total. HSA VI's ESRD population is also steadily growing, increasing by 1.7 percent each of the past five years.

Table 1 – Dialysis Patients by North Carolina HSA (2022)

HSA	Dialysis Patients
I	1,969
II	3,246
III	3,435
IV	3,591
V	3,125
VI	3,646

Source: Table 9B: ESRD Dialysis Station Need Determinations by Planning Area (NC Dept of Health and Human Services, Division of Health Service Regulation, 2022)

Most people with CKD are not aware of it (Chronic Kidney Disease in the United States, 2021); hence reported numbers are lower than the number who have the disease.

African Americans, Native Americans, and Hispanic populations are genetically at elevated risk for CKD. According to MedPAC, 35 percent of ESRD patients covered by Medicare are African American (MedPAC, 2022). Yet, the Census reports 13.6 percent of the US population is Black or African American alone. Table 2 profiles racial/ethnic at-risk residents in HSA VI. Relative to the other HSAs, HSA VI has high percentages of demographically at-risk residents. African Americans represent about 400,000 residents, almost 30 percent of its population (NC Office of State Budget and Management, 2023).

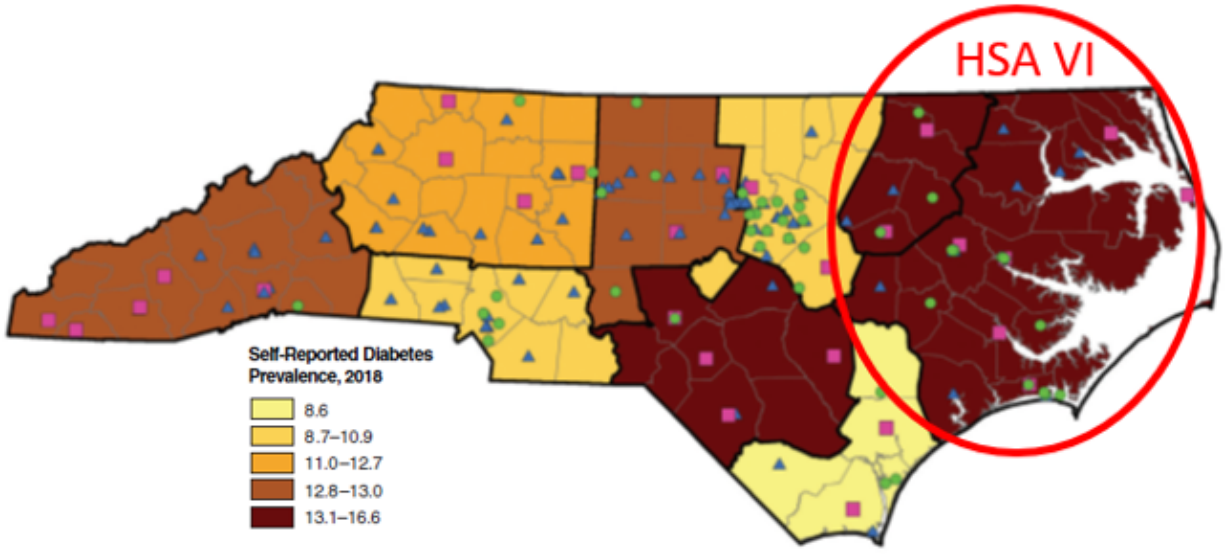
Table 2 – At Risk Demographic Groups in HSA VI (2022)

Race	Population	% of Total Population
African American	403,084	29.22%
Hispanic	24,390	1.77%
Native American	12,920	0.94%

Source: (NC Office of State Budget and Management, 2023)

Diabetes is the number one cause of CKD. In 2018, 28 of the 29 HSA VI counties between 13 and 17 percent self-reported having diabetes; the state average was 10 percent (North Carolina Diabetes Profile, 2022). Figure 3 shows that HSA VI diabetes rates are among the highest in the state. Attachment D has more detail.

Figure 3 - Diabetes Prevalence in NC (2018)



Source: North Carolina Diabetes Fact Sheet, Attachment D

HSA VI has the Largest Land Mass

HSA VI covers 13,709 square miles, or 28 percent of North Carolina; it is the largest HSA by about 3,000 square miles (U.S. Census Bureau quickfacts: North Carolina, n.d.). It also has the largest number of counties.

Table 3 – Geographic Sizes of North Carolina HSAs

HSA	Size (in sq. miles)	Number of Counties
I	10,763.	26
II	5,384.	11
III	3,650.	8
IV	5,345.	11
V	9,771.	15
VI	13,709.	29

Source: (U.S. Census Bureau quickfacts: North Carolina, n.d.)

HSA VI's large geography makes it difficult for dialysis patients to commute to any one Vascular Access ASC. Today, the closest is in Raleigh, in HSA VI. This commute is especially difficult for counties on the outskirts of HSA VI like Currituck, Carteret, and Dare which have travel times of about three hours to Raleigh or to the center of the HSA.

Distribution is a key access factor. The large geography, coupled with the high population of dialysis patients, justifies more Vascular Access ASCs to provide convenient care for this frequently needed procedure.

Most HSA VI Counties are Ineligible for the 2025 Statutory CON Exemption for ASCs

If completed in the 2023 NC Budget, Part III of the Medicaid Reform statute, SL2023-7 will exempt counties with populations over 125,000 from CON requirements for ASCs. However, only two of the 29 counties are eligible: Pitt and Onslow, adjacent counties on the eastern side of the HSA. Moreover, even this opportunity will not likely be available until 2026 or 2027 at the earliest.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS NOT MADE

Physical Effects

OBLs are at risk of closing, many already have. Without a local outpatient ASC option for these critical vascular access procedures, patients are at risk of not getting timely vascular access care. Without timely care, they can end up in the hospital with life-threatening vascular blocks and infections. Their care will also be more expensive in these settings.

ESRD patients from HSA VI have a low baseline state of health. Most dialysis patients have limited resources, and most have underlying chronic diseases like hypertension and diabetes. National CMS data for 2022 indicate that over 54 percent have prevalent comorbidities (Medicare Dialysis Facilities State and National Averages 2023, 2023). With no vascular ASCs, HSA VI ESRD residents have four choices: go to an OBL, visit the emergency department ("ED"), travel to Raleigh, or do nothing. Given that ESRD patients are commonly in poor health, a local and convenient vascular access treatment option is important.

The do-nothing option can result in death because without the procedure, the patient can no longer attain access to lifesaving dialysis. The ED option will result in long wait times, possible hospital admission, and insertion of a catheter. Though better than imminent death, the catheter solution provided in most hospitals welcomes infection because it is an external connection to the heart. Travel to Raleigh can mean an hours long one-way trip and finding someone else to drive. As North Carolina population increases, so does road congestion and these times will increase.

Financial Effects

Vascular access procedures are outpatient, which means insured persons have copayments. For a service that patients may need every three months, the lower cost at a freestanding ASC is important. Medicare covers most patients, eventually, but it requires a 20 percent copayment. Not every Medicare patient will have supplemental insurance to cover the copayment. For poor persons, Medicaid pays the copayment; hence people with this dual Medicare and Medicaid coverage get the title, "Dual -eligible." The state budget shares the cost of the Medicaid payment with the federal government. Thus, the state wins when the copayment is low.

People who have private or supplemental Medicare insurance may not pay the copayment directly. They have a delayed impact when they use the higher cost facilities. Their insurance premiums increase in subsequent years because of the higher cost. In fact, their costs could drive up insurance costs for other people in the geographic area.

Numerous studies demonstrate that patients have better outcomes, get timelier, and more affordable care in outpatient vascular access facilities compared to hospitals. See Attachments B and C. Without a special need to assure presence of distributed vascular access in the 2024 SMFP, the patients in HSA VI would continue to face high medical costs associated with getting any vascular work done at the hospital. The 3,646 patients in HSA VI require these procedures about two to four times a year (Lok, 2019) (Wong SPY, 2022). Difficulty receiving and scheduling care often leads patients to forego care, having catastrophic or even fatal results.

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

Provide an OBL in HSA VI

An OBL is a safe and practical location for providing vascular access procedures and for maintaining existing vascular access grafts. There are now three OBLs in this region. However, OBLs are at risk of extinction. In 2017, CMS began bundling codes and effectively reducing Medicare payment rates to OBLs.

Medicare is the primary payer for ESRD (Kirchoff, 2018). Medicare pays less for vascular access services provided in OBLs than in a hospital or ASC; and until recently, this was a satisfactory arrangement, with payment covering more than cost. The Medicare OBL payment reductions began in 2017 with a 39 percent cut and have escalated since then. In 2022, CMS instituted another 18 percent cut (Dialysis Vascular Access Coalition, 2021). CMS cut payments 8 percent in 2023 and plans to continue these cuts for the next three years. As illustrated in Table 4, in 2023, Medicare reimburses OBLs up to 53 percent less of the cost for vascular access procedures. Unfortunately, Medicare cuts for OBLs are quickly making them unsustainable, whereas the reimbursements for ASCs are drastically more favorable. Table 4 compares Medicare rates of common vascular access procedures.

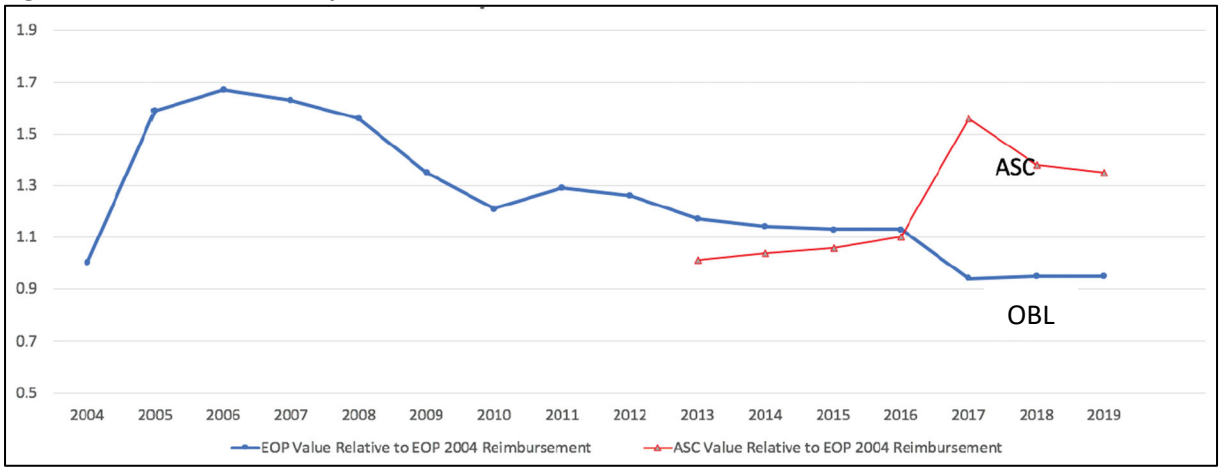
Table 4 – Medicare Rates for Vascular Access Services OBL and ASC 2023

CPT	Procedure Description	OBL	ASC	Difference
36901	Fistulagram	$671	$726	18%
36902	Peripheral Angioplasty	$1,148	$2,447	53%
36903	Stent + Peripheral Angioplasty	$4,062	$6,905	42%
36904	Thrombectomy (no angioplasty)	$1,723	$3,322	48%
36905	Thrombectomy + Peripheral Angioplasty	$2,170	$6,115	65%
36906	Thrombectomy + Peripheral stent	$5,154	$11,412	55%

**Includes professional and facility component*
Source: https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=2&CT=1&H1=36901&H2=36906&C=40&M=5

Figure 4 compares ASC and OBL reimbursements per encounter relative to the 2004 OBL rates. It demonstrates that even though ASC payment is dropping, it is better than OBL payment. Indeed, it can still support a modest ASC.

Figure 4 – Reimbursement per Encounter Relative to 2004 OBL Rates



Source: Vascular access outpatient reimbursement trend **(Litchfield, 2019)**

Offer Vascular Access Procedures in Local Hospital Operating Rooms

Local hospitals have operating room capacity but lack trained vascular access physicians necessary to respond to the unplanned, though non-emergent, nature of dialysis vascular access procedures. Hospitals, by their nature, provide a broad scope of care. When performed in a hospital, even scheduled procedures risk delays when other emergency cases take precedence over vascular access cases; and hospital procedures are always much more expensive than an ASC.

Timely care is critical for ESRD patients. Because hospital staff do not have the specialized training for vascular access, but do have staff trained to insert catheters, hospitals often opt for the catheter option over the surgical AV shunt. Data clearly associate this solution with shortened lives for the patients. Hospitals rely on staff at hand, and this is rarely an interventional nephrologist. Furthermore, owing to their competing responsibilities, hospital interventional radiology departments often only temporize an urgent or emergent clotted fistula or graft merely by placing a catheter, until the schedule allows enough time for a thrombectomy procedure. This can further prolong the hospitalization leading to poor health outcomes when using a catheter for dialysis.

Dialysis patients have weakened immune systems and are at elevated risk of infections and other complications in a hospital setting. Large population-based studies have documented better outcomes across all measures for patients treated in freestanding centers compared to those treated in a hospital outpatient department. See Attachments B and C.

Even with scheduled outpatient appointments, dialysis patients risk delays to accommodate more urgent hospital patients. This can be problematic for diabetic patients who are unable to fast for

extended periods of time before a procedure. Also, an emergency patient will not likely get a same day procedure and would be at life threatening risks of missing dialysis if the procedure moves to even the next day. The dialysis center would have discovered the emergency but will be closed by the time the patient is discharged. That center, where the patient gets regular treatment, works on a tight schedule to stay efficient. It may not have an open slot the next day. So, the patient would have to wait two days for their routine slot at the dialysis center. There are no Sunday slots, so the delay could extend to three to five days. By then, the patient is retaining excess fluids, toxins, and is at life-threatening risk.

Frequently, the physicians performing access procedures in the local hospitals do not know the ESRD patients or their vascular access history well enough to decide the individual's best treatment.

As illustrated in Table 5, hospital payments are higher across the board for vascular access procedures – on average 56 percent more expensive than an ASC. Patient copayments for a procedure would also be 20 percent cheaper. Table 6 compares average patient copayments.

For North Carolina Dual eligible patients, Medicaid pays ASCs and OBLs a zero copayment. Medicaid pays hospitals 20 percent of the Medicare allowable amount. Medicaid would save over $5 million per year if HSA VI vascular access procedures were done in ASCs rather than HOPD. For details, see the Medicaid cost savings calculations in Attachment F. This calculation is based on Carolina Vascular Care's patient and procedure percentages (which are similar to national averages) and does not include the cost savings associated with the emergency room visit that does not occur.

Table 5– Medicare Rates for Vascular Access Services HOPD and ASC 2023

CPT	Procedure Description	HOPD Total	Medicare Pays	% Covered
36901	Fistulagram	$ 1,653	$ 1,323	80%
36902	Peripheral Angioplasty	$ 5,451	$ 4,361	80%
36903	Stent + Peripheral Angioplasty	$ 10,925	$ 9,263	85%
36904	Thrombectomy (no angioplasty)	$ 5,578	$ 4,462	80%
36905	Thrombectomy + Peripheral Angioplasty	$ 11,052	$ 9,364	85%
36906	Thrombectomy + Peripheral stent	$ 17,680	$ 15,980	90%

CPT	Procedure Description	ASC Total	Medicare Pays	% Covered
36901	Fistulagram	$ 749	$ 599	80%
36902	Peripheral Angioplasty	$ 2,562	$ 2,050	80%
36903	Stent + Peripheral Angioplasty	$ 7,145	$ 5,716	80%
36904	Thrombectomy (no angioplasty)	$ 3,433	$ 2,746	80%
36905	Thrombectomy + Peripheral Angioplasty	$ 6,343	$ 5,074	80%
36906	Thrombectomy + Peripheral stent	$ 11,747	$ 9,398	80%

Source: https://www.medicare.gov/procedure-price-lookup/

Table 6– Patient Bill Costs for Vascular Access Services HOPD and ASC 2023

CPT	Procedure Description	HOPD Cost	ASC Cost	ASC Savings as a % of HOPD
36901	Fistulagram	$330	$149	55%
36902	Peripheral Angioplasty	$1,090	$512	53%
36903	Stent + Peripheral Angioplasty	$1,662	$1,429	14%
36904	Thrombectomy (no angioplasty)	$1,115	$686	38%
36905	Thrombectomy + Peripheral Angioplasty	$1,687	$1,268	25%
36906	Thrombectomy + Peripheral stent	$1,700	$2,348	-38%

Source: https://www.medicare.gov/procedure-price-lookup/

Maintain the Status Quo

As demonstrated throughout this petition, OBLs are at considerable risk of closing as Medicare continues its programmed cuts. By Federal FY 2025 the OBLs will be unsustainable, leaving dialysis patients to seek vascular access care at local hospitals or to travel long distances to an ASC. The drive *from* is only part of the story. The procedure takes about 2 hours including procedure and recovery time. The traveling option also places a high burden on the patient's family and friends, because most vascular access procedures involve anesthesia.

The 2023 SMFP asks the three HSA VI OBLs to compete for one ASC, which risks tying up the vascular access option for years in CON appeals. The Proposed 2024 Plan shows no need for more vascular access operating rooms.

Hope for Approval of Two Vascular Access ASC CONs from the 2023 Plan

Though a possibility, this alternative is far from guaranteed. One Vascular Access CON could be approved in the Pitt County 2023 Operating Room batch and one from the HSA VI Vascular Access Operating Room batch. However, it is equally possible that existing OBLs will compete with one another for the one available HSA VI vascular access operating room. To address this contingency, the SHCC could make the need in the plan contingent on no award of another Vascular Access Center CON by June 2024. That would cover this possibility and provide for the necessary access. At minimum, this geography needs at least two more vascular access ASCs.

EVIDENCE OF NO UNNECESSARY DUPLICATION OF SERVICES

This proposed special need will not represent unnecessary duplication. Local hospitals do not want to offer this service, and none do. Without the change, at least one of the existing OBLs will cease to exist due to Medicare cuts. If the OBLs convert to ASCs, this important life-saving service will remain closer to rural residents.

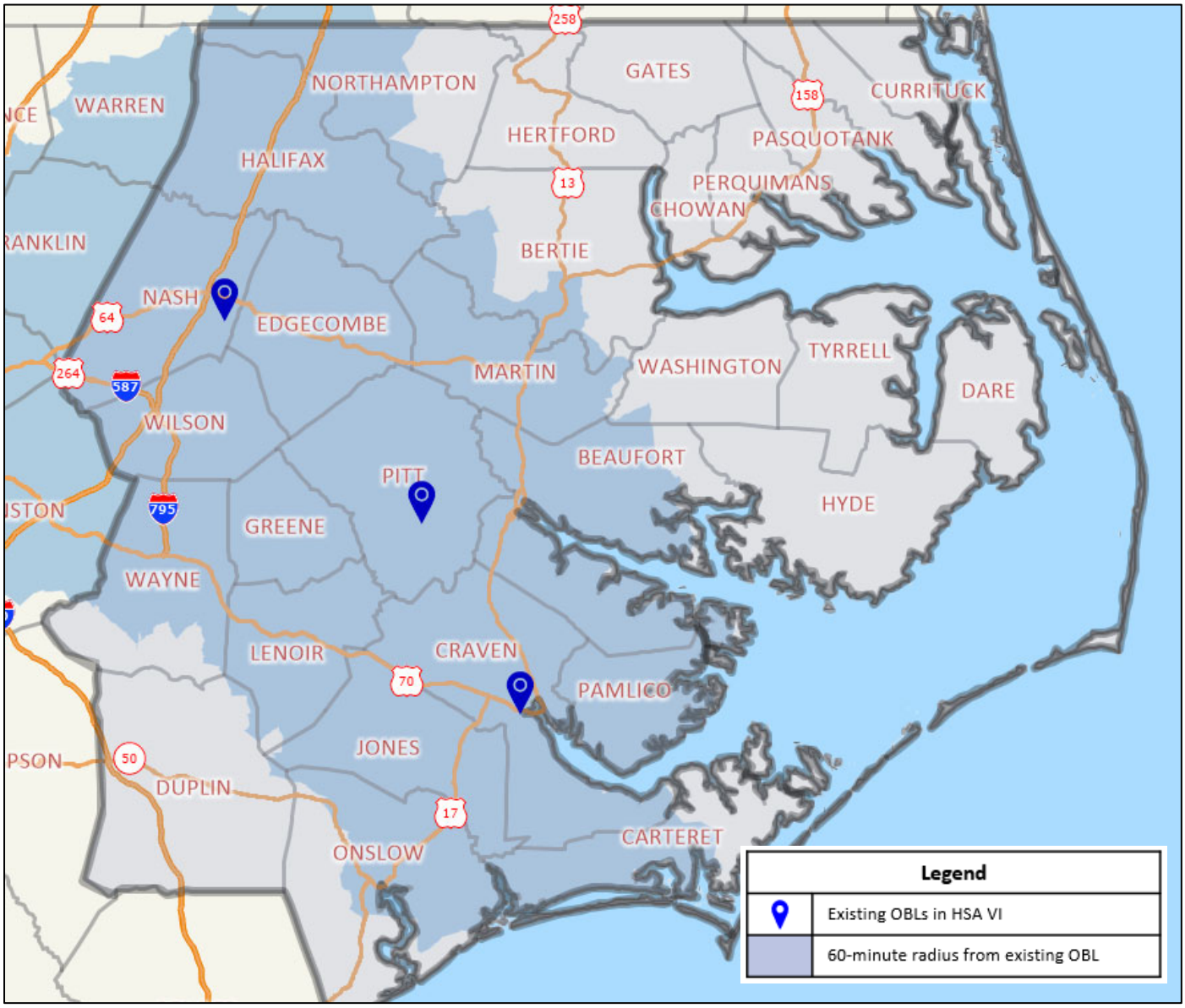
By the standard methodology parameters, the area needs three distributed vascular access operating rooms. There were 3,646 dialysis patients in HSA VI in 2022. If, conservatively, each dialysis patient needed a vascular access procedure twice per year, there would be 7,292 annual procedures needed. Using the Chapter 6 Methodology standard of 1,312 hours of surgical operating room time and an average procedure time of half an hour, there would be enough need to support three vascular access operating rooms. Following this methodology:

1. 3,646 (patients) * 2 (procedures per year) = 7,292 (procedures)
2. 7,292 (procedures) * 0.5 (hours per procedure) = 3,646 (procedure hours)
3. 3,646 (procedure hours) / 1,312 (hours per OR) = 2.78 (ORs needed) in 2022 alone

HSA VI needs <u>at least</u> three vascular access ASCs to serve just the present dialysis patients. The map in Figure 5 demonstrates the difficulty of providing even access with only three. Limited highways and few key bridges make travel challenging. Even three vascular access ASCs could not put the service within a 60-minute drive time of all residents of HSA VI.

In fact, in response to Carolina Vascular's 2022 petition, the Agency calculated the total state needed 15 Vascular Access Operating Rooms. It included only 6 in the 2023 SMFP.

Figure 5 - 60-Minute Coverage from Key Population Centers in HSA VI



EVIDENCE OF CONSISTENCY WITH NORTH CAROLINA STATE MEDICAL FACILITIES PLAN

Basic Governing Principles

1. Safety and Quality

This basic principle notes:

> "*…priority should be given to safety, followed by clinical outcomes, followed by satisfaction.*
>
> *"…As experience with the application of quality and safety metrics grows, the SHCC should regularly review policies and need methodologies and revise them as needed to address any persistent and significant deficiencies in safety and quality in a particular service area*."

Vascular access procedures are better for the patient when provided in a surgical setting that is subject to oversight. North Carolina licensure and CMS Certification bodies provide that quality regulation. OBLs are not subject to the same level of outside review.

Research also shows better clinical outcomes when vascular access procedures occur in a vascular access center rather than a hospital outpatient department. See Attachments B and C.

As demonstrated by a patient letter of support and in the speeches from Dr. Saxena and Mr. Baggett, patients are more satisfied with the freestanding vascular access centers than with the hospital emergency rooms or outpatient department solutions (See Attachments I, J and K).

2. Access

This basic principle notes:

> "*…The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.*
>
> *"…The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards."*

As noted, HSA VI needed an estimated 7,292 procedures in 2022 alone. Without an adjusted need for vascular access OR/ASCs, patients will face expensive costs and inefficient service at hospitals or travel long distances to other ASCs within or outside the state.

Dialysis patients are not seeking vascular access care in their local hospitals. Local hospitals do not have the staffing and expertise required for ideal AV fistula and shunt procedures. The issue is not the institution's number of operating rooms, but availability of a dedicated specialty vascular access care team.

3. Value

This basic principle notes:

> *"The SHCC defines health care value as the maximum health care benefit per dollar expended.*
>
> *"…Cost per unit of service is an appropriate metric…*
>
> *" …At the same time overutilization of more costly and/or highly specialized low-volume services without evidence-based medical indication may contribute to escalating health costs without commensurate population-based health benefit."*

An OBL is less expensive than a surgery center, but existing and planned Medicare cuts will soon make this option unsustainable. The next least expensive setting is a single specialty ambulatory surgery center dedicated to vascular access. It has limited equipment requirements. Without the vascular access procedure-only limitation, the Plan need could have the unintended consequence of producing a generic multi-specialty surgery center that would not guarantee organization for the special emergency standby requirement of the renal dialysis patient.

As demonstrated in the "Evidence of No Unnecessary Duplication of Services" section, HSA VI could support three vascular access ASCs.

The addition of these ASCs to HSA VI would bring more specialty services to the region. This would have the complimentary value of expanding the local medical care knowledge base. Licensure and certification standards require ASCs to arrange emergency coverage with local hospitals. The presence of well operated vascular access ASCs will prevent emergency after hours demand for this service. Moreover, vascular access ASCs organize to accommodate after-hours emergency patients with a first-thing, next-day schedule slot.

If Carolina Vascular Care's Rocky Mount practice is representative of the whole area, then Medicaid is paying either the full Medicare rate for Medicaid only patients or the 20 percent copayment for Dual Eligibles who use hospitals for these procedures. NC Medicaid pays zero copayment for OBL or ASC. Table 7 on the next page compares Medicare, Medicaid, and dual eligible cost differences for vascular access procedures by CPT code.

In HSA VI, these Medicaid payment differences could translate to substantial cost differences - more than $5 million in Medicaid spending saved per year in 2022. Calculations assume that all vascular access procedures occurred in ASCs and each dialysis patient received only two such procedures a year. Savings could be higher because some patients receive up to four procedures a year.

Refer to Attachment F for the detailed calculations. The calculations are based on Carolina Vascular Care's patient percentages by payor and CPT code scaled out to the total dialysis patients in HSA VI. This calculation does not include the cost savings associated with the emergency room visit.

Table 7– HOPD and ASC Reimbursement Rates for Vascular Access Services 2023

			Medicare Patients		Medicaid Patients		Dual Enrolled Medicaid/Medicare Patients*			
CPT	**Procedure Description**	**HOPD Total**	**Medicare Pays**	**% Covered**	**Medicaid Pays**	**% Covered**	**Medicare Pays**	**Medicare %**	**Medicaid Pays**	**Medicaid %**
36901	Fistulagram	$ 1,653	$ 1,323	80%	$ 1,323	80%	$ 1,058.40	64%	$ 264.60	16%
36902	Peripheral Angioplasty	$ 5,451	$ 4,361	80%	$ 4,361	80%	$ 3,488.80	64%	$ 872.20	16%
36903	Stent + Peripheral Angioplasty	$ 10,925	$ 9,263	85%	$ 9,263	85%	$ 7,410.40	68%	$ 1,852.60	17%
36904	Thrombectomy (no angioplasty)	$ 5,578	$ 4,462	80%	$ 4,462	80%	$ 3,569.60	64%	$ 892.40	16%
36905	Thrombectomy + Peripheral Angioplasty	$ 11,052	$ 9,364	85%	$ 9,364	85%	$ 7,491.20	68%	$ 1,872.80	17%
36906	Thrombectomy + Peripheral stent	$ 17,680	$ 15,980	90%	$ 15,980	90%	$ 12,784.00	72%	$ 3,196.00	18%

*Medicaid pays 20% of Direct Medicare

			Medicare Patients		Medicaid Patients		Dual Enrolled Medicaid/Medicare Patients*			
CPT	**Procedure Description**	**ASC Total**	**Medicare Pays**	**% Covered**	**Medicaid Pays**	**% Covered**	**Medicare Pays**	**Medicare %**	**Medicaid Pays**	**Medicaid %**
36901	Fistulagram	$ 749	$ 599	80%	$ 599	80%	$ 599	80%	$ -	0%
36902	Peripheral Angioplasty	$ 2,562	$ 2,050	80%	$ 2,050	80%	$ 2,050	80%	$ -	0%
36903	Stent + Peripheral Angioplasty	$ 7,145	$ 5,716	80%	$ 5,716	80%	$ 5,716	80%	$ -	0%
36904	Thrombectomy (no angioplasty)	$ 3,433	$ 2,746	80%	$ 2,746	80%	$ 2,746	80%	$ -	0%
36905	Thrombectomy + Peripheral Angioplasty	$ 6,343	$ 5,074	80%	$ 5,074	80%	$ 5,074	80%	$ -	0%
36906	Thrombectomy + Peripheral stent	$ 11,747	$ 9,398	80%	$ 9,398	80%	$ 9,398	80%	$ -	0%

*Medicaid pays nothing, Medicare does the full reimbursement

Source: https://www.medicare.gov/procedure-price-lookup/

CONCLUSION

The proposed changes are consistent with and support the Basic Principles that govern the SMFP, and the need is sufficient to support the proposed special need adjustment to the 2024 SMFP.

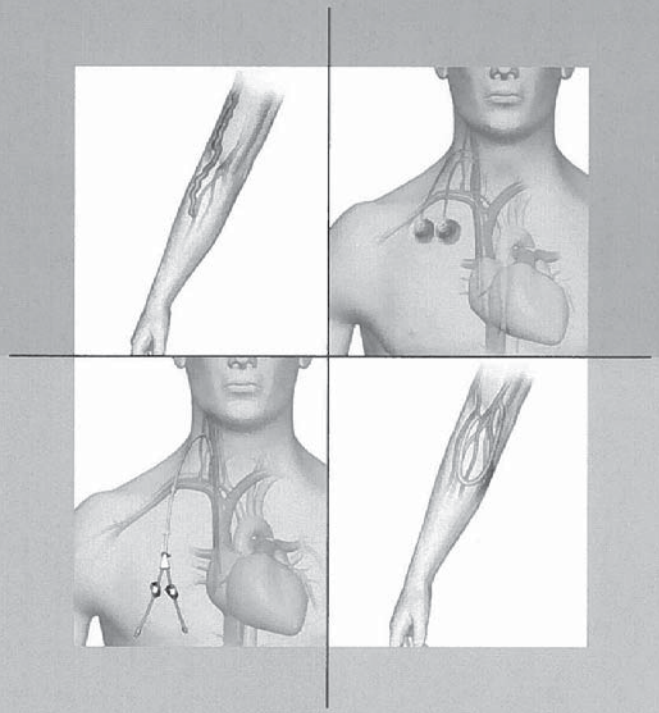
ATTACHMENTS

Attachment A

Understanding Your Hemodialysis Access Options

American Association of Kidney Patients

Understanding Your Hemodialysis Access Options



aakp
American Association of Kidney Patients

aakp
American Association of Kidney Patients
3505 E. Frontage Road, Suite 315 • Tampa, FL 33607
Toll-Free: 800-749-2257 • Fax: 813-636-8122 • www.aakp.org

Overview

HEMODIALYSIS, is the most often used treatment for end-stage renal disease (ESRD), more commonly known as kidney failure. During a hemodialysis treatment, a machine pumps blood from your body by way of a flexible, plastic tube, cleans it and then returns it to your body through a separate tube. In order to perform hemodialysis, an access must be created. An access is a site from which blood can be safely removed and returned to your body. The access site is often referred to as your "lifeline."

There are two types of dialysis accesses. The first kind involves the creation of a permanent connection between an artery and a vein under the skin. The two kinds of permanent accesses, fistulas and grafts, are used for patients with renal failure who are expected to need long-term dialysis treatment. Fistulas and grafts are usually placed in the arm, but they may also be placed in the leg. They are surgically placed a few months before dialysis is scheduled to begin in order to allow for the site to heal and develop properly.

The other type of access involves the direct placement of a tube into a large vein in the neck, chest or groin. As described in this brochure, catheters are most appropriately reserved for patients needing short-term dialysis or patients on long-term dialysis who no longer have a place to insert a fistula or graft.

This brochure contains a brief description of the most common types of accesses. It is divided into two sections covering permanent and temporary access options and provides information on how each type of access is placed, when they are used and the limitations of each.

The following guidelines can help keep all types of vascular accesses in good health:

- Wear a Medical Alert bracelet to notify healthcare providers that you are on dialysis and the location and type of your vascular access. Also state that no blood pressures or vein punctures are to be done on your access limb.
- Pay attention to the machine during dialysis. Possible signs of access problems include: a) trouble maintaining good blood flow (above 300-350 ml/min), b) excessively negative pre-pump arterial pressure (greater than -200 to -250), or c) high venous pressure (causing the alarm to go off often).

"I was looking for something when I originally started dialysis that would be as pain-free as possible and easy to take care of."

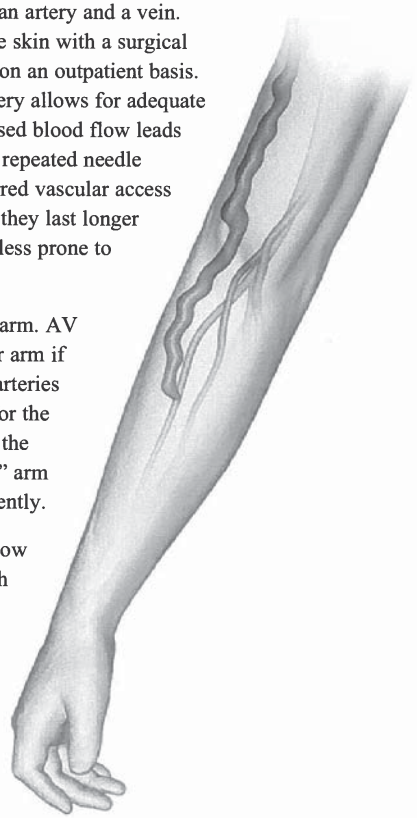
Jamie – Ottawa, Canada

PERMANENT ACCESS OPTIONS

The *arteriovenous* or AV fistula is a type of vascular access involving a direct connection between an artery and a vein. This connection is made underneath the skin with a surgical procedure that can often be performed on an outpatient basis. The connection between a vein and artery allows for adequate blood flow during dialysis. This increased blood flow leads to larger and stronger veins and makes repeated needle insertions easier. Fistulas are the preferred vascular access for long-term dialysis patients because they last longer than any other vascular access and are less prone to infection and clotting.

The fistula is usually placed in the forearm. AV fistulas may also be placed in the upper arm if an access in the forearm fails or if the arteries or veins in the forearm are unsuitable for the creation of a fistula. It is preferred that the fistula be placed on the "non-dominant" arm or the arm that you do not use as frequently.

A few months are usually needed to allow the fistula to properly develop, although it may take longer in some cases. Once the fistula has developed, you are ready for hemodialysis. A healthcare professional will insert two needles into the fistula, one for withdrawing blood from the body and the other to return dialyzed or filtered blood to the body.



The connection between a vein and artery allows for proper blood flow during dialysis.

Not everyone is eligible for an AV fistula. They can be difficult to create in some patients due to small veins and other conditions. Your surgeon may order a test of the blood flow in your arms or legs to determine if you are eligible for a fistula. The most common problem with the AV fistula after it has been successfully placed is a condition known as *stenosis*, which is a narrowing in the width of a blood vessel. In the case of fistulas, this narrowing involves either the vein or artery leading to the access. This may lead to a decrease in blood flow or clotting.

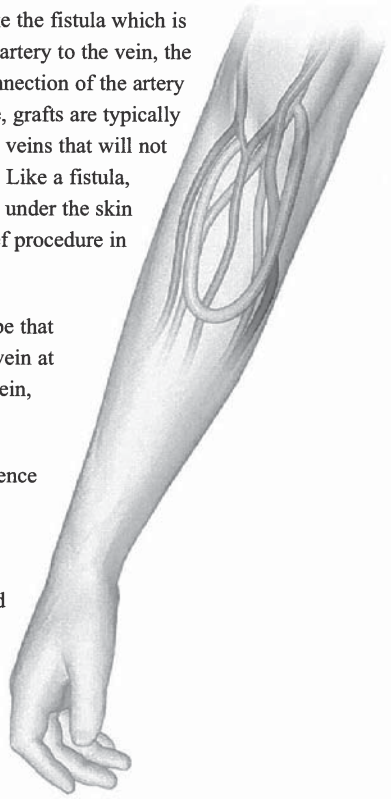
PROS	CONS
• Best overall performance	• Visible on the forearm
• Considered the best vascular access	• May take a while to develop
• Less chance of infection than other types of accesses	• May require temporary access while fistula matures
• Tend to last many years	• Not feasible for all patients due to other medical conditions
• Predictable performance	• Bleeding after the needles are removed
• Increased blood flow	• Fistulas may fail to mature

"I've had my fistula for 22 years, the entire time I've been on dialysis. I make sure to take care of it because it's my lifeline and allows me to receive dialysis. I have learned to put my own needles in because I like to be involved in my own care."

Tom – Dallas, TX
22-year hemodialysis patient

GRAFTS

Grafts are similar to AV fistulas. Unlike the fistula which is created by the direct connection of the artery to the vein, the graft is formed through the indirect connection of the artery to a vein by a synthetic tube. Therefore, grafts are typically used when patients have small or weak veins that will not properly develop into a suitable fistula. Like a fistula, this type of access is usually implanted under the skin in your arm. A surgeon performs a brief procedure in order to properly place the graft.



The graft is usually a soft, synthetic tube that connects to an artery at one end and a vein at the other. The tube acts like a natural vein, allowing blood to flow through it.

Following the surgery, you may experience pain and swelling in the area over the graft for three or four weeks. The arm should be kept elevated. After the swelling goes down, a graft can be used for hemodialysis. Grafts can be used repeatedly for needle insertion during dialysis treatment.

PROS	CONS
• Can be readily implanted	• Increased potential for clotting
• Predictable performance	• Increased potential for infection
• Can be used faster than an AV fistula (within 3 or 4 weeks)	• Does not usually last as long as a fistula

Care for Fistula and Grafts

Find out if your vascular access is a *native fistula*, moved vessel fistula or a synthetic graft. You need to know which way the blood is flowing within your access and which area is used for the *arterial* (red) and *venous* (blue) segments. You need to ensure the dialysis staff person inserts the needles in the proper orientation to the blood flow and then connects the bloodlines red to red and blue to blue.

Learn how to properly hold the patches after the dialysis needles are removed. Also learn how to hold pressure to a needle site in case it bleeds after dialysis. Have in your purse or pocket an emergency supply of gauze dressings and tape to reapply a clean dressing if the needle sites bleed on the way home from dialysis.

Wash the skin over the access with soap and water daily and before dialysis.

Make certain the staff is using proper techniques in preparing your skin before inserting the needles into the access. Ask what these techniques are for your particular unit.

Watch for signs of infection. These may include redness, tenderness or pus. Cleanliness is one of the most important ways to prevent infection. Any signs of infection should be reported to your doctor or nurse immediately.

Feel your access and check for a *thrill* (vibration) or pulse every day. Check also if you have experienced low blood pressure, dizziness or lightheadedness. If you cannot feel a pulse, listen to your access for a *bruit* (swishing sound). If you do not think your access is working, contact your dialysis unit or physician immediately. They can arrange to have the surgeon or radiology specialist examine you.

Try not to carry heavy items draped over the access arm or wear tight fitting clothing over the access arm or leg.

It is important to try not to sleep on the access arm or leg.

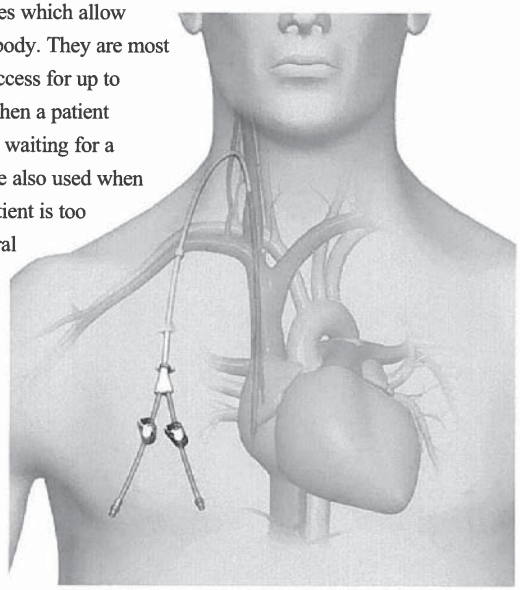
If your fistula or graft develops an *aneurysm* (looks like a small balloon), notify your doctor or nurse immediately. It may need surgery or simply to be closely monitored. Better rotation on needle sites must be used to prevent aneurysm formation or enlargement.

Develop a close relationship with your patient care technician and nurse. You can help remind them to rotate needle sites for each treatment. You can also learn a lot about caring for your access from them. You may even want to learn to put your own needles in for each treatment.

TEMPORARY ACCESS OPTIONS

CATHETERS

Catheters are flexible, hollow tubes which allow blood to flow in and out of your body. They are most commonly used as a temporary access for up to three weeks. This is often done when a patient needs dialysis immediately and is waiting for a fistula or graft to mature. They are also used when a permanent access fails and a patient is too unstable to delay treatment. Several different types of catheters exist.



Internal *jugular* catheters are inserted into the jugular vein on the side of your neck. *Subclavian* catheters are placed into the subclavian vein under the collarbone on the chest. *Femoral* catheters are placed in the large femoral vein in the leg near the groin.

Catheters are flexible, hollow tubes which allow blood to flow in and out of your body. They are most commonly used as a temporary access for up to three weeks.

After a catheter has been placed, needle insertion is not necessary to receive hemodialysis treatment. Catheters contain an *exit site*, which is covered with bandages or other types of dressing. These dressings need to be changed and kept dry at all times. Many physicians recommend mupirocin ointment treatment at the exit site.

PROS	CONS
• Dialysis can be performed immediately	• Not ideal as a permanent access
• Readily inserted with an outpatient procedure	• High infection rates
• Easy removal and replacement	• Difficult to obtain sufficient blood flow to allow for adequate toxin removal
• Avoids needlesticks	• May cause narrowed veins
	• Swimming and bathing is not recommended

"I was told I needed to begin dialysis immediately after being rushed to the emergency room. Of course, I was really scared but the doctor assured me that he could begin dialysis immediately with a catheter. I was only required to keep the catheter in for a few weeks until my fistula was ready, but I was so glad to have it as an option during the emergency."

Margaret – Ashville, NC
1-year hemodialysis patient

Care of Catheters

Your catheter exit site should be cleaned with each dialysis treatment and clean dry gauze applied. You must wear a mask for the dressing change, on and off procedures for dialysis or any time your dialysis catheter is opened for use. Ask your dialysis staff what the unit specific dressing procedure is and how you are to care for the catheter at home. Specifically ask about mupirocin ointment.

For non-cuffed catheters, the *sutures* must remain in place for as long as you have the catheter. For tunneled cuffed catheters, the sutures should be removed once the catheter is healed into place to prevent infection from the sutures.

Your catheter caps must remain on the catheter and only removed by the dialysis staff. The clamps must remain closed at all times. Your dialysis catheter must only be used by the dialysis staff unless authorized by your nephrologist. If the clamp comes undone, close the clamp immediately. If a catheter cap becomes loose and falls off, make sure the catheter remains clamped and report to your dialysis center or emergency room for you are at risk for an infection or air entering your bloodstream and need urgent care. If any portion of the catheter develops a hole, leak or part separation, then you must ensure the catheter is clamped off above the problem area. The catheter clamp may be movable and can be slid up on the body of the catheter to close off the catheter, or you may need to kink the catheter with your fingers to *occlude* the catheter and then call 911. If blood leaks out, air can enter and cause an air embolism. You need immediate help to prevent serious injury.

Glossary

Aneurysm - An abnormal enlargement of a blood vessel. Aneurysms may occur around an access site in the form of what appears to be a small balloon.

Arterial - Characterized or related to the function of the arteries.

Arteriovenous - Term used in dialysis to refer to a connection between an artery and a vein. An arteriovenous connection is used to create fistulas for
hemodialysis treatment.

Bruit - Any of several abnormal sounds produced by an artery.

Exit Site - The site where the catheter emerges.

Jugular - Related to the jugular vein, located in the region of the neck or throat.

Native Fistula - A type of vascular access created by connecting a patient's own artery to his own vein using no artificial parts.

Occlude - To close or obstruct.

Stenosis - A narrowing in the width of a blood vessel.

Subclavian - Related to the subclavian artery or vein, located beneath the clavicle.

Suture - Material used to surgically close a wound or join tissues.

Thrill - A tremor or vibration in the circulatory system.

Tunneled Catheter - A specialized type of catheter that is "tunneled" or placed under the skin.

Vascular - Related to the arteries or veins.

Venous - Characterized or related to the function of the veins.

Attachment B

Clinical and Economic Value of Freestanding Office-Based Centers

Seminars in Dialysis

Investigation

Clinical and Economic Value of Performing Dialysis Vascular Access Procedures in a Freestanding Office-Based Center as Compared with the Hospital Outpatient Department among Medicare ESRD Beneficiaries

Al Dobson,* Audrey M. El-Gamil,* Matthew T. Shimer,* Joan E. DaVanzo,* Aris Q. Urbanes,† Gerald A. Beathard,‡ and Terry Foust Litchfield†

*Dobson DaVanzo & Associates, LLC, †Lifeline Vascular Access, a DaVita Healthcare Partners® affiliate, and ‡Lifeline Vascular Access a DaVita Healthcare Partners® affiliate and Clinical Professor of Medicine at the University of Texas Medical Branch

ABSTRACT

Dialysis vascular access (DVA) care is being increasingly provided in freestanding office-based centers (FOC). Small-scale studies have suggested that DVA care in a FOC results in favorable patient outcomes and lower costs. To further evaluate this issue, data were drawn from incident and prevalent ESRD patients within a 4-year sample (2006-2009) of Medicare claims (USRDS) on cases who receive at least 80% of their DVA care in a FOC or a hospital outpatient department (HOPD).

Using propensity score matching techniques, cases with a similar clinical and demographic profile from these two sites of service were matched. Medicare utilization, payments, and patient outcomes were compared across the matched cohorts (n = 27,613).

Patients treated in the FOC had significantly better outcomes ($p < 0.001$), including fewer related or unrelated hospitalizations (3.8 vs. 4.4), vascular access-related infections (0.18 vs. 0.29), and septicemia-related hospitalizations (0.15 vs. 0.18). Mortality rate was lower (47.9% vs. 53.5%) as were PMPM payments ($4,982 vs. $5,566).

This study shows that DVA management provided in a FOC has multiple advantages over that provided in a HOPD.

Maintaining healthy vascular access is critical to ensuring the efficacy of hemodialysis treatments and overall patient quality of life. Clinical practice guidelines and research have identified the types of dialysis vascular access (DVA) patients should receive to achieve optimal outcomes (1). Proper care during and after vascular access placement can reduce complications and overall utilization.

In recent years, patients have typically received DVA management services in either a freestanding office-based center (FOC) or the hospital outpatient department (HOPD). The literature suggests that DVA management can be optimized when patients receive care in a FOC, as this setting can provide the "highest quality medical care at the lowest possible cost." HOPDs are multipurpose facilities and have issues associated with DVA care, including delayed treatments, unnecessary hospitalizations, unnecessary use of temporary catheters, and excessive cost (2).

To date, there have been only a few regional and small-scale studies that compare Medicare payments and outcomes of receiving DVA management services in a FOC versus an HOPD. The purpose of this study was to conduct a retrospective cohort study using 4 years of Medicare claims data (2006-2009) from the United States Renal Data System (USRDS). USRDS is a national data system funded directly by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in conjunction with the Centers for Medicare & Medicaid Services (CMS). The USRDS database contains all healthcare utilization and Medicare payment claims for end-stage renal disease (ESRD) patients, as well as select clinical information, including ESRD-specific laboratory values, patient functional status, and comorbidities.

This study compares Medicare payments and outcomes for patients who received DVA procedures in a FOC with those who received DVA care in the HOPD for a defined episode of care. This study also investigates the impact of physician specialty

Address correspondence to: Audrey El-Gamil, Dobson DaVanzo & Associates, LLC, 440 Maple Avenue East, Suite 203, Vienna, VA 22180, Tel.: 703-260-1764, Fax: 703-636-0130, or e-mail: audrey.el-gamil@dobsondavanzo.com.

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and care processes on patient outcomes within this context. Patients are matched using a propensity score model that controls for observable selection bias across sites of service.

Propensity score matching techniques are widely used in observational studies when randomized controlled trials (RCTs) are not available, able to be generalized to the population, or are unethical or impractical to administer (3). Literature suggests that applying this technique to observational studies is sufficient to remove observable selection bias among treatment and comparison groups and can result in findings that mimic RCTs (4–7).

Methods

Study Design and Population

The study sample was drawn from all incident and prevalent ESRD patients with Medicare fee-for-service coverage between 2006 and 2009. The design is a retrospective cohort study of Medicare claims data informed by published literature and ongoing communication with a clinical advisory committee. The clinical advisory committee was consulted to develop a patient episode framework, inform and validate all analytic assumptions, and to provide clinical interpretation of data results. Quantitative analyses are based on the USRDS datasets, which contain all healthcare utilization and Medicare payments for ESRD patients, as well as selected clinical information, including ESRD-specific laboratory values (i.e., body mass index (BMI), HbA1C, albumin, and creatinine), functional status, and comorbidities.

Through rigorous propensity score matching techniques, study group patients who received DVA-related care in a FOC were matched to comparison group patients with a similar clinical and demographic profile who received DVA-related care in an HOPD. Medicare utilization, payments, and patient outcomes were compared across the matched cohorts.

Data Collection

A single episode of care was created from the data for each patient that captured all DVA and dialysis-related services, and all related or unrelated hospitalizations over the span of the study period (2006-2009). An episode started with the first DVA-related service during the study period and ended either with patient death, or the end of the study period. Episodes included claims across all settings, including inpatient and outpatient hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, long-term care hospitals, physicians, hospices, and durable medical equipment.

Patient episodes were administratively defined by the site of service in which at least 80% of the patient's DVA-related services were provided: either a FOC (identified as a physician's office in the claims), or the HOPD, including all outpatient settings (i.e., outpatient hospital, emergency room, dialysis center, and state/local public health clinic). FOC is identified by the physician's office site of service in the Medicare claims (site of service 11). HOPD is identified by sites of service 22, as well as other hospital-based sites of service, including 23, 65, or 71. Given the equipment and staff requirements to perform vascular access services, we assume that all relevant services performed in the physician's office are FOCs.

Patients were clinically defined within each cohort by the first type of DVA service within the episode. This clinical definition attempted to identify incident from prevalent ESRD patients based on the first service they received. Services were placed into two groups: 1) placement services, defined as the creation of a fistula or a graft, vessel mapping, or catheter placement prior to any dialysis treatment (incident ESRD patients), and 2) maintenance services, defined as receiving dialysis treatments prior to any DVA-related service such as a placement or treatment service (prevalent patients).

Patient pathways were identified in each episode to track the receipt of specific DVA services across settings and over time using a hierarchical design. As many DVA services consist of multiple separate procedures billed on the same claim, the hierarchy distinguished between the primary (most relevant) service and the ancillary service. Pathways were unique to each individual and allow for comparison of treatments and outcomes across patient cohorts. The use of hierarchical pathways allowed for the identification of whether each service was a maintenance or anticipatory service (angioplasty or angiogram—performed to maintain the health and function of the access site) or a resuscitative service (salvage procedure performed once the access became dysfunctional). Table 1 presents the hierarchy for identifying DVA services within the patient episode, the codes used to identify them, and whether they were identified as an anticipatory or resuscitative service. Consistent with the USRDS methodology, procedures were identified using CPTs, MS-DRGs, and ICD-9s, as appropriate. Despite the use of a hierarchical pathway to identify the services, all access procedures provided during the study period are captured in the analysis.

There were three types of outcomes for which the study and comparison groups were compared. The primary outcome was selected clinical indicators, including number of infections due to dialysis vascular device, implant and graft (CPT 99662), septicemia-related hospitalizations (MS-DRGs 416, 575, 576 prior to October 2007; 870-872 after October 2007), and related (MS-DRGs: 682-685 prior to October 2007; 316-317 after October 2007; ICD-9s: 585, 586) and unrelated hospitalizations. The second outcome was the all-cause mortality rate. Finally, the third outcome was average PMPM Medicare payment for DVA-related care (including and excluding dialysis treatments and drugs).

TABLE 1. Hierarchy for identifying patient pathways in episode

Hierarchical Rank	Description (CPT Codes)	Service Type
1	Creation of fistula (36821, 36818, 36819, 36820, or 36825) Creation of graft (36830)	Treatment
2	Catheter placement (36558)	Resuscitative
3	Catheter exchange (36581)	Treatment
4	Thrombectomy (36870)	Resuscitative
5	Cannulation & injection (36005) Scan of arteries (93931, 93930, 93970, 93971) Vessel mapping (G0365)	Treatment
6	Catheter removal (36589)	Treatment
7	Arteriogram of extremity (75710)	Treatment
8	Stent placement (37205 & 75960)	Treatment
9	Arterial/venous angioplasty (35475 & 75962, 35476 & 75978, G0393, G0392) Angiogram (36145, 36147, 75790, 75791)	Anticipatory
10	Hospitalization	Treatment
11	Dialysis (90935–90947)	Treatment
12	Aranesp (J0882) Epogen (J0885, J0886, Q4081) TPA (J2997)	Treatment

Statistical Analyses

A two-step process was used to match patients who received DVA services in the FOC with those who received care in the HOPD.

First, many-to-many matching of patients was carried out across cohorts on a series of variables that directly impact how patients receive care and how Medicare determines payments. These include whether the patient first received placement or maintenance services within the episode; whether the patient had a confirmed fistula or graft during the episode to ensure that outcomes are not due to a disproportionate use of catheters as the primary access type within a given setting; the date from first DVA-related service during study period (within 30 days); whether the patient was a new Medicare enrollee (used to calculate hierarchical condition categories—HCC—scores as a measure of patient severity); and the metropolitan statistical area (MSA) of the patient's residence to control for geographic differences in Medicare payments and practice patterns. HCCs are used in the Medicare Advantage program to determine per member–per month payments based on historical utilization. For rural patients, the first number of their ZIP code was used instead. By matching patients on the start of their dialysis in the study period within 30 days, the Medicare payments are adjusted for medical inflation cost.

Second, following the initial match, propensity score techniques were used to refine the match of patients across settings. This statistical method is used to reduce observable selection bias between the two cohorts and is used in this study to isolate the impact of site of service on all three types of patient outcomes. The propensity score indicated the probability of a patient receiving care in the FOC, based on the patient's demographic and clinical characteristics.

A propensity score for each patient was calculated based on patient demographic characteristics, clinical characteristics, and functional status variables. Patient demographic characteristics included age; gender; race; years since first ESRD service; dual eligibility for Medicare and Medicaid; and smoking and alcohol and drug dependence. Clinical characteristics included comorbidities; history of a transplant; laboratory values for BMI, HbA1c, albumin, and creatinine at start of dialysis; HCC score; and whether the patient historically received care from: 1) a nephrologist and/or 2) a dietician. Functional status was based on the patient's ability to ambulate or transfer, and whether the patient needed assistance with the activities of daily living. All matching variables, except the confirmed access type, were defined and identified by USRDS.

Patients were matched one-to-one within 0.2 standard deviations of the logit function that determined their propensity score, consistent with the caliper width traditionally used in the literature (8). The rigor of the matching techniques isolated the effect of site of service from other observable causal effects. Patients who were not able to be matched were excluded from the analysis.

Following the matching process, patient outcomes were compared across cohorts and descriptive statistics on nonmatching variables were calculated to identify potential drivers of the outcomes. Two main drivers of interest were the distribution of episodes within the care setting by the physician specialty that performed the majority of the patient's DVA-related services and the impact of receiving maintenance/anticipatory services on outcomes. The impact of anticipatory care is conducted across all patients (not just the matched cohorts) to better understand if increases in anticipatory services are related to decreases in patient outcomes, regardless of where care is received. Prevalence of anticipatory care is defined as the ratio of anticipatory services to the total number of anticipatory, resuscitative, and catheter placement services. The sum of resuscitative and catheter placement services is used instead of the total number of treatments provided to isolate the services provided to maintain access health as opposed to all DVA-related care. That is, the number of angioplasties and angiograms received divided by the total number of angioplasties and angiograms, thrombectomies, and catheter placement services.

Results

Patient Characteristics of Matched Cohorts

A total of 27,613 patients were matched across each cohort (n = 55,226), representing approximately 10 percent of all ESRD patients contained

in the USRDS claims during the study period. Following the propensity score match, patient demographic characteristics were very similar across cohorts for variables included in the match or propensity score (Table 2). Both patient cohorts had an average age of 61 years and a comparable proportion of patients who are White (56%) and dual-eligible (41%). Furthermore, patients are matched on clinical laboratory values at the time of dialysis (BMI, HbA1c, albumin, and creatinine),

TABLE 2. Patient characteristics of matched cohorts for variables included in propensity score matching

Matching and propensity score variables	FOC (n = 27,613)	HOPD (n = 27,613)	Difference[a] (FOC − HOPD)	95% confidence interval
Demographic characteristics				
Average age	61.0	60.5	0.5*	(0.2, 0.8)
Female	46.1%	47.3%	−1.2%**	(−2.1%, −0.4%)
Race/ethnicity				
Asian	3.7%	3.9%	−0.2%	(−0.2%, 0.2%)
Black	38.6%	39.2%	−0.6%	(−0.9%, 0.2%)
Native American	1.3%	1.2%	0.1%	(−0.1%, 0.2%)
White	56.1%	55.3%	0.8%	(−0.3%, 0.8%)
Other races	0.3%	0.3%	0.0%	(−0.1%, 0.1%)
Dual-eligible	40.8%	41.3%	−0.5%	(−1.3%, 0.3%)
Had transplant	11.4%	12.0%	−0.6%**	(−1.2%, −0.1%)
Years since first ESRD service	2.5	2.6	−0.1***	(−0.1, 0.0)
New medicare enrollees[b]	53.6%	53.6%	0.0%	(−0.8%, 0.8%)
Clinical characteristics at start of episode				
HCC Score—New medicare enrollee	1.00	1.00	0.00	(−0.01, 0.01)
HCC Score—Community risk	4.36	4.38	−0.02	(−0.07, 0.03)
HCC Score—Institutional risk	4.06	4.08	−0.02	(−0.06, 0.02)
Average BMI	28.6	28.6	0.0	(−0.2, 0.2)
Average HbA1c (%)	7.34	7.45	−0.11	(−0.49, 0.28)
Average albumin value (g/dl)	3.13	3.13	0.00	(−0.02, 0.02)
Average creatinine value (mg/dl)	6.38	6.35	0.03	(−0.05, 0.11)
Patient under care of dietician	10.7%	11.3%	−0.6%	(−1.3%, 0.3%)
Patient under care of nephrologist	64.9%	64.8%	0.1%	(−1.1%, 1.3%)
Comorbidities & functional status				
Congestive heart failure	34.4%	34.5%	−0.1%	(−1.2%, 1.0%)
Atherosclerotic heart disease	22.2%	21.8%	0.4%	(−0.6%, 1.3%)
Other cardiac disease	17.1%	16.7%	0.4%	(−0.4%, 1.3%)
Cerebrovascular disease, CVA, TIA	10.4%	9.8%	0.6%	(−0.1%,1.3%)
Peripheral vascular disease	14.2%	13.8%	0.4%	(−0.4%, 1.2%)
History of hypertension	85.2%	85.4%	−0.2%	(−1.0%, 0.7%)
amputation	3.2%	3.1%	0.1%	(−0.2%, 0.6%)
Diabetes, currently on insulin	35.1%	34.9%	0.2%	(−0.9%, 1.3%)
Diabetes, on oral medications	14.2%	14.0%	0.2%	(−0.6%, 1.0%)
Diabetes, without medications	5.6%	5.5%	0.1%	(−0.4%, 0.7%)
Diabetes retinopathy	8.2%	8.3%	−0.1%	(−0.7%, 0.6%)
Chronic obstructive pulmonary disease	7.9%	7.0%	0.9%**	(0.3%, 1.5%)
Tobacco use (current smoker)	4.8%	4.7%	0.1%	(−0.4%, 0.6%)
Malignant neoplasm, cancer	6.8%	7.0%	−0.2%	(−0.9%, 0.3%)
Toxic nephropathy	0.4%	0.4%	0.0%	(−0.1%, 0.1%)
Alcohol dependence	1.2%	1.0%	0.2%	(−0.1%, 0.4%)
Drug dependence	1.0%	0.9%	0.1%	(−0.1%, 0.3%)
Inability to ambulate	6.6%	7.1%	−0.5%	(−1.0%, 0.1%)
Inability to transfer	3.1%	3.5%	−0.4%***	(−0.9%, −0.1%)
Needs assistance with daily activities	11.8%	11.9%	−0.1%	(−0.8%, 0.7%)
Institutionalized	7.3%	6.9%	0.4%	(−0.2%, 1.0%)
Institutionalized—Assisted living	0.6%	0.6%	0.0%	(−0.1%, 0.2%)
Institutionalized—Nursing home	7.1%	6.7%	0.4%	(−0.2%, 1.0%)
Institutionalized—Other institution	0.5%	0.3%	0.2%	(0.0%, 0.3%)
Nonrenal congenital abnormality	0.2%	0.2%	0.0%	(−0.2%, 0.0%)
No comorbidities	1.9%	2.0%	−0.1%	(−0.4%, 0.2%)
Access type				
Confirmed fistula/graft during episode[b]	71.6%	71.6%	0.0%	(−0.8%, 0.8%)
Confirmed catheter, but no confirmed fistula/graft during episode[b]	28.4%	28.4%	0.0%	(−0.8%, 0.8%)

Totals do not add due to rounding.
[a]Difference represents the percentage point difference of FOC minus HOPD.
[b]Matching variable prior to propensity score matching.
*Statistically significant at $p < 0.001$.
**Statistically significant at $p < 0.01$.
***Statistically significant at $p < 0.05$.

access type, and comorbidities. The only statistically significant difference between the two groups was the proportion of patients who were female (46.1% for FOC patients vs. 47.3% for HOPD patients, 95% Confidence Interval of the difference [CI] −2.1%, −0.4%); the proportion who had received renal transplants (11.4% for FOC patients vs. 12.0% for HOPD patients, CI −1.2%, −0.1%) and the number of years since first ESRD service (2.5 years for FOC patients vs. 2.6 years for HOPD patients; CI −0.1, 0.0). While the years since first ESRD service are statistically significant, the results are not clinically significant. Furthermore there is a slightly higher rate of COPD among FOC patients and a lower inability to transfer than HOPD patients.

Outcomes across Matched Cohorts

Matched patients who received their DVA services in a FOC had an average Medicare per member–per month (PMPM) payment (including dialysis treatments and drugs) that was $584 lower than those who received care in the HOPD ($4,982 vs. $5,566, CI -$694, -$473). This represents an average annual difference in Medicare payment of $7,008. The difference in Medicare payments for only DVA services was $626 PMPM ($3,162 vs. $3,788, CI -$736, -$516) (Table 3).

Higher PMPM payments for patients treated in the HOPD are probably driven by an increase in negative outcomes during the episode (Table 3). Patients treated in the FOC have significantly fewer related and unrelated hospitalizations, infections, and septicemia-related hospitalizations than those treated in the HOPD ($p < 0.001$). As a result of fewer hospitalizations among patients treated in the FOC, patients who received their DVA services in the FOC had a larger proportion of their episode in an outpatient setting, and therefore had higher PMPM payments for outpatient dialysis treatments and drugs compared with patients treated in the HOPD ($1,820 vs. $1,777, CI $29, $56). As both groups receive a similar number of outpatient dialysis treatments per week, patient compliance (as defined by missed dialysis treatments) does not appear to be driving the results.

Patients treated in the FOC also had a significantly lower mortality rate (47.9% vs. 53.5%, CI −6.5%, −4.8%) (11.7% difference). This lower mortality rate resulted in a longer average episode length compared with those treated in the HOPD (2.3 years vs. 2.1 years, CI 0.1, 0.2). Therefore, patients treated in the FOC had lower PMPM payments, better outcomes, and live longer than those treated in the HOPD.

Potential Drivers of Outcomes across Matched Cohorts

The PMPM episode payment by physician specialty for the majority of the DVA-related services and the distribution of DVA services contained within the episode were investigated as drivers of outcomes. The distribution of physician specialties and the average PMPM episode payment within a specialty was different across cohorts (Table 4). A larger proportion of patients treated in the FOC received interventional DVA care primarily by a nephrologist compared with patients treated in the HOPD (64.2% vs. 47.9%, CI 15.5%, 17.2%). Given the lack of a designated specialty code for interventional nephrologists, it is the authors' assumption that nephrologists who provide DVA services are interventional nephrologists. However, patients receiving DVA care from nephrologists in the FOC had PMPM payments that were $1,365 lower than those receiving care from a nephrologist in the HOPD ($3,436 vs. $4,801, CI -$1,492, -$1,238). Data suggest that, within each setting, nephrologists treat higher severity patients than the other specialties, as indicated by the average community HCC

TABLE 3. Distribution of outcomes by matched cohort

	FOC (n = 27,613)	HOPD (n = 27,613)	Difference[a] (FOC − HOPD)	95% confidence interval
DVA PMPM payment (including dialysis & drugs)	$4,982	$5,566	−$584*	(−$694, −$473)
DVA PMPM (excluding outpatient dialysis & drugs)	$3,162	$3,788	−$626*	(−$736, −$516)
DVA PMPM for outpatient dialysis & drugs	$1,820	$1,777	$42*	($29, $56)
Outcomes per patient				
Average number of related and unrelated hospitalizations per year	3.8	4.4	−0.6*	(−0.7, −0.5)
Average number of infections per year	0.18	0.29	−0.11*	(−0.13, −0.10)
Average number of septicemia hospitalizations per year	0.15	0.18	−0.03*	(−0.04, −0.02)
Outpatient dialysis treatments per week	2.8	2.9	−0.1**	(−0.1, 0.0)
All-cause mortality rate during episode	47.9%	53.5%	−5.6%*	(−6.5%, −4.8%)
Episode length (years)	2.3	2.1	0.2*	(0.1, 0.2)

Totals do not add due to rounding.
[a]Difference represents the percentage point difference of FOC minus HOPD.
*Statistically significant at $p < 0.001$.
**Statistically significant at $p < 0.01$.
***Statistically significant at $p < 0.05$.

TABLE 4. Distribution of Episodes by Physician Specialty Providing the Majority of DVA-Related Services by Matched Cohort

	FOC (n = 27,613)		HOPD (n = 27,613)		Difference[a] (FOC − HOPD)			
	Percentage of episodes	Average PMPM	Percentage of episodes	Average PMPM	Percentage of episodes	95% confidence interval	Average PMPM	95% confidence interval
Nephrology	64.2%	$3,436	47.9%	$4,801	16.4%*	(15.5%, 17.2%)	−$1365*	(−$1492, −$1238)
Diagnostic/ Interventional radiology	16.3%	$2,577	26.0%	$2,485	−9.7%*	(−10.4%, −9.0%)	$92	(−$142, $325)
Internal medicine	6.2%	$3,952	5.2%	$5,389	1.0%*	(0.6%, 1.4%)	−$1437*	(−$2194, −$682)
Vascular surgery	5.4%	$2,165	7.9%	$2,808	−2.6%*	(−3.0%, −2.2%)	−$643***	(−$1217, −$68)
General surgery	3.6%	$1,719	7.0%	$2,212	−3.4%*	(−3.8%, −3.0%)	−$494**	(−$799, −$189)
Thoracic surgery	0.4%	$2,529	0.9%	$2,208	−0.6%*	(−0.7%, −0.4%)	$322	(−$660, $1304)
Cardiology	0.4%	$2,926	0.8%	$4,193	−0.4%*	(−0.6%, −0.3%)	−$1,267	(−$3620, $1086)
Other	3.6%	$2,569	4.3%	$3,118	−0.7%*	(−1.0%, −0.3%)	−$549***	(−$1091, −$8)
Total	100.0%	$3,162	100.0%	$3,788	–	–	−$626*	(−$736, −$516)

Totals do not add due to rounding.
[a]Difference represents the percentage point difference of FOC minus HOPD.
*Statistically significant at $p < 0.001$.
**Statistically significant at $p < 0.01$.
***Statistically significant at $p < 0.05$.

TABLE 5. Number of annualized services per patient and average PMPM by type of service, by cohort

	FOC (n = 27,613)		HOPD (n = 27,613)		Difference[a] (FOC − HOPD)			
	Number of services per patient[b]	Average PMPM[c]	Number of services per patient[b]	Average PMPM[c]	Number of Services per Patient	95% confidence interval	Average PMPM	95% confidence interval
Average number of DVA services per patient	20.5	–	23.9	–	−3.4**	(−5.3, −1.6)	–	–
Prevalence of anticipatory care	63.0%	–	53.0%	–	10.0%*	(9.1%, 10.9%)	–	–
Anticipatory services per year								
Angioplasty & angiograms	8.4	$268	7.1	$176	1.3***	(0.2, 2.4)	$92*	($67, $116)
Resuscitative services per year								
Catheter placement	1.3	$27	2.0	$54	−0.8*	(−1.0, −0.5)	−$27*	(−$36, −$17)
Thrombectomy	0.8	$49	0.8	$25	0.0	(−0.2, 0.2)	$24*	($14, $35)
Treatments per year								
Creation of fistula/graft	0.5	$22	2.3	$110	−1.8*	(−2.1, −1.4)	−$87*	(−$104, −$70)
Catheter exchange	0.5	$9	0.7	$17	−0.2	(−0.4, 0.0)	−$8*	(−$11, −$4)
Related and unrelated hospitalizations (including septicemia-related)	2.3	$2,720	2.8	$3,283	−0.5*	(−0.6, −0.4)	−$563*	(−$661, −$465)
Vessel mapping	1.6	$7	2.0	$5	−0.4*	(−0.5, −0.2)	$2*	($1, $2)
Catheter removal	3.2	$14	3.6	$31	−0.4	(−1.0, 0.3)	−$17*	(−$23, −$11)
Stent placement	0.6	$30	1.4	$67	−0.8*	(−1.2, −0.4)	−$36**	(−$63, −$10)
Arteriogram of extremity	1.3	$15	1.2	$22	0.0	(−0.3, 0.4)	−$7	(−$16, $2)

Totals do not add due to rounding.
[a]Difference represents the percentage point difference of FOC minus HOPD.
[b]Calculated as the number of services divided by the number of total patient years.
[c]Average PMPM includes the Medicare payment for the specific service divided by the total number of patient months across all episodes, including those who did not receive the service.
*Statistically significant at $p < 0.001$.
**Statistically significant at $p < 0.01$.
***Statistically significant at $p < 0.05$.

score (data not shown). This may explain the higher PMPM payments for nephrologists' patients within a setting compared with the other specialties. About one-quarter (26.0%) of patients treated in the HOPD primarily received DVA-related care from a diagnostic or interventional radiologist compared to 16.3% of patients treated in the FOC.

The types of DVA services received during an episode also differed by cohort (Table 5). Patients treated in the FOC had less complex patient

pathways (received fewer DVA services) than those treated in the HOPD (20.5 vs. 23.9, CI -5.3, -1.6), despite having longer episodes and lower mortality rates. Not only are they receiving fewer total services, patients treated in the FOC received a significantly higher proportion of maintenance/anticipatory care (63.0% of all services vs. 53.0%, CI 9.1%, 10.9%). Anticipatory services were defined by the prevalence of angioplasties and angiograms, which was significantly higher for patients treated in the FOC compared with patients treated in the HOPD (8.4 vs. 7.1, CI 0.2, 2.4). The lower number of services and higher proportion of anticipatory services resulted in a lower average PMPM payment.

The largest difference in the average PMPM payment across cohorts was due to the prevalence of related and unrelated hospitalizations per year. Patients treated in the FOC had significantly fewer related and unrelated hospitalizations per year during their episode compared with patients treated in the HOPD (2.3 vs. 2.8, CI -0.6, -0.4). The lower use of hospital services resulted in a $563 lower PMPM payment ($2,720 vs. $3,283, CI -$661, -$465).

With the exception of arteriograms and thrombectomies, patents treated in the FOC had lower utilization of all treatment services, resulting in lower PMPM payments over the length of the episode. The number of thrombectomies and vessel mappings per annualized episode was the same or lower for patients treated in the FOC, but the total number of patients receiving these services was higher, resulting in a higher average PMPM for patients treated in the FOC.

Impact of Anticipatory Care on Average PMPM Payments

The results suggest that anticipatory care was associated with better patient outcomes and lower average PMPM payments. Figure 1 illustrates the average infection rate, mortality rate, and PMPM payments for DVA services by the percentage of anticipatory care a patient received. This analysis was not divided by patient cohort, but rather investigated the overall impact of anticipatory care, regardless of site of service. Across all patients and care settings, prior to matching, as the proportion of anticipatory care services increased, the infection rate, mortality rate, and average PMPM payment decreased significantly.

Discussion

Based on a large retrospective matched cohort analysis of Medicare ESRD beneficiaries using claims data from 2006 to 2009, this study demonstrates that patients who receive DVA care in a FOC have statistically significantly better outcomes, including fewer related and unrelated hospitalizations, infections, septicemia-related hospitalizations, and all-cause mortality, despite having longer patient episodes. Furthermore, patients treated in the FOC have lower average PMPM payments than patients treated in an HOPD. That is, patients treated in the FOC live longer as a result of the lower mortality rate and have lower PMPM payments.

These results are consistent with other research concluding that receiving DVA care in a FOC is

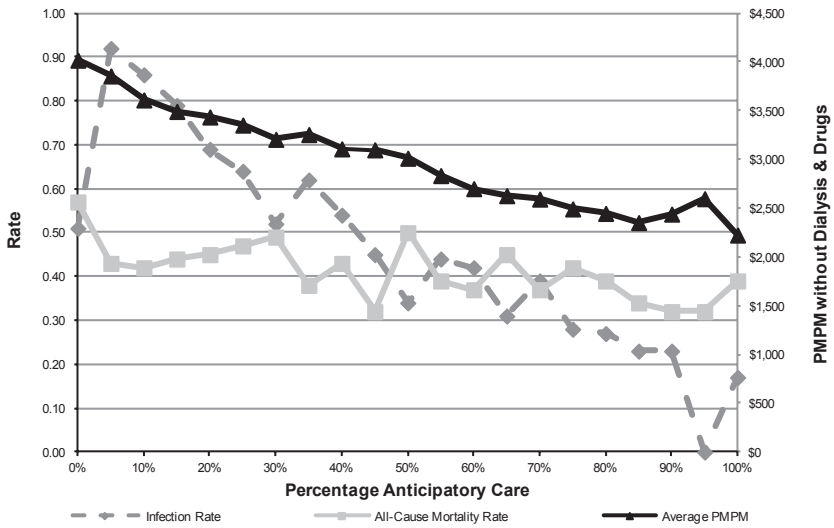

FIG. 1. Impact of Anticipatory Care on Infection Rate, All-Cause Mortality Rate, and Average PMPM Payments. Prevalence of patient outcomes by percentage of anticipatory care, defined as the proportion of dialysis vascular access (DVA) services for anticipatory services (angioplasties and angiograms) to resuscitation services (thrombectomies and additional placements). Infection rate (dashed line); all-cause mortality (gray solid line); average per member–per month (PMPM) payment excluding outpatient dialysis treatments and drugs (black solid line).

associated with a significant decrease in DVA-related hospitalizations. Researchers have concluded that FOCs demonstrate efficiency and have better outcomes even while treating emergent DVA problems (9–13). One study specifically noted that FOCs use best-demonstrated practices for both diagnosis and treatment and provide the comprehensive set of skills needed to achieve quality results with an acceptably low complication rate (10).

This study enables attribution of patient outcomes to the site of service at which patients receive over 80% of their DVA care. Patient outcomes are probably influenced by the presence of care coordination across specialties, physician specialty performing DVA procedures, and the provision of anticipatory care to maintain access function. The data suggest that nephrologists are less likely, and diagnostic/interventional radiologists are more likely, to be providing the majority of a patient's DVA-related care in the HOPD than in the FOC. Because the study patients were not risk-adjusted by specialty within setting, the study cannot determine the cost-effectiveness of DVA-related care provided by specialty. However, literature suggests that nephrologists are associated with safe, successful, and quality outcomes, resulting in decreased morbidity and cost (14). Several studies also suggest that receiving DVA services by nephrologists increases the chances of receiving permanent access placed prior to dialysis (15–19). Furthermore, appropriately trained interventional nephrologists have been shown to perform DVA procedures effectively and safely with a low major complication rate (20).

In addition to specialty and anticipatory care, the presence of a dedicated access team and team coordinator improves patient outcomes and reduces cost. Coordinators have been identified as essential for managing interaction among different disciplines, such as vascular surgeons, nephrologists, and interventionalists (21). Using a nephrologist in the role of interventionist and key decision maker enhances the ability to practice coordinated care (22). The literature asserts that a dedicated team is better able to assess fistula and graft maturation, organize timely interventions, and establish a multidiscipline prevention strategy. Close collaboration among nephrologists, surgeons, radiologists, and dialysis staff, streamlined by a dedicated access coordinator, improves DVA management and outcomes (23).

The results of this study, informed by the published literature, suggest that patients treated in the FOC achieve favorable results due to the synergy of the provider specialty, receipt of anticipatory care, and use of a dedicated access team with proper coordination. The exclusion of any one of these aspects may inhibit favorable outcomes. Based on the results of this and other studies investigating the impact of FOCs on patient outcomes and Medicare payments, proper incentives could be developed to ensure that patients are receiving care in the setting that provides for the best patient outcomes.

This study serves as the first published research to analyze patient outcomes using a 4-year national dataset that captures all care across all sites of service. This methodology allows for very rigorous risk-adjustment methods to be implemented and spans beyond the practice patterns of select, geographically focused access centers. Furthermore, this study includes over 55,000 ESRD patients matched on demographic characteristics, clinical characteristics (laboratory values and comorbidities), and access type, who represent about 10% of ESRD patients nationally.

There are, however, limitations to this approach. First, while all healthcare utilization is captured in the USRDS database, this study was limited to the use of administrative claims data and select clinical information. USRDS data includes several clinical fields, but the use of medical records would have increased our ability to identify DVA-related outcomes beyond the specificity of CPT and ICD-9 coding. All comorbidity and clinical values, however, were defined using USRDS methodology. Second, the reliance on administrative claims over a fixed period of time precludes examining the patients' healthcare utilization prior to the study period. Therefore, prior complications or historical utilization cannot be included in our propensity score model. As indicated by the ability to match patients across sites of service based on rigorous patient demographic and clinical characteristics, we believe, however, that this study reflects minimum residual selection bias among those who are treated in the FOC compared with those who are treated in the HOPD.

In conclusion, these results suggest that patients who receive care from a FOC that provides a multidisciplinary approach with a dedicated care team have significantly better patient outcomes and lower mortality rates at a significantly reduced cost to Medicare. These outcomes may be the result of receiving anticipatory care to maintain DVA health from dedicated physician specialists working within a coordinated care environment.

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Attachment C

Vascular Access Setting and Maintenance Services

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ORIGINAL RESEARCH ARTICLE

ASDIN

What is the best setting for receiving dialysis vascular access repair and maintenance services?

Audrey M. El-Gamil[1], Al Dobson[1], Nikolay Manolov[1], Joan E. DaVanzo[1], Gerald A. Beathard[2], Terry Foust Litchfield[2], Brook Cowin[2]

[1] Dobson DaVanzo and Associates, LLC, Vienna, VA - USA
[2] Lifeline Vascular Access, a DaVita Healthcare Partner ®, Vernon Hills, IL - USA

ABSTRACT

Introduction: Advances in dialysis vascular access (DVA) management have changed where beneficiaries receive this care. The effectiveness, safety, quality, and economy of different care settings have been questioned. This study compares patient outcomes of receiving DVA services in the freestanding office-based center (FOC) to those of the hospital outpatient department (HOPD). It also examines whether outcomes differ for a centrally managed system of FOCs (CMFOC) compared to all other FOCs (AOFOC).

Methods: Retrospective cohort study of clinically and demographically similar patients within Medicare claims available through United States Renal Data System (USRDS) (2010-2013) who received at least 80% of DVA services in an FOC (n = 80,831) or HOPD (n = 133,965). Separately, FOC population is divided into CMFOC (n = 20,802) and AOFOC (n = 80,267). Propensity matching was used to control for clinical, demographic, and functional characteristics across populations.

Results: FOC patients experienced significantly better outcomes, including lower annual mortality (14.6% vs. 17.2%, p<0.001) and DVA-related infections (0.16 vs. 0.20, p<0.001), fewer hospitalizations (1.65 vs. 1.91, p<0.001), and lower total per-member-per-month (PMPM) payments ($5042 vs. $5361, p<0.001) than HOPD patients. CMFOC patients had lower annual mortality (12.5% vs. 13.8%, p<0.001), PMPM payments (DVA services) ($1486 vs. $1533, p<0.001) and hospitalizations ($1752 vs. $1816, p<0.001) than AOFOC patients.

Conclusions: Where nephrologists send patients for DVA services can impact patient clinical and economic outcomes. This research confirmed that patients who received DVA care in the FOC had better outcomes than those treated in the HOPD. The organizational culture and clinical oversight of the CMFOC may result in more favorable outcomes than receiving care in AOFOC.

Keywords: Dialysis, Dialysis access, ESRD, Freestanding office-based center, Hospital outpatient department, USRDS

Introduction

Over the past two decades, significant changes in dialysis vascular access (DVA) have occurred. There has been a progressive change from primarily arteriovenous grafts (AVGs) to primarily arteriovenous fistulas (AVFs) (1, 2). There has also been an increasing number of endovascular procedures performed for DVA maintenance. The profile of these procedures has changed from approximately equal numbers of angioplasties and thrombectomies performed on AVG to primarily angioplasties performed on AVF (3). Site of service has also changed progressively toward the freestanding outpatient facility (FOC) dedicated to DVA from hospital outpatient departments (HOPD). In the FOC, fluoroscopically guided, endovascular treatments are being performed, utilizing sedation/analgesia in an outpatient environment primarily by interventional nephrologists. Questions arise about their effectiveness, safety, quality, and economy.

In a previous study (4), based on Medicare claims and United States Renal Data System (USRDS) data from 2006 to 2009, a large cohort of cases receiving DVA management care in an FOC was compared using propensity score matching with a cohort of cases managed in an HOPD. This study showed significantly better outcomes for the FOC setting, including fewer vascular access-related infections, fewer septicemia-related hospital admissions, and fewer related and unrelated hospital admissions than those who received care in a HOPD (p<0.001 for each metric). Furthermore, FOC cases had significantly lower mortality and lower per-member-per-month (PMPM) Medicare payments than HOPD cases.

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Corresponding author:
Joan E. DaVanzo
Dobson DaVanzo and Associates, LLC
450 Maple Avenue East, Suite 303
Vienna, VA 22180, USA
joan.davanzo@dobsondavanzo.com

Since the period covered by this report, medical practice as related to DVA has continued to evolve. AVF utilization in prevalent patients has continued to increase under the Centers for Medicare & Medicaid Services' (CMS') Fistula First Breakthrough Initiative designed to improve the AVF rate and reduce catheter use (5). The number of AVF maintenance procedures (3) has also increased. With an increasing percentage of AVF procedures has come an increased level of complexity. According to 2015 Medicare claims data, approximately one-third of these procedures take place in an FOC. In addition, the patient population has changed with a continuing increase in the percentage of elderly patients having a higher penetration of comorbidities (6, 7). There has also been the creation of larger bundles for dialysis services including drugs and other items previously billed in addition to the dialysis treatment and the beginning of the Medicare Meaningful Use incentives and the Physician Quality Reporting System (PQRS) (8).

It is not clear how these changes may have affected the comparison of FOC-based treatment versus that provided in the HOPD. The purpose of this study is to first replicate the previous analysis using more recent data reflecting current practice patterns and to determine if the changing profile of DVA has affected the site-of-service comparison. A secondary purpose is to determine if differences in the quality and economy of DVA services existed within the FOC group.

Methods

Study design and patient selection

This retrospective cohort study was based on Medicare claims and data from the USRDS for 2010-2013. USRDS database contains all health-care utilization and Medicare payment claims for end-stage renal disease (ESRD) patients, as well as select clinical information including ESRD-specific lab values, patient functional status, and comorbidities.

The study sample was drawn from all incident and prevalent ESRD patients with Medicare fee-for-service coverage between 2010 and 2013. A single episode of care that captured all DVA and dialysis-related services, and all related or unrelated hospitalizations during the whole study period was created for each patient. This included services across all settings, including inpatient and outpatient hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, long-term care hospitals, physicians, hospices, and durable medical equipment (Tab. I). An episode started with the first DVA-related service during the study period and ended either with patient death or the end of the study period.

Place of service (POS) was determined from CMS designations. Patients who did not receive at least 80% of their DVA maintenance and placement services in either a FOC (POS 11) or a hospital-associated outpatient environment, including HOPD (POS 22), emergency departments (POS 22), emergency departments (POS 23), dialysis centers (POS 65), and state/local public-health clinics (POS 71) were excluded. The study had two phases. In the first phase, the study population was divided into two cohorts: patients who received 80% or more of DVA services in an FOC, and patients who received 80% or more of DVA services in an HOPD.

TABLE I - Dialysis vascular access services included in analysis

Description	CPT codes (unless otherwise noted)
DVA placement services	
Creation of fistula	36821, 36818, 36819, 36820, 36825
Creation of graft	36830
Catheter placement	36558
DVA maintenance services	
Catheter exchange	36581
Catheter repair	36575, 36796
Thrombectomy	36870
Vein cannulation with contrast injection	36005
Ultrasound of vein and artery	93931, 93930, 93970, 93971
Vessel mapping	G0365
Catheter removal	36589
Arteriogram of extremity	75710
Stent placement	37205 & 75960
Arterial/venous angioplasty	35475 & 75962, 35476 & 75978
Cannulation of dialysis access with angiogram	36147
Venous angiogram	75791, 75825, 75827, 75898
Dialysis	
Dialysis	90935-90947, 90999
Hospitalizations	
Septicemia-related	MS-DRGs 870-872
ESRD-related	MS-DRGs: 316-317; ICD-9s: 585, 586
Unrelated	All other MS-DRGs

CPT = current procedural terminology; DVA = dialysis vascular access; ESRD = end-stage renal disease.

In the second phase of this study, a homogeneous subgroup of centrally managed FOCs (CMFOC) using standardized policies and practices was identified and compared to all other members of the FOC group (AOFOC) using propensity score matching. The attributes of the CMFOC include: (i) central oversight of the quality and utilization of its physicians through a single electronic health system; (ii) comparison of center and physician utilization rates with feedback provided at regular intervals; (iii) one-on-one patient education to identify risk factors for adverse events and ensure patient satisfaction; (iv) central training of clinical staff to reduce process variation in routine clinical scenarios; (v) accreditation to provide consistent quality, safety, and leadership; and (vi) review of complicated cases through a robust peer-review process.

A list of Medicare beneficiaries who received at least one DVA service in the CMFOC between 2010 and 2013 was used. URSDS cross-walked the Medicare beneficiary identifier to the USRDS encrypted patient identifier to allow the study team to identify CMFOC in the USRDS claims.

The study was Health Insurance Portability and Accountability Act compliant. As the study only consisted of medical claims data, without patient identifiers, the study was deemed to be research without human subjects. No formal institutional review board approval was required.

Outcome measurements

Three types of outcomes were compared over the four-year study period. The primary metrics were health indicators such as all-cause mortality rate (annually and across the study period), and the number of 21-day infection episodes due to dialysis vascular device, implant, or graft (ICD-9 996.62) and bloodstream infections due to central venous catheter (ICD-9 999.32). The 21-day metric ensured that infections that required, on average, 21-days to be treated, were not measured as multiple infection events. The second outcome included the average annual rate of DVA-related services provided per patient; rate of septicemia-related, ESRD-related, and unrelated hospitalizations; and dialysis treatments (expressed as a weekly rate). The third outcome was average PMPM Medicare payment including DVA-related care, inpatient hospitalizations, and dialysis treatments.

Statistical analysis

Propensity statistics were used to match cohorts based on a series of variables that directly impact the way in which patients receive DVA care. A propensity score for each patient was calculated to indicate the probability of a patient receiving care in the FOC (for FOC vs. HOPD) or of receiving care in the CMFOC (for CMFOC vs. AOFOC). This statistical method isolated the impact of site of service from other causal factors on all three types of outcomes. Propensity score matching techniques are widely used in observational studies when randomized controlled trials (RCTs) are not available or are unethical or impractical to administer (9). Literature suggests that applying this technique to observational studies is one approach for removing observable selection bias among treatment and comparison groups and can result in findings that mimic RCTs (10-13).

Metrics used in calculating the propensity score included patient demographics, clinical characteristics, and historical DVA-related and unrelated health-care utilization. Patient demographic characteristics included: age, gender, race, geographic region of the patient's residence, dual eligibility for Medicare and Medicaid, and smoking and alcohol or drug dependence. Clinical and functional characteristics included: comorbidities used to calculate CMS Hierarchical Condition Category (HCC) scores, history of kidney transplant, body mass index (BMI), and whether the patient was institutionalized and needs assistance with activities of daily living (ADLs). Historical DVA-related and unrelated health-care utilization included: years since first ESRD service, whether the patient first received placement or maintenance services within the study episode, whether the patient had a confirmed fistula or graft during the episode to ensure that outcomes were not due to a disproportionate use of catheters as the primary access type of a given setting, and whether the patient had a catheter as the sole dialysis access. All matching variables, except the confirmed access type, were defined and identified by USRDS.

Patients were matched using an algorithm that compares their propensity score to guarantee the closest match across groups. Matches were made in intervals of probability less than 0.2 standard deviations of estimates of the logit function that determined their propensity score, an approach consistent with the literature (14). Patients who were not able to be matched were excluded from the analysis.

Results

Between 2010 and 2013, 869,587 ESRD patients were identified in the USRDS database, representing the universe of patients for the study. After removing patients with fewer than 80% of their DVA services in FOC or HOPD, 154,322 FOC patients and 209,111 HOPD patients were considered for propensity score matching. Of the FOC population, 61,695 patients received at least one DVA-related service in the CMFOC, with the remaining population (123,226) representing AOFOC (Fig. 1). The propensity match yielded 80,831 FOC and 133,965 HOPD patients, and 20,802 CMFOC and 80,267 AOFOC patients.

FOC versus HOPD: patient characteristics

Following propensity score matching, patient demographics for FOC and HOPD were very similar (Tab. II). Both had an average age of 63 years, 45% female, 60% white, and 16% dually eligible for Medicare and Medicaid. The populations had the same proportion of incident ESRD patients (12%) as defined by the proportion of patients with an access placement as their first DVA service. There were no meaningful differences in the geographic distribution of patients. Despite matching, FOC patients were more likely to have had a transplant (5.0% vs. 4.3%, $p<0.01$), had lower BMI (29.46 vs. 29.57, $p<0.01$), had lymphatic, head, neck, brain or other major cancer (2.2% vs. 2.0%, $p<0.01$), and were less likely to have had congestive heart failure (31.2% vs. 31.7%, $p<0.01$) than HOPD patients. FOC patients were less likely to need assistance with ADLs (8.9% vs. 9.2%, $p<0.01$).

FOC versus HOPD: health indicators, utilization, and costs

Across all outcome measures, FOC patients had better outcomes than those treated in the HOPD (Tab. III). The annual mortality rate for FOC patients was 15.1% lower (14.6% vs. 17.2%, $p<0.001$) than HOPD patients and the overall mortality across the entire study period was 10.9% lower (37.5% vs. 42.1%, $p<0.001$).

FOC patients received, on average, fewer DVA-related services than HOPD patients. Patients treated in the FOC had fewer placement services, including fistula, graft, catheter, and catheter exchanges than HOPD patients ($p<0.001$). FOC patients received slightly more vessel mapping services (0.06 vs. 0.05, $p<0.001$). They also received significantly fewer dialysis treatments per week (2.91 vs. 2.99, $p<0.001$). This difference may have had greater economic significance (i.e., the overall cost of dialysis treatments) than clinical relevance since both groups essentially received three treatments per week.

FOC patients had fewer related and unrelated hospitalizations per patient per year than patients treated in the

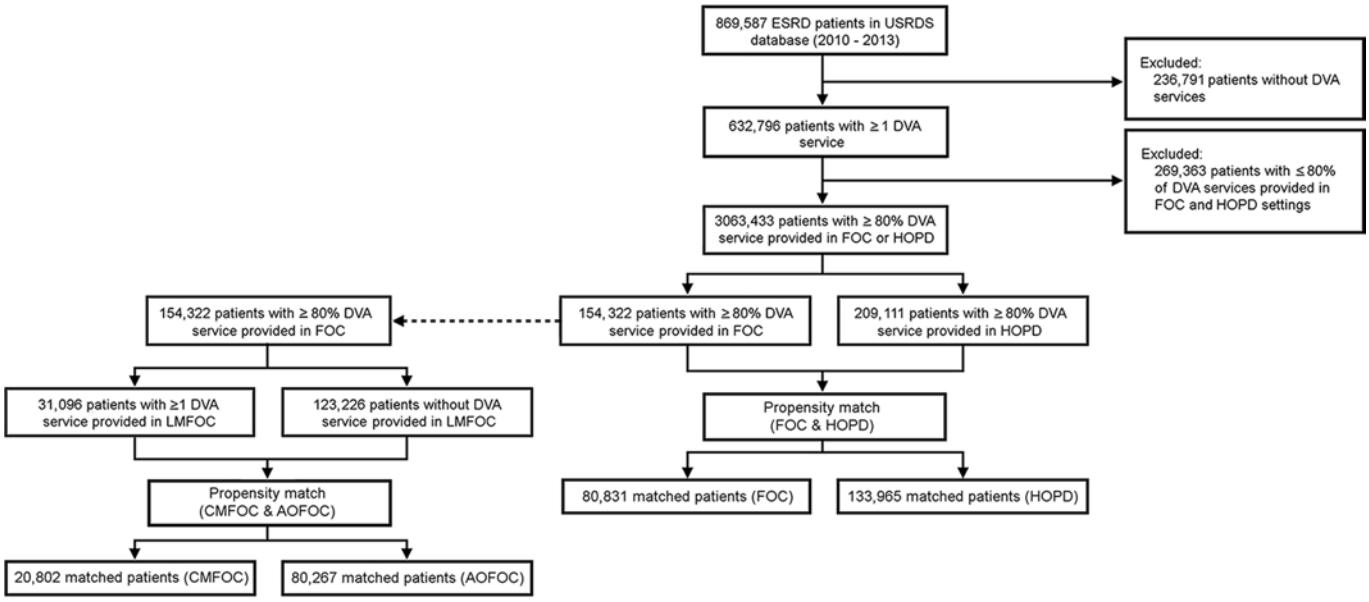

Fig. 1 - Study population. Flow diagram of patient selection.

HOPD. This difference was predominately driven by unrelated hospitalizations (1.56 vs. 1.81, p<0.001). However, FOC patients also had lower rates of septicemia-related hospitalizations (0.08 vs. 0.10, p<0.001).

Because of fewer total hospitalizations and dialysis treatments, matched FOC patients had an average total Medicare PMPM payment (including DVA services, hospitalizations, and dialysis treatments) that was $318 lower than HOPD patients ($5042.70 vs. $5360.97, p<0.001). This difference was primarily due to the differences in hospitalizations ($1958.35 vs. $2250.65, p<0.001) and dialysis ($1588.60 vs. $1613.67, p<0.001), as the cost of DVA services were similar.

CMFOC versus AOFOC: patient characteristics

The FOC population was subdivided and further analyzed to determine if there were significant differences between cases treated in a CMFOC and those treated in AOFOC. Following propensity score matching, CMFOC patients were demographically similar to AOFOC patients. Average age was 62 years, with 43% female, 56% white, and 15% dually eligible for Medicare and Medicaid. CMFOC patients had a higher kidney transplant rate (4.3% vs. 3.9%, p<0.05) and had ESRD for a longer period (3.26 vs. 3.24 years, p<0.01). There was no statistical difference in the rate of DVA placement as the first vascular access service between the two groups, nor in the geographic distribution of patients, their comorbidities, or the functional status (Tab. IV).

CMFOC versus AOFOC: health indicators, utilization, and costs

Compared to patients who received care in AOFOCs, CMFOC patients had comparable hospitalizations, and PMPM spending. However, they had a 9.4% lower annual mortality rate (12.5% vs. 13.8%, p<0.001) and 6.1% lower overall mortality (33.6% vs. 35.8%, p<0.001) (Tab. V). In addition, CMFOC patients were statistically more likely to have an infection (0.16 vs. 0.15, p<0.01).

There were statistically significant differences in the utilization of DVA services between these populations, but the clinical significance of these differences is questionable. CMFOC patients received fewer fistulas (0.09 vs. 0.10, p<0.001), but more catheter exchanges (0.14 vs. 0.09, p<0.001) than AOFOC patients. They also received fewer ultrasounds of veins and arteries (0.33 vs. 0.37, p<0.001) and vessel mapping services (0.06 vs. 0.05, p<0.001), neither of which the authors feel are clinically significant. CMFOC patients received more dialysis treatments per week (2.97 vs. 2.94, p<0.001); however, while this could have an economic impact, it is doubtful that it is of clinical significance.

CMFOC patients had lower PMPM payments for DVA services ($1485.82 vs. $1533.31, p<0.001) and hospitalizations ($1751.92 vs. $1816.47, p<0.001), which was largely due to the cost of unrelated hospitalizations. Higher dialysis treatments per week also resulted in higher dialysis PMPM payments for CMFOC patients ($1676.88 vs. $1574.44, p<0.001).

Discussion

Hemodialysis access has been referred to as the patient's lifeline; however, this access is not without problems. Over the study period, Medicare payments per patient increased disproportionately to the increase in the number of patients being treated (6, 7). A significant portion of this expenditure has been dedicated to the maintenance of dialysis access (treatment of access dysfunction). These services have been, and continue to be, provided in multiple medical settings. Questions arise as to whether there are significant differences in the quality and cost between different settings.

This study examined a large cohort of patients treated in an FOC matched to patients treated in an HOPD. The propensity

TABLE II - Patient characteristics of matched populations for variables included in propensity score matching: FOC versus HOPD

Patient characteristics	FOC (n = 80,831)	HOPD (n = 133,965)	Difference[a]
Age (y)	62.88	62.96	-0.08
Gender (% female)	45.3%	45.4%	-0.1%
Dual eligible	16.0%	16.2%	-0.2%
Geographic region			
New England	3.9%	3.9%	0.0%
Middle Atlantic	14.3%	14.3%	0.0%
East North Central	12.5%	12.6%	-0.1%
West North Central	4.3%	4.5%	-0.2%
South Atlantic	24.7%	24.3%	0.4%*
East South Central	7.3%	7.5%	-0.1%
West South Central	14.5%	14.5%	0.0%
Mountain	5.5%	5.3%	0.2%
Race			
White	60.7%	60.5%	0.2%
Black	33.5%	33.6%	-0.1%
Asian	4.2%	4.2%	-0.1%
Native American	1.3%	1.3%	0.0%
Historical DVA services			
Placement as first vascular access service	12.3%	12.6%	-0.2%
Fistula/graft access type	32.9%	33.4%	-0.5%*
Catheter, no history of fistula/graft	23.9%	24.6%	-0.7%◊
Time since first ESRD service (y)	3.24	3.21	0.03†
History of transplant	5.0%	4.3%	0.7%†
Years since last transplant (y)	9.51	10.02	-0.51†
Comorbidities			
Body mass index	29.46	29.57	-0.10◊
Metastatic cancer and acute leukemia	0.9%	0.9%	0.0%
Lung, upper GI, and other severe cancers	1.0%	1.0%	0.0%
Lymphatic, head and neck, brain, and other major cancers	2.2%	2.0%	0.1%◊
Breast, prostate, colorectal and other cancers and tumors	5.1%	5.1%	0.0%
Diabetes without complication	52.3%	52.4%	-0.1%
Diabetes with renal or peripheral circulatory manifestation	34.4%	34.7%	-0.3%
Diabetes with neurologic or other specified manifestation	14.4%	14.5%	-0.1%
Congestive heart failure	31.2%	31.7%	-0.5%◊
Acute myocardial infarction	2.5%	2.6%	0.0%
Vascular disease	22.7%	23.0%	-0.3%
Chronic obstructive pulmonary disease	14.5%	14.7%	-0.2%
Chronic ulcer of skin, except decubitus	7.3%	7.4%	-0.1%
Specified heart arrhythmias	15.1%	15.2%	-0.1%
Functional status/independence			
Institutionalized	5.8%	5.9%	-0.1%
Institutionalized - assisted living	0.5%	0.5%	0.0%
Institutionalized - nursing home	4.9%	5.1%	-0.1%
Institutionalized - other institution	0.4%	0.4%	0.0%
Needs assistance with daily activities	8.9%	9.2%	-0.3%◊

† Statistically significant at p<0.001.
◊ Statistically significant at p<0.01.
* Statistically significant at p<0.05.
[a] Difference represents the percentage point difference of FOC minus HOPD.
FOC = freestanding office; HOPD = hospital outpatient department; DVA = dialysis vascular access; ESRD = end-stage renal disease; GI = gastrointestinal.

TABLE III - Distribution of outcomes by matched population: FOC versus HOPD

Outcome measures	FOC (n = 80,831)	HOPD (n = 133,965)	Difference[a]
Health indicator			
Mortality during episode	37.5%	42.1%	-4.6%[†]
Mortality per year	14.6%	17.2%	-2.6%[†]
21-day infection episodes per year (count)	0.16	0.20	-0.04[†]
Vascular access related services (count) (per year, unless otherwise noted)			
Fistula	0.11	0.14	-0.03[†]
Graft	0.05	0.06	-0.01[†]
Catheter placement	0.35	0.44	-0.09[†]
Catheter exchange	0.10	0.11	-0.01[†]
Ultrasound of vein and artery	0.41	0.49	-0.09[†]
Vessel mapping	0.06	0.05	0.01[†]
Catheter removal	0.22	0.23	-0.01[†]
Thrombectomy	0.00	0.00	0.00
Dialysis (per week)	2.91	2.99	-0.08[†]
Inpatient admissions per year			
All inpatient admissions	1.65	1.91	-0.26[†]
Vascular-related	0.00	0.00	0.00
Septicemia-related	0.08	0.10	-0.01[†]
Unrelated	1.56	1.81	-0.25[†]
PMPM cost			
Total PMPM	$5042.70	$5360.97	-$318.27[†]
DVA	$1495.75	$1496.65	-$0.90
Inpatient admissions	$1958.35	$2250.65	-$292.30[†]
Vascular related inpatient	$0.05	$0.11	-$0.06
Septicemia-related inpatient	$109.08	$123.44	-$14.36[†]
Unrelated inpatient	$1849.21	$2127.10	-$277.89[†]
Dialysis	$1588.60	$1613.67	-$25.07[†]

[†] Statistically significant at p<0.001.
[a] Difference represents the percentage point difference of FOC minus HOPD.
FOC = freestanding office; HOPD = hospital outpatient department; DVA = dialysis vascular access; PMPM = per-member-per-month.

score model controls for selection bias across different sites of service by matching on observable clinical and demographic characteristics, making the cohorts essentially "twin-like" (Tabs. III, V). There are a few metrics where statistically significant differences were noted. These were not issues that would affect DVA and were not felt by the authors to be clinically significant. Literature indicates that applying this matching technique to an observational study can result in findings that closely correlate with those from an RCT (10-13).

The results from the comparison of FOC-treated to HOPD-treated patients confirmed the findings of our previous report based on 2006 to 2009 data (4). Patients who received DVA care in an FOC had significantly better outcomes, including lower all-cause mortality, fewer infections, and fewer septicemia-related and unrelated hospitalizations than those treated in the HOPD. In addition, patients treated in the FOC had lower average total PMPM payments including DVA services, dialysis, and hospitalizations than patients treated in an HOPD.

Facilities that identify as FOCs represent a heterogeneous group. They vary in size, organization, practice pattern, and staffing. Physicians working in these facilities vary by medical specialty, and degree and type of training in DVA maintenance procedures. The CMFOC group was studied to determine if significant differences existed within the FOC. CMFOC was selected because it represented a homogeneous group characterized by having a uniform system of peer review, an organized program for quality improvement and utilization, a formal accredited training program for clinical staff and operator physicians utilizing a standardized curriculum, and an organized program for DVA education of individual patients and supported dialysis clinics.

Comparison of outcomes for the CMFOC and AOFOC cohorts identified a 9.4% lower annual mortality rate and a 6.1% lower overall mortality in the CMFOC cohort. Other statistically significant differences were felt to not be of clinical significance. CMFOC demonstrated an economic advantage in the DVA-service category and for overall hospitalizations.

TABLE IV - Patient characteristics of matched population for variables included in propensity score matching: CMFOC versus AOFOC

Patient characteristics	CMFOC (n = 20,802)	AOFOC (n = 80,267)	Difference[a]
Age (y)	62.23	62.36	-0.14
Gender (% female)	42.5%	42.8%	-0.2%
Dual eligible	14.7%	14.9%	-0.2%
Geographic region			
New England	0.2%	0.2%	0.0%
Middle Atlantic	10.6%	10.9%	-0.4%
East North Central	12.6%	12.5%	0.1%
West North Central	3.6%	3.5%	0.1%
South Atlantic	27.2%	27.4%	-0.3%
East South Central	7.3%	7.4%	0.0%
West South Central	16.3%	16.2%	0.1%
Mountain	6.4%	6.4%	0.0%
Race			
White	56.5%	56.3%	0.2%
Black	38.1%	38.3%	-0.3%
Asian	4.5%	4.4%	0.1%
Native American	0.7%	0.7%	-0.1%
Historical DVA services			
Placement as first vascular access service	10.4%	10.7%	-0.3%
Fistula/graft access type	27.4%	28.0%	-0.6%
Catheter, no history of fistula/graft	21.7%	22.5%	-0.8%◊
Time since first ESRD service (y)	3.26	3.24	0.02◊
History of transplant	4.3%	3.9%	0.3%*
Years since last transplant (y)	10.26	10.21	0.05
Comorbidities			
Body mass index	29.45	29.41	0.04
Metastatic cancer and acute leukemia	0.7%	0.7%	0.0%
Lung, upper GI, and other severe cancers	0.8%	0.8%	0.0%
Lymphatic, head and neck, brain, and other major cancers	1.8%	1.8%	0.1%
Breast, prostate, colorectal and other cancers and tumors	4.9%	4.8%	0.1%
Diabetes without complication	51.4%	51.5%	-0.1%
Diabetes with renal or peripheral circulatory manifestation	34.3%	35.0%	-0.7%
Diabetes with neurologic or other specified manifestation	13.6%	13.7%	0.0%
Congestive heart failure	28.2%	28.5%	-0.3%
Acute myocardial infarction	2.2%	2.2%	0.0%
Vascular disease	21.5%	21.5%	0.0%
Chronic obstructive pulmonary disease	12.4%	12.5%	-0.1%
Chronic ulcer of skin, except decubitus	6.2%	6.4%	-0.2%
Specified heart arrhythmias	12.8%	12.8%	0.0%
Functional status/independence			
Institutionalized	4.6%	4.8%	-0.1%
Institutionalized - assisted living	0.4%	0.4%	0.0%
Institutionalized - nursing home	3.9%	4.1%	-0.1%
Institutionalized - other institution	0.3%	0.3%	0.0%
Needs assistance with daily activities	7.6%	7.8%	-0.3%

◊ Statistically significant at p<0.01.
* Statistically significant at p<0.05.
[a] Difference represents the percentage point difference of CMFOC minus AOFOC.
CMFOC = centrally managed freestanding office; AOFOC = all other FOCs; DVA = dialysis vascular access; ESRD = end-stage renal disease; GI = gastrointestinal.

TABLE V - Distribution of outcomes by matched population: CMFOC versus AOFOC

Outcome measures	CMFOC (n = 20,802)	AOFOC (n = 80,267)	Difference[a]
Health indicator			
Mortality during episode (%)	33.6%	35.8%	-2.1%[†]
Mortality per year (%)	12.5%	13.8%	-1.3%[†]
21-day infection episodes per year (count)	0.16	0.15	0.01[◊]
Vascular access related services (count) (per year, unless otherwise noted)			
Fistula	0.09	0.10	-0.01[†]
Graft	0.05	0.04	0.00
Catheter placement	0.31	0.31	0.00
Catheter exchange	0.14	0.09	0.05[†]
Ultrasound of vein and artery	0.33	0.37	-0.04[†]
Vessel mapping	0.06	0.05	0.01[†]
Catheter removal	0.20	0.20	0.00
Thrombectomy	0.00	0.00	0.00
Dialysis (per week)	2.97	2.94	0.03[†]
Inpatient admissions per year			
All inpatient admissions	1.53	1.55	-0.01
Vascular-related	0.00	0.00	0.00
Septicemia-related	0.07	0.08	0.00
Unrelated	1.46	1.47	-0.01
PMPM cost			
Total PMPM	$4914.62	$4924.22	-$8.69
DVA	$1485.82	$1533.31	-$47.49[†]
Inpatient admissions	$1751.92	$1816.47	-$64.55[†]
Vascular-related inpatient	$0.03	$0.05	-$0.02
Septicemia-related inpatient	$93.99	$99.51	-$5.52
Unrelated inpatient	$1657.90	$1716.91	-$59.01[◊]
Dialysis	$1676.88	$1574.44	$102.44[†]

[†] Statistically significant at p<0.001.
[◊] Statistically significant at p<0.01.
[a] Difference represents the percentage point difference of CMFOC minus AOFOC.
CMFOC = centrally managed freestanding office; AOFOC = all other FOCs; DVA = dialysis vascular access; PMPM = per-member-per-month.

However, differences in PMPM payments for hospitalizations were primarily due to unrelated conditions. CMFOC patients had higher PMPM payments for dialysis than AOFOC patients, as expected due to receiving significantly more dialysis treatments per week.

An explanation for the superiority of CMFOC's mortality rate is not readily apparent; however, it is characterized by its organization as a homogeneous, centrally managed group of facilities with standardized practices and policies. The culture of medical organizations has been shown to be important in the care of chronic illnesses (15). Organizational cultures that emphasize group affiliation, teamwork, and coordination have been associated with greater implementation of quality improvement practices (16), adoption of group practice guidelines (17), and enhancement of the delivery of patient-centered medical care (18).

A major strength of this study is the large number of patients included. In addition, the methodology allows for rigorous matching of patient cohorts across settings to ensure that comparisons are being made on clinically and demographically similar populations. There are, however, limitations to this approach. First, the study was limited to Medicare claims and USRDS data. The use of medical records would have increased the ability to identify DVA-related outcomes with greater specificity. Second, a reliance on administrative claims over a fixed period precludes examining the patients' health-care utilization prior to the study period. Therefore, prior complications or historical utilization could not be included in the propensity score model. Third, while a characterization of the facilities comprising the CMFOC subgroup was possible, such a characterization was not possible for those facilities in the AOFOC group.

Conclusion

Management of DVA dysfunction is an important part of medical care required by the hemodialysis patient. The site

at which these DVA-services are provided has a direct impact on patient clinical and economic outcomes. Patients receiving care in an FOC have lower all-cause mortality, fewer infections, and fewer septicemia-related and unrelated hospitalizations than those treated in the HOPD. This improved quality of care is also more economically favorable. Within the FOC facilities, a homogeneous subgroup of centrally managed facilities has a lower annual and overall mortality rate when compared to all other FOCs.

Disclosures

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Attachment D

North Carolina Diabetes Fact Sheet

North Carolina Diabetes Advisory Council

DiabetesManagementNC.com

TYPE 2 DIABETES IN NORTH CAROLINA

Fact Sheet

What is diabetes?

- Diabetes is marked by high levels of blood glucose (sugar) resulting from defects in the production or action of insulin, a hormone that regulates blood glucose levels.
- People with diabetes, working together with their support network and health care team, can take steps to control the disease and lower their risk of serious complications and premature death.
- Type 2 diabetes accounts for about 90% to 95% of all diagnosed cases of diabetes.[1]

How many people have diabetes?

- Diabetes is the seventh leading cause of death in both the United States and North Carolina.[1,2] In 2018, diabetes was the primary cause for 3,021 deaths (3.2% of all deaths) and a contributing cause to many more deaths in North Carolina.[2]
- An estimated 30.3 million people in the United States have diabetes, and of these, about a quarter (7.2 million people) are unaware.[1] In North Carolina, about 1 million (12.5%) adults report having been diagnosed with diabetes.[3]
- In 2018, diabetes was listed as the primary diagnosis for 23,713 hospital discharges in North Carolina.[4]
- The North Carolina Medicaid program spent over $655 million on 164,757 beneficiaries who have diabetes in 2018.[5] That's about $3,978 per beneficiary with diabetes.
- Over 50,000 adults are newly diagnosed in North Carolina with diabetes each year.[6]

1 out of 10 adults in North Carolina is diagnosed with diabetes.

For every 10 people diagnosed with diabetes, only 5 have taken a class to manage their diabetes. (NC BRFSS, 2017)

What are the risk factors for type 2 diabetes?

- The risk factors include: older age (45 years and older), a family history of type 2 diabetes (parent, brother or sister) and race/ethnicity (African-Americans, Hispanics and other minority groups), overweight/obesity, physical inactivity, high cholesterol, high blood pressure and smoking.
- Additional risk factors specific to women include: gestational diabetes (abnormal blood sugar during pregnancy), giving birth to a baby who weighed more than 9 pounds and having a history of polycystic ovary syndrome (a common condition characterized by irregular menstrual periods, excess hair growth and obesity).

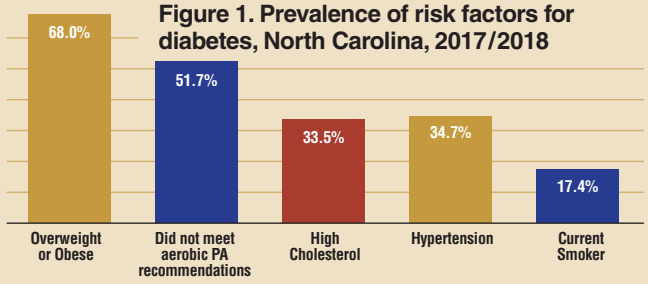


Figure 1. Prevalence of risk factors for diabetes, North Carolina, 2017/2018

Data Source: North Carolina State Center for Health Statistics. Behavioral Risk Factor Surveillance System (BRFSS). www.schs.state.nc.us/data/brfss/survey.htm

How is diabetes diagnosed?

- Fasting blood glucose, oral glucose tolerance test and HbA1c are blood tests used to diagnose diabetes as shown in Table 1.
- In North Carolina, only three out of five adults (60.5%) without a known diagnosis of diabetes have had a blood sugar test within the past three years.[7]

What are the complications of type 2 diabetes?

- Diabetes affects multiple areas of the body and can lead to serious complications including: heart disease and stroke, hypertension, hearing loss, blindness and other eye problems, kidney disease, nerve damage (e.g., impaired sensation or pain in the feet or hands, slow digestion of food in the stomach, erectile dysfunction), amputations (mainly of the lower limbs), dental disease (especially of the gums), excessively large babies, diabetic coma, increased susceptibility to pneumonia and influenza, and depression.

How is type 2 diabetes managed?

- Many people with type 2 diabetes can control their blood glucose by following a healthy meal plan and exercise program, losing excess weight, taking oral medication and/or, in some cases, insulin.
- Preventing complications, especially heart disease, is a key component of diabetes management. The **ABC**s of diabetes management include optimal blood glucose, blood pressure and cholesterol targets.
  - **A.** A1c less than 7.0%
  - **B.** Blood pressure less than 140/90 mmHg
  - **C.** Cholesterol-LDL less than 100 mg/dl
- Many people with diabetes also need to take medications to control their cholesterol and blood pressure.

Table 1: Diagnostic criteria for diabetes

Test	Normal	Prediabetes	Diabetes
Fasting Blood Glucose (FBG)	less than 100 mg/dl	100 to 125 mg/dl	126 mg/dl or higher
Oral Glucose Tolerance Test (OGTT)	less than 140 mg/dl	140 to 199 mg/dl	200 mg/dl or higher
HbA1c	less than 5.7%	5.7% to 6.4%	6.5% or higher

Source: American Diabetes Association, Diagnosing Diabetes and Learning About Prediabetes. diabetes.org/diabetes-basics/diagnosis

- The American Diabetes Association recommends that all people with diabetes participate in Diabetes Self-Management Eduction and Support (DSMES)—training that focuses on self-care behaviors such as healthy eating, being active and monitoring blood sugar. DSMES is a key step in improving health outcomes and quality of life for people with diabetes.
  - —People with diabetes should receive DSMES when their diabetes is diagnosed and as needed thereafter.
  - —To obtain information about DSMES programs in North Carolina, visit DiabetesManagementNC.com.

How can complications of type 2 diabetes be prevented?

- Adherence to the ABCs of diabetes control—optimal control of blood glucose, blood pressure and blood cholesterol.
- Detection and treatment of diabetes related eye disease.
- Comprehensive foot care including risk assessment, education, preventive therapy, treatment of foot problems and referral to specialists.
- Detection and treatment of early diabetes related kidney disease.
- Vaccination against the flu and pneumonia.

How can type 2 diabetes be prevented?

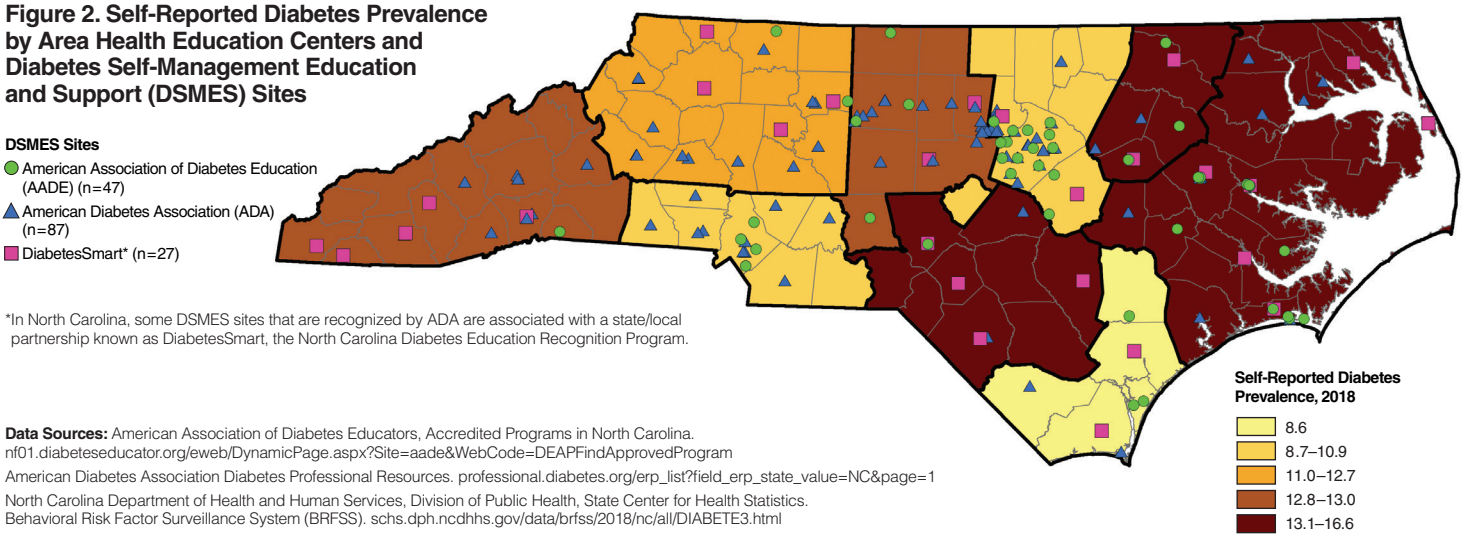
For individuals who do not have a diagnosis of diabetes, prevention can be achieved by addressing modifiable risk factors:

- Losing a modest amount of weight (5% to 7% of total body weight) through healthy eating and moderate physical activity, with the help of a lifestyle change program, such as the CDC-recognized National Diabetes Prevention Program, has been proven to be the most effective way of delaying or preventing progression from prediabetes to type 2 diabetes.[8]
  - —For more information, visit DiabetesFreeNC.com or call the North Carolina Diabetes Prevention Program Navigator at 844-328-0021.
- Metformin, a drug used to control blood sugar, has also been shown to be somewhat effective in delaying or preventing progression from prediabetes to type 2 diabetes, but it is not as effective as lifestyle change.[8]
- Preventing and/or controlling high cholesterol and high blood pressure through lifestyle modification and medications if necessary.
- Avoiding tobacco products and secondhand smoke for non-smokers and quitting for current smokers. For general information about smoking and how to get help quitting please visit quitlinenc.com or call 1-800-QUIT-NOW.

What are the disparities, inequalities and inequities in the burden of diabetes?

- Non-Hispanic African-Americans (prevalence = 15.9%) are more likely to have been diagnosed with diabetes compared to Non-Hispanic Whites (prevalence = 12.2%) in North Carolina.[3]
- Diabetes is the seventh leading cause of death among Whites, the fifth leading cause of death for American Indians and the fourth leading cause of death for African-Americans in North Carolina.[9]
- African-Americans (age-adjusted death rate = 43.2 per 100,000) as well as American Indians and Alaska Natives (age-adjusted death rate = 30.9 per 100,000) are more likely to die from diabetes compared to Whites (age-adjusted death rate = 19.4 per 100,000) in North Carolina.[10]
- Type 2 diabetes in children and adolescents is being diagnosed more frequently among U.S. minority populations than in non-Hispanic Whites.[1]
- There is geographic variation in the burden of diabetes (prevalence, mortality rates and hospitalization rates). Figure 2 shows the prevalence of diabetes throughout North Carolina.

Figure 2. Self-Reported Diabetes Prevalence by Area Health Education Centers and Diabetes Self-Management Education and Support (DSMES) Sites



*In North Carolina, some DSMES sites that are recognized by ADA are associated with a state/local partnership known as DiabetesSmart, the North Carolina Diabetes Education Recognition Program.

Data Sources: American Association of Diabetes Educators, Accredited Programs in North Carolina. nf01.diabeteseducator.org/eweb/DynamicPage.aspx?Site=aade&WebCode=DEAPFindApprovedProgram

American Diabetes Association Diabetes Professional Resources. professional.diabetes.org/erp_list?field_erp_state_value=NC&page=1

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Attachment E

Medicare CMS Data on Vascular Centers

Beneficiary Status of Patients in Dialys Facilities Per CMS ESRD Medicare dataset

Retrieved From: https://data.cms.gov/quality-of-care/medicare-dialysis-facilities

Retrieved From: 41.01 Patient Demographic Report 7-19-23

Date Accessed: 07.13.23

Incident Patients - Medicaid (2021-2023)				
Location	Description	Total Patients	Percent	Year
Carolina Vascular Care	Incident Patients - Percent with Medicaid coverage only, 2023	36	6.4	2023
NC	S (2728): Incident Patients - Percent with Medicaid coverage only, 2021		9.88	2021
US	US (2728): Incident Patients - Percent with Medicaid coverage only, 2021		13.49	2021

Incident Patients - Medicare (2021-2023)				
Location	Description	Total Patients	Percent	Year
Carolina Vascular Care	Incident Patients - Percent with Medicare coverage only, 2023	124	29.76	2023
Carolina Vascular Care	Incident Patients - Percent with Medicare and other coverage, 2023	47	8.15	2023
NC	S (2728): Incident Patients - Percent with Medicare coverage only, 2021		45.55	2021
NC	S (2728): Incident Patients - Percent with Medicare and other coverage, 2021		10.38	2021
US	US (2728): Incident Patients - Percent with Medicare coverage only, 2021		46.1	2021
US	US (2728): Incident Patients - Percent with Medicare and other coverage, 2021		8.37	2021

Incident Patients - Medicare and Medicaid (2021-2023)				
Location	Description	Total Patients	Percent	Year
Carolina Vascular Care	Incident Patients - Percent with Medicare and Medicaid coverage only, 2023	243	42.39	2023
NC	S (2728): Incident Patients - Percent with Medicare and Medicaid coverage only, 2021		7.62	2021
US	US (2728): Incident Patients - Percent with Medicare and Medicaid coverage only, 2021		7.49	2021

Attachment F

Medicaid Cost Saving Calculations

Estimated HSA VI Medicaid Cost Savings: ASC Versus Hospital Outpatient Department

Total Dialysis Patients in HSA VI (2022)	3646

Profile of Carolina Vascular Care ESRD Patients by Payor	
% Dual Eligible (Medicare and Medicaid)	42.39%
% Direct Medicaid Only	6.40%
% Direct Medicare Only	29.76%
% Self Pay	0.52%
% Commercial	20.93%
Total	100.00%

Source: Carolina Vascular, similar to CMS North Carolina estimate

Profile of Carolina Vascular Care Vascular Access Patients by CPT code

CPT Code	% of Procedures
36901	2.89%
36902	55.35%
36903	21.26%
36904	0%
36905	11.57%
36906	8.93%

Carolina Vascular Care data

Copayment for Medicare Outpatient	20%
Percentage of copayment covered by NC Medicaid Plan	
Hospital	100%
ASC	0%

Total Medicaid Savings	**$ 5,017,641**

= Sum of all CPT savings

NC Medicaid Payment Estimates and Net ASC Savings by CPT Code (2022)

CPT 36901

		HOPD	ASC
	Total Dual Eligibile Dialysis Patients	105	105
	Medicare Cost per Procedure	$ 1,323	$ 599
20%	Copayment	264.6	0
	Procedures per patient per year	2	2
	Percent Dual	42%	42%
	Percent Direct Medicaid	6%	6%
	Savings for Duals	$ 23,637	$ -
	Savings for Direct Medicaid	$ 8,922	$ 4,039
	Total	$ 32,559	$ 4,039
		Difference:	**$ 28,520**

CPT 36902

		HOPD	ASC
	Total Dual Eligibile Dialysis Patients	2018	2018
	Medicare Cost per Procedure	$ 4,361	$ 2,050
20%	Copayment	872.2	0
	Procedures per year	2	2
	Percent Dual	42%	42%
	Percent Direct Medicaid	6%	6%
	Savings for Duals	$ 1,492,258	$ -
	Savings for Direct Medicaid	$ 563,249	$ 264,770
	Total	$ 2,055,506	$ 264,770
		Difference:	**$ 1,790,737**

Estimated HSA VI Medicaid Cost Savings: ASC Versus Hospital Outpatient Department

CPT 36903

		HOPD	ASC
	Total Dual Eligibile Dialysis Patients	775	775
	Medicare Cost per Procedure	$ 9,263	$ 5,716
20%	Copayment	1852.6	0
	Procedures per year	2	2
	Percent Dual	42%	42%
	Percent Direct Medicaid	6%	6%
	Savings for Duals	$ 1,217,461	$ -
	Savings for Direct Medicaid	$ 459,528	$ 283,565
	Total	$ 1,676,988	$ 283,565
		Difference:	**$ 1,393,424**

CPT 36904

no data

CPT 36905

		HOPD	ASC
	Total Dual Eligibile Dialysis Patients	422	422
	Medicare Cost per Procedure	$ 9,364	$ 5,074
20%	Copayment	1872.8	0
	Procedures per year	2	2
	Percent Dual	42%	42%
	Percent Direct Medicaid	6%	6%
	Savings for Duals	$ 669,784	$ -
	Savings for Direct Medicaid	$ 252,808	$ 136,987
	Total	$ 922,592	$ 136,987
		Difference:	**$ 785,605**

Estimated HSA VI Medicaid Cost Savings: ASC Versus Hospital Outpatient Department

CPT 36906

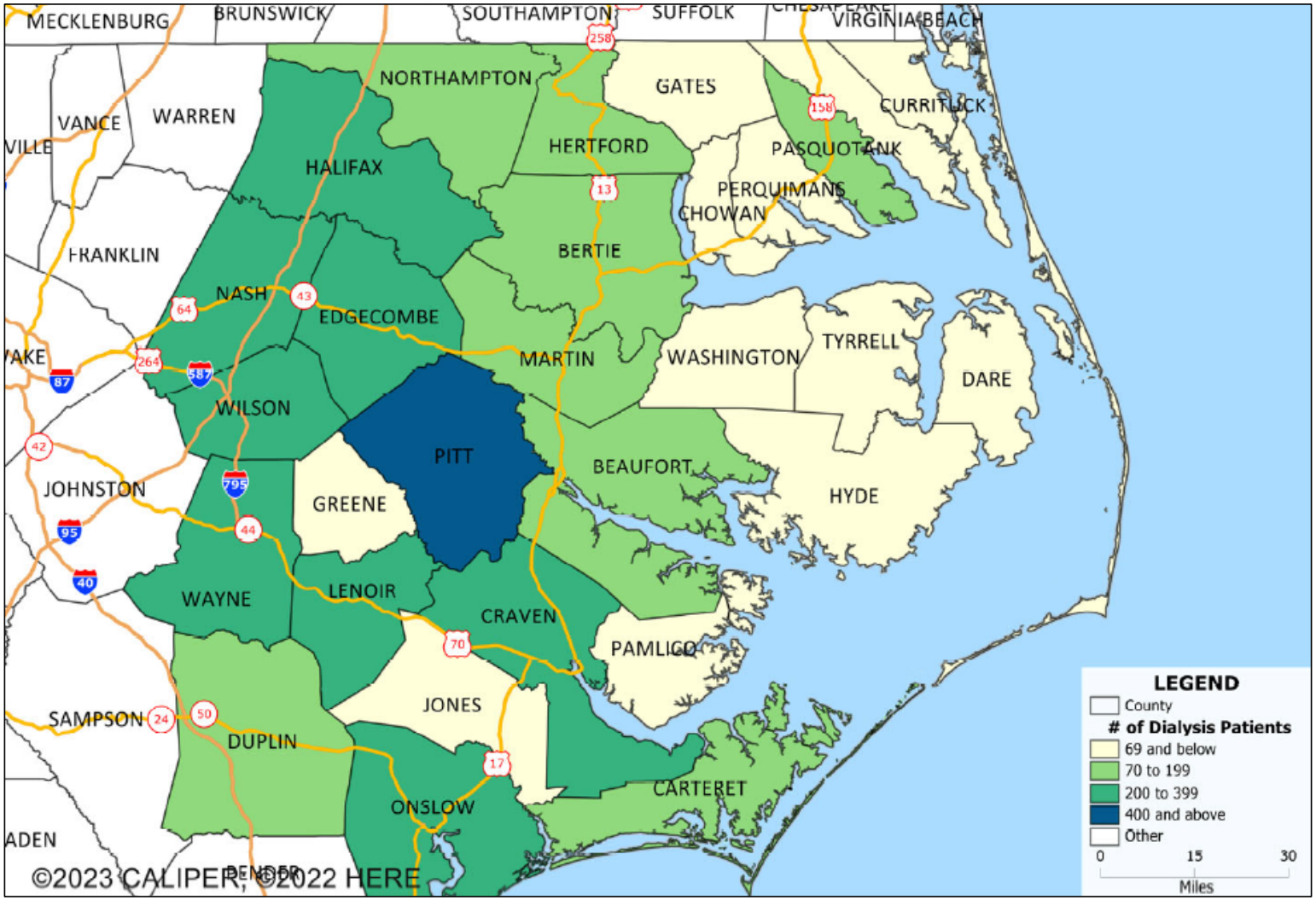
		HOPD	ASC
	Total Dual Eligibile Dialysis Patients	326	326
	Medicare Cost per Procedure	$ 15,980	$ 9,398
20%	Copayment	3196	0
	Procedures per year	2	2
	Percent Dual	42%	42%
	Percent Direct Medicaid	6%	6%
	Savings for Duals	$ 882,203	$ -
	Savings for Direct Medicaid	$ 332,985	$ 195,832
	Total	$ 1,215,188	$ 195,832
		Difference:	**$ 1,019,356**

Total Saved **$ 5,017,641**

Attachment G

Dialysis Patient Population Map of HSA VI

Number of Dialysis Patients in HSA VI



Attachment H

Speeches, Dr. Karn Gupta

July 10, 2023 and July 12, 2023

Presentation of Special Needs Petition for

Two Specialty Vascular Access Operating Rooms in HSA VI,

Proposed 2024 State Medical Facilities Plan

Raleigh, July 10, 2023

Presented by: Karn Gupta, MD, Carolina Vascular Care

Introduction

Hello, my name is Dr. Karn Gupta. I am a physician at Carolina Vascular Care, an independent vascular access medical practice. I am here to ask members of the State Health Coordinating Council to modify the Proposed *2024 State Medical Facilities Plan* (2024 SMFP) to include a special need for the addition of two operating rooms limited to an ambulatory surgery facility for outpatient vascular access procedures in HSA VI, making a total possibility of three such facilities in the Health Service Area ("HSA"). This would be a modification to Chapter 6, Table 6D of the *SMFP*, addressing HSA VI.

I would first like to thank the Agency for considering the vascular access issues and previously adjusting the 2023 State Medical Facilities Plan to include operating rooms restricted to vascular access procedures.

Background

In the United States, one in seven adults suffers from chronic kidney disease. This can eventually lead to End Stage Renal Disease (or "ESRD") needing dialysis. ESRD patients get dialysis via a specialized connection, or shunt, between an artery and a vein called an AV access. These AV accesses are not natural to the human body and therefore the body tries to slow or close them down by forming scar tissue inside the blood vessels which leads to AV access dysfunction. These AV accesses are the lifeline of dialysis patients, without which they cannot survive. Any dysfunction of the AV access leads to missed dialysis which is life threatening if not treated in time. Given the immediate need to treat such dysfunction, these AV accesses are

treated at specialized outpatient Vascular Access Centers who can provide quick, timely and cost-effective care. An average dialysis patient needs these “maintenance procedures” about 2-4 times a year to stay alive.

Current Situation

Last year, you generously granted one vascular access operating room to each of the state’s six HSAs. Though helpful, it is not enough for HSA VI. You may recall that the Agency report concluded that the state needs 15 operating rooms to address the needs of vascular access patients. The SHCC awarded 6, one for each HSA, thinking that office-based procedure centers (OBLs), hospitals or one of the two already approved vascular access surgery centers – in Charlotte and Raleigh – could meet the rest of the need. However good, that solution did not address the distribution of need compared to resources available. Moreover, this approach forces patients to seek care in the hospitals which in turn leads to unnecessary hospitalizations and high cost to Medicare, Medicaid as well as higher out of pocket costs to the patient.

For several decades, outpatient office-based centers (“OBLs”) have provided these timely, cost efficient, and safe vascular access procedures to dialysis patients. Most of them are on Medicare. Unfortunately, starting in 2017, Medicare began significantly cutting payments to office-based centers which was as much as about 40% reduction in the first year (2017). These office-based procedure payments were further reduced over the years including another 8% cut in 2023. These Medicare payment cuts are slated to continue for the next 3 years as per Medicare’s budget neutrality policy. These payment cuts have led to closure of a significant number of OBLs across the country. Most that have remained open did so by converting to ambulatory surgery centers. Due to these ongoing cuts along with higher labor and supply costs, operating an OBL is becoming unsustainable. The current reimbursement rates will not continue to offset the inherent high-cost structure of providing these services. However, Medicare’s reimbursement rules do support performance of these procedures in an Ambulatory Surgery Center (or ASC).

Last fall, I opened an OBL in Rocky Mount to provide the long needed and critical vascular access care to ESRD patients in and around Nash County. Our center is already on track to perform over 1700 vascular access procedures this year. I may be able to make it work today, but I cannot keep it open unless I, too, can convert to an ASC. You may be thinking there is an easy solution available to me: apply for the one HSA VI vascular access operating room. Unfortunately, there are three OBLs in HSA VI that have the same problem. So, we will end up competing with one another. Whoever does not get it would be at high risk of closing down their center, making the vascular access situation even worse in the already limited care available in HSA VI. Moreover, the HSA VI CON applications are not available until the November batch. By the time that CON Batch decision occurs, the SHCC will have finished work on the 2024 SMFP and it will be 2025 before you could tackle the problem, and 2026 before anyone can start construction. That will be too late.

Reasons

Dialysis patients in this eastern part of the state actually need three dedicated vascular access outpatient surgery centers. I am asking for two more because of its unique requirements in HSA VI.

Access

- The dialysis population is not proportionally divided across the 6 North Carolina HSA's. HSA VI has the most dialysis patients of the six HSA's – 3,646 – almost 20% of North Carolina's total dialysis patients.
- Based on the SMFP operating room methodology, in 2023, HSA VI patients need at least three ASC vascular access operating rooms.

Growth

- The HSA VI ESRD population is steadily growing, increasing by 1.7% each of the past five years.

Travel / Location

- HSA VI has the largest land mass. At 13,709 square miles, it has 28% of North Carolina's land area, making it the largest HSA by about 3,000 square miles. It takes about three to four hours to traverse the area.
- The March 2023 CON statute change for urban ASCs will not help. It applies only to counties with more than 125,000 residents. Unfortunately, only two of the 29 HSA VI counties would qualify, and they are concentrated on the eastern side of the HSA.

Higher Amount of At-Risk Patients

- HSA VI has a high percentage of genetically at-risk residents. African American, Hispanic, and Native Americans account for about 32% of HSA VI, almost 440,000 people.
- Diabetes is the number one cause of kidney disease. In 2018 on the BRFSS survey, 28 of the 29 counties self-reported between 13% and 17% having diabetes. The state average is 10%.

Value / Cost Efficient:

- Vascular access services in HSA VI are at risk. Today, three OBLs provide services with relatively good geographic coverage. This level of care cannot be maintained without becoming ambulatory surgery centers. Patients will be forced to seek care in emergency rooms and alternative, more expensive solutions.
- Neither of the two multispecialty ASCs in HSA VI offer vascular access procedures. None of the hospitals in HSA VI do these maintenance vascular access procedures on an outpatient basis (HOPD). Even if hospitals did provide them, the cost of doing so in the Hospital Outpatient Department is on average **56% more expensive** than an ASC.

Safety and Quality

- For these procedures, the quality of care at an ASC is better than the hospital. In a hospital, these already immunocompromised dialysis patients are at high risk for infection and complications. They also experience longer wait times and procedural delays.

Conclusion

Quite simply, the one vascular access specialty operating room for HSA-VI in 2023 is not enough. The vast geographic region and high population of dialysis patients in HSA VI are difficult to serve from only one specialty operating room. Under the standard SMFP Operating Room methodology, rural counties that make up nearly all of HSA VI will likely never show a need for more operating rooms and would therefore never be able to attain the ideal vascular access care that is now available in larger urban counties in other HSAs. The calculated OR need will always go to the larger counties.

Our ask for a special need determination for two operating rooms, single specialty vascular access Ambulatory Surgical Centers in HSA VI, is in accordance with the governing principles in the State Medical Facilities Plan of maximizing quality, access, and value. These underserved dialysis patients need timely, lifesaving, and cost-efficient vascular access care in a local specialized ambulatory surgical facility. This solution would also keep the overall healthcare spending on dialysis patients down and avoid needless hospitalizations.

Thank you for your time and consideration. I will be happy to answer any questions.

Presentation of Special Needs Petition for

Two Specialty Vascular Access Operating Rooms in HSA VI,

Proposed 2024 State Medical Facilities Plan

Raleigh, July 12, 2023

Presented by: Karn Gupta, MD, Carolina Vascular Care

Introduction

Hello, my name is Dr. Karn Gupta. I am a vascular nephrologist with Carolina Vascular Care, an independent vascular access medical practice. I am here to ask members of the State Health Coordinating Council to modify Chapter 6, Table 6D of the Proposed *2024 State Medical Facilities Plan* (2024 SMFP) to include a special need for two more operating rooms limited to an ambulatory surgery facility for outpatient vascular access procedures in HSA VI. This would make it possible to have three such facilities in this HSA.

I would first like to thank the Agency for recognizing the vascular access issue and adjusting the 2023 Plan.

Background

Last year, you generously granted one vascular access operating room to each of the state's six HSAs. Though helpful, it is not enough for HSA VI. The Agency report concluded that the state needs 15 such operating rooms but only added 6 to the 2023 SMFP. The SHCC reasoned that office-based centers (OBLs), hospitals, or one of the two already approved vascular access surgery centers could meet the remaining need. This may work for the other five HSAs. However, no hospital or ASC in HSA VI offers the service.

Outpatient office-based centers ("OBLs") have effectively provided vascular access procedures to dialysis patients - most are Medicare and Medicaid beneficiaries. Unfortunately, starting in 2017, Medicare began significantly cutting payments to office-based centers. The first reduction

was about 40%; more occurred in following years, including an 8% cut in 2023; and still more are scheduled for the next 3 years. The cuts led to closure of many OBLs nationwide. Most that remained open did so by converting to ambulatory surgery centers. Last fall, I opened an OBL in Rocky Mount and expect to perform over 1700 vascular access procedures this year, serving patients from Nash and surrounding counties. But I cannot keep it open unless I, too, can convert to an ASC.

I can apply for the one HSA VI vascular access operating room in the 2023 Plan. Unfortunately, there are three OBLs in HSA VI and all have the same problem. We serve different patients, instead of collectively providing this critical service we will be competing. Whoever does not get the CON will be at risk of closing down. Moreover, the HSA VI CON applications will not be decided until March 2024. By then, the 2024 Plan will be published; it will be the 2025 Plan before you could tackle the problem, and 2026 before anyone can start construction. That will be too late, and some centers will risk closure. Patients will have less access to critical vascular care.

Reasons

HSA VI is unique.

Access

- HSA VI has the most dialysis patients, almost 20% of North Carolina's total.
- The number of people with ESRD is steadily increasing, averaging 1.7% more in each of the past five years.
- It has the largest land mass, 28% of North Carolina. It takes three to four hours to traverse.
- 27 of the 29 counties are Rural. Those 27 will likely never show a need for more operating rooms.
- The March 2023 CON statute change for urban ASCs will not help. It applies only to counties with more than 125,000 residents.
- No hospital or ASC in HSA VI offers outpatient vascular access procedures.

At-Risk Patients

- Groups at high risk for chronic kidney disease, African American, Hispanic, and Native Americans, account for about one-third of HSA VI, almost 440,000 people.
- Diabetes is the number one cause of kidney disease: 13 to 17% of residents in HSA VI self-reported having diabetes. The state average was 10%.

Value / Cost Efficient:

- Even if hospitals provided vascular procedures, the cost to Medicare, patients, or insurance companies, is on average **56% more expensive** than an ASC.
- Most dialysis patients have Medicare as the primary payor. However, 60 percent of my patients are on Medicaid. The cost to Medicaid for a procedure in an ASC or OBL is zero. In a hospital, Medicaid would pay the 20% copay, about $1800. That means that the state Medicaid program saves $7.8 million a year, assuming approximately 2100 dually eligible Medicare/ Medicaid ESRD patients in HSA VI, each getting two procedures in an ASC or OBL, rather than a hospital. This is low. It does not include the cost savings associated with the emergency room visit.

Conclusion

Quite simply, the one vascular access specialty operating room for HSA-VI in 2023 is not enough. The vast geographic region and high population of dialysis patients in this HSA cannot be served by only one specialty operating room. It needs at least two.

Our ask for a special need determination for two more operating rooms, located in single specialty vascular access Ambulatory Surgical Centers in HSA VI, is in accordance with the governing principles: maximizing quality, access, and value. These dialysis patients need timely, lifesaving, cost-efficient vascular access care in a local specialized ambulatory surgical facility. This would reduce healthcare spending on dialysis patients and avoid needless trips to the emergency room for a simple outpatient procedure.

Thank you for your time and consideration. I will be happy to answer any questions or to explain more about vascular access procedures.

Attachment I

Speeches, Dr. Saxena

Presentation of Special Needs Petition for

Two Specialty Vascular Access Operating Rooms in HSA VI,

Proposed 2024 State Medical Facilities Plan

Raleigh, July 25, 2023

Presented by: Dr. Nakshatra Saxena

Good afternoon. My name is Dr. Nakshatra Saxena and I am a nephrologist with Boice Willis Clinic in Rocky Mount, NC and HSA VI. I am here today to speak in support of Carolina Vascular Care's special need petition for two additional operating rooms dedicated to vascular access procedures in HSA VI for the 2024 Plan.

As you all might already know, patients with End Stage Renal Disease (ESRD) need to receive lifesaving dialysis treatments three times a week via vascular access. These vascular accesses are known to develop dysfunction over time and frequently require maintenance procedures to keep them functional. If not treated in time, they can lead to missing dialysis which can be life threatening. In HSA VI these outpatient procedures are not available in any ASC or hospital outpatient department (HOPD) and are only performed at three office-based centers, who unfortunately have been struggling to stay open due to extensive Medicare reimbursement cuts over the last 6 years. Despite these significant and ongoing cuts, these centers have been taking care of our patient's vascular access needs but may not be able to do so any longer. If they close down, our dialysis patients would have no choice but to either get admitted to a hospital and get a dialysis catheter or travel long distances to Raleigh. Based on Medicare's reimbursement rules, these centers can only survive if they convert to an Ambulatory Surgical Center (ASC) which has more favorable payments.

While the grant of a singular operating room dedicated to vascular access procedures in HSA VI in the 2023 plan was greatly appreciated, it is not enough to serve HSA VI's population. Along with comprising 28 percent of North Carolina's land mass, HSA VI is home to approximately 20

percent of the state's dialysis patients. For such a large portion of North Carolina's residents who rely on these specialized procedures, there is an additional need for two specialty ORs dedicated to vascular access care in HSA VI. I request that these should be implemented into the 2024 Plan so that dialysis patients can continue to get timely and affordable care in a local ASC setting.

Thank you for your time and consideration. I am happy to answer any further questions.

Attachment J

Speeches, Mr. Baggett

Presentation of Special Needs Petition for

Two Specialty Vascular Access Operating Rooms in HSA VI,

Proposed 2024 State Medical Facilities Plan

Raleigh, July 26, 2023

Presented by: Mr. Robert Baggett

Good afternoon. I am Robert Baggett, 35-year retired police officer. I tell police cadets all the time where you stand is what you see. I am standing before you today as a dialysis patient living in Rocky mount i.e., Nash County. I am here today to speak in support of Carolina Vascular Care's special need petition for additional vascular access operating rooms in HSA VI for the 2024 Plan.

My kidneys do not work, so I depend on dialysis to keep me alive. My life involves three half days a week at a dialysis center to get my blood cleaned. It also involves regular maintenance of the surgical shunt in my arm through which I get dialysis. This is the place where the technician connects me to the dialysis machine. If I take good care of it, everything will go well. Each time I go for dialysis, the technicians check the shunt to be sure it is functioning before hooking me up to the dialysis machine.

The shunt takes a lot of wear and tear, and my body naturally tries to close it up. To keep it open and functional, I need about two to four maintenance procedures on the shunt a year. Sometimes these are scheduled procedures and sometimes I need them emergently due to the shunt not working. During these times, you are not receiving any treatments at all: meaning your body is building a lot of fluid, toxins and you just do not feel good; And it takes a while to get back to normal.

Some might say, why don't you just go to the hospital emergency room. That is an

option but is not a good one. Fistula emergencies are not real emergencies in the emergency room. They deal with crimes, car wrecks and other surgical needs. Also, the emergency room at Nash UNC and other local hospitals does not have a fistula vascular surgeon(s), only general surgeons. The cost of going to the emergency room is 4x higher than going to a vascular clinic. Vascular access centers are clearly the better choice for most patients as they are significantly more affordable, and you don't have to deal with the uncertainty of wait times at a hospital.

I am just one of thousands of patients in the Eastern North Carolina, that need these special procedures done several times a year to stay alive.

This is the life of a person on dialysis. You can see why we need to have the vascular access centers as close to our homes as possible. Currently, we have three office-based centers in HSA VI where we can these access procedures done. But they will not stay open unless they can convert to ambulatory surgery centers. Please help them stay open by adding more vascular access operating rooms to the state's plan to meet the needs of us dialysis patients.

Thank you for your time.

Robert Baggett
96 Clifton Rd, Rocky Mount NC 27804
252-903-9978
rbaggett@suddenlink.net

Attachment K

Patient Letter of Support

July 26, 2023

Ms. Sandra Greene, PhD, Chair
State Health Coordinating Council

Andrea Emanuel, PhD, Interim Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation

DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

RE: Carolina Vascular Care, PLLC Petition for Two Operating Rooms restricted to an Ambulatory Surgery Center and restricted to vascular access procedures in HSA VI

Dear Dr. Greene and Dr. Craddock,

On behalf of myself and other dialysis patients in my center, I ask that DHSR Planning Staff recommend and that the full State Health Coordinating Council approve the request from Carolina Vascular Care, PLLC for an adjusted need determination in the *2024 State Medical Facilities Plan* for two additional operating rooms in HSA VI restricted to vascular access procedures and located in ambulatory surgical centers.

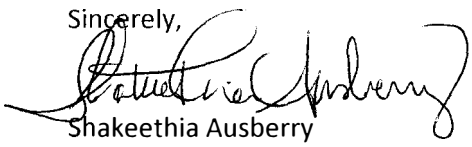
Presently, no ambulatory surgery centers or hospital outpatient department (HOPD) in HSA VI offer vascular access procedures. People like me, who depend on renal dialysis to stay alive, are currently using the office-based centers (OBL's) located in Rocky Mount, Greenville, and New Bern for these procedures. My understanding is that these OBLs are facing severe financial difficulties due to Medicare's reimbursement cuts and are at high risk of closing unless they can convert to ASCs. Without these centers we will not be able to get the local, specialized vascular access care we need to stay alive. It will force us to use hospital emergency rooms, be admitted to the hospitals to get a dialysis catheter or travel long distances to other parts of NC or other states.

Hospitals do not have outpatient departments organized for this service and emergency room visits are far too expensive. Other medical emergencies put people like us low on the priority list for procedures, and even if we have supplemental insurance coverage the costs, including personal costs of long waits and delays, are far from ideal.

We are familiar with Dr. Gupta and his excellent history in this field. He is advocating not just for his center, but for all the centers in HSA VI. Please approve his request, so that we can be assured that these outpatient services will continue to be available on a well distributed basis in HSA VI.

Please approve the petition from Carolina Vascular Care, PLLC to include a special need for two operating rooms restricted to vascular access procedures in ambulatory surgery centers in HSA VI. I would be happy to answer any questions you may have. Thank you for your time and attention to this critical issue.

Sincerely,



Shakeethia Ausberry
708 Lincoln Drive
Rocky Mount 27801

Attachment L

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