Petition to the State Health Coordinating Council
Regarding Special Need Single Specialty ASC for Vascular Access
for Nash County
2023 State Medical Facilities Plan

July 27, 2022

Petitioner:		*Contact:*	
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STATEMENT OF REQUESTED ADJUSTMENT

Carolina Vascular Care, PLLC requests the following change to the *2023 State Medical Facilities Plan* (*SMFP*) to address a special need for a single specialty ambulatory surgical center dedicated to vascular access in Nash County:

> *There is a special need in Nash County for one operating room that can only be located in an ambulatory surgical center dedicated to vascular access procedures.*

REASONS FOR THE PROPOSED ADJUSTMENT

Overview

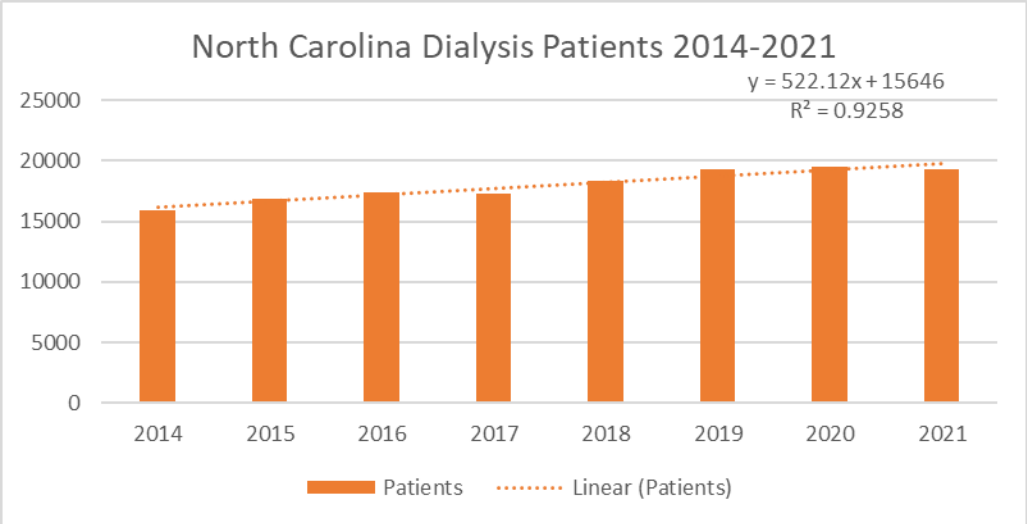
A critical element of dialysis care involves frequent maintenance of the access point for the dialysis procedure. Very few nephrologists in this state are trained and experienced to do these procedures. Today, the procedures are most efficient and cost-effective when done in a vascular access ambulatory surgery center. There are only two of these in North Carolina, one in Raleigh and one in Charlotte. A five-county area around Rocky Mount has more than enough dialysis patients to support one in Rocky Mount, but there is no need in the Proposed 2023 State Medical Facilities Plan ("SMFP") that would enable its development. The five counties are Nash, Edgecombe, Halifax, Northampton, and Wilson.

Importance of Vascular Access in Dialysis Care

Approximately 1 in 7 US adults have some level of chronic kidney disease (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 on renal dialysis in 2021 and their numbers are steadily increasing (NCHSR, 2021).

Figure 1 – North Carolina Dialysis Patients, 2014-2021



Source: (NCHSR, 2021)

These individuals must have either dialysis or a kidney transplant to survive. They require hemodialysis every other day in order 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 or graft, 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).

When 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. When the access point gets 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 three to six 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. Catheters have a 20 percent infection rate, AV grafts a 10 percent infection rate, and AV fistulas a 0.5 percent infection rate. All vascular accesses are susceptible to some 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 mean life-threatening complications and death.

Vascular Access Settings

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

Eastern North Carolina has no health facility that offers vascular access procedures in an ambulatory surgical setting. The nearest is in Raleigh. In HSA VI, the geographic region around Nash County now has enough renal dialysis patients to support a vascular access care ambulatory surgery center. The following paragraphs will provide more information.

SMFP Operating Room Methodology and Vascular Access Centers

North Carolina licenses operating rooms in two places: hospitals, and ambulatory surgical centers ("ASC"). Certificate of Need governs the number of operating rooms. Physician offices cannot have operating rooms in North Carolina. In North Carolina, with the exception of GI endoscopy centers, an ASC license requires at least one operating room.

The number of operating rooms is determined by the SHCC using a standard methodology for calculating operating room need by service area. Three of the five counties, Nash, Edgecombe, and Wilson are single county service areas. Halifax/Northampton is a two-county service area.

In the Proposed 2023 SMFP, according to the standard methodology, every existing operating room is a generic room. The underlying and unstated assumption is that every operating room has the same capabilities. Alternately, it assumes that the mathematics will balance out the few specialty operating rooms in each service area. Because of this, the standard methodology will only generate need for generic operating rooms. In large service areas, there will be sufficient operating supply to permit approval of a specialized facility dedicated to vascular access. Mathematically, this will not occur in small service areas like those included in this proposal. However, there are small geographies, like the one centered around Nash County, that can support a specialized vascular access center. Nash is already a specialty center for other services. It has a significant complement of nephrologists.

Although 90 percent of Nash County's ESRD residents receive dialysis in Nash County, according to the Table of Dialysis Data by County of Patient Origin, there is no option for them to maintain their vascular access in a freestanding outpatient setting (See Table 6B) (NC Dept of Health and Human Services, Division of Health Service Regulation, 2022). Most go to Raleigh for maintenance of their access.

The same is true for the ESRD patients from Northampton, Halifax, Edgecombe, and Wilson County. These counties have dialysis centers, but do not have a freestanding vascular access surgical center.

The 2023 Proposed SMFP shows no need for additional operating rooms in any county in NC. It shows a surplus of 5.21 operating rooms in Nash County and a surplus of 4.05 operating rooms in the Halifax/Northampton County group. By extension, without a Special Need in the 2023 SMFP, there is no way for anyone other than the hospitals to initiate a new vascular access ASC in Nash, Halifax, or Northampton in 2023, and the hospitals have shown no interest. This is not surprising. Vascular access maintenance requires more than a physical facility. It requires a trained, skilled vascular access nephrologist or a vascular surgeon who regularly performs the procedures, and a specialized support staff.

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

ESRD patients from Nash and surrounding areas have a low baseline state of health. The nearest vascular access ASC is in Raleigh. These patients must travel 60 to 90 miles for routine or emergent vascular access care. As many as one in five is dually eligible for Medicaid. For most, resources are limited, and most have underlying chronic diseases like hypertension and diabetes.

With no vascular access surgery center in Nash or the other four counties, ESRD residents have three choices: go to the emergency room, travel 60 to 90 miles, or do nothing. Most choose the first two options. Both require transportation assistance because the procedures involve sedation and driving is prohibited after the procedure. The do-nothing option can result in death when the dialysis provider can no longer attain access for lifesaving dialysis. The ER option will likely result in long wait times, hospital admission, and insertion of a catheter. Though better than imminent death, the catheter solution welcomes infection because it is an external connection to the heart. Many choose to travel, but as North Carolina population increases, so does road congestion and this option becomes less and less attractive to the older and frail ESRD patient population. Vascular access procedures are outpatient, which means patient copayment is required. Thus, for a service that may be needed the service every three months, the lower cost at a freestanding ASC is important. Not every Medicare patient will have the supplemental insurance to cover the copayment. Those who have supplemental insurance risk paying higher premiums later because of the higher cost.

Numerous studies have shown that patients have better outcomes and get more timely and much cheaper care in outpatient vascular access facilities compared to hospitals. See Attachments B and C. Without a special need for one operating room in the 2023 SMFP, the patients in Nash County and surrounding areas would continue to face high medical costs associated with getting any vascular work done at the hospital. In 2021 there were at least 1,183 ESRD patients in Nash, Halifax, Edgecombe, Wilson, and Northampton Counties. They require these procedures about two to four times a year (Lok,

2019) (Wong SPY, 2022). At this frequency, patients and their support systems often give up, accepting untimely death over the inconvenience.

Table A – Estimated Dialysis Patients by County, 2021

County	2019	2020	2021
Nash	293	303	303
Northampton	98	94	98
Halifax	253	259	242
Edgecombe	247	264	279
Wilson	316	314	261
Total	**1207**	**1234**	**1183**

Source: Dialysis Data by County of Patient Origin **(NCHSR, 2021)**

Table B – Estimated Vascular Access Procedures by County 2021

County	2019	2020	2021
Nash	879	909	909
Northampton	294	282	294
Halifax	759	777	726
Edgecombe	741	792	837
Wilson	948	942	783
Total	**3621**	**3702**	**3549**

Source: Table A multiplied by an average of 3 procedures per patient per year

For this cluster of counties, Nash is an accessible location and a traditional referral center.

Frequently, the physicians performing access procedures in the local hospitals, including Nash, do not know the ESRD patients or their vascular access history well enough to decide the best possible treatment option for them. The only freestanding ASC in these counties; Wilson Surgery Center, closed in 2020. Moreover, the ambulatory surgery center approved for Wilson Regional Medical Center in 2021 does not propose to offer vascular access procedures.

According to MedPAC, nationally, 35 percent of ESRD patients covered by Medicare are African American (MedPAC, 2022). African Americans, Native Americans and Hispanic populations are genetically at higher risk for chronic kidney disease. It is important to note that most people with chronic kidney disease are not aware of it (Chronic Kidney Disease in the United States, 2021). That indicates that the number of beneficiaries is likely much lower than the number of people who potentially could become beneficiaries.

Nash, Edgecombe, Halifax, Northampton and Wilson counties have very high population of African American, Hispanic and Native American residents.

Figure 2 – North Carolina African American Residents, 2018

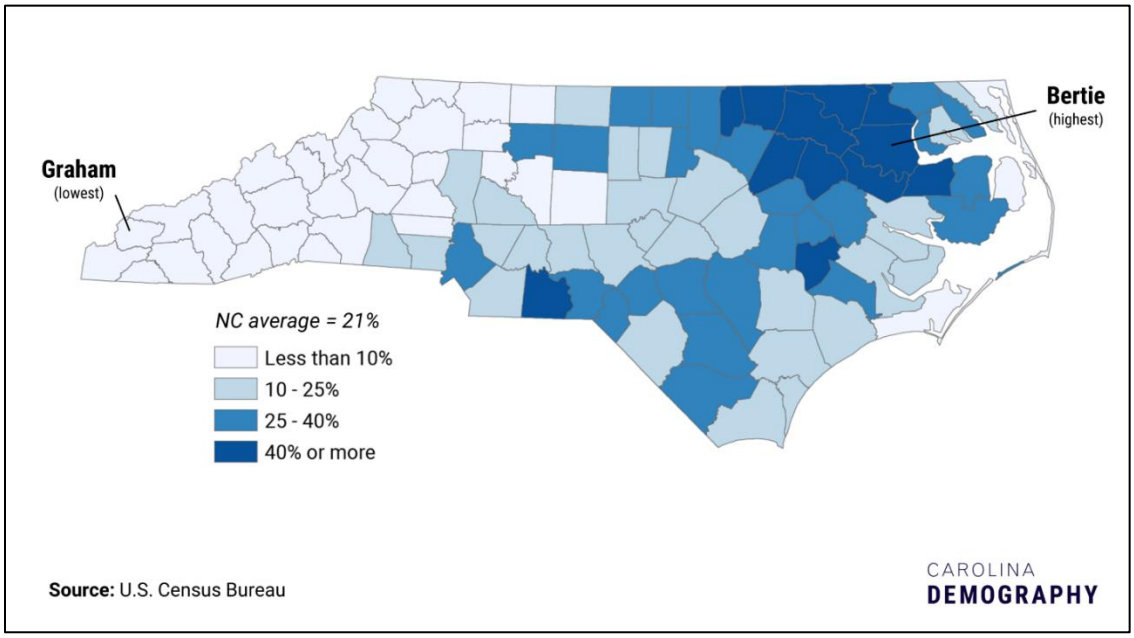


Figure 3 – North Carolina Hispanic Residents, 2018

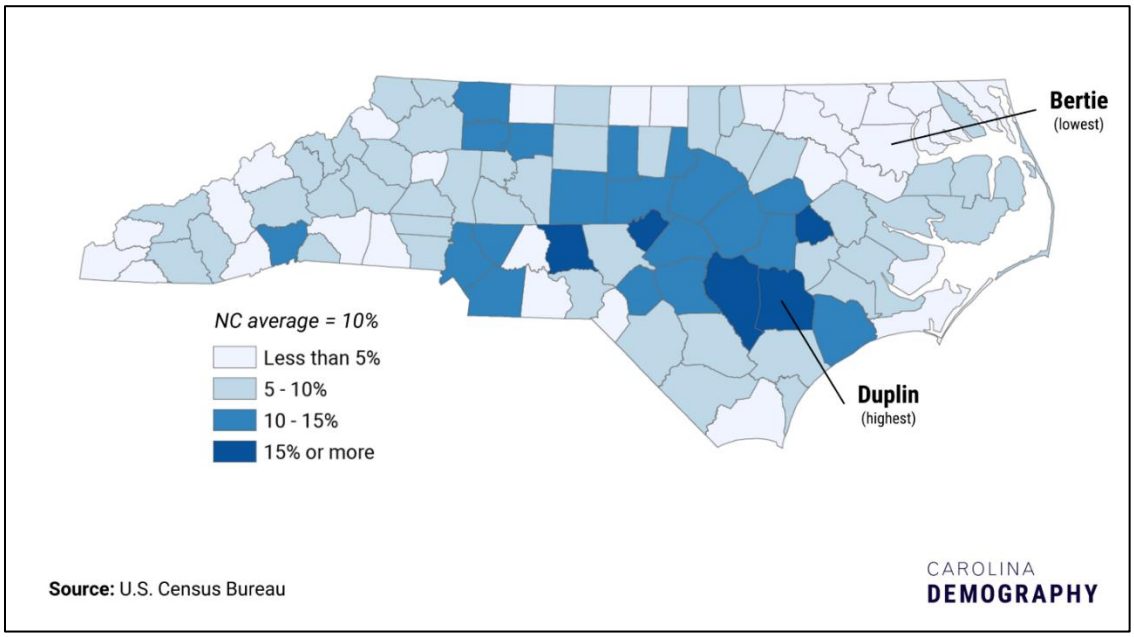
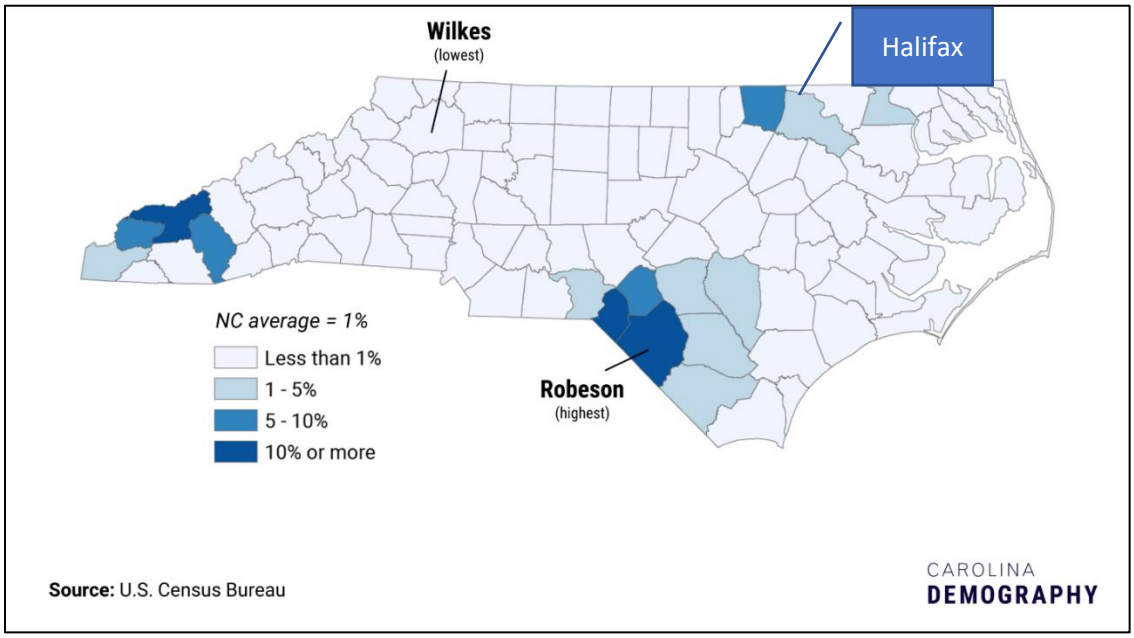


Figure 4 – North Carolina American Indian Residents, 2018



STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

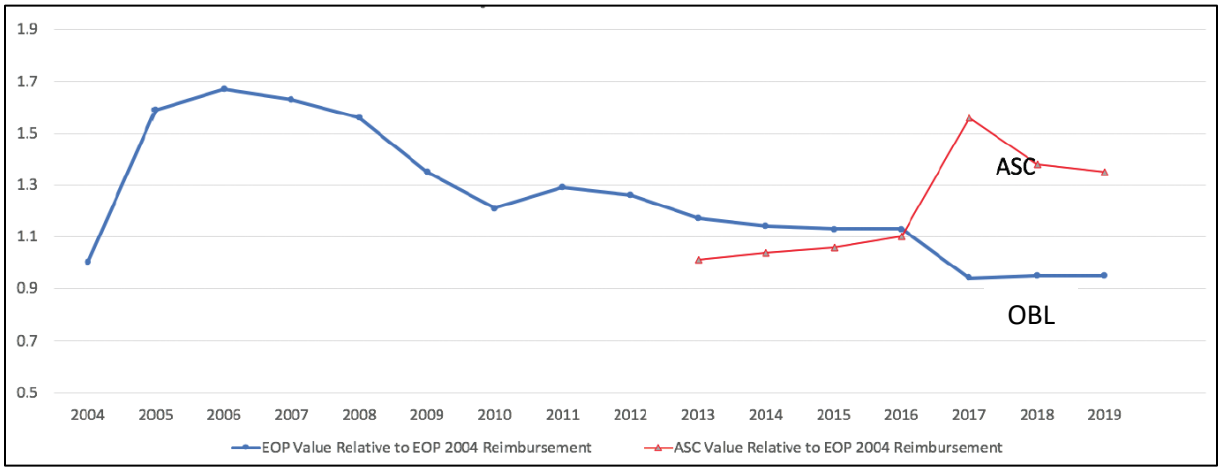
Provide an OBL in the Five-County Region

An OBL is a safe and practical location for providing vascular access procedures and for maintaining existing vascular access grafts. 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). CMS has a different methodology for setting each rate. 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). More cuts are written into regulations for the next four years.

The following figure comparing OBL and ASC reimbursement rates for vascular access over time was developed by the American Society of Diagnostic and Interventional Nephrology (Litchfield, 2019).

Figure 5 – Reimbursement per Encounter Relative to 2004 OBL Rates



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

CMS has announced plans to continue the reductions (Dialysis Vascular Access Coalition, 2021). CMS is pushing the OBL payment below OBL operating breakeven points. As this happens, OBLs will continue to disappear. The Dialysis Vascular Access Coalition is tracking the status of OBLs. Its website notes that more than 20 percent of respondents surveyed in 2018 stated that their centers had closed due to the cuts (Litchfield, 2019).

Carolina Vascular Care, PLLC has started planning for **an OBL (office-based lab)** in Nash County but unfortunately given the persistent reimbursement cuts from Medicare, this solution is not likely sustainable. Fixed operating expenses exceed income potential; 30 percent of all OBLs around the country have closed as reimbursement cuts continue the trend started in 2017 (Dialysis Vascular Access Coalition, 2021). The only way to keep a vascular access center open and functioning is to operate it as an ASC. Most patients, about 80 percent, are Medicare beneficiaries and the Medicare payment for the same procedure in an ASC is not overly generous, but it is enough to support operations. See Tables C and D.

Table C – OBL Comparison to ASC

CPT	Procedure Description	2022 Global Total Payments (Final)	2022 Pro + Facility (Final)	ASC - OBL	Variance %
36901	Fistualgram	$ 731	723	$ (8)	-1.1%
36902	Peripheral Angioplasty	$ 1,257	2,443	$ 1,186	94.3%
36903	Stent + Peripheral Angioplasty	$ 4,525	6,899	$ 2,374	52.5%
36904	Thrombectomy (no angioplasty)	$ 1,877	3,314	$ 1,437	76.6%
36905	Thrombectomy + Peripheral Angioplasty	$ 2,380	6,106	$ 3,726	156.6%
36906	Thrombectomy + Peripheral stent	$ 5,722	11,402	$ 5,680	99.3%
36907	Central Angioplasty	$ 613	143	$ 470)	-76.7%

Source: Data from CMS Final Physician Fee schedule 2022 https://www.cms.gov/medicare/physician-fee-schedule/search

Offer Vascular Access Procedures in Local Hospital Operating Rooms

Local hospitals have operating room capacity, but are not designed 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 when the procedure is scheduled, vascular access cases are often delayed by other emergency cases (untimely); and are always much more expensive than when done in an ASC. Timely care is critical for ESRD patients because the access point is their lifeline. Because their staff is not trained in vascular access, hospitals often opt for the catheter option over the surgical AV shunt because every hospital with an ICU has staff trained to insert catheters. 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 IR 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 and the deleterious sequelae of using a catheter for dialysis.

So why not do these procedures in the surplus operating room capacity at Nash General? There are many reasons, to name a few:

1. Since COVID, Nash has closed its day hospital where the focus was on outpatients alone. Now all surgery is done in the main hospital surgical suite.
2. Vascular access requires a special program with planned capacity for emergencies and a specialized staff that understands dialysis care. Nash has a hospital dialysis unit, and the necessary imaging equipment. Even that is not enough. The imaging equipment must be in the OR suite. Moreover, in the main hospital operating room suite, even the scheduled outpatient is at risk of getting delayed to accommodate a more urgent hospital patient. Please remember, a lot of these patients are diabetics who cannot fast for a prolonged time prior to their procedure. Also, an emergent patient will likely not be able to get accommodated for a same day procedure and would be at life threatening risks of missing dialysis. The dialysis center would have discovered the emergency but will be closed by the time he 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 his 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.

3. These dialysis patients have weakened immune systems and are at high risk of infections and other complications in a hospital setting, risking patient safety. 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.
4. There is no vascular access specialist in Nash and surrounding counties. I have met with the clinical staff at Nash and with the local nephrology group. Nash is not organized to and does not provide this care. Staff told me they are excited that I would consider offering vascular access services in Rocky Mount. Unfortunately, as I mentioned, I cannot afford to offer these services in Nash without an ASC.
5. Based on insurance claims data, for the Rocky Mount zip code, the patient cost to get these procedures in the hospital outpatient department can be 5 to 6 times higher than in an ASC. For example, a routine angioplasty, which is the most common procedure for these patients, costs about $1,500 in an ASC compared to $8,000 in a hospital outpatient department, see Table D. Additionally, the patient would also be charged more for an anesthesia fee in a hospital setting. Because these are outpatient procedures, the patient must cover 20 percent of their medical bills which adds up significantly due to the frequent need for these procedures.

Table D – Reimbursements Rates for Vascular Access Procedures Based on Site of Service

CPT Code	Procedure	ASC	Hospital
36901	Fistulagram	596	957
36902	Peripheral Angioplasty	1,485	7,978
36903	Stent + Peripheral Angioplasty	1,240	5,042
36905	Thrombectomy + Peripheral Angioplasty	2,749	12,894

Source: https://www.fairhealthconsumer.org/medical/results , All prices are in-network and based on Rocky Mount zip code: 27804. Accessed 7/25/2022. This database is updated twice a year.

An interventional nephrologist knows the intricacies of ESRD and vascular access care, as well as other medical conditions that can affect vascular access. Although Carolina Vascular Care, PLLC is considering an OBL, that OBL will be only temporary unless it can procure a CON to become an ASC. Approved Medicare payment reductions will make the OBL unsustainable in the next few years.

Provide Vascular Access ASC in a Different Geography

As required of the summer petitions, this petition is focused on the geographic need in one part of the state. Carolina Vascular Care, PLLC has not investigated need in other geographies. What is clear to Carolina Vascular Care, PLLC is that the five-county region including Nash and surrounding counties needs its own vascular access ASC. Carolina Vascular Care, PLLC has studied this area and its patients and is advocating for the special needs of these patients.

Maintain the Status Quo

As demonstrated throughout this petition, the status quo already places a high travel burden on patients and puts them at the mercy of increasingly busy vascular access ambulatory surgery capacity in Raleigh. The local hospital option is at best, inefficient and expensive.

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 it does not exist in this area. It would place a life-saving service closer to a large number of rural residents. As noted:

- There is no freestanding ASC in Nash, Halifax, Edgecombe, or Northampton Counties and the 2023 SMFP shows no need for an operating room that would be needed to permit a CON application for a center.
- No hospital has offered to joint venture its excess inventory and a joint venture would of itself increase the cost of initiating the center.
- With the exception of Wilson County, all surgery in these counties is hospital-based. In 2021, Wilson County was approved to develop a freestanding multi-specialty ASC however, that center did not include vascular access in its scope of proposed services.
- There are enough potential procedures and ESRD patients in the counties that relate to Nash to justify a vascular center – about 1200 patients and an estimated 3500 annual procedures (See Tables A and B).
- Patients and referring nephrologists have encouraged development of a vascular access ASC in Nash County (see Attachments D and E for speeches from SHCC public hearings).

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 are done in a vascular access center rather than a hospital outpatient department. See Attachment B and C.

As demonstrated in the public hearing presentations by Mr. Robert Baggett (See Attachment D), patients are clearly more satisfied with the freestanding vascular access centers than with the hospital emergency rooms or outpatient department solutions.

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 in Table B, dialysis patients in Nash, Halifax, Edgecombe, Northampton, and Wilson counties, will need an estimated 3,500 procedures a year. Without a vascular access ASC, they will travel three hours or more for each procedure and an individual patient will make multiple trips a year. The life of a person on dialysis is already consumed by hours of routine weekly dialysis treatments. Denying this group better access is unreasonable.

Dialysis patients are not seeking vascular access care in their local hospitals because the 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 the availability of the 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 is important that the special need specify dedication to vascular access. Otherwise, the Plan need could have the unintended consequence of producing a generic multi-specialty surgery center that would likely not be organized for the special emergency standby requirement of the renal dialysis patient.

Nash County and nearby communities have sufficient need to support a small, functional vascular access ASC with an efficient staff. Routine need is sufficient to provide a minimum of 1,312 hours of operating room care. Vascular access procedures take a minimum of 40 minutes each, this translates to approximately 1,968 procedures a year to achieve the 1,312 hours requirement. This is significantly less than the 3,500 procedures per year estimated in Table B. This is also more than it would take for the ASC to be financially viable.

A vascular access ASC would bring one more specialty to the Rocky Mount area. This would have the complimentary value of expanding the local medical care knowledge base. The ASC would be required by licensure and certification standards to make arrangements with local hospitals for emergency coverage. The presence of a vascular access ASC well operated, will prevent emergency after hours demand for this service. Moreover, the vascular access ASC will be organized to accommodate any after hour emergency patients with a first-thing, next-day schedule slot.

CONCLUSION

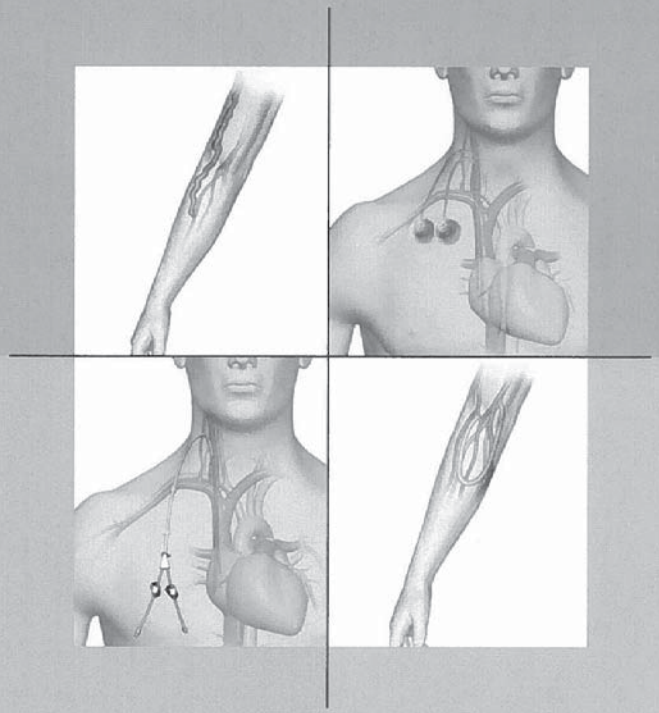
The proposed changes are consistent with and support the Basic Principles that govern the SMFP and the need is sufficient to support the proposed special need adjustment to the 2023 SMFP.

ATTACHMENTS

Attachment A

Understanding Your Hemodialysis Access Options, American Association of Kidney Patients

Understanding Your Hemodialysis Access Options



aakp
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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."

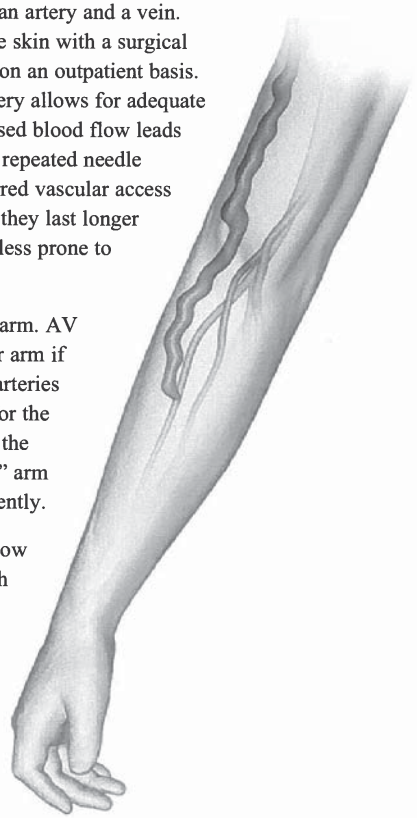
Jamie – Ottawa, Canada

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.

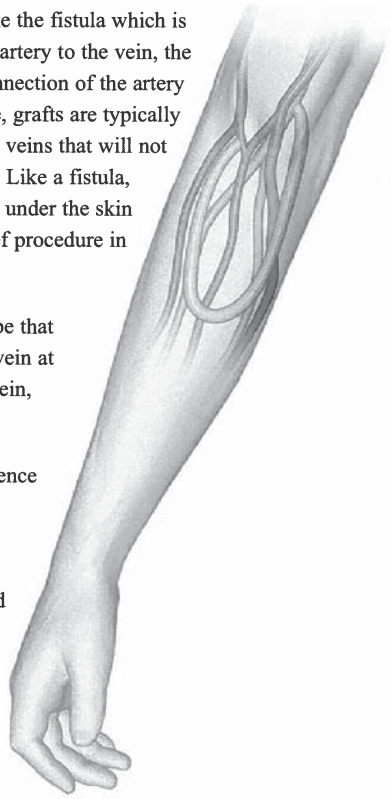
PROS	CONS
• Best overall performance	• Visible on the forearm
• Considered the best vascular access	• May take a while to develop
• Less chance of infection than other types of accesses	• May require temporary access while fistula matures
• Tend to last many years	• Not feasible for all patients due 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.

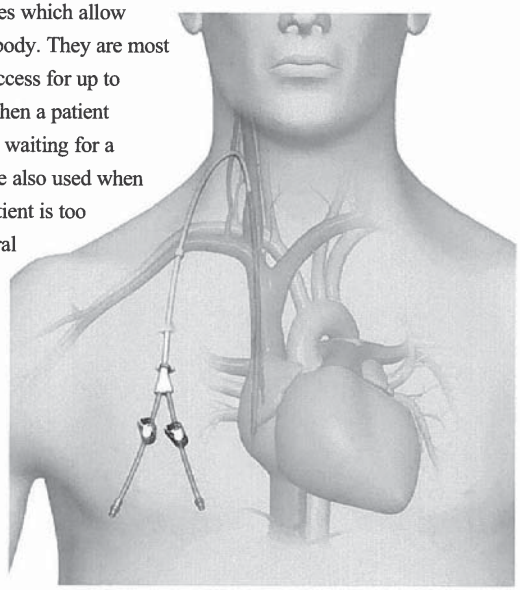
If your fistula or graft develops an *aneurysm* (looks like a small balloon), notify your doctor or nurse immediately. It may need surgery or simply to be closely monitored. Better rotation on needle sites must be used to prevent aneurysm formation or enlargement.

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

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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

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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

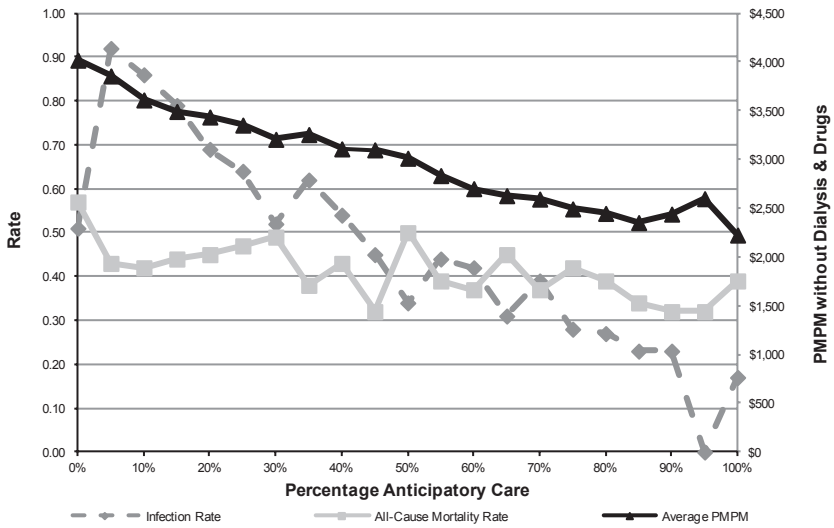

FIG. 1. Impact of Anticipatory Care on Infection Rate, All-Cause Mortality Rate, and Average PMPM Payments. Prevalence of patient outcomes by percentage of anticipatory care, defined as the proportion of dialysis vascular access (DVA) services for anticipatory services (angioplasties and angiograms) 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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References

1. National Kidney Foundation: KDOQI Clinical Practice Guidelines for Vascular Access. *Am J Kidney Dis* 48(Suppl 1):S176–S273, 1996.
2. Beathard GA: Integrated vascular access management. *Blood Purif* 21:89–98, 2003.
3. Trojano M, Pellegrini F, Paolicelli D, Fuiani A, Di Renzo V: Observational studies: propensity score analysis of non-randomized data. *International MS Journal* 16:90–97, 2009.
4. Austin PC: An introduction to propensity score methods for reducing the effects of confounding in observational studies. *Multivar Behav Res* 46:399–424, 2011.
5. Kuss O, Legler T, Borgermann J: Treatments effects from randomized trials and propensity score analyses were similar in similar populations in an example from cardiac surgery. *J Clin Epidemiol* 64(10):1076–84, 2011.
6. Dehejia R, Wahba S: Propensity score-matching methods for nonexperimental causal studies. *The Review of Economics and Statistics* 84 (1):151–161, 2002.
7. Rosenbaum PR, Rubin DB: The central role of the propensity score in observational studies for causal effects. *Biometrika* 70(1):41–55, 1983.
8. Austin PC: Optimal caliper widths for propensity-score matching when estimating differences in means and differences in proportions in observational studies. *Pharm Stat* 10:150–161, 2011.
9. Arnold WP: Improvement in hemodialysis vascular access outcomes in a dedicated access center. *Semin Dialysis* 13:359–363, 2001.
10. Jackson J, Litchfield T: How a dedicated vascular access center can promote increased use of fistulas. *Nephrol Nurs* J33:195, 2006.
11. Kian K, Takesian K, Wyatt C, Vassalotti J, Mishler R, Schon D: Efficiency and outcomes of emergent vascular access procedures performed at a dedicated outpatient vascular access center. *Semin Dial* 20:346–50, 2007.
12. Mishler R, Sands JJ, Ofsthum NJ, Tend M, Schon D, Lazarus JM: Dedicated outpatient vascular access center decreases hospitalization and missed outpatient dialysis treatments. *Kidney Int* 69:393–398, 2006.
13. Jain K, Munn J, Rummel M, Vaddineni S, Longton C: Future of vascular surgery is in the office. *J Vasc Surg* 51:509–514, 2010.
14. Asif A, Besarab A, Roy-Chaudhury P, Spergel LM, Ravani P: Interventional nephrology: from episodic to coordinated vascular access care. *J Nephrol* 20:399–405, 2007.
15. Schwab S: Vascular access for hemodialysis. *Kidney Int* 55:2078–2090, 1999.
16. US Renal Data System: *USRDS 2011 Annual Data Report: Atlas of End-Stage Renal Disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2011
17. Wasse H, Speckman RA, Frankenfield DL, Rocco MV, McClellan WM: Predictors of delayed transition from central venous catheter use to permanent vascular access among ESRD patients. *Am J Kidney Dis* 49:276–253, 2007.
18. Astor BC, Eustace JA, Powe NR, Klag MJ, Sadler JH, Fink NE, Coresh JC: Timing of nephrologist referral and arteriovenous access use: the CHOICE study. *Am J Kidney Dis* 38:494–501, 2001.
19. Stehman-Breen CO, Sherrard DJ, Gillen D, Caps M: Determinants of type and timing of initial permanent hemodialysis vascular access. *Kidney Int* 57:639–645, 2000.
20. Beathard GA, Litchfield T: Physician operators Forum of RMS Lifeline, Inc: effectiveness and safety of dialysis vascular access procedures performed by interventional nephrologists. *Kidney Int* 66:1622–1632, 2004.
21. Kalman P, Pope M, Bhola C, Richardson R, Sniderman K: A practical approach to vascular access for hemodialysis and predictors of success. *J Vasc Surg* 30:727–733, 1999.
22. Jackson J, Lewis JL, Brouillette JR, Brantley RR Jr: Initial experience of a nephrologist-operated vascular access center. *Semin Dialysis* 13:354–358, 2008.
23. Allon M: Current management of vascular access. *Clin J Am Soc Nephrol* 2:786–800, 2007.

Attachment C

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

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ORIGINAL RESEARCH ARTICLE

ASDIN

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

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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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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

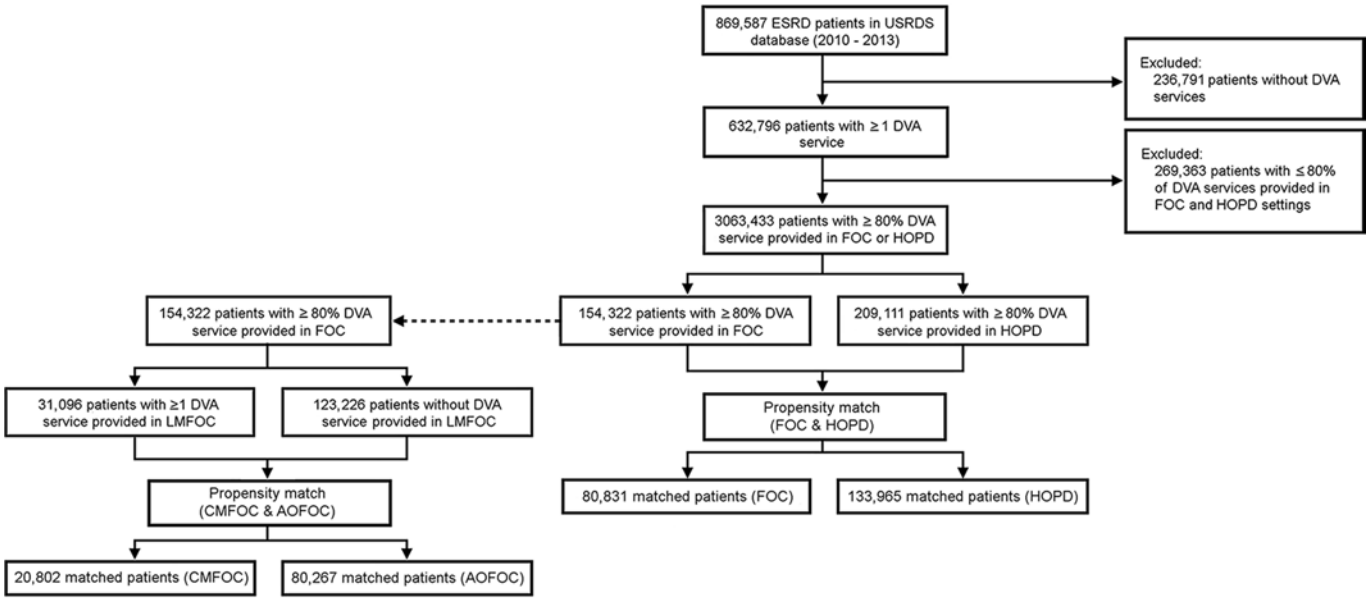

Fig. 1 - Study population. Flow diagram of patient selection.

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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References

1. U.S. Renal Data System. USRDS 1995 Annual Data Report, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD. Available from: https://www.usrds.org/atlas95.aspx. Accessed July 20, 2017.
2. U.S. Renal Data System. USRDS 2016 Annual Data Report, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD. Available from: https://www.usrds.org/adr.aspx. Accessed July 17, 2017.
3. Beathard GA, Urbanes A, Litchfield T. Changes in the Profile of Endovascular Procedures Performed in Freestanding Dialysis Access Centers over 15 Years. Clin J Am Soc Nephrol. 2017;12(5): 779-786.
4. Dobson A, El-Gamil AM, Shimer MT, et al. 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. Semin Dial. 2013;26(5):624-632.
5. Fistula First Breakthrough Initiative. National Vascular Access Improvement Initiative. Available from: http://fistulafirst.esrdncc.org/ffcl/. Accessed July 19, 2017.
6. U.S. Renal Data System. USRDS 2012 Annual Data Report, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD. Available from: http://www.ajkd.org/issue/S0272-6386(12)X0003-9. Accessed July 14, 2017.
7. U.S. Renal Data System. USRDS 2015 Annual Data Report, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD. Available from: https://www.usrds.org/2015/download/vol2_USRDS_ESRD_15.pdf. Accessed July 14, 2017.
8. Maddux FW. Impact of the bundled end-stage renal disease payment system on patient care. Blood Purif. 2012;33(1-3): 107-111.
9. Trojano M, Pellegrini F, Paolicelli D, Fuiani A, Di Renzo V. observational studies: propensity score analysis of non-randomized data. Int MS J. 2009;16(3):90-97.
10. Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. Multivariate Behav Res. 2011;46(3):399-424.
11. Kuss O, Legler T, Börgermann J. Treatments effects from randomized trials and propensity score analyses were similar in similar populations in an example from cardiac surgery. J Clin Epidemiol. 2011;64(10):1076-1084.
12. Dehejia R, Wahba S. Propensity score-matching methods for nonexperimental causal studies. Rev Econ Stat. 2002;84(1): 151-161.
13. Rosenbaum PR, Rubin DB. The central role of the propensity score in observational studies for causal effects. Biometrika. 1983;70(1):41-55.
14. Austin PC. Optimal caliper widths for propensity-score matching when estimating differences in means and differences in proportions in observational studies. Pharm Stat. 2011;10(2): 150-161.
15. Rundall TG, Shortell SM, Wang MC, et al. As good as it gets? Chronic care management in nine leading US physician organisations. BMJ. 2002;325(7370):958-961.
16. Zazzali JL, Alexander JA, Shortell SM, Burns LR. Organizational culture and physician satisfaction with dimensions of group practice. Health Serv Res. 2007;42(3 Pt 1):1150-1176.
17. Sharma S, Pandit A, Tabassum F. Potential facilitators and barriers to adopting standard treatment guidelines in clinical practice. Int J Health Care Qual Assur. 2017;30(3):285-298.
18. Hung D, Chung S, Martinez M, Tai-Seale M. Effect of Organizational Culture on Patient Access, Care Continuity, and Experience of Primary Care. J Ambul Care Manage. 2016;39(3):242-252.

Attachment D

Patient Speech (Robert Baggett) from SHCC Public Hearings

Public Hearing Notes on the proposed 2023 State Medical Facilities
Recommendation for Vascular Surgical Facility in Nash County

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.

My kidneys do not work. I go to dialysis 3 times a week. I leave at 7 o'clock in the morning and get home at 12-noon. The first thing they do at the clinic is take my temperature, listen for my vitals, weigh me, and check out my fistula. The fistula surgically implanted that connects my body to the machine through needles.

The fistula takes a lot of wear and tear. I need 2-4 procedures done a year at a vascular clinic. The problem is the nearest clinic is an hour and half away. So, I drive for an hour and half; stay there an hour and half; and drive home an hour and half, if everything goes smooth. This is inconvenient but is manageable. The problem is when you have an emergency case. When your dialysis clinic says your fistula is not working, they must schedule this appointment. Sometimes it takes 2-3 days to get an appointment scheduled. 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 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. You can see an emergency case done at a hospital is not as good as doing an emergency fistula case by a vascular surgeon.

I am just one of thousands of patients in the Rocky Mount area, that need this procedure done several times a year. If Dr. Gupta is willing to set up a vascular surgery center and invest in my health, I support him 100%.

Robert Baggett
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Attachment E

Speech, Dr. Jasane

Wilson Physician Speech

Good afternoon. My name is Dr. Nirav Jasani. I am a practicing nephrologist (kidney doctor) at North Carolina Kidney Care with offices in Wilson and Rocky Mount. I am here to speak in support of the request from Dr. Karn Gupta and Carolina Vascular Care for a special need for one operating room dedicated to vascular access procedures in Nash County for the 2023 Plan.

I take care of patients with End Stage Kidney Disease requiring dialysis. These patients need routine monitoring and frequent interventions do keep their dialysis vascular access functional. Without a functioning vascular access they cannot survive. The vascular access points fall in three categories, but all of them are artificial and frequently develop problems. When this happens, they need immediate evaluation and treatment. This can most efficiently be performed in an outpatient vascular access facility which is organized for these type of patients, will cause them minimum downtime; and most often will enable a patient to resume his or her dialysis schedule without much delay. Unfortunately, due to lack of a dedicated local vascular access center, our patients in Wilson, Nash and nearby communities are left at the mercy of the vascular access center in Raleigh. The patients do not like to go to the hospital for these procedures because they have to first, wait forever and then get admitted for any procedure. This is quite inconvenient and leads to costly medical bills.

We have a lot of these unfortunate dialysis patients in Nash, Wilson and surrounding counties. We have good dialysis treatment facilities but do not have a local outpatient center for maintaining a vascular access.

I am aware of the significant Medicare reimbursement cuts in the last 5 years for vascular access procedures done in an office based setting. This has in turn lead to closure of several vascular centers across the nation which has negatively affected the already suboptimal vascular access care for our dialysis patients. Unfortunately, due to the new reimbursement rules, these vascular access facilities can remain functional only if they operate as an ambulatory surgical center.

The dedicated vascular access centers in Raleigh and Charlotte have already converted to ambulatory surgical centers. Unfortunately, the 2023 State Medical Facilities Plan using the standard methodology does not show any need for OR in Nash or surrounding counties, so a special need for a dedicated operating room for vascular access if the only option. Nash is a good central location. Other specialists are there. The need is big enough. Please support these patients and allocate a special need in the 2023 State Medical Facilities Plan.

Thank you for your kind consideration. I am happy to answer questions.

Attachment F

Speech, Dr. Gupta (two versions)

Presentation of Special Needs Petition for Single Specialty Vascular Access Ambulatory Surgery Center in Nash County, Proposed *2023 State Medical Facilities Plan* Raleigh, July 20, 2022

Presented by:
Karn Gupta, MD
Carolina Vascular Care

Hello, my name is Dr. Karn Gupta. I am a physician at Carolina Vascular Care, an independent vascular access medical practice. I would like to start with a true story.

Robert is an African American male, mid 60's, who lives in Nash County and has diabetes, hypertension and End Stage Kidney Disease, a condition that requires maintenance dialysis at least three times a week just to stay alive. The dialysis process requires access to the bloodstream to have blood removed, cleaned, and returned to a patient's body via specially created surgical shunts called vascular accesses. This vascular access essentially becomes his lifeline. Since these shunts are surgically created to divert blood from its normal flow pattern, they are highly prone to developing dysfunction due to blockages, blood clots and various other issues. They require frequent monitoring and maintenance to keep them functional. An average dialysis patient needs about 3-4 maintenance procedures per year

As with almost all dialysis patients, Robert develops dysfunction of his vascular access. He needs immediate evaluation and treatment to continue dialysis and avoid complications of missing dialysis or access failure. Since there are no vascular access specialists in and around Nash County, he only has 2 choices - go to a local hospital or travel about 50-60 miles one way to Raleigh to an outpatient vascular access surgery center.

Going to the local hospital, he will face lengthy wait times in the emergency room and eventually be admitted for a few days. Once admitted, he will likely not get his dysfunctional vascular access treated; and instead, he may get a temporary dialysis catheter placed. He would also miss timely dialysis and would be at higher risk of infection, morbidity and mortality in the hospital as demonstrated in various studies. Alternatively, given the absence of outpatient vascular access centers in Nash and surrounding Counties, he will need to arrange transportation to and from the center in Raleigh. Frequently, these far away centers have full schedules and cannot accommodate him immediately.

Robert's experience is typical and highlights why I am here today. Quite simply, we need a dedicated vascular access outpatient surgery center in Nash County to take care of the approximately 1200 dialysis patients in Nash, Edgecombe, Halifax, Northampton and Wilson counties. More importantly, these counties have very high population of African American, Hispanic and Native American residents who have a significantly higher prevalence of End Stage Kidney Disease.

For several decades, outpatient office-based centers have been providing these timely, cost efficient and safe vascular access procedures to dialysis patients. Unfortunately, starting in 2017, Medicare has significantly cut payments to office-based centers. In 2017 itself, Medicare cut payments by 39%. By 2018, reimbursement levels were so inadequate that 20% of the centers had to close. More recent data confirms a 30% decrease in office based vascular

access services. Most others have converted to an ambulatory surgery center to remain operational. Unfortunately, in 2022 Medicare finalized yet another round of huge 20% cuts. These reimbursement rates are slated to drop another 20% over the next 4 years. Due to these ongoing cuts, operating an office based vascular access center is no longer sustainable due to inherent high-cost structure to provide these services. Interestingly enough, the new reimbursement rules support performance of these procedures in an Ambulatory Surgery Center (ASC).

Quite simply, an Ambulatory Surgery Center is clearly a better solution than a hospital for people like Robert. We are asking for a special need determination for a one operating room, single specialty vascular access Ambulatory Surgical Center in Nash County. The request 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, cost efficient and lifesaving vascular access care in a local specialized ambulatory surgical facility. This solution would also keep the overall healthcare spending on dialysis patients down by avoiding needless hospitalizations.

Our request for a special need is reasonable. Our calculated need of procedures based on just a fraction of the dialysis patients in these counties is well above the 1312 hours of surgical OR time needed for a CON.

I am a specialist in vascular access but I am restricted by the Plan from helping our dialysis patients. A special need would provide relief for people like Robert in Nash and surrounding Counties. The Plan shows no need for operating rooms in 2023. Without a special need in the Plan, we cannot do for Nash what other vascular access applicants did in Wake and Mecklenburg Counties. Under the standard methodology, these rural counties 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.

If granted the related CON, Carolina Vascular Care will be able to provide timely, lifesaving, and cost-effective vascular access services to the debilitated dialysis patients in Nash and surrounding counties.

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

I have been asked as to why the current excess operating room capacity in Nash County cannot take care of these dialysis patients. Indeed, the draft plan shows a surplus of more than 5 operating rooms at Nash General hospital. There are no ambulatory surgery operating rooms in Nash County. So why not do these procedures in the surplus capacity at Nash General.

1. Since COVID, Nash has closed its day hospital where the focus is on outpatients alone.
2. In the main hospital operating room, even the scheduled outpatient is at risk of getting delayed to accommodate a more urgent hospital patient. Recall that many of these patients are diabetics who cannot fast for a prolonged time prior to their procedure. Also, an emergent patient will likely not be able to get accommodated for a same day procedure and would be at life threatening risks of missing dialysis.
3. There is no vascular access specialist in Nash and surrounding counties. I have met with the folks at Nash and the local nephrology group and they are excited that I would

consider offering vascular access services in Rocky Mount. Unfortunately, as I mentioned, I cannot afford to offer these services in Nash without an ASC.

4. Based on claims data of Nash County, the patient cost to get these procedures in the hospital outpatient department is about 5-6 times higher compared to an ASC. For example, a routine angioplasty in an ASC costs about $1500 vs $8000 in a hospital outpatient department. In addition, the patient would be charged for an anesthesia fee in a hospital setting. Because these are outpatient procedures, the patient must cover 20% of their medical costs which adds up significantly due to the frequent need of these procedures.

Questions

- How many procedures/patients will you need to break even? (Sandra Greene)
    - Approximately 600 patients visiting for 3 procedures per year would meet the 1312 hours requirements for OR's if each procedure is 40 minutes (1968 procedures exactly if operating at 40 minute rate)
- What will happen with patients after hours? If they had an emergency? (Lyndon Jordan)
    - They will be fit in the very next day if there's an emergency after hours.
- Is an ASC more economic than an OBL? Will you provide other services/procedures? (Robert McBride)
    - Yes due to CMS reimbursement cuts, ASC's are more financially viable for vascular access procedures. No other services.
- No OR need? Is there capacity in hospital? (John Young)
    - No specialist
    - Busy scheduling puts patients at risk when they have to wait multiple days for treatment (fasting, diabetes, dangerous)

Presentation of Special Needs Petition for Single Specialty Vascular Access Ambulatory Surgery Center in Nash County, Proposed *2023 State Medical Facilities Plan* Raleigh, July 25, 2022

Presented by:
Karn Gupta, MD
Carolina Vascular Care

Hello, my name is Dr. Karn Gupta. I am a physician at Carolina Vascular Care, an independent vascular access medical practice. I am here asking for a special need for one operating room limited to an ambulatory surgery facility for outpatient vascular access procedures in Nash County.

Many of you have heard me speak about Robert, a dialysis patient, who needs outpatient vascular access procedures two to four times a year to stay alive. Some of these procedures can be scheduled, others are spontaneous emergencies. He cannot maintain his dialysis routine without getting his vascular access fixed the same day.

Robert's experience is typical and highlights why I am here today. Quite simply, we need a dedicated vascular access outpatient surgery center in Nash County to take care of the approximately 1200 dialysis patients in Nash, Edgecombe, Halifax, Northampton and Wilson counties. More importantly, these counties have very high population of African American, Hispanic and Native American residents who have a significantly higher prevalence of End Stage Kidney Disease.

For several decades, outpatient office-based centers have been providing these timely, cost efficient and safe vascular access procedures to dialysis patients. Unfortunately, starting in 2017, Medicare has significantly cut payments to office-based centers. In 2017 itself, Medicare cut payments by 39%. By 2018, reimbursement levels were so inadequate that 20% of the centers had to close. More recent data confirms a 30% decrease in office based vascular access services. Most others have converted to an ambulatory surgery center to remain operational. Unfortunately, in 2022 Medicare finalized yet another round of huge 20% cuts. These reimbursement rates are slated to drop another 20% over the next 4 years. Due to these ongoing cuts, operating an office based vascular access center is no longer sustainable due to inherent high-cost structure to provide these services. Interestingly enough, the new reimbursement rules support performance of these procedures in an Ambulatory Surgery Center (ASC).

I have been asked why the current excess operating room capacity in Nash County cannot take care of these dialysis patients. Indeed, the draft plan shows a surplus of more than 5 operating rooms in Nash County, all of which are at Nash General hospital. There are no ambulatory surgery operating rooms in Nash County. So why not do these procedures in the surplus capacity at Nash General? Few reasons:

1. Since COVID, Nash has closed its day hospital where the focus was on outpatients alone.

2. Vascular access requires a special program with planned capacity for emergencies and a specialized staff who understand dialysis care. Nash has a hospital dialysis unit, and the necessary imaging and OR equipment. Even that is not enough. The imaging equipment must be in the OR suite. Moreover, in the main hospital operating room suite, even the scheduled outpatient is at risk of getting delayed to accommodate a more urgent hospital patient. Please remember, a lot of these patients are diabetics who cannot fast for a prolonged time prior to their procedure. Also, an emergent patient will likely not be able to get accommodated for a same day procedure and would be at life threatening risks of missing dialysis. The dialysis center would have discovered the emergency, but will be closed by the time he is discharged and the center may not have an open slot the next day. So he would have to wait another day for his routine slot at the dialysis center.
3. These dialysis patients have weakened immune systems and therefore are at high risk of infections and other complications in a hospital setting, risking patient safety. 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.
4. There is no vascular access specialist in Nash and surrounding counties. I have met with the clinical staff at Nash and with the local nephrology group. Nash is not organized to and does not provide this care. Staff told me they are excited that I would consider offering vascular access services in Rocky Mount. Unfortunately, as I mentioned, I cannot afford to offer these services in Nash without an ASC.
5. Based on insurance claims data of Nash County, the patient cost to get these procedures in the hospital outpatient department is about 5-6 times higher compared to an ASC. For example, a routine angioplasty, which is the most common procedure for these patients, costs about $1500 in an ASC vs $8000 in a hospital outpatient department. Additionally, the patient would also be charged more for an anesthesia fee in a hospital setting. Because these are outpatient procedures, the patient must cover 20% of their medical bills which adds up significantly due to the frequent need for these procedures.

Quite simply, an Ambulatory Surgery Center is clearly a better solution than a hospital for people like Robert in Nash and surrounding counties. The Plan shows no need for operating rooms in 2023. Under the standard methodology, these rural counties 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. Without a special need in the Plan, we cannot do for Nash what other vascular access applicants did in Wake and Mecklenburg Counties.

Our ask for a special need determination for a one operating room, single specialty vascular access Ambulatory Surgical Center in Nash County 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, cost efficient and lifesaving vascular access care in a local specialized ambulatory surgical facility. This solution would also keep the overall healthcare spending on dialysis patients down by avoiding needless hospitalizations.

Our request for a special need is reasonable. Our calculated need of procedures based on just a fraction of the dialysis patients in these counties is well above the 1312 hours of surgical OR time needed for a CON.

If granted the related CON, Carolina Vascular Care will be able to provide timely, lifesaving, and cost-effective vascular access services to the debilitated dialysis patients in Nash and surrounding counties.

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

Attachment G

Works Cited

WORKS CITED

Chronic Kidney Disease in the United States. (2021, March 4). Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html#:~:text=CKD%20Is%20Common%20Among%20US%20Adults&text=More%20than%201%20in%207,are%20estimated%20to%20have%20CKD.&text=As%20many%20as%209%20in,not%20know%20they%20have%20CKD

CKD Related Health Problems. (2021, March 4). Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/kidneydisease/publications-resources/annual-report/ckd-related-health-problems.html

Dialysis Access Management. (2021, November 30). Retrieved from Vein & Endovascular Medical Care: https://www.astraveinvascular.com/dialysis-access-management/

Dialysis Vascular Access Coalition. (2021). *CY 2022 Physician Fee Schedule Proposed Rule.* Dialysis Vascular Access Coalition. Retrieved from https://www.dialysisvascularaccess.org/_files/ugd/4d8e3a_e77146a2f6f64b9aad2430a6b6d6a4d3.pdf

Dialysis Vascular Access Coalition. (2021). *Priorities*. Retrieved May 31, 2019, from Dialysis Vascular Access Coalition: http://dialysisvascularaccess.org/priorities

Grapsa, K. P. (2012). Vascular access today. *World journal of nephrology*. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3782199/

Kirchoff, S. M. (2018). *Medicare Coverage of End-Stage Renal Disease (ESRD).* Congressional Research Service. Retrieved from https://sgp.fas.org/crs/misc/R45290.pdf

Litchfield, T. (2019). *Dialysis Access Coding Essentials, Recent Changes, and Locatoin Distinctions* (June 2019 ed., Vol. 18). Endovascular Today. Retrieved June 28, 2022, from https://assets.bmctoday.net/evtoday/pdfs/et0619_F6_Litchfield.pdf

Lok, C. E. (2019). Fistula interventions: Less is more. *Journal of the American Society of Nephrology : JASN*. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6830789/

MedPAC. (2022). *Chapter 6 Outpatient Dialysis Services.* Washington DC: Medical Payment Advisory Commission. Retrieved from https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch6_SEC.pdf

NC Dept of Health and Human Services, Division of Health Service Regulation. (2022). *Proposed North Carolina 2023 State Medical Facilities Plan.* Raleigh, North Carolina : NC DHSR.

NCHSR. (2021). *Chapter 9: Dialysis Data by County of Patient Origin.* NCHSR. Retrieved from https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/01-Ch9PatOrigin_Final.pdf

Wong SPY, R. T. (2022). Long-term Outcomes Among Patients With Advanced Kidney Disease Who Forgo Maintenance Dialysis: A Systematic Review. *JAMA Netw Open*. Retrieved from https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2790040

World Kidney Day. (n.d.). *Chronic Kidney Disease.* Retrieved from http://www.worldkidneyday.org/faqs/chronic-kidney-disease/.