As of 2010, more than 590,000 patients in the United States were being treated for end-stage renal disease (ESRD), a tenfold increase from 1980. Of these, almost 384,000 were on maintenance hemodialysis (65% of the entire ESRD population) at a cost of $87,561 per patient per year. Of the nearly 117,000 patients who were started on renal replacement therapy the same year, almost 91% entered the program on hemodialysis. Although prevalence rates for ESRD have continued to increase, the number of “incident patients” has actually stabilized over many years. This is attributable to a drop in mortality rates by 26% since 1985, despite the ESRD patient’s mortality remaining about sixfold higher than the matched general population. Accompanying this improvement in mortality is the added care for illnesses and comorbidities that continue to affect dialysis patients, even as they are maintained on a relatively stable course of renal replacement.

OUTPATIENT DIALYSIS ACCESS CARE AND ORGANIZATIONAL SUPPORT

Freestanding outpatient centers dedicated to the care of the dialysis vascular access began entering the picture around the late 1990s. By 2000 or so, more physician practices were taking note of the clinical and financial benefits of access centers, and nephrologists began embracing hemodialysis vascular access care after years of having abdicated the responsibility to other providers. The American Society of Diagnostic and Interventional Nephrology was founded in 2000 and became the professional society that advocated for and supported nephrologists’ ability to provide this care. Soon thereafter, other professional societies started recognizing this burgeoning specialty and began featuring “interventional nephrology” and access care symposia.

The growth and expansion of the discipline was facilitated by several factors. Training was available to nephrologists who were interested in providing this care. Management companies provided assistance, guidance, and direction with clinical and business operations. Progress was also aided by the fortuitous confluence of a favorable reimbursement schedule and a clinical environment in which there was a systematic promotion of the arteriovenous fistula (AVF) as the favored path of access. Critical mass was achieved in a relatively brief period of time, so much so that in the short span of 5 years, the number of freestanding access facilities increased to 58 by 2005. Rapid growth of the industry was seen from 2005 to 2007, with an increase in the number of centers in excess of 40% annually.

As part of the End-Stage Renal Disease Networks Statement of Work beginning in July 2003, the Centers for Medicare & Medicaid Services, the ESRD Networks, and key provider representatives jointly recommended adoption of a National Vascular Access Improvement Initiative. The primary goal of the Continuous Quality Improvement project was to increase the appropriate
use of AVFs for hemodialysis access and to reach or exceed the National Kidney Foundation Kidney Disease Outcomes Quality Initiative practice guidelines of 50% in incident patients and 40% in prevalent patients.

In July 2003, the prevalent AVF rate was 32.2%, and since the implementation of this quality improvement initiative, this goal was reached in August 2005, 10 months earlier than anticipated. In 2005, the National Vascular Access Improvement Initiative was recognized by the Centers for Medicare & Medicaid Services as a breakthrough initiative and became known as the Fistula First Breakthrough Initiative (FFBI). The national prevalent AVF rate goal was increased to 66%. As of April 2012, the prevalent AVF rate is 60.6%.

The engagement of multiple stakeholders and clinical disciplines underlines the success of the FFBI. The concerted efforts of the renal networks, thought leaders, dialysis organizations, and medical specialty organizations helped propel the principles and philosophy of the FFBI to meaningful, relevant, and applicable concepts. The freestanding access centers, typically in association with a nephrology practice or practices, were instrumental in operationalizing many of the concepts that were espoused by the FFBI and were therefore integral to its success.

Horizontally and vertically integrated access care combined with aggressive patient and caregiver education and dialysis facility outreach, an increased understanding and appreciation of access pathology, monitoring and treatment options, and effective and efficient communication have aided the access center’s ability to position itself as a key player in ensuring the success of the FFBI. Although access care continues to be delivered in the inpatient hospital setting, the lack of a coordinated and integrated system of care plagues this environment and makes it a less-efficient and less-effective catalyst for the changes that the FFBI espouses.

Although both incident and prevalent AVF rates have indeed risen, this is at the expense of a drop in prosthetic arteriovenous graft (AVG) use. For example, from July 2003 through April 2012, the incident AVF rate has risen from 12.7% to 18%, with the AVG rate falling from 10.9% to 9.7%, and the central venous catheter (CVC) rate remaining about the same at 72.1% to 72.3%.

For the same time period, the prevalent AVF rate increased from 32.2% to 60.6%, while the AVG rate dropped from 40.1% to 19.4%, and the CVC rate dropped from 26.9% to 20%. That both incident and prevalent CVC rates remain high is a challenge that the FFBI and other parties, including the access centers, must address. This requires even more aggressively identifying appropriate chronic kidney disease patients for preparation and referral for AVF creation before initiating renal replacement, monitoring for maturation and functionality of placed AVFs, repair and salvage of accesses in use, and the identification of patients in need of new accesses or creation of secondary AVFs.

Once more, the access center will play a critical role in delivering all of these services in a timely and expeditious fashion.

The movement of access-related maintenance procedures away from the hospital setting to the outpatient arena is evidenced by data from the United States Renal Data System showing a drop in hospitalization rates for vascular access by 49.7% from 1994 to 2010. It is unlikely that patients are requiring less of this care, but rather, that the care is being delivered outside the confines of the hospital. Not surprisingly, this observation parallels the growth and expansion of outpatient access facilities nationwide.

**OVERCOMING CHALLENGES**

A challenge that freestanding access centers have faced, and continue to face although in a much less formidable regard, is the ability to validate the quality and safety of the work product. As far back as the mid-2000s, it was apparent to a few independent freestanding access facilities, as well as those affiliated with one of the corporate-managed systems of centers, that third-party accreditation through the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities was crucial and signaled a level of operations that met stringent standards to which other similar health organizations were held.

This accreditation served an important role of dispelling many of the concerns that interventional access care provided outside of the hospital setting was unsafe and not subject to the same rigor or level of scrutiny. Some states do in fact use accreditation as an acceptable equivalent to mandatory state inspection and approval before moderate sedation can be administered outside of the hospital. Today, most of the corporate-managed and many of the independent nonhospital-affiliated access facilities are accredited by one of these three organizations.

Discussions of the safety of performing these procedures on an admittedly challenged and challenging set of patients outside of the hospital and by nephrologists was the subject of a seminal article by Beathard et al. Two related publications by the same group enlightened us on the safety of sedation/analgesia and radiation use and exposure as it pertains to these procedures in these points of service.
In a study that is soon to be published, multivariate matching of patients in the freestanding outpatient centers to the hospital outpatient facilities using the United States Renal Data System dataset from the years 2006 through 2009 showed that patients treated in the outpatient centers experienced lower per/member-per-month payments for vascular access–related care, lower mortality rates, and lower rates of hospitalization, infections, and septicemia-related hospitalizations. This is the largest study of this kind that specifically addresses the issues of quality and outcomes in these centers.

The challenge of the outpatient access center has primarily been one of ensuring efficient and effective delivery of quality-driven care in a safe environment while in a business climate that is, at a minimum, revenue neutral. Although the number of freestanding outpatient access centers has risen from 58 in 2004 to 210 in 2013, in fact, the growth of the industry has been stagnant from 2009 to 2013 with a growth rate of 3% per year. It is not coincidental that the plateau in growth parallels that of the relative reimbursement rate for the same interval. Relative to 2004, reimbursement rates peaked in 2006 and declined steadily thereafter to a nadir in 2010, followed by a modest upward excursion from 2011 to 2013. Current reimbursement rates are about 69% compared to their peak in 2006.

Given these existing and immutable challenges, for a center to remain financially viable and continue to provide these much-needed services to their patients, a few options remain available. Cost control remains critical but should not be done at the expense of safety or quality. The estimated referral base of nephrology patients that would generate the necessary number of visits for financial survival and the average number of visits in any given day have both increased. Whereas a referral base of 425 patients was formerly considered a minimum, this has now been recalculated to be 475 patients. And whereas the average number of visits was previously calculated to be a minimum of 2.8 per day as a financial break-even point, this has also now been reviewed and is thought to be 3.2 per day.

Increasing the referral base of patients can be daunting when operating in a freestanding outpatient facility, especially in certain geographic areas where competing practices offer similar services or in the rural locations where the distance patients must travel for care significantly restricts their choices. Therefore, many centers have chosen to expand their service lines and diversify the menu of services available, many of which are logical extensions given the hard infrastructure, disposable medical supplies, and background, training, and competencies of the clinic staff. There has been significant interest and growth in peritoneal dialysis–related procedures. Endovenous ablation and peripheral arterial interventions are becoming more common in the access centers as interventional radiologists, surgeons, and cardiologists perform these procedures.

CONCLUSION

The freestanding outpatient facility has evolved into a mainstay of dialysis access care and has been shown to provide consistently reliable and efficient care. Initial concerns with safety and quality have been largely quieted and dispelled. Challenges regarding the growth and survival of these centers are now largely focused around public policy, regulations, and the erosion of reimbursement schedules. With Accountable Care Organizations and the ESRD Seamless Care Organizations, the access center may have an opportunity to play an even more pivotal role as scarce resources are allocated to delivery systems that favor efficiency, effectiveness, safety, quality, and integration.

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TAKE-HOME POINTS

- The concept of freestanding outpatient centers that are dedicated to the care of dialysis vascular access patients began in the late 1990s, and by 2005, 58 of these centers were operational in the United States.
- Partnerships with the American Society of Diagnostic and Interventional Nephrology, Centers for Medicare & Medicaid Services, ESRD Networks, the FFBI, and others have garnered validity and recognition of these outpatient centers.
- These centers have faced challenges in proving their clinical safety and effectiveness and in acquiring adequate reimbursement.