

# Vascular Access Innovation in a Changing Health Care Environment

An opinion piece describing how global payment systems could potentially incentivize vascular access innovation.

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**H**emodialysis vascular access is the lifeline for more than 400,000 patients on hemodialysis in the United States. Unfortunately, due to the high incidence of dialysis vascular access dysfunction, it is also the “Achilles’ heel” of hemodialysis.<sup>1-3</sup> There are currently three main forms of permanent dialysis vascular access, all of which have their benefits and disadvantages.<sup>4</sup>

Arteriovenous fistulas (AVFs) are the preferred form of permanent dialysis vascular access because of good long-term survival and low rates of infection. Unfortunately, they have a very high failure-to-mature rate (ie, the inability of the AVF to increase blood flow and diameter adequately to support hemodialysis),<sup>5,6</sup> likely a result of a combination of neointimal hyperplasia and a lack of outward or positive remodeling.<sup>7</sup> Arteriovenous grafts (AVGs) do not have these early “failure to mature” problems; in fact, over 90% can be used for hemodialysis within the first 6 weeks.<sup>1</sup> However, AVGs have a dismal 1-year unassisted patency rate of only 23% due to a predictable and aggressive stenosis at the graft-vein anastomosis as a result of neointimal hyperplasia.<sup>8</sup> The least desirable form of permanent dialysis vascular access is the tunneled dialysis catheter (TDC), which carries a high morbidity and mortality burden as a result of catheter-related bloodstream infections; fibrin sheath formation, which leads to inadequate blood flow; and central vein stenosis.<sup>9</sup> Despite the problems associated with TDC dysfunction, almost 80% of new (incident) patients start hemodialysis with a TDC.<sup>10</sup>

The complications result in a significant morbidity and mortality burden for hemodialysis patients, substantially degrading their quality of life and imposing a heavy financial burden on our health care system. The total cost of dialysis vascular access is thought to be over \$1 billion per year with each additional interventional procedure costing between \$5,000 (angioplasty alone) and \$15,000 (thrombectomy and stent placement). In addition, each

episode of a catheter-related bloodstream infection is estimated to cost between \$15,000 and \$20,000.

This article describes the clinical problem of dialysis vascular access dysfunction, identifies possible reasons for the current lack of effective therapies for this important clinical problem, provides an overview of the current sweeping changes in the health care environment with a particular emphasis on added value, and speculates on how these changes could incentivize the development of innovative therapies for vascular access dysfunction.

## LACK OF EFFECTIVE THERAPIES FOR DIALYSIS VASCULAR ACCESS DYSFUNCTION

Despite the magnitude of the clinical problem and the fact that there have been significant advances in our understanding of the pathogenesis of AVF and AVG stenosis (neointimal hyperplasia and inadequate vascular remodeling) as well as TDC-related infections (biofilm formation), effective therapies for this critically important problem are lacking. There are a number of reasons for this paradox.

First, although an important strength of vascular access is its multidisciplinary nature, this has also been a weakness. The clinical leadership for vascular access care is fragmented and disorganized, which has resulted both in a lack of clearly defined research initiatives and clinical protocols in this area.<sup>11</sup> Second, at the level of health care economics, the presence of a fee-for-service model has not incentivized the development of preemptive therapies that would prevent downstream interventions and complications (eg, hospitalizations, readmissions, emergency department and interventional suite visits).

## CHANGES IN THE HEALTH CARE ENVIRONMENT: VALUE VERSUS VOLUME

We are currently in the midst of profound changes in health care. At the core of these changes is the focus



Figure 1. Continuum of United States health care payment systems. Note the gradual progression from fee-for-service, episodic care systems on the left to more global, population-focused, preventive, and holistic payment systems on the right.

on increasing value in health care, with “value” defined as improved outcomes at the same or lower cost.<sup>12,13</sup> In order to improve outcomes, we are rapidly moving from a volume-based system to a value-based system—from caring for an individual to caring for populations and from reactive care to preemptive care. Simultaneously, the payment systems are being realigned to pay for quality rather than quantity, by transitioning from a fee-for-service system to payment for performance to bundled payments to global payment systems (Figure 1).

Nowhere are these changes more apparent than within nephrology, particularly with regard to hemodialysis patients. The reason for this is in some ways self-apparent. Hemodialysis patients have extremely poor outcomes (35% mortality at 5 years<sup>14</sup>), but at the same time, these patients cost a lot of money to manage (poor value by any standard). For example, the total cost of hemodialysis for a single patient in the United States is \$85,000 per year, and the total cost of managing end-stage renal disease (ESRD), including hemodialysis, peritoneal dialysis, and transplantation, is \$49.3 billion.<sup>14</sup>

### THE ESRD SEAMLESS CARE ORGANIZATION MODEL

The combination of poor outcomes and extremely high costs is one of the reasons why the Centers for Medicare & Medicaid Services Innovation Center decided to develop the first disease-specific accountable care organization, known as the ESRD Seamless Care Organization (ESCO), for hemodialysis patients.<sup>15</sup> To date, there are 13 test ESCOs, most of which are partnerships between a nephrology physician group, a large dialysis organization, and a health care organization. For example, in Phoenix, Arizona, there is an ESCO that includes the Southwest Kidney Institute (a large, forward-thinking, community nephrology practice), Davita (a large dialysis organization), and Banner Health (a large health care organization that is also one of the nation’s most successful pioneer accountable care organizations).

In brief, in the ESCO model, the ESCO agrees to take on the entire cost of health care for at least 300 dialysis patients for a fixed sum of money. If the ESCO is able to manage these patients for less than the allotted amount (while meeting certain quality indicators), the ESCO

shares in the profit. On the other hand, if the ESCO spends more money than what was agreed upon, it shares in the loss. It is likely that the physician groups, large dialysis organizations, and health care organizations with the best and most streamlined process of care pathways will be successful in this global payments system model. However, in all cases, the likely winner will be the patient, as the ESCO model will move the needle toward a more preventive and holistic model of care as compared to the current episodic and interventional process of care.

Although the jury is still out on the clinical quality, process of care feasibility, and economic viability and success of the ESCOs, an additional benefit that has not been emphasized enough to date is that the ESCO model could also incentivize innovation within the world of kidney disease, especially in the context of vascular access. In particular, the ESCO model would favor interventions (eg, drugs, devices, and biologics) that reduce downstream costs due to hospitalizations or interventions. One could argue that the real benefit of the GORE® VIABAHN® Endoprosthesis in the setting of polytetrafluoroethylene graft stenosis was not necessarily the significant improvement in 6-month postinterventional unassisted primary patency (which diminishes), but rather the 27% reduction in costly downstream interventions over a 2-year period.<sup>16,17</sup>

### INCENTIVIZING NOVEL THERAPIES FOR VASCULAR ACCESS DYSFUNCTION

In the current fee-for-service, episode-of-care payment system, there is little incentive to develop interventions that reduce the number of downstream interventions and complications. In fact, the additional procedures could be important revenue generators. For example, consider a device that, when applied to an AVF at the time of surgery, ensures AVF maturation in 4 weeks, with no downstream episodes of TDC-related infection or endovascular/surgical procedures to help with AVF maturation. In the current fee-for-service system where payment is episodic, a \$2,000 price tag for such a therapy might be unsustainable because the benefit of this quicker and more successful maturation (less TDC-related infection and fewer endovascular maturation procedures) is not part of the same payment pie. In fact, in previous years (prior to the institution of quality metrics), the additional

downstream patient morbidity and cost generated by AVF maturation failure, such as TDC-related bacteremia and endovascular procedures, were actually important revenue generators.

In a global payment system such as the ESCO, an intervention that enhances AVF maturation priced at \$2,000 and that results in a shorter TDC contact time (due to rapid AVF maturation) and fewer maturation procedures would be a huge money saver. It has been estimated that each episode of TDC-related infection costs \$15,000 to \$20,000, and each angioplasty/stent placement costs between \$5,000 and \$15,000. Decreasing the number of TDC-related infections by only one episode and the number of endovascular maturation procedures by two for each unique patient would result in a per-person savings of \$40,000, which would pay for the \$2,000 cost of the device many times over. This would be separate from the huge, yet intangible, benefits that would accrue as a result of a reduction in morbidity and an improvement in the quality of life.<sup>18</sup>

## SUMMARY

Although there is uncertainty with regard to the introduction of global payment systems such as the ESCOs, one benefit that has been underplayed is the fact that these global payments could actually incentivize the development and use of innovative devices that would reduce downstream costs as a result of fewer hospital admissions and procedures—a true example of added value (eg, improved outcomes at a lower overall cost) due to innovative therapies. ■

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