

# Medicare Reimbursement Policies and Hemodialysis Vascular Access Outcomes: A Need for Change

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## ABSTRACT

In March 2010, the Center for Medicare and Medicaid Services (CMS) convened several clinical technical expert panels (C-TEP) to provide recommendations for improving various aspects of hemodialysis management. One of the C-TEPs was tasked with recommending measures to decrease vascular access-related infections. The members of this C-TEP, who are the authors of this manuscript, concluded unanimously that the single most important measure would be to remove financial and regulatory barriers to timely placement and revision of hemodialysis fistulas and the concurrent avoidance of catheter use. The following position paper outlines the financial barriers to improved vascular access outcomes and our proposals for a future CMS demonstration project.

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Vascular access management remains one of the most challenging aspects of caring for hemodialysis patients. There is broad consensus within the nephrology community about the major goal: patients should have a mature vascular access, preferably an arteriovenous fistula, when they initiate maintenance hemodialysis, to minimize the need for hemodialysis catheters.<sup>1</sup> Unfortunately, this goal is frequently not achieved. Common reasons for this failure include late referral of patients with chronic kidney disease to nephrologists, delayed access surgery, non-maturation of new fistulas requiring percutaneous or surgical revisions, or difficulty in cannulation of new fistulas by hemodialysis staff.<sup>2</sup> Negotiating these hurdles successfully requires a close multidisciplinary collaboration among the stakeholders, including nephrologists, access surgeons, inter-

ventionalists, hemodialysis staff, and patients.<sup>3</sup> Having a recognized position dedicated as vascular access coordinator can help to streamline this process.<sup>4</sup>

Whenever the process breaks down, for whatever reason, the patient initiates hemodialysis with a catheter.<sup>5</sup> Despite substantial progress in increasing the number of prevalent hemodialysis patients dialyzing with a fistula, about 80% of new hemodialysis patients (incident patients) in the United States use a catheter for hemodialysis.<sup>6</sup> Moreover, there are long delays before these patients make the transition to a mature fistula.<sup>7,8</sup> Compared with the use of a fistula, catheter use associates strongly with all-cause mortality, and changing from a catheter to a fistula or graft is associated with significantly improved patient survival.<sup>9</sup> The most overt and devastating complication of catheter dependence is access-related infection, a risk that is largely ab-

rogated by using a fistula or graft. Catheter-related bacteremia often leads to hospitalizations, serious complications, and substantial cost to the health care system<sup>10</sup>; infectious hospitalization rates in the first months of dialysis are now almost equal to rates of cardiovascular hospitalization, a finding that is new over the past decade.<sup>6</sup>

The economic magnitude of catheter-related bacteremia is staggering. Of the 400,000 hemodialysis patients in the United States, approximately 25% are dialyzing with catheters ([www.fistulafirst.org](http://www.fistulafirst.org)). The cumulative risk of bacteremia in catheter-dependent patients is nearly 50% at 6 months.<sup>7</sup> Each hospitalization for catheter-related bacteremia costs an average of \$23,000.<sup>11</sup> Thus, any measures implemented to reduce catheter-dependence in hemodialysis patients, particularly incident patients, would substantially reduce both early and late complications, and the economic burden associated with hospitalization or additional interventional procedures. Of the approximately 110,000 incident hemodialysis patients in the United States

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in 2007, 88,000 (80%) initiated hemodialysis with a catheter. Assuming these patients average one hospitalization for treatment of catheter-related bacteremia, the cumulative cost is  $88,000 \times \$23,000 = \$2.0$  billion. If measures were successful in reducing catheter use among incident patients by 50%, this would translate into a \$1 billion savings annually to Center for Medicare and Medicaid Services (CMS).

Both inadequate insurance coverage and insurer policies among those with insurance coverage are important obstacles to achieving optimal vascular access in hemodialysis patients. This problem spans the continuum from predialysis patients to newly initiated hemodialysis patients, and persists even in well-established hemodialysis patients. Chronic kidney disease (CKD) occurs disproportionately in low-income populations, and these patients frequently lack medical insurance or are underinsured.<sup>12,13</sup> In fact, the largest increase in the population using emergency departments over the past decade is in patients with Medicaid insurance. This implies that, despite some insurance coverage, access limitations to chronic care remain substantial among low-income individuals.<sup>14</sup> This may be a manifestation of underinsurance, often defined as the lack of needed benefits or services, limited access to providers, or extensive out-of-pocket costs.<sup>15</sup> Among insured adults between the ages 19 and 64 years, it is estimated that 25 million are underinsured.<sup>16</sup> As a result, it is difficult for many patients with CKD to establish appropriate predialysis medical care, including specialized nephrology care, obtain necessary predialysis fistula access in preparation for dialysis, or undergo predialysis surgical or percutaneous access revisions, when indicated. This decreases their likelihood of initiating hemodialysis with a preferred fistula and defaults them to a costly catheter.

The greatest barriers to increasing fistula use in the United States are present in the predialysis period before uninsured patients qualify for Medicare coverage. Thus, whereas the frequency of fistula use among prevalent hemodialysis

patients has increased substantially over the past few years (from 24% in 1996 to 56% in April 2010), the use of fistulas among incident hemodialysis patients remains <20%.<sup>17</sup> There is evidence that removal of financial barriers to placement of predialysis vascular access improves vascular access outcomes. For example, several European countries that provide universal health coverage report much higher fistula use in their incident hemodialysis populations compared with the United States (65 *versus* 15%).<sup>18</sup> Within the United States, the closest model of universal health care coverage in the predialysis population exists in the Department of Veterans Affairs and Department of Defense. Hurst *et al.*<sup>19</sup> recently reported that, among patients receiving their care in these two health care models in 2005 to 2006, the proportion of fistula use among incident patients was 21.4% compared with only 13.5% among patients with Medicare coverage, further illustrating a potential role of underinsurance. These differences persisted even after adjustment for multiple demographic factors and comorbidities. Potential advantages of the Department of Veterans Affairs and Department of Defense system that promoted greater access to subspecialty care for CKD patients include established health coverage, use of electronic health records, case management services, colocation with surgeons, and a defined referral algorithm for CKD.

A recent cross-sectional study of 28,135 patients observed an inverse correlation between county-level poverty and the proportion of facility patients initiating hemodialysis with a fistula: the higher the poverty level, the lower the proportion of patients with a fistula.<sup>20</sup> Although not explicitly stated, patients in high poverty areas are more likely to be uninsured or underinsured. Critically, prevalent AVF rates in this study increased in all centers independent of local poverty, suggesting that access to the Medicare ESRD program mitigated the effects of poverty on dialysis access. To illustrate how this observation applies at the facility level, we reviewed the experience of one of the authors (M.A.), a med-

ical director of a large dialysis unit (approximately 125 patients), in a high-poverty urban area. Of 31 new patients initiating hemodialysis in 2009 at this facility, 19 (61%) had no type of insurance, and all 19 of these patients initiated dialysis with a catheter and no secondary vascular access. Within 1 year of initiating hemodialysis, 16 of these 19 patients had either a fistula or graft. Contrast this high proportion of uninsured incident hemodialysis patients at a high-poverty urban unit to the national rate of 7.5% documented as uninsured patients who started dialysis between 2006 and 2008.<sup>21</sup>

Again, this discrepancy strongly suggests that removal of financial barriers to optimal vascular access management might improve outcomes.<sup>22</sup> Whereas poverty is associated with lower fistula rates among incident patients, it is not associated with the rate of fistulas among established hemodialysis patients who already qualify for Medicare and often have access to secondary insurance or other resources to assist with the 20% not covered by Medicare.<sup>20</sup>

What explains these disparities, both within and between the United States and other nations? To begin, nearly all previously uninsured and underinsured patients in the United States eventually qualify for Medicare coverage after initiating maintenance hemodialysis, thereby removing an important barrier to vascular access procedures: the creation and revision of fistulas. Unfortunately, unless the patient undergoes training for home dialysis (only approximately 8% of the total U.S. dialysis population), there is a substantial waiting period, up to 3 months, before they are Medicare eligible. Surgeons and interventionalists are understandably reluctant to perform preoperative evaluation (vessel mapping or venography) and vascular access procedures (fistula creation and subsequent revisions) without reimbursement. As a result, these vascular access procedures are shifted to 3 months after initiation of hemodialysis. By that time, such patients will have had at least one hemodialysis catheter with all its associated risks and costs. Their catheter dependence is further prolonged while waiting for creation

of the fistula and appropriate revisions, which may take a few months before the fistula is suitable for hemodialysis.

Another critical and often overlooked factor is that, among both incident and established hemodialysis patients with insurance coverage, including Medicare, current reimbursement rules do not promote efficient vascular access management when an initial hemodialysis access must be created or the existing hemodialysis access fails. For example, when a patient undergoes both a fistula and dialysis catheter placement on the same hospital day, only one of the two procedures is fully reimbursed by Medicare. To avoid this financial disincentive, a patient with Medicare coverage may receive only a catheter on that day, with the fistula surgery being postponed to a future date. This type of delay prolongs catheter dependence. Another example is the patient who initiates maintenance hemodialysis in the hospital. Placing a fistula during that initial hospitalization would optimize medical management but would result in a loss

of revenue for the hospital, even if it did not result in a prolonged hospitalization, unless the diagnosis-related group reimbursement for that hospitalization can be expanded to allow for fistula surgery.

CMS is sending mixed messages to the nephrology community. On the one hand, CMS is strongly promoting fistula use in hemodialysis patients and chastising nephrologists for having too many catheter-dependent hemodialysis patients. On the other hand, existing CMS reimbursement policies create substantial financial barriers for prompt and proactive care, making timely achievement of fistulas more difficult than is appropriate, particularly among incident hemodialysis patients for whom the burden of care has been shifted away from the predialysis setting and onto hemodialysis providers.

We propose several elements to be considered for a future CMS demonstration project (Table 1). First, we suggest that Medicare policy be revised to allow for earlier disbursement of

Medicare benefits for vascular access procedures to uninsured and underinsured patients who would ultimately be eligible for full Medicare coverage. We propose that Medicare provide sufficient reimbursement for creation of native fistulas, as well as for subsequent surgical and radiologic revisions needed to achieve fistula maturation and maintain fistula patency for hemodialysis. Specifically, these payments should be made available both for uninsured patients who are not yet on hemodialysis, as well as for newly initiated hemodialysis patients who have not yet qualified for Medicare. This would remove financial barriers to timely fistula creation in predialysis patients and new hemodialysis starts. Second, as an added incentive, we propose that full Medicare coverage take effect in all patients initiating hemodialysis with a functional fistula. Third, we propose that, if fistula use has been accomplished before the first 90 days of dialysis, full Medicare coverage would take effect immediately. Medicare has al-

**Table 1. Recommended changes in Medicare reimbursement for hemodialysis vascular access management**

Earlier disbursement of Medicare benefits to uninsured patients requiring fistula placement

Uninsured individuals with CKD before requiring hemodialysis: provide payment for surgical and radiological procedures necessary for the creation of hemodialysis fistulas, as well as surgical and radiologic modifications necessary to achieve fistula maturation during the pre-dialysis period for uninsured CKD patients who ultimately would qualify for Medicare coverage once they have initiated hemodialysis. In patients whose hemodialysis fistula has failed despite appropriate interventions or those patients deemed to be unsuitable candidates for fistula creation, Medicare will provide reimbursement for hemodialysis graft procedures.

Uninsured new ESRD patients within the first 90 days of hemodialysis: for uninsured new hemodialysis patients who initiate hemodialysis with a catheter only, and who would be eligible for Medicare coverage at 90 days after initiating hemodialysis, provide immediate payment for surgical and radiological procedures necessary for the creation of native arteriovenous fistula, as well as surgical and radiologic modifications necessary to achieve fistula maturation. In patients whose hemodialysis fistulas have failed despite appropriate interventions or those patients deemed unsuitable candidates for fistula creation, Medicare will provide reimbursement for hemodialysis graft procedures.

Incentives for achieving a mature, functional fistula in new hemodialysis patients: new uninsured hemodialysis patients who initiate hemodialysis with a fistula or whose fistula is successfully used for dialysis before the first 90 days of dialysis with catheter removal, would qualify for immediate, full Medicare coverage during the first 90 days of dialysis, similar to the benefit currently available for those patients who begin a period of home dialysis training prior to the end of the 90-day waiting period.

Changes to the current physician and hospital reimbursement for fistula placement

Physician payments: if both a hemodialysis catheter and fistula are placed on the same day, current Medicare payment policy results in only partial payment, reimbursing fully for only one of the two accesses placed on that day. We recommend that CMS provide a full rate of payment to the surgeon, interventionalist, and hospital for both accesses placed on the same day, when one of the procedures is creation of a fistula. This incentive will discourage delays in permanent access placement (fistula) among hemodialysis patients, by avoiding scheduling of the fistula placement to a date later than that of catheter placement.

Physician payment: for incident hemodialysis patients, we recommend an additional incentive payment to surgeons, interventionalists, and nephrologists for any fistula that is used satisfactorily for hemodialysis at initiation and for the following four months, as indicated by sustained catheter removal.

Facility payment: for patients who initiate hemodialysis urgently in the hospital, we recommend an expanded diagnosis-related group reimbursement to allow for prolonging the hospitalization to accommodate surgery for placement of a hemodialysis fistula or graft.

ready set a precedent, whereby full reimbursement occurs for patients who successfully perform peritoneal dialysis within 90 days. Fourth, we recommend enhanced reimbursement for physicians and hospitals to expedite timely hemodialysis fistula placement. This would include provision of the full Medicare rate of payment for both procedures if a patient requires creation of a new fistula and a tunneled hemodialysis catheter during a single hospitalization, as well as incorporation of an incentive payment to the access surgeon, interventionalist, and nephrologist for any fistula that is used successfully at initiation of dialysis or if the bridging catheter is removed within 4 months of creation of a functioning fistula. Finally, in patients hospitalized with an urgent need to initiate maintenance hemodialysis, the diagnosis-related group reimbursement for that hospitalization should be expanded to encourage permanent access placement (fistula or graft) during that same hospitalization. Ultimately, the effects of the above items will need to be assessed with evidence-based performance measures that take into account both patient preferences and mortality and infectious outcomes, as well as overall access rates.

There are other possible ways in which these goals could be attained, all of which require more substantial changes in healthcare policies. An Accountable Care Organization (ACO) model for healthcare reform that incorporates both late-stage CKD and ESRD can implement fistula attainment as a priority. For example, if dialysis providers assumed the role of an ACO, they will undoubtedly explore financing the creation of predialysis access for potential patients. Under the ACO model, they will be exempt from the current federal anti-kickback statute (42 U.S.C. 1320-7b) and the patient inducement statute (42 U.S.C. 1320-7a). This model will also allow for the ACO provider to fund pay-for-performance incentives for surgeons and nephrologists in anticipation of accruing savings from decreased hospitalization and improved

survival, such as those previously proposed by Hakim and Himmelfarb.<sup>23</sup> Although the ACO model lends itself well to directly address the issue, the details and ramifications of implementing this model have yet to be examined fully.

We harbor no illusions that all of the changes we propose can be implemented by CMS without legislative changes to relevant statutes. Albert Einstein once said, "All meaningful and lasting change starts first in your imagination and then works its way out." Although proposing any change to the Medicare system may seem overly optimistic, it is only by publicizing these ideas that change even has a chance to occur. Others have already sounded the alarm bells,<sup>23</sup> but it is important to focus on very specific ideas and garner wide-based support from various stakeholders that are at least as diverse as the composition of the expert panel. Accordingly, in this document we stressed practical reasons why change is needed and have outlined a plan that may benefit all stakeholders, including payers, providers, hospital systems, and patients.

Specifically, by removing financial barriers to timely vascular access procedures, these proposed changes will provide economic incentives to reduce catheter use in new hemodialysis patients and thereby minimize access-related infections and other adverse consequences. The enormous savings realized from a reduction in catheter-related infection should easily offset the additional costs incurred by this revised reimbursement policy. We suspect that the impact of this sensible policy on patient health, satisfaction, and quality of life will be substantial.

## DISCLOSURES

M.A. is a consultant for CorMedix and HemoSphere and the Medical Director of a DaVita hemodialysis unit. L.D. is a consultant for HemoSphere, Teleflex Medical, Genentech, Covidien, and SurgPro. E.L. is an employee of Fresenius Medical Care, North America. C.E.L. is a consultant for CorMedix. T.S. is on the Medical Advisory Board for American Renal Associates. D.E.W. receives research funding from Covidien and Dialysis Clinics

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