Payment for Quality in End-Stage Renal Disease

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The Centers for Medicare and Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Program has served as a model for health care policy innovation because of several unique features: the program provides dialysis and kidney transplantation services where the alternative to renal replacement therapy is death; the program has a circumscribed, easily tracked population of patients; and the cost associated with the program has afforded administrators and providers opportunity for innovation and improvement in care delivery over the past three decades (1). Additionally, the wealth of detailed information available from unique databases such as the United States Renal Data System that have been designed to follow the ESRD population have facilitated assessment of the effect of evidence-based guidelines that have shaped health care delivery and policy. The recent publication of the Final Physician Fee Schedule Rule by CMS, the release of the Medicare Payment Advisory Commission (MedPAC) report on payment for outpatient dialysis, and the Medicare Modernization Act (MMA) of 2003 have focused attention on the goal of linking payments to quality care in the ESRD setting. The leadership of the American Society of Nephrology and the National Kidney Foundation recently convened a working group of experts to examine whether the ESRD system of payment can be redesigned to encourage quality-based care delivery. The deliberations of this group (Appendix) helped formulate this article.

Quality Improvement Efforts and Patient Outcomes in the ESRD Program

The ESRD Program has long been associated with quality assurance and continuous quality improvement efforts that have taken place at the individual dialysis facility and provider level (2). Notably, the Forum of ESRD Networks are not-for-profit contractors with CMS that are charged with oversight of outpatient dialysis and transplantation facilities, whose central activity is the development and use of quality measures and quality improvement processes. The central activity of the 18 networks is the development and use of quality measures and quality improvement processes. In 1992, Medicare introduced the Health Care Quality Improvement Program (HCQIP), with the goal of a systems focus on consistent improvements in patient outcomes (3). Included in the ESRD HCQIP was the National/Network ESRD Core Indicators Project, CMS’s first nationwide population-based study designed to assess and identify opportunities to improve the care of ESRD patients. The ESRD Core Indicators Project has subsequently been merged into CMS’s ESRD Clinical Performance Measures Project on the basis of the National Kidney Foundation’s Dialysis Outcome Quality Initiative (DOQI) Clinical Practice Guidelines. Sixteen ESRD Clinical Performance Measures (CPM) (five for hemodialysis [HD] adequacy, three for peritoneal dialysis [PD] adequacy, four for anemia management, and four for vascular access) were developed. The ESRD CPM are collected annually on a national random sample of adult hemodialysis patients and peritoneal dialysis patients.

These efforts have led to consistent and widespread improvement in ESRD care. For example, in each of the years from 1993 to 2003, measures of dialysis adequacy as well as the treatment of anemia improved nationwide (Figure 1). The consistent improvement in these clinical performance measures serve as a model of quality improvement for other aspects of the health care industry. CMS has also sponsored a collaboration entitled “The National Vascular Access Improvement Initiative” with the Institute for Health Care Improvement and the ESRD Networks to improve the quality of vascular access for hemodialysis patients. The Forum of ESRD Networks, Renal Physician’s Association, and the National Patient Safety Foundation have completed the initial phases of an ESRD Patient Safety Initiative, designed to identify action agendas to improve patient safety in dialysis care. Thus, there have been major efforts and several tangible successes in improving overall quality in the ESRD program. However, there remains wide variation in meeting these metrics, and there have also been only minimal improvements over a decade in risk-adjusted mortality for dialysis patients (4). Thus, there are opportunities for continued quality improvement.

Defining and Measuring Quality Care

The Institute of Medicine defines health care quality as “the degree to which health services for individuals and populations
increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (5). Donabedian (6) first proposed a framework of assessing quality of medical care consisting of structure, process, and outcome. In this framework, structure consists of the stable elements that form the basis of the health care system; process consists of the technical and interpersonal components of what is done within the structure; and outcome consists of what happens to the health of the patient and the end results of health care practices or interventions. In Donabedian’s framework, structure influences process and both structure and process influence outcomes (Figure 2). Providing financial incentives for the desired outcomes themselves would seem to be the simplest and most straightforward strategy for implementation; however, there is often limited understanding of the many determinants of desired patient outcomes and attaching reimbursement to a global measure may not direct providers to the specific activities that can achieve a desirable outcome. By contrast, there are often more extensive data as to specific performance measures that are associated with improved patient outcomes including in ESRD patients. It is important to recognize, however, that improving structure/process components that lead to improved intermediate outcomes might not necessarily improve overall outcomes. As an example, in a cross-sectional study, an increased frequency of physician visits to dialysis patients improved compliance with attendance at dialysis sessions, the latter being associated with reduced mortality in other analyses. Nevertheless, increased physician visits was not itself associated with reduced mortality (7).

Current Payment System to Physicians for Dialysis Services

In the November 7, 2003, Final Physician Fee Schedule Rule, CMS announced its final decision on the new Monthly Capitation Payment (MCP, the per patient, per month payment that Medicare provides to the nephrologist for ESRD services) that would be effective January 1, 2004. CMS has implemented a system that uses temporary “G” codes that establish different payments for the services represented by the MCP on the basis of the number of nephrologist-dialysis patient interactions in the month. Four nephrologist-dialysis patient interactions would receive an increased payment, but one, two, or three visits/mo payments for the MCP services would be reduced. On the basis of the published payment in the final rule, the approximate adult MCP payment levels are: $287 for four visits or more; $239 for two to three visits; and $191 for one visit. In the final rule, the degree of payment variability has been compressed compared with the August 15, 2003, notice of proposed rulemaking, but continues to adhere to the graduated payment system. For home dialysis, the MCP will be reimbursed at $237 for a full month of home dialysis. Two sets of home dialysis codes have been established, one for the full month and one for less than a full month.

Current Payment System to Facilities for Dialysis Services

Medicare pays a prospective payment (the composite rate) for each dialysis treatment provided in dialysis facilities (in-center) or in patients’ homes. The average composite rate was about $130 per dialysis treatment and this accounted for 59% of total Medicare payments to facilities in 2001. In addition, facilities receive separate payments for services such as injectable drugs, and these payments averaged about $80 per dialysis treatment in 2001 and constituted 41% of total Medicare payments to facilities. Medicare spending for outpatient dialysis services increased 9% between 1996 to 2001, largely driven by growth in the ESRD population and increased use of new technologies and drugs. The MMA of 2003 recommends the following important changes in the payment for ESRD: (1) a case mix–adjusted payment system for certain services; (2) a
report to the Congress on the design and features of a bundled prospective payment for dialysis services; (3) the conduct of a demonstration study of a bundled payment system; (4) other changes including an update of the composite rate by 1.6 percent in 2005 and restoration of the exemption to the composite rate for pediatric facilities, and (5) changes in payment for separately billable drugs.

Case Mix–Adjusted Payments

Beginning on January 1, 2005, the Secretary of Health and Human Services is required to enact a basic case mix–adjusted payment system for dialysis services. The current composite rate is adjusted for differences in labor costs by means of two dated hospital wage indices. MedPAC has recommended that the Secretary develop a wage index based on market wage rates for occupations typically used in furnishing dialysis. The key is that the Medicare Modernization Act (MMA) requires that the case mix–adjusted payment system result in the same aggregate amount of expenditures for such services as would have been made in 2005, 2006, and 2007 if payments were not case mix adjusted. The new composite rate payment will include the “spread” between the current average wholesale prices and the acquisition cost of injectable drugs and biologicals, while the acquisition cost of these injectable drugs and biologicals will be paid outside the composite rate.

Bundled Payment System

The Secretary is required to submit to the Congress by October 1, 2005, a report on broadening the outpatient dialysis payment system to include injectable drugs, laboratory tests, and other items currently excluded from it.

Demonstration Project

Beginning on January 1, 2006, the Secretary is required to conduct a 3-yr demonstration to test a broader payment bundle that includes injectable drugs and clinical laboratory tests that are currently excluded from it.

Payment for Quality in Health Care

Efforts have begun to redesign the system of reimbursement to provide financial incentives for improved patient/population outcomes (8,9). Physicians are generally familiar with financial incentives designed to achieve “quality” health care and are more likely to respond to such incentives than to financial incentives designed to control the use of services (9). Designing a reimbursement system that provides financial incentives for desired health outcomes requires consensus as to what constitutes desirable patient outcomes, and what the components of health care delivery are that lead to these desirable outcomes (so-called quality health care). Achieving this consensus for a given disease or syndrome requires long-term, extensive research as to the characteristics of the population with the disease and longitudinal outcome data. The lack of this consensus has limited the use of financial incentives for quality on a national level in the United States.

The Institute of Medicine has recently called on government payers to increase payments to health care providers for the delivery of high-quality care (5). Several private payers have already begun a transition to financial incentives for improved adherence to standards of care, improved patient outcomes, and patient satisfaction (9). This is a important departure from incentives in an earlier era that were primarily targeted at controlling utilization. The National Health System in the United Kingdom has recently adopted a wide-ranging initiative to increase payment for performance (10,11). However, in the United States, there has not yet been an attempt on a national level for government payers to increase payments to health care providers on the basis of a measurement of higher-quality care. Thus, a plan to institute payment for quality in the ESRD program would be a unique and groundbreaking effort.

Feasibility of Payment for Quality in Dialysis Care

Currently, dialysis conditions of coverage are mainly structural requirements designed to ensure the capacity of facilities to safely furnish quality health care. Medicare can exclude
Considerations for Effective Quality Incentives in ESRD Care

Alignment of Incentives. When appropriate, dialysis facilities and physicians together should be held accountable to the same set of performance indices because delivery of quality care to ESRD patients requires a close and continuous collaboration between these two partners. This should be feasible because provider and facility payments are both under Medicare Part B. Nevertheless, some quality indices may be influenced more by one party than the other. A case in point is arteriovenous fistulae: dialysis units would have little control of the prevalence of arteriovenous fistulae, but nephrologists can affect this metric if involved in the care of the patient before ESRD. Aligning incentives to improve care may help to reconcile financial differences that can currently exist between nephrologists and providers, for example, with vascular access monitoring or with the use of newer peritoneal dialysis solutions for ultrafiltration failure.

Quality Targets: Quality Assurance or Continuous Quality Improvement?. The question as to whether incentives should be based on improving care from current levels, exceeding national averages, or some combination needs further study. MedPAC believes that a fair and balanced approach will reward providers on the basis of combined methods, allowing providers at both ends of the quality spectrum to achieve financial incentives (12). Linking payments only to improvements from current levels could reward providers who achieve marked improvement but remain at the bottom tier of the quality spectrum. In contrast, establishing a single target could encourage all providers to improve. However, the level of goal-setting poses a dilemma. Setting goals too high might discourage providers at the low end from trying to improve, and setting target goals too low might not motivate high-quality providers to improve outcomes. Despite the advent of accurate risk adjustors, both methods individually run the risk of providers cherry-picking their patients. Providers would have an incentive to select patients with lower outcome scores if the payment were linked solely to exceeding target goals.

Size and Source of Incentives. MedPAC believes that linking quality to payment should not require additional funding by Medicare (12). However, most large dialysis providers would argue that a high dose of dialysis requires incremental resources including more expensive dialyzers and personnel time. Similarly, most nephrologists would strongly argue that, for example, increased resources will be required to meet changing and escalating quality targets. With either approach, it would be appropriate to begin with a small incentive pool for changing and escalating quality targets. With either approach, it would be appropriate to begin with a small incentive pool for distribution to providers reaching quality targets because this approach minimizes the adverse effect on providers who initially are not able to meet quality criteria, and still emphasizes improvements in areas outside the incentive program. A 1% quality pool would equal about $70 million for dialysis facilities (Medicare payments for dialysis and injectable drugs in 2001 was $7 billion), and $15 million for physicians (Medicare payments were $1.5 billion in 2001) and could be used for this purpose. As experience accumulates and providers become more accustomed to being rewarded for quality, the pool for quality could increase as could the number of measures used to measure quality of care. Over time, if Part A savings are accrued as a result of improved quality of care resulting in decreased hospitalization rates, they should be redistributed to
physicians and facilities (Part B) to further expand the incentive pool and continuously drive the quality imperative to higher levels of achievement.

**Measures of Quality.** Whether process or outcome measures are the most valid and precise measures of quality is unresolved (13). Many researchers recommend balancing process and outcome measures to better assess quality improvement efforts while simultaneously providing evidence that such efforts are benefiting patients (14,15). Credible quality measures should be science based, easily measurable, timely and sensitive to change. As noted, the NKF K/DOQI clinical practice guidelines are a good starting point for evaluating available evidence in adequacy of dialysis, vascular access, anemia, nutrition, bone and mineral metabolism, lipids, and BP. Metrics such as patient satisfaction, adherence, quality-adjusted life expectancy, and standardized mortality and hospitalization rates can also be considered. However, specific metrics for quality payments should be carefully calibrated with the active involvement of the nephrology community.

**Beneficiaries Should Participate in Improvements in Care.** Patients also contribute importantly to improving dialysis outcomes (16). Outcomes are adversely affected for patients who do not comply with their treatment regimens. Patient adherence may also be affected by economic factors and needs to be appropriately case mix adjusted. Furthermore, patient preferences must be considered in evaluating clinical performance. As an example, performance should be viewed differently when patients refuse a screening test, compared with patients not being offered a screening test (17).

**Potential Pitfalls in Paying for Quality in ESRD**

**The Strength of Evidence.** The standard of evidence forming the basis for current clinical practice guidelines in the care of dialysis patients is derived largely from epidemiologic studies and not from randomized clinical trials. There are a paucity of randomized clinical trials in the dialysis population demonstrating that any process of care is associated with an improved outcome (18). Notably, the HEMO Study, the most comprehensive clinical trial performed to date in the hemodialysis population, supported the null hypothesis for the interventions (dose of dialysis and dialysis membrane flux) on primary outcomes, despite robust epidemiologic data suggesting that these process variables would be related to patient outcomes (19). The lack of evidence supporting improved outcomes from clinical trials also accentuates the crucial need for further clinical trials in the dialysis population.

**The Individual Physician (The “Tyranny of Small Numbers”).** A caveat, particularly when paying individual physicians for high quality ESRD care, is the recognition that an individual nephrologist often takes care of fewer than 60 dialysis patients. At this relatively low volume level, it is difficult to fully adjust the case mix with sufficient reliability to accurately evaluate individual physician performance. In an analogous study assessing the reliability of individual physician “report cards” in the care of patients with diabetes mellitus, it has been suggested that a “shrinkage factor” should be applied to each physician’s profile to adjust the performance measure to the level of reliability (20). The same applies to small dialysis centers. Furthermore, with a relatively low “panel” of patients, nephrologists may be tempted to cherry-pick patients to ensure a good profile by refusing to care for sicker patients, less adherent patients, and those who have not responded to previous therapeutic interventions.

**Careful Assessment of Quality Indicator Numerics (The “Tyranny of Large Numbers”).** The substantial improvement that has already occurred in anemia management and dialysis adequacy suggest that improvements in these clinical performance measures might be approaching a plateau (Figure 1). Furthermore, there can be important differences in the percent of patients achieving a target goal on the basis of the time period of averaging values, as the tails of the population distribution for a given biologic variable tend to increase when variables are averaged over a greater time period. This is particularly important if intrapatient variability is unidirectional, where averaging over greater periods of time may “worsen” outcomes. An excellent example of this in the dialysis population is the serum albumin concentration, where a lower than normal albumin (as a function of malnutrition and/or inflammation) is much more common than a supra-physiologic albumin. Consequently, the percentage of patients whose serum albumin is within target range varies with the averaging time interval.

**Feedback Loop.** A crucial requirement for a successful quality payment program is a requirement for frequent and timely feedback on performance to physicians and providers (14). As noted by MedPAC and others, despite the availability of claims files and performance data, CMS to date has not been able to rapidly turn around information and report it in a sufficiently timely fashion. CMS would need to improve its performance in this area to close the feedback loop.

**Incomplete Case Mix Adjustment.** As a general rule, differences in physician practice variations generally account for less than 4% of an outcome when data are sufficiently adjusted for case mix variation (21). In the dialysis population, despite the identification of a number of laboratory-, demographic-, and morbidity-associated data predictors of patient outcomes, unknown and unmeasured variables account for the bulk of patient outcomes (22). Facility-specific data also suggest that incomplete case mix adjustment may account for much of the observed differences in facility-specific outcomes (23–25).

**The First Six Months.** A related issue is the deferment of patients who have been on dialysis for less than 6 mo to stabilize dialysis care and treat the complications of chronic kidney disease, which are often suboptimally managed before start of dialysis (26). Dialysis units and nephrologists caring for ESRD patients should not be held responsible for suboptimal care before initiation of dialysis.

**Spectrum of Quality Indicator Selection.** Directing financial incentives at a small number of individual indicators of clinical quality is unlikely to yield broad-scale improvements in the quality of care (20). Rotating measures and expanding over time the battery of performance indicators that are tied to financial payments will probably be more successful strategies
(27). However, many researches have suggested that there are unintentional consequences with this approach (28–30). This suggests that ongoing research will assist in the development of a credible system in this area, and emphasizes the need for information feedback loops in monitoring quality measures.

The Problem Segments. Some segments will challenge quality-based incentives. Pediatric dialysis facilities are a particular challenge because they are few in number and have few patients, and pediatric patients tend to have multiple medical and psychosocial problems requiring many more resources. Likewise, a reduction in payment for facilities in underserved communities not meeting expected quality targets might lead to closure, thereby leaving patients with less desirable alternatives. Individual physicians who own their own units, small chains, and hospital-based units also pose challenges.

Conclusion

The Medicare ESRD program began providing reimbursement for dialysis services to patients since 1973, creating a well-defined, accessible, and trackable population of patients that has been extensively analyzed with regard to morbidity and mortality. In addition, the United States Renal Data System has collected an extensive body of data on this population since 1988, providing the database that continues to be used to investigate ESRD patient outcomes, the determinants of these outcomes, and how interventions influence the outcomes. Consequently, the ESRD population represents an excellent population for which to design a reimbursement system that provides incentives for quality health care.

A properly formulated incentive-based system for paying for high quality dialysis care is a desirable and achievable goal. This system must use validated measures of quality that can be reliably measured, must align incentives between physicians and dialysis providers to maximize cooperation, must be willing to provide increased reimbursement for increased resource expenditure, and must be supported by a timely continuous feedback of information to physicians and providers to be successful. Although many parameters essential for aligning objectives and performance metrics are challenging and require additional and ongoing evaluation, it is reasonable to begin moving toward a quality-based incentive program for dialysis reimbursement at this time. A successful collaboration between CMS, physicians, and dialysis providers is likely to improve the care of Medicare beneficiaries requiring dialysis care, and may serve as an effective model for other components of Medicare reimbursement.

Appendix

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References


