Evaluating the Evidence behind Policy Mandates in US Dialysis Care

Kevin F. Erickson1,2,3 and Wolfgang C. Winkelmayer1

1Department of Medicine, Selzman Institute for Kidney Health, Section of Nephrology, and 2Department of Medicine, Center for Innovations in Quality, Effectiveness, and Safety, Baylor College of Medicine, Houston, Texas; and 3Baker Institute for Public Policy, Rice University, Houston, Texas

Approximately 25% of patients initiating dialysis in the United States are covered by state Medicaid programs, and Medicare covers 65% of all prevalent patients receiving dialysis, presenting significant challenges for federal and state budgets.1 In an effort to contain costs without compromising the quality of dialysis care delivered, public payers tightly regulate the provision of dialysis care. Federal mandates, in particular, have affected nearly all areas of dialysis care delivery. Yet, the evidence supporting federal mandates varies, contributing to differences in the achievement of stated policy objectives.

A recent perspective outlined key features to consider when assessing the evidence behind policy mandates, including: (1) clearly defining the policy of interest, (2) evaluating policy within the context of specific goal(s), and (3) assessment of the magnitude of the policy’s effect on the stated goal(s).2 We apply these principles to evaluate the evidence behind two prior federal mandates affecting the care of patients with ESRD receiving hemodialysis: reform of the Monthly Capitation Payment (MCP) for nephrologists providing outpatient dialysis care in 2004, and inclusion of injectable medications into the ESRD composite rate payment to dialysis facilities in 2011. More than 20 years of combined follow-up since these policies were enacted provide sufficient time to assess how the quality of evidence supporting each policy contributed to its overall success.

Nephrologist Reimbursement Reform

In July of 2003, the Centers for Medicare and Medicaid Services (CMS) announced a plan to transform reimbursement to nephrologists for the delivery of outpatient dialysis care. At the time, nephrologists received a single monthly payment for providing outpatient dialysis care, regardless of how frequently they visited a patient. Beginning in 2004, CMS implemented a tiered fee-for-service payment system, where reimbursement varied according to the number of times per month that a physician (or advanced practitioner) saw a patient. At the time of its proposal, CMS wrote that the goals of the physician payment reform were to “align incentives,” “encourage increased frequency of face-to-face visits for patients who require it,” and, in doing so, to “improve the quality of care delivered.”3

Evidence before the MCP reform from other areas of health care indicated that physicians responded to economic incentives, although this had not been explicitly studied in the outpatient dialysis setting. Evidence since the policy was enacted suggests that the policy effectively led physicians to increase visits to patients who were most likely to benefit from closer supervision. In a national study after the MCP reform, sicker patient populations, those living in poorer areas, and those in rural areas were less likely to be seen weekly than those who were healthier and less vulnerable socioeconomically, suggesting that the policy may have led to more frequent visits in places where they were less necessary or of potential benefit.7 Although the MCP appears to have succeeded—at least partially—in encouraging more frequent physician visits before reimbursement reform, the overall magnitude of the policy’s effect on visit frequency remains unknown. Importantly, the economic (or “opportunity”) cost associated with the policy, which characterizes the cost (or time) associated with practitioners spending more of their finite effort delivering care in the outpatient dialysis setting, is unknown and may vary widely depending on the extent to which visit frequency actually increased in response to the policy.6 It is also unknown whether the reimbursement reform successfully led physicians to increase visits to patients who were most likely to benefit from closer supervision. In a national study after the MCP reform, sicker patient populations, those living in poorer areas, and those in rural areas were less likely to be seen weekly than those who were healthier and less vulnerable socioeconomically, suggesting that the policy may have led to more frequent visits in places where they were less necessary or of potential benefit.7

Published online ahead of print. Publication date available at www.jasn.org

Correspondence: Dr. Kevin F. Erickson, Baylor College of Medicine, 2002 Holcombe Boulevard, Mail Code 152, Houston, TX 77030. Email: kevin. erickson@bcm.edu

Copyright © 2018 by the American Society of Nephrology
there is no evidence that the policy led to desired improvements in the quality of care delivered. Cross-sectional studies examining the associations among nephrologist visit frequency and health outcomes—both before and since the 2004 policy—are inconclusive.4–8,11–14 For example, national studies suggest that more frequent nephrologist visits during outpatient hemodialysis are associated with slightly fewer hospitalizations, more substantial reductions in 30-day hospital readmissions, and earlier placement of arteriovenous fistulas,11–13 but that they are not associated with patient mortality and that they may lead to more wasteful vascular access procedures.5,11–14 Meanwhile, policy evaluations comparing periods before versus after the policy reform have consistently failed to observe any associated changes in relevant health outcomes.4,6,14 To the extent that more frequent visits are associated with improvements in certain health outcomes, increased visits resulting from the payment reform did not yield similar benefits.6

Unfortunately, the stated objective of “aligning incentives” is not clearly defined. There was no mention in the time leading up to the policy of what specific incentives were being aligned. This lack of clarity prevents assessment of one of the policy’s primary objectives, impeding efforts to evaluate the policy’s effectiveness in its entirety.

“BUNDLED” PAYMENT FOR DIALYSIS

The Medicare Improvements for Patients and Providers Act of 2008 required CMS to add injectable medications administered during dialysis to the Composite Rate bundle of dialysis services beginning in 2011. In its final rule released to the public in 2010, CMS summarizes three primary objectives of this policy: (1) reduce the overuse of profitable separately billable drugs, particularly erythropoietin (EPO); (2) through flexibility offered, increase desirable outcomes and enhance the quality of care; and (3) target payment to facilities with more costly patients in order to promote equitable payment and access to services.15

The first two stated objectives of the expanded ESRD Bundle were on the basis of the expectation that dialysis facilities would respond to the economic incentive to deliver fewer injectable medications, and that the flexibility to reduce the use of separately billable drugs through a variety of means would not impair, and might improve, patient health. Evidence examining EPO use in the period before enactment of the policy supported both of these assertions. A report from the Government Accountability Office in 2006 found that dialysis providers responded to two prior changes in reimbursement incentives by reducing EPO use.16 Clinically, one small randomized, controlled trial of patients with ESRD followed by two larger trials of patients with CKD indicated that delivering more EPO does not improve patient health and may be harmful.17–19

Extensive data on the administration of injectable medications, including erythropoietin-stimulating agents (ESAs), were recorded in Medicare claims before and after the expanded ESRD bundle, enabling rapid monitoring of utilization changes after enactment of the policy. Evidence on the basis of these data, and monitored health outcomes, suggests that the policy achieved its first two aims. After the ESRD Bundle, the use of ESAs and other injectable drugs administered during outpatient dialysis declined.20 Although this decline occurred in tandem with the reimbursement reform, the Food and Drug Administration approved a revised label for ESAs near this time (6/24/2011), which likely contributed to reduced ESA prescribing patterns. Despite substantial reductions in the use of ESAs, there was very little change in the rate of blood transfusions21; there was no associated increase in all-cause mortality, cardiovascular mortality, and myocardial infarction; and there may have been a decrease in stroke, thrombosis, and heart failure.22 The effect of declining hemoglobin levels on patients’ quality-of-life remains one area that has not yet been studied.

Evidence supporting the third aim of the expanded ESRD Bundle is less conclusive.

Although reports commissioned by CMS before enactment of the policy suggested that existing databases could be leveraged to adequately adjust facility reimbursement for differences in the patient resource requirements, it is unknown how well the current mechanisms of risk adjustment achieve this goal. Issues such as under-reporting of comorbidities, and temporal changes in practice patterns, ultimately led CMS to revise the adult case-mix model in 2016.23 It is encouraging that annual reports from Medicare Payment and Advisory Commission have found no evidence of limited access to dialysis care among Medicare beneficiaries—any potential payment differences resulting from the expanded ESRD bundle do not appear to have compromised access to dialysis care.24

LESSONS FOR FUTURE MANDATES

Our analysis of two federal mandates indicates how differences in the clarity of stated policy objectives, the quality of data collected at the time of policy enactment, and in prior evidence supporting policy objectives can influence a policy’s success as well as efforts to evaluate its success. In the case of physician reimbursement reform, an absence of clear evidence to support the policy’s goals coincided with no observed effect of the policy on health outcomes. Data necessary to fully evaluate the economic implications of the policy were not collected, preventing precise evaluation of its cost. Furthermore, a lack of clarity around one of the policy’s primary objectives has muddied discussion of the policy’s success. In contrast, the expanded ESRD bundle included clearly stated policy objectives that were supported by several clinical trials conducted before the policy’s enactment. It coincided with a system of data collection that enabled monitoring of its effects on patient care and health outcomes, which have provided reassurance that the policy effectively led to reductions in the use of ESAs with no associated decline in patient health.
In 2009, after a review from the American Medical Association’s Relative Value Scale Update Committee, the temporary “G-codes” reforming the nephrology MCP became permanent. Nephrology practices have since responded to the reimbursement system by restructuring their practices and hiring advanced practitioners to see patients more frequently, and many patients have come to expect weekly visits from their nephrologist. Consequently, there has been little interest in revisiting the system of nephrologist reimbursement, despite evidence that more frequent visits did not improve patient health, may have led to an unnecessary expense of time and effort, and may create disincentives to placing patients on home dialysis or to spend needed time for the care of patients with advanced CKD.5,25 This aversion to change underscores the importance of having high-quality evidence before mandates are implemented.

Payment Models. In the setting of ESRD care, the Merit-Based Quality Incentive Program, and the growing list of quality metrics used to evaluate dialysis facilities in the ESRD Quality Incentive Program, and the evaluation of physicians according to cost and quality measures in Comprehensive ESRD Care Models, the Merit-Based Incentive Payment System, and Alternative Payment Models. In the setting of increasing regulation, it is critical that clinical and research communities work closely with policy-makers to build the evidence base available for policy-makers to draw upon and systems of data collection that allow for rapid policy evaluation. Without high-quality evidence, and the data necessary to evaluate future policies after their enactment, ongoing mandates will fall far short of achieving their fundamental objective of fostering high-quality, cost-effective care.

DISCLOSURES

K.F.E. received funding from the National Institute of Diabetes and Digestive and Kidney Diseases (grant 5K23DK101693-05), the American Society of Nephrology Foundation for Kidney Research Carl W. Gottschalk Research Scholar Grant, and the National Kidney Foundation Research Grant Program - Southeast Texas Research Grant.

REFERENCES

3. Centers for Medicare and Medicaid Services: Medicare program; revisions to payment policies under the physician fee schedule for calendar year 2004; proposed rule. Federal register 68: 63195, 2003