Implementing Evidence-Based Medicine Through Medicare Coverage Decisions

What stands in the way of Medicare's achievement of evidence-based behavior?

by Susan Bartlett Foote and Robert J. Town

PROLOGUE: From a historical standpoint, at the turn of the twenty-first century there was high drama in the documentation of major performance shortcomings in health care by the Institute of Medicine and others, and in medicine's subsequent response: a veritable social movement to promote evidence-based care. Nothing less is at stake than the medical profession's claim to the mantle of science, on which much of the profession's prestige depends. Reining in excess cost growth also depends on establishing the scientific legitimacy of evidence-based medicine (EBM), without which the quest for value-based purchasing is likely to be seen as a mere smokescreen for cutting costs.

In addition to tests of scientific validity, though, EBM faces perhaps a larger challenge in its implementation. Provider incentives are the focal point for many current strategies but have not yet proved their power to effect fundamental change. Refining the coverage policies of public and private payers offers another promising avenue for exerting wholesale influence on the application of appropriate treatments, reduction in geographic variations in care, and rational management of technology diffusion. Medicare has taken several important steps toward such a rationalization, particularly in the creation of its new "coverage with evidence development" policies. But in practice, coverage decisions in Medicare are implemented by the private contractors who administer claims for the program. In this paper, Susan Foote (foote003@umn.edu) and Robert Town outline the considerable barriers that have prevented contractors from wielding their authority to its optimum potential. One problem is that the law creating Medicare prohibited the program from interfering with the practice of medicine. But there are others.

The role of Medicare's private contractors is consistently overlooked and underestimated in the health services literature. But Foote's work on technology diffusion and the role of Medicare contractors spans most of the past two decades. She is a professor and former head of the Division of Health Policy and Management in the University of Minnesota School of Public Health. Town is an associate professor in the same division.

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ABSTRACT: Management of technology diffusion to improve quality and constrain spending in health care remains an elusive goal. Along with efforts to improve the quality of evidence, providers and payers must ensure that evidence actually effects changes in practice. Medicare coverage policies grant, limit, and condition payment based on evidentiary standards. This paper identifies the sizable barriers to implementation of evidence-based medicine in Medicare and proposes policy solutions to address them. [*Health Affairs* 26, no. 6 (2007): 1634–1642; 10.1377/hlthaff.26.6.1634]

Technology has been identified as a key culprit in the relentless escalation in health care spending.[1] There have been a variety of proposals over the past forty years to manage technology diffusion, including controlling the supply of technology or limiting use through rationing.[2] More recently, the debate about cost control has been linked to enhancing value, not by controlling supply but by changing the behavior of providers and consumers through the use of evidence. In the 1970s and 1980s, the role of technology assessment, including appropriate evaluation criteria, organization, and mix of government and private-sector processes, was hotly debated; a variety of institutional relationships and authority were tried over time.[3] Today, technology assessment is subsumed under the more popular term "evidence-based medicine," which connotes a broader role for evaluation of all health interventions using increasingly sophisticated analytical tools. Gail Wilensky's discussion of the need for credible, objective information on comparative effectiveness represents the most recent push for better data to improve value.[4]

Medicare has expanded its role in evidence-based medicine primarily in the context of coverage policy development. This paper discusses Medicare's challenges in marshalling evidence to manage the diffusion and use of technology, identifies the barriers to successful achievement of evidence-based behavior in Medicare, and proposes policy changes to accelerate its progress.

Evolution Of Evidence In Medicare's Coverage Policy

The 1965 Medicare statute was the result of political compromise. To assure provider support for the new program, the legislation prohibited Medicare from interfering with the practice of medicine.[5] In other provisions, Congress defined the covered benefit categories (such as hospital or physician services), placed limitations on some services (such as dental or chiropractic care), and excluded some categories (such as cosmetic or personal comfort items or services). The law clearly assumed that future questions of coverage might arise, providing that the Medicare program may not reimburse "for items and services which are not reasonable and necessary for the diagnosis and treatment of an illness or injury."[6] The statute delegates to private contractors the job of processing claims for payment.[7]

In the early years of the program, interpretation of the reasonable and necessary provision presented few problems. Contractors deferred to providers and any conflicts were resolved informally.[8] However, as coverage policy development has

evolved, policies have become evidence-based directives that define specific clinical parameters for appropriate use of services. Medicare has become deeply involved in acquisition, development, evaluation, dissemination, and implementation of evidence.

There are two pathways to coverage in Medicare: national coverage determinations (NCDs) and local coverage determinations (LCDs).[9] Although most of the thousands of health care services provided in Medicare are not subject to coverage policies, Medicare now has thousands of LCDs and a growing body of NCDs.[10] At the national level, when the Centers for Medicare and Medicaid Services (CMS) decides to develop a coverage policy, the agency requires clinical evidence from manufacturers, physicians, and other advocates. Recently, the CMS developed a process to provide incentives for the production of evidence; this process is known as coverage with evidence development (CED). Under the CED process, the CMS will reimburse promising but not proven technologies in return for additional clinical trial or registry data.[11] The CMS has also formalized and strengthened its analytical processes for development of coverage decisions.[12] The Medicare Coverage Advisory Committee (MCAC) was established in 1998 to advise the CMS on the interpretation of the "reasonable and necessary" provision through evaluation of medical literature, technology assessments, and data on effectiveness and appropriateness. In January 2007, MCAC was renewed. The directive also changed the name to Medicare Evidence Development Coverage Advisory Committee (MedCAC) to highlight its new role in the CED process.[13]

At the local level, there are structured rules that contractors must follow for LCD development, including consultations with physician organizations in local Carrier Advisory Committees (CACs), the posting of proposed LCDs with a comment period, and publishing LCDs that include data on the evidence used to develop the policy.[14]

The resulting LCDs and NCDs establish evidence-based rules on appropriate use of technologies and procedures. They can grant, limit, or exclude items or services from Medicare. A small percentage of Medicare coverage policies focus on new technologies, such as deep brain stimulation for tremor and implantable cardiac defibrillators. The majority of policies specify conditions for use of common, widely diffused services such as debridement for mycotic toenails or use of conventional chest x-rays.

The local contractors disseminate coverage policies and apply them at the point of payment. Medicare's *Program Integrity Manual* establishes the required functions for contractors.[15] When a claim is received, if there is no relevant coverage policy, it is processed using existing procedure and diagnostic codes or temporary codes, or on a case-by-case review. However, when there is a policy in place, the CMS directs the contractor to "apply" the policy provisions to determine whether a claim complies with a policy's provisions in deciding whether to pay or deny it.

Evidence That Coverage Policies Don't Change Behavior

Have coverage policies changed provider behavior to comply with the evidence-based provisions? It appears that policies have had little impact on utilization. John Wennberg, Elliott Fisher, and others have found significant and persistent variations in utilization patterns in Medicare, even adjusting for age and severity-of-illness differences regionally. Their findings show important differences in the ways in which medicine is practiced and services are used across the country, which suggests that misuse, underuse, and overuse of services are widespread.[16] If NCDs changed behavior, we would expect to see a convergence in use patterns based on the coverage policy provisions. However, variations persist. In relation to stent use specifically, researchers Sanjay Kaul and George Diamond found that only about 20 percent of drug-coated stents are inserted in patients with the clinical conditions supported by clinical trial data that led to initial federal approval of stents.[17] With more than one million Americans receiving stents each year, utilization that is contrary to clinical evidence costs billions of dollars and, according to Kaul and Diamond, potentially causes 2,160 deaths.[18]

A team from the University of Minnesota evaluated eight cases studies to measure the impact of coverage policies on utilization in Medicare.[19] The study measured use of the services before and after the effective date of specific coverage policies. In seven of the eight cases, there were no measurable changes in use, which suggests that providers continued to behave as they had prior to the policy's enactment.[20] The data strongly suggest that these policies have the potential to guide utilization, but there is no consistent evidence that they do.

How Institutional Barriers Impede Policy Implementation

The conclusion is not surprising once Medicare's policy implementation process is understood. A closer look at institutional arrangements reveals sizable barriers in the way of effective implementation.

■ **Information limitations.** To determine if a claim complies with an existing coverage policy, a contractor is directed to "apply" the policy—that is, to compare the information on the submitted claim form to the policy's provisions. Although this process sounds simple, there are many challenges to this task.

There are information disconnects between the claim form and the policy requirements in many cases. Some coverage policies require that a patient receive certain services first, and only after that specific therapy fails does the policy cover the alternative. For example, transesophageal echocardiography (TEE) is an invasive procedure with potential morbidity. The local coverage policies for TEE specify that it should be used only after the noninvasive alternative, transthoracic echocardiography (TTE), has proved to be not technically adequate in that case.[21] However, there is no field or code to designate the required preconditions on the claim form. Similarly, Medicare permits magnetic resonance imaging (MRI) for a certain type of headache. However, because there is only one code for headache, it

is not possible to distinguish the type on the claim form.[22] Contractors cannot verify whether or not providers complied with the policy's limits. There are also problems tracking appropriateness of services over time. In the case of serial treatments (repeat visits for ongoing treatment), the codes for each claim are the same whether there are claims for three visits or thirty. Are there thirty visits because the patient is sicker, or are the continued treatments unnecessary? Medicare does not have automated edits that precisely match each coverage decision in every payment setting, and there are not always specific codes that precisely match every NCD or LCD. There are major concerns about the thirty-year-old *International Classification of Diseases,* Ninth Revision, Clinical Modification (ICD-9-CM), codes, which are dated and inflexible.[23]

Contractors have the authority to request additional documentation through patient chart review. Indeed, some policies require clinical documentation in the patient record. For example, toenail debridement policies may require providers to take dated photographs of the affected nails and place them in the patient's file. Thus, appropriateness review requires acquisition of each patient's chart. Manual record review is time-consuming and expensive, and it rarely occurs among the millions of claims processed.

■ **Incentives lacking.** Contractors have little incentive to aggressively implement coverage policies, even if the information limitations could be overcome. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 included many contractor-reform provisions to consolidate operations and improve information technology (IT) platforms. However, Michael O. Leavitt, secretary of health and human services (HHS), states that the goal of contractor reform is increased efficiency and cost reduction in claims processing. Competitive bids for contracting services will reward bidders that can process claims faster with a lower cost per claim.[24] If contractors are encouraged to process claims faster and more cheaply, why would they invest in the additional work required to manually review patient charts?

■ **Intent to enforce.** Perhaps the most serious barrier is the absence of a clear intent to enforce coverage policies within the complex regional contractor system. There are detailed processes for suspected fraud. Suspicious claims must be referred to Program Safeguard Contractors (PSC) who are independent of the claims payment system and follow their own pathways for investigation and referral.[25] Contractors can implement medical review (MR) to deal with suspected inadvertent billing errors for Part B claims. Part A claims, which account for a sizable amount of spending in the program, are not part of the medical review program and must be referred to the Quality Improvement Organizations (QIOs) for claims review. Local contractors can launch a medical review probe to validate problems, initiate further steps to confirm billing errors, and subject providers to corrective action, including education and prepayment and postpayment claims review.[26] However, the goal is to correct inadvertent errors through feedback and education, not to root out fraudu-

lent practices. The CMS can track contractor error through the Comprehensive Error Rate Testing (CERT) program as well.

However, the fact is that not all claims that do not comply with a coverage policy are either fraudulent or attributable to provider or contractor error. Wennberg and others have identified variations in practice patterns and intensity of care reflecting overuse or misuse of services.[27] These practice variations are precisely what the coverage policies intend to target—how to manage and limit use to specifically defined situations, providers, or conditions to ensure that care is appropriate and effective. Coverage policies announce evidence-based limitations on use. The CMS doesn't appear to have the intent to aggressively enforce policies that touch on medical judgments, even if those decisions are inconsistent with the evidence. This situation reflects the tension between the statutory noninterference language and the statutory directive to pay only for services that are "reasonable and necessary" defined specifically in evidence-based coverage policies.

Making Medicare Coverage Work

Contractors lack the infrastructure to encourage best practices using policy enforcement tools.[28] If policymakers want coverage policies to change providers' behavior, reforms will be necessary. Four critical changes include the following.

■ **Improve information.** It is not possible to "apply" the policy to the claim in a consistently effective manner unless the contractor has all the available information to evaluate compliance. One option would be to change the claims form to ensure complete information consistent with the policy. This is not an easy task. Changing claims data requires compliance with processes governed by the Health Insurance Portability and Accountability Act (HIPAA) and administered by HHS. Numerous public and private entities have an interest in controlling claims forms, and the process of change is administratively complex.[29]

An alternative is the development and expansion of special codes that require providers to report additional information. Others have suggested that the coding system itself is too limited, and adoption of the new ICD-10 coding system will bring greater accuracy and flexibility, improve record keeping, and provide enhanced documentation to support accurate payment.[30] Any changes to accomplish these goals, however, encounter broader and more complex issues relating to electronic data, data standards, and other highly technical considerations. This area, although daunting from technical and bureaucratic perspectives, should be high on policymakers' agenda, particularly if Medicare intends to pay for performance and quality in the future. Congress should convene a panel of experts to find consensus on these changes and develop an implementation plan using legislative and administrative tools.

■ **Align incentives.** If we want contractors to enforce and monitor compliance with coverage policies, we need to design incentives consistent with that goal. Contractors are rewarded for efficient, low-cost claims processing, not for enforcement

of coverage policies. Current incentives treat contractors as efficient bill payers, not as guardians of quality and efficiency.[31] Enforcing coverage policies collides with the currently limited view of contractors and would require major realignment of their roles. Many changes can be accomplished administratively within the framework of MMA. More substantial reform, including replacing the local contractors with other types of decisionmakers, would require statutory reform.

■ **Invest in compliance.** In the short run, enforcement of coverage policies will require Congress to invest in the contractor infrastructure. Contractors need additional resources to request and review patient charts. A highly effective and visible effort is necessary to inform providers that policies will be enforced. With a greater focus on compliance with best practices, as defined in coverage policies, behavior might change.

■ **Improve education.** Contractors are the buffer between providers and the Medicare program. They are the vehicle for education of providers on all aspects of the program. Providers might not be sufficiently aware of the details of every coverage policy. Better dissemination of policies, and better communications with providers, may help. It can be argued that draconian enforcement may be less effective than collaborative engagement of providers in the development, diffusion, and implementation of evidence-based policies.

Management of the diffusion of technology has been a challenge in the U.S. health care system. However, to reap the value of investment in evidence, Medicare must ensure that providers use the evidence to improve care and constrain spending. Widespread compliance should reduce variation in care patterns as well as costs associated with misuse or overuse. These efforts might well forestall the use of the blunt instruments of supply controls or rationing.

The management of health care services is not without its risks. The experience of private managed care organizations in the 1990s, when health plans were accused of managing costs, not care, illustrates the point. Medicare should be applauded for its focus on the development of evidence-based coverage policies at the national and local levels. However, utilization variations across the country and the rising costs of the Medicare program demonstrate that much more needs to be done. Medicare cannot achieve the important quality and efficiency goals necessary to its survival without attention to compliance.

Inevitably, and arguably appropriately, Medicare does influence medical practice. In a recent *Modern Healthcare* op-ed, Todd Sloane commented on the advisability of a comparative effectiveness center: "We submit that unless all payers and providers agree to use the new data to begin fine-tuning our system, it may be time for the federal government to step in and make them."[32] Medicare has the authority and the responsibility to implement its coverage policies. It is time to reform the infrastructure so that coverage policies will make a difference in the quality and cost of health care in Medicare.

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NOTES

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5. Social Security Amendments, sec. 1801.
6. Ibid., sec. 1862[a][1].
7. The contractors were originally called fiscal intermediaries for Part A and carriers for Part B. The Medicare Modernization Act of 2003 required a consolidation of contractor regions, merged the Part A and B contractors, and gave them the new name of Medicare Administrative Contractors (MACs). These changes will be fully implemented by 2011. For clarity, we use the term "contractors" to describe this function. For updated information on implementation, see Centers for Medicare and Medicaid Services, "Medicare Contracting Reform: Overview," 15 March 2006, http://www.cms.hhs.gov/medicarereform/contracting reform (accessed 9 August 2007). For evaluation of the reform, see U.S. Government Accountability Office, *Medicare Contracting Reform: CMS Plan Has Gaps and Anticipated Savings Are Uncertain,* Pub. no. GAO 05-873 (Washington: GAO, August 2005).
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