

SOUNDING BOARD

Medicare and Cost-Effectiveness Analysis

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The Medicare program has been a notable holdout in the global movement toward the use of cost-effectiveness analysis to inform health care decisions. Unlike the reimbursement authorities in Canada and Australia, and in many countries in Europe, Medicare officials do not formally consider cost-effectiveness when determining the coverage of new medical interventions, even as they also confront ever-growing worries about the program's fiscal solvency.^{1,2}

In this article, we discuss the road ahead for cost-effectiveness analysis in the Medicare program. We examine resistance to its application, opportunities for its use, and ways in which the United States might move beyond its anxiety about the use of this technique.

RESISTANCE

In 1989, Medicare formally proposed the use of cost-effectiveness as one of several criteria for covering new medical technologies.³ The proposal proved controversial and was never adopted.⁴ The reasons for Medicare's resistance to the use of cost-effectiveness analysis are many and include Americans' affinity for new medical technology, a distaste for explicit limit setting, a sense of entitlement with regard to Medicare funds, the perception that in a vast and wealthy country, health care resources are not really constrained, a political system in which interest groups wield enormous influence, and a splintered and pluralistic health care system in the United States, in which no single payer is responsible for allocating resources for health care.⁴⁻⁷

Other reasons include widespread mistrust of the making of medical decisions by organizations, rather than by individual physicians and patients, concern about the transparency of the decision-making process, and mistrust of the methods used in cost-effectiveness analysis.⁸ American physicians, too, play a role in this resistance. Even if they

wanted to serve as judicious stewards of scarce health care resources, they have had little incentive to do so within Medicare's largely fee-for-service system.

Still, the problem posed by rising Medicare spending is not abating and is liable to worsen, with expenditures increasing faster than the growth of the gross domestic product and taking an ever greater share of federal revenues and national income.⁹ Medicare's policy of paying for any medical advance that has positive benefits, regardless of its costs, is unsustainable. Recent decisions to pay for therapies such as lung-volume-reduction surgery, implantable cardioverter-defibrillators, left ventricular assist devices, and positron-emission tomography to treat Alzheimer's disease could add billions per year to Medicare spending.^{10,11}

THE MEDICARE MODERNIZATION ACT

The recently enacted Medicare Modernization Act (MMA) provides a few openings for cost-effectiveness analysis. However, the act largely sidesteps and delegates the issue of cost-effectiveness analysis in order to avoid the accusation that the Centers for Medicare and Medicaid Services (CMS) will explicitly ration needed care for older Americans.

PRIVATE FORMULARY MANAGEMENT

Cost-effectiveness information may assume a more important role in future coverage decisions with regard to outpatient prescription drugs, but at the level of the private plan, rather than at the national level. The MMA envisions a new landscape in which competing regional prescription-drug plans assume risk and deliver outpatient drugs to Medicare beneficiaries. It also encourages enrollment in risk-sharing Medicare Advantage plans, which will offer health care benefits, including prescription drugs.

Private plans will exercise considerable influence through their management of formularies.¹²

Though the plans must abide by certain MMA requirements (e.g., coverage of at least two drugs in each therapeutic class, as defined by the CMS), they retain substantial discretion over which drugs within a crowded therapeutic class to include and how to design tiered copayments, lists of preferred drugs, and prior-authorization requirements. The plans will also decide how to assemble and use information to inform decisions on formularies. In all likelihood, the plans' use of cost-effectiveness information to guide such decisions will increase, expanding on the growing movement among many plans and pharmacy-benefit managers to adopt evidence-based and value-based formulary guidelines.¹³

COMPARATIVE-EFFECTIVENESS RESEARCH

The MMA contains a provision calling on the Agency for Healthcare Research and Quality (AHRQ) to conduct research on the outcomes, comparative clinical effectiveness, and appropriateness of health care, including prescription drugs. The goal is to strengthen the government's role in conducting and disseminating research results on how alternative therapies compare with one another.¹⁴ Notably, the act omits any mention of cost-effectiveness analysis, which would have been a natural extension of the idea that health care providers need more and better evidence of the comparative value of competing interventions. However, the notion of adding costs to the comparative-effectiveness equation was politically untenable.

The comparative-effectiveness clause rests on an important premise: that left to its own devices, the marketplace and existing public institutions — including the Food and Drug Administration, the National Institutes of Health (NIH), and the AHRQ — undersupply information on the comparative worth of alternative drugs. But the legislation also highlights the strong opposition to provisions that would strengthen the hand of government over the pharmaceutical market and foretells the challenges that any cost-effectiveness provision would confront in the future. It explicitly prohibits the AHRQ from mandating national standards of clinical practice and bars the CMS from using data obtained from comparative-effectiveness research to withhold coverage of prescription drugs. Moreover, only \$50 million per year was authorized for comparative-effectiveness research (in contrast, the NIH's 2005 annual budget is more than \$28 billion), and this amount was later reduced to \$15 million.¹⁵

FUNCTIONAL EQUIVALENCE

The MMA contains language prohibiting Medicare from applying a “functional equivalence” standard to drugs or biologic agents (unless the standard was in place before enactment of this legislation). Functional equivalence reflects a reference-pricing technique applied to a therapeutic category — reimbursement for compounds of similar efficacy within a therapeutic class set to the lowest-priced product in the class.¹⁶ Essentially, a standard of functional equivalence applies a cost-effectiveness principle: assuming that alternative interventions are equivalent, one should not pay more for one of them.

In practice, products of different chemical entities are seldom if ever identical, differing usually in terms of effectiveness, adverse events, or tolerability. The key consideration is whether the assumption of functional equivalence is reasonable in particular circumstances and, more important, whether Medicare should have the power to make the determination. The MMA's emphatic answer on this latter point was no.

KEY QUESTIONS ABOUT COST-EFFECTIVENESS ANALYSIS

A number of key questions need to be answered with regard to cost-effectiveness analysis.

IS THE METHOD SOUND?

Critics of cost-effectiveness analysis have long worried that published analyses reflect the hidden biases of investigators and the sponsors of the analyses.¹⁷⁻¹⁹ In a widely cited editorial published in the *Journal* in 1994, for example, Kassirer and Angell commented: “We recognize that bias can compromise even original scientific studies, but we believe that the opportunities for introducing bias into economic studies are far greater, given the discretionary nature of model building, and data selection in these analyses.”¹⁷ It would be useful to move beyond such notions. To be sure, research shows that methodologic variation in published analyses continues and that cost-effectiveness analyses sponsored by the pharmaceutical industry tend to report more favorable results than studies not sponsored by industry.²⁰ However, in the United States, standards have been published,^{21,22} and methods have discernibly improved since that time.²⁰ More important, rather than worrying helplessly about bias and poor

quality, Medicare could follow the example of payers worldwide who have developed their own expertise and procedures for evaluating cost-effectiveness information.²³

WILL IT SAVE MONEY?

Cost-effectiveness analysis is not a cost-containment tool but, rather, a technique to improve value. The use of cost-effectiveness analysis may or may not save money. Indeed, its wider application would probably uncover examples of underused services that increase costs but represent good value for the money, as well as “cost-ineffective” and overused services (Table 1). The use of cost-effectiveness analysis could save money, but this will depend on how generously or strictly policymakers apply cost-effectiveness thresholds and how aggressively payers attempt to remove existing practices that are shown to be cost-ineffective.

WILL IT HARM INNOVATION?

Representatives of the medical-products industries have expressed concern that the adoption of cost-effectiveness analysis would impede innovation by creating another hurdle in the marketplace.⁴⁹ However, innovation depends on many factors, including incentives offered by payers to

hospitals, health care providers, and consumers; society’s overall willingness to spend money on health care; the supply of capital funds to support investment; and how firmly a cost-effectiveness threshold is applied. The use of cost-effectiveness analysis might even stimulate manufacturers to bring more cost-effective products to market in the first place. Moreover, the absence of such analysis does not necessarily translate into an innovation-friendly environment; instead, it might simply mean that payers will find other, less visible ways to ration care. Finally, cost-effectiveness analysis need not be used rigidly: the threshold might be higher for some contexts (e.g., treatment of life-threatening conditions) and lower for others. Decision makers could supplement the information with considerations with regard to access and fairness. For example, in the United Kingdom, the National Institute for Health and Clinical Excellence (NICE), an agency within the National Health Service that is charged with assessing the clinical effectiveness and cost-effectiveness of drugs, devices, and procedures, recommended coverage of the drug imatinib to treat chronic myeloid leukemia, citing equity considerations, despite a high cost-effectiveness ratio according to the agency’s usual standards.⁵⁰

Table 1. Cost-Effectiveness and Use of Selected Interventions in the Medicare Population.*

Intervention	Cost-Effectiveness (Cost/QALY) †	Implementation
Influenza vaccine	Cost saving ^{24,25}	40–70% ²⁶⁻²⁸
Pneumococcal vaccine	Cost saving ²⁹	55–65% ²⁶
Beta-blockers after myocardial infarction	<\$10,000 ³⁰	85% ^{29,30}
Mammographic screening	\$10,000–\$25,000 ³¹	50–70% ^{26,28,32,33}
Colon-cancer screening	\$10,000–\$25,000 ^{24,31}	20–40% ^{26,27,32}
Osteoporosis screening	\$10,000–\$25,000 ³¹	35% ^{34,35}
Management of antidepressant medication	Cost saving up to \$30,000 ³¹	40–55% ³³
Hypertension medication (DBP >105 mm Hg)	\$10,000–\$60,000 ³¹	35% ³³
Cholesterol management, as secondary prevention	\$10,000–\$50,000 ^{36,37}	30% ³⁸
Implantable cardioverter–defibrillator	\$30,000–\$85,000 ^{10,39-41}	100,000 cases per year ^{10,40}
Dialysis in end-stage renal disease	\$50,000–\$100,000 ^{10,42}	90% ⁴³
Lung-volume–reduction surgery	\$100,000–\$300,000 ⁴⁴	10,000–20,000 cases per year ¹⁰
Left ventricular assist devices	\$500,000–\$1.4 million ^{10,45}	5000–100,000 cases per year ¹⁰
Positron-emission tomography in Alzheimer’s disease	Dominated ⁴⁶ ‡	50,000 cases per year ^{47,48}

* Ranges are provided, rather than point estimates, because the actual cost-effectiveness will vary according to the target populations and the strategies used. Additional data on the cost-effectiveness ratios associated with public health interventions and medical interventions can also be found at the Harvard Center for Risk Analysis Cost-Effectiveness Registry (at www.hsph.harvard.edu/cearegistry). QALY denotes quality-adjusted life-year, and DBP diastolic blood pressure.

† The calculation was based on 2002 dollars.

‡ With the use of this intervention, benefits are lower and costs are higher than with the use of the standard workup.

WILL AMERICANS EVER TOLERATE EXPLICIT RATIONING BY MEDICARE?

Americans' preferred style of rationing health care has been to avoid saying no directly and to squeeze the health care system in less obvious ways, such as adjusting cost-sharing arrangements, cutting payments to doctors and hospitals, and allowing one sixth of our citizens to go without health insurance.

Put another way, the question is whether Americans will ever tolerate cost-effectiveness analysis for Medicare. From today's vantage point, such tolerance seems unlikely to occur in the near future. Medicare is a top concern among older Americans, who vote in large numbers.⁵¹ Opposition from interest groups remains strong. Politicians rarely, if ever, mention limits or rationing when discussing Medicare policy.⁵² Still, there are concrete steps that could be taken toward the use of cost-effectiveness analysis for Medicare.

GETTING FROM HERE TO THERE

INVOLVING STAKEHOLDERS

The use of cost-effectiveness analysis for Medicare will probably require a campaign to educate policymakers and the public about its trade-offs and benefits. It will also require outreach to an array of stakeholders, from the pharmaceutical and medical-device industries to physicians and consumer advocates. Public meetings, briefings with policy officials, and an enduring dialogue about the rationale for using cost-effectiveness analysis will be critical.² Also critical will be the process involved: transparent procedures, the use of the best scientific evidence, and the opportunity for public comment and stakeholder participation will be important ingredients.⁵³ In recent years, the CMS has developed a more open and rigorous process for scrutinizing clinical evidence on which to base national coverage decisions, a process that could serve as a model for future deliberations on the use of cost-effectiveness analysis.⁵⁴ Leadership at other levels will help considerably, including that by the academic community and by state and local government, where officials have been mounting efforts to compare the safety, effectiveness, and value of drugs.

POSSIBLE CONGRESSIONAL ACTION

In theory, the CMS could interpret Medicare's statutory authority to cover "reasonable and necessary"

services as a license to use cost-effectiveness analysis, though such a step would almost certainly require formal rule-making procedures (i.e., publishing regulations in the *Federal Register*), because it would change long-standing policy not to consider cost-effectiveness. To date, this course has proved to be impossible.^{4,7}

Another course would involve congressional action. Congress could legislate, for example, the criteria (including evidence of cost-effectiveness) that Medicare should use in covering new technologies.¹⁰ When adding new benefits to the Medicare program (e.g., the MMA added cardiovascular-screening tests and diabetes screening), Congress could mandate that the CMS determine the most cost-effective strategy for implementing such services.

VALUE-BASED REIMBURSEMENT

Even without explicitly using cost-effectiveness analysis, Medicare could pursue cost-effective care by using innovative approaches to link coverage and reimbursement to considerations of value. For example, to avoid paying for ineffective technologies, the CMS is actively pursuing a policy of "coverage with evidence development," whereby Medicare covers a technology at the same time that it enrolls beneficiaries in clinical studies to determine the effectiveness of the technology.⁵⁵ The CMS can also explore ways to link reimbursement to cost-effectiveness, whereby providers would receive payment for the provision of an intervention on the basis of its cost-effectiveness. Indeed, the CMS has in some circumstances essentially adopted this approach: in covering left ventricular assist devices, for example, it set the price below the market rate, which was equivalent to deciding implicitly on an acceptable cost threshold and then computing the costs needed to achieve the ratio.

Medicare could further examine risk-sharing arrangements, under which the CMS would cover a drug or device but hold the manufacturers at risk for the cost of providing the drug if expectations with regard to its effectiveness did not develop — an arrangement being tested in the United Kingdom for drugs used in the treatment of multiple sclerosis.⁵⁶

The use of cost-effectiveness analysis may seem at odds with recent policy initiatives that move toward consumer-driven care and "payment for performance," which promise decentralization and incentive-based approaches, rather than having a

single decision maker apply a top-down standard. But it is likely that the system needs both strategies. As a national program, the CMS will inevitably have to make national coverage decisions that confront cost-effectiveness considerations, implicitly or explicitly. Moreover, the different approaches are not mutually exclusive; for example, cost-effectiveness analysis could inform the payment-for-performance practice, so that physicians would be paid more to deliver services that have been shown to be cost-effective.

LESSONS FROM ABROAD

The growing use of cost-effectiveness analysis by payers in other countries highlights opportunities and challenges for the United States. In the United Kingdom, the NICE has been criticized on numerous grounds: that it is overly responsive to external pressure, that the basis for its decisions is not clear, and that it imposes a bureaucratic “one-size-fits-all” population-based view of medicine.⁵⁷⁻⁶⁰ Moreover, cost-effectiveness analysis is not a panacea: where it has been implemented, tensions with regard to efficiency, equity, and costs persist,⁶¹ as do questions about the method itself and the extent to which the data are actually used.⁶² Still, officials have not shied from including cost-effectiveness analysis in deliberations, and indeed, its reach is expanding beyond decisions on drugs to other areas of health care.^{61,63}

DOES THE UNITED STATES NEED A NEW INSTITUTE?

Who would produce or evaluate cost-effectiveness information in the United States is a long-standing question. The CMS itself is an obvious candidate, but history indicates the difficulties it faces. Other public institutions have different missions and different political constraints. A better idea is to create a new Institute of Medicine–like entity to provide advice on cost-effectiveness. The experience of the NICE demonstrates the potential of a new organization with a specific mandate to consider cost-effectiveness. Alternatively, several independent institutes could be created to conduct such research and disseminate the information.⁶⁴

Information and advice would be distributed as public goods to help target resources to improve health. Medicare — and its private contractors — would be free to accept or reject the recommendations. The nonbinding nature of these recommen-

dations is important: decision makers themselves would decide how much weight to give cost-effectiveness evidence and how much to give to other factors. Moreover, a healthy marketplace in which other groups can produce information will endure — the recent effort of *Consumer Reports* to compare the prices and effectiveness of prescription drugs is but one example.⁶⁵

Who would fund such an entity is another important question. Public funding poses a challenge, but various arrangements are possible. Uwe Reinhardt, a professor of economics at Princeton University, has proposed that funding come from a small surcharge levied by the federal government on the nation’s annual spending on prescription drugs.⁶⁴ The alternative is funding by Congress, though the annual appropriations would inevitably be linked to political pressures.

CONCLUSIONS

The use of cost-effectiveness analysis can help Medicare to target its health care resources more efficiently. The obstacles to wider use of such analysis are not primarily methodologic but, instead, matters of politics, process, and leadership. The MMA provides small openings for cost-effectiveness analysis and also highlights challenges for the future. Progress should continue on other fronts. Cost-effectiveness analysis will not solve all of Medicare’s problems. Policymakers would do well to keep expectations modest. Cost-effectiveness analysis must be part of a comprehensive strategy that involves changing incentives at multiple levels. It is fashionable to say that cost-effectiveness analysis is not feasible in the United States. But the day may be dawning when the Medicare system will face a severe financial crisis, and the available alternatives will be far worse.

Dr. Weinstein reports holding equity in Innovus, a consulting firm that conducts research on health economics and outcomes (including cost-effectiveness analysis) for a variety of clients, including pharmaceutical companies.

We are indebted to Amanda Patrick, Meredith Sobel, and Bin Zhang for research assistance.

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