



Value Proposition: The Role of Cost-Effectiveness in Coverage Decisions

Introduction

Federal spending on Medicare and Medicaid as a proportion of GDP is set to double within 25 years, warned Douglas Elmendorf, head of the Congressional Budget Office, in July 2009. Speaking before the Senate Finance Committee, he asserted that this kind of spending is “unsustainable” and that Medicare must change the way it pays providers “to encourage a focus on cost-effectiveness.”¹

Many economists and health care professionals believe that too much of health care spending goes toward services that have little value in terms of improved health or quality of life. One study found that up to 30 percent of the medical care dispensed in the U.S. is inappropriate or unnecessary.² Importantly, more care is not necessarily good for our health; research on Medicare patients found that more care was associated with poorer health outcomes and higher costs.³

To find out which health interventions are most effective, many health care managers and policy analysts support the use of comparative effectiveness research, defined by the Institute of Medicine as “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.”⁴ To encourage comparative effectiveness research, Congress built \$1.1 billion for such studies into the 2009 budget stimulus bill. Directing the work will be the National Institutes of Health, the Agency for Healthcare

Research and Quality, and the Department of Health and Human Services, overseen by a Federal Coordinating Council for Comparative Effectiveness Research.⁵ Importantly, the legislation specifies that the Council may not mandate coverage reimbursement or other policies for any public or private payer.

Some policy leaders are concerned about extending comparative effectiveness research to include cost and cost-effectiveness because of the conventional wisdom that Americans will not accept cost considerations in deciding what services should and should not be covered in a health plan.⁶

This issue brief challenges that notion and addresses the potential role of cost-effectiveness analysis (CEA) as a part of comparative effectiveness research.⁷ It presents findings from recent studies suggesting that members of the public and health care decisionmakers are receptive to considering information on both the benefits and costs of health care interventions. Further, it explores Medicare’s potential to provide leadership and develop infrastructure that will allow the public’s values and priorities to be taken into account.

What Is CEA?

While comparative effectiveness research evaluates alternative interventions to improve specific health outcomes for specific diseases (for example, symptom relief or better life expectancy for patients with diabetes), CEA is a method for evaluating the health outcomes and resource costs (in dollars) of health interventions.⁸ Unlike a “cost

minimization study,” which simply identifies the least expensive intervention, CEA balances the health benefits of different interventions relative to their cost.

Further, CEA allows care to be compared both within and across multiple conditions. For example, it can compare the efficiency of different drugs in controlling blood pressure, and can also be used in assessing a broad range of medical and public health interventions designed to decrease heart attacks. Thus, a CEA might compare a public health education campaign promoting exercise and nutrition to medications to control high blood pressure or cholesterol. CEA achieves this, in part, through measuring health benefits using the generic quality-adjusted life year (QALY), which allows the effects of medical treatments to be evaluated in terms of quality of life and longevity.

CEA also provides guidance as to what the cost of a therapy would have to be in order for it to be a “good” value. The “cost” part of an analysis depends in part on the price paid for the interventions being compared. If the price of a “borderline” intervention is lowered, it might become a good value. CEA can also inform decisions about the maximum price a purchaser should be willing to pay for a given intervention.

Who Uses CEA, Who Doesn't

Although conversations about the trade-offs between value and cost are commonplace in other sectors, they have met resistance in the health care setting. The discomfort is understandable in that the use of CEA challenges the notion that there is always enough money to do everything that a patient or physician may desire. Some fear that CEA will leave patients and clinicians with fewer choices and little access to new or expensive technologies. Others fear that intervening in the marketplace will inhibit the development of better drugs, devices, and interventions.

Medicare does not use cost or cost-effectiveness as a criterion for coverage, but some managed care

organizations routinely do.⁹ In a survey of 228 U.S. managed care organizations covering 118 million people, 90 percent of the plans reported considering cost in decisions about what to cover in their benefit package; 40 percent used formal CEA procedures.¹⁰ Wellpoint has been explicit in fashioning a process for review of drug cost-effectiveness evidence.¹¹ Both the Department of Veterans Affairs¹² and the Department of Defense¹³ make explicit use of CEA in decisions about what to include on their drug formularies.

In a number of developed nations, CEA is a formal part of coverage decisionmaking. Canada, Australia, and the Netherlands use CEA in the pharmaceutical area, while New Zealand and the United Kingdom use it more broadly in considering new technologies.¹⁴ England's National Institute for Health and Clinical Excellence (NICE), established in 1999 by the National Health Service, issues “appraisals” of drugs and other treatments based on cost-effectiveness as well as clinical effectiveness.

Public Reactions: Two Studies

Public resistance to limit-setting in health care is often cited as a major impediment to the use of CEA in the U.S. However, there have been few empirical investigations of actual public attitudes. Two recent studies, discussed below, help to fill this gap.

Best Bang for the Buck

“Getting Good Value,”¹⁵ a 2006 Northern California project conducted by the Center for Healthcare Decisions, was designed to answer two questions:

- Do consumers believe that a medical treatment can be too expensive relative to the benefit it brings to include in an insurance plan?
- Should society use a value-based approach (considering both costs and clinical benefits) when making decisions about insurance coverage?

Twenty-seven discussion groups were held, each with demographically diverse community members. Three vignettes were presented showing situations where the clinical benefit was low compared to the cost for: (1) a life-extending treatment; (2) a quality-of-life improving intervention; and (3) a prevention measure. Participants were asked to imagine being members of a National Health Benefits Committee who must decide whether these interventions should be approved for coverage by public insurance such as Medicare.

Most participants thought it was appropriate to consider value relative to cost in making coverage decisions, although some were hesitant about not covering a life-saving intervention. The dominant reason participants gave for including cost in the mix was to avoid inefficient use of health care dollars. Very few mentioned that saving money *per se* was the rationale; rather, they were seeking the “best bang for the buck.” One participant said, “I think we have to be realistic and say, at some point, ‘You have to do the greatest good for the greatest number of people.’”

Some participants spoke of the tension between maximizing benefit for the individual and societal limitations: “For us, for each person, we want them to have the very, very best care possible. But if it was like a society, then we wouldn’t really think about it that way.” Others did not want CEA decisions to affect them personally. Those who objected most strongly expressed the view that one cannot “put a price on life,” while others feared that if expensive new treatments were not supported, it would discourage medical innovation.

Interestingly, many respondents were surprised that the federal government did not already use cost-effectiveness criteria when considering coverage of new technologies, and they were convinced that private plans have been doing this for many years.

In a post-discussion survey, only 12 percent of respondents said cost-effectiveness should never be used to decide what insurance should pay for. Eighty percent argued for using it in either “most” or “some” situations.

The study did not address the mechanics of CEA, and instead queried participants on their reactions to weighing medical benefit (e.g., additional years of life) relative to cost (e.g., the dollars required to keep one person alive for an extra year).

Reordering Public Priorities

In another 2006 study, members of the public delved into the formal use of CEA in the context of the Medicare program. Gold and colleagues assessed the general public’s ability to understand CEA; whether and how CEA information influenced public priorities for service coverage; and the public’s views on its relevance and acceptability.¹⁶

Participants, recruited from the New York County jury pool, attended two group sessions, each lasting about three hours. The sessions included presentations, exercises, and discussion on health care costs, CEA methods, and ethical concerns. Participant surveys assessed changes in their knowledge of health care cost issues, understanding of CEA, and opinions about health care coverage policy options.

The central exercise presented 14 condition/treatment pairs described in lay terms. These included examples of real technologies that had been approved by Medicare, such as lung-volume reduction surgery and implantable cardioverter defibrillators. As in the California study, participants were asked to assume the role of a social decisionmaker, in this case specifically for the Medicare program. They were asked to rank these treatments for coverage under Medicare using clinical effectiveness data only. Then, CEA findings for each condition/treatment pair were presented and participants were invited to reconsider their priority listings.

With the new CEA information, participants moved more cost-effective interventions toward the top of the list. Finally, when asked if they would feel comfortable using CEA to inform Medicare coverage of new treatments, 11 percent of participants said “very comfortable” and 64 percent said “somewhat comfortable.”

The authors concluded that most members of the public can understand CEA, are willing to engage in discussions on priority-setting in health care, and see economic efficiency as an appropriate consideration within Medicare coverage policy.

Both studies indicate that the public may be more accepting of CEA than has been assumed, at least in the context of societal decisions.

Decisionmaker Perspectives

To understand the views of policy and health care decisionmakers, a third study explored CEA with individuals responsible for purchasing or overseeing health care delivery.

Looking for Medicare to Lead

Adopting a workshop model, Bryan, et. al., explored state decisionmaker attitudes toward CEA.¹⁷ Half-day workshops were held in six California-based health care organizations including regulatory agencies, private and public insurers, and purchasers. Pre- and post-workshop surveys were administered to assess changes in understanding of CEA as well as changes in support of its use in Medicare and private insurance coverage.

As in the Gold study, participants were asked to assume the role of a social decisionmaker and rank 14 condition/treatment pairs in order of priority for coverage. Cost-effectiveness data were then introduced to test their impact on participants’ decisions. Again, participant decisions changed with the introduction of this information; the more cost-effective interventions moved up the priority list.

The great majority of participants supported the use of CEA by Medicare and also by private plans. In fact, only two of the 57 respondents stated that CEA should not be part of the information considered by Medicare when making coverage decisions, and only four had that view about private plans.

Stated barriers to the use of CEA in their own organizational settings included legal/regulatory challenges. Participants believed that having the resources of a major public insurer to work through regulatory reforms and potential litigation was important. A majority of participants indicated they were concerned about bias in CEA when there is sponsorship by the manufacturer of the product.

A recurring theme for these decisionmakers was the importance of leadership from the Medicare program.

Proposing a Plan for CEA

A panel of decisionmakers, convened on behalf of the Agency for Healthcare Research and Quality (AHRQ), confirmed the work of Bryan and colleagues.¹⁸ This panel recognized the importance of federal leadership in supporting use of CEA as a component of coverage decisionmaking, especially for developing skills in and understanding of CEA, and for establishing guidelines that conform with federal and state law.

The panel proposed a 10-year strategic plan for implementing CEA into health policy decisions. One recommendation was for a mechanism by which public values can be incorporated into the decisionmaking process. This is important, the panel said, because coverage policy might at times conflict with the public’s views about who should be given priority and under what circumstances. For example, because CEA counts all QALYs equally, trade-offs between old and young, between better- and worse-off (economically and in terms of health status), and between improving quality of life and saving lives are not transparent in a summary

cost-effectiveness result. The panel believed that the ethical assumptions embedded within CEA require careful examination by the society for whom the resources are intended.

Gaining Public Input

Recognizing the difficulties involved in limiting cost growth in a reformed health care system, President Obama has called for broader discussions outside of formal political channels. How could the views of Americans be accessed? England's NICE program offers a promising model. Its 30-member "Citizen Council" (CC) brings the views of the public into the technical appraisal process where evidence on cost and effectiveness is evaluated. Council members, who serve three-year terms, are recruited from a broad spectrum of the English and Welsh population. The CC meets semi-annually for three days, deliberating on ethical issues that are used to guide the NICE appraisal committee. Issues discussed by the CC have included whether age should enter into priority-setting considerations; trade-offs between disease prevention, life-saving interventions, and quality-of-life improvements; and whether priority should be placed on promoting the health of disadvantaged populations. The NICE program enables the public to weigh in on the value choices applied to health policy decisions.

A good place to start such work in the U.S. is within Medicare, since virtually all Americans have a stake in this large public program. Historically, Medicare has provided leadership in innovations such as the adoption of the Resource Based Relative Value Scale, as well as Diagnosis Related Groups, both of which created important shifts in health care financing.¹⁹

If Medicare took leadership in implementing CEA as a criterion for coverage, the existing Medicare Evidence Development Coverage Advisory Committee (MedCAC) could serve as a meeting place in which to engage public deliberations. Serving as technical advisers to Medicare, MedCAC shares similar functions to those of

NICE appraisal committees. A standing committee of citizens advising MedCAC could deliberate on whether and how CEA should be used in Medicare coverage decisionmaking. An open process closely covered by the media would foster dialogue and fuller public understanding of the challenges policymakers face in building a sustainable health care system.

Conclusion

CEA is sometimes painted as a harbinger of rationing, which can be seen as a threat to both patient access and to established industry revenue streams. In reality, CEA is simply a technique that allows decisionmakers to understand how to gain best value from health care expenditures. This will become increasingly urgent as health technologies evolve and funding remains limited. The research described above suggests that the public as well as the decisionmakers find worth in having cost and effectiveness information presented together, thereby offering insights into return on investment in health care.

Americans in their dual roles as tax-payers and users of health care have key roles to play in contributing to the discussion of priority-setting. Frank and extensive public deliberation is essential to restraining cost growth while improving health care access and outcomes. Medicare, as the nation's largest publicly financed health care program, is well-placed to set the course for bringing cost and cost-effectiveness into the coverage equation in ways that reflect the public's values.

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