Cite this article as:
A M Garber
Can technology assessment control health spending?
Health Affairs 13, no.3 (1994):115-126
doi: 10.1377/hlthaff.13.3.115

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Prologue: In the new-ending search for ways to cut rising health care costs, medical technology is arguably the most controllable component of health spending growth. Thus, physician-economist Alan Garber argues in this paper, no plan to reform the nation’s health care system by limiting its budget can succeed unless it has some influence on how technology is disseminated. To do this requires a deliberate, standardized approach to assessing new technologies as they are being developed.

Garber believes that cost-effectiveness analysis, while not the only method, is particularly promising because, by definition, it addresses both the cost and the effectiveness of technological advances. However, Garber cautions, it is important to emphasize both the effectiveness and the cost, because “if a treatment is not effective, it cannot be cost-effective, and it is usually less expensive to demonstrate effectiveness if an intervention is cost-effective.” The continued development and refinement of cost-effectiveness analyses is of great interest to insurers, consumers, and the government, each of which has a massive stake in seeing health care costs brought under control while preserving America’s commitment to technological advances in medicine.

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Abstract: Because medical technology is the most important controllable component of health spending growth, the success of strategies for limiting spending growth depends upon their impact on technology dissemination. Technology assessment is fundamental to any strategy for controlling the adoption of medical technologies. Cost-effectiveness analysis holds particular promise as a method for evaluating alternative health care technologies because it explicitly incorporates costs. This paper describes how the widespread adoption of health insurance promoted the dissemination of medical technologies and how technology dissemination fueled spending growth. It then describes approaches to technology assessment and the ways in which technology assessment, in the form of cost-effectiveness analysis, can be applied to help control spending growth.

Technological change, broadly defined, may be the most important controllable component of health spending growth; thus, no plan to limit the health care budget will be successful unless it influences the dissemination of medical technology. For the purposes of this discussion, medical technology includes medical practices, procedures, devices, and drugs, whether new or established. Technology assessment has become a basic ingredient of strategies to control the adoption and use of such technology. Technology assessment is not solely or even primarily a mechanism for cost containment; expenditure caps, price controls, regulations, and enhancement of competitive market forces may all represent more direct means of restraining expenditures. Technology assessment is designed to complement such approaches by determining the value of technologies, making it possible to adopt and abandon medical interventions selectively. The usefulness of this approach depends heavily on how it can and will be used. In this paper I discuss the relationship between insurance coverage and technology growth and the use of medical technology and health spending growth; I describe technology assessment and the kinds of information that it provides; and finally, I discuss the ways in which technology assessment can be applied to help control spending growth.

Insurance Coverage And Technology Growth

Although scientific and technical progress often is portrayed as an engine for increased productivity and economic growth, the emerging view of technological change in health care is decidedly more wary. Health insurance, by acting as a price subsidy for insured patients, leads to overuse of health services (moral hazard) in the short run. In the long run, the insurance-based subsidy influences the kinds of technologies that are developed and the speed with which they are disseminated. These long-run effects can dwarf short-run overutilization. As Burton Weisbrod and others have noted, the insurance subsidy has meant that new technologies must compete primarily on the basis of quality rather than price. Effective but costly procedures such as heart and bone marrow transplan-
tation and some new biotechnology products might never have become generally available if they had not been covered by health insurance. Where it not for the impact of health insurance, it seems unlikely that new technologies would so frequently add to, instead of displacing, older technologies. For example, when coronary angioplasty was introduced as a treatment for coronary heart disease in the mid-1980s, it appeared to be a less expensive, less risky substitute for coronary artery bypass surgery. Between 1986 and 1990 the number of coronary angioplasties performed in the United States more than doubled, from 133,000 to 284,000 per year. Over the same four years the number of bypass operations, instead of falling, increased substantially, from 284,000 per year to 392,000 per year. As a result, combined expenditures for these two procedures grew rapidly throughout the 1980s. Presumably, many patients who would not have received bypass surgery were treated with angioplasty, and many patients received both procedures. More recently, laparoscopic cholecystectomy, a less expensive and usually less invasive alternative to traditional cholecystectomy, appears to have greatly increased the rate at which the operations are performed. This phenomenon is not limited to the introduction of new therapies; new diagnostic tests often complement older tests, rather than substituting for them.

During the 1980s American health insurers experimented with a number of strategies to overcome the influence of the price subsidy. To traditional cost-sharing provisions (deductibles and copayments) they added various disincentives to overuse that were targeted at the provider rather than the patient. Many physicians expressed concern that patients’ health would be compromised as the new programs influenced health care delivery. Indeed, many of the programs were implemented with little information about their potential impact on health. Claims that cost containment efforts would reduce the delivery of both highly effective care and ineffective practices could not be dismissed, especially because so little was known about what care was effective.

Expansion Of Technology Assessment

Two factors contributed greatly to the expansion of technology assessment in the 1980s. First was a recognition that health care technology contributed to health spending growth. Rapid advances in biotechnology and other areas of medical research meant that the flow of potentially expenditure-enhancing technologies would increase, not slow. Second, by the end of the decade, it was apparent that cost containment efforts did little to reduce spending growth. The annual real rate of per capita health spending growth between 1980 and 1985 was about 3.5 percent (adjusted
by the gross domestic product [GDP] deflator) and rose to 5.2 percent between 1985 and 1990. Much of this growth was blamed on technology, which has been the label attached to the residual growth rate after adjustment for demographic factors and general price inflation. However, the residual growth rate encompasses more than the adoption of new or expensive technologies. It includes increased intensity of treatment and diagnostic testing and excess growth of the prices of medical products and services, as well. Presumably patients underwent more tests, received more expensive or numerous treatments, or simply received more comprehensive services. The “technology” component accounted for a large part of growth in overall health spending, hospital spending, and Medicare payments for physician services. Because little can be done about demographic contributions to spending growth, which will become more important when baby boomers begin to experience the infirmities of middle and old age, the residual is seen as the key to controlling health expenditures.

A third reason for interest in technology assessment is the recognition that little is known about the effectiveness of commonly used drugs, devices, diagnostic procedures, and treatment practices. This uncertainty applies to both new and old technologies. Although the number of well-designed clinical trials has grown dramatically in recent years, many technologies have not been subjected to rigorous evaluation, and even well-designed randomized trials leave substantial uncertainty about the generalizability of their findings. Unless some of this uncertainty is resolved, the health consequences of cost containment efforts might be unacceptable. Maximizing the benefits of health expenditures requires more information about what health practices work, in what settings, and at what cost.

Technology Assessment Approaches

Cost-effectiveness analysis. Information about the costs and benefits of health practices is the province of technology assessment, which the Institute of Medicine (IOM) defines as “any process of examining and reporting properties of a medical technology used in health care.” For many investigators it is nearly synonymous with cost-effectiveness analysis, although technology assessment often explores broader issues such as the ethical and societal implications of the use of a technology. Cost-effectiveness analysis has become the principal analytic method for incorporating costs into evaluations of health care technologies.

A fundamental task of cost-effectiveness analysis is the selection of a specific measure of health outcomes that is relevant for a wide range of health interventions. The most widely accepted and most comprehensive such measure is the QALY, or quality-adjusted life year. However, the
measure most commonly used, thanks to its more modest demands on data and analysis, is life expectancy. A QALY is a generalization of life expectancy, in which years of life in the future are discounted and time marred by pain or suffering is given less weight than years in good health.

The cost-effectiveness ratio is essentially a price for obtaining a QALY by using a specific technology. It is the ratio of incremental costs (difference in costs between two alternative medical technologies; the alternatives could be different levels of an intervention, like different dosages of a drug) and incremental QALYs. The foremost application of cost-effectiveness analysis in making decisions about health care is the ranking of alternative health interventions, in ways that value both expenditures and health outcomes. Does cost-effectiveness analysis offer a valid and consistent mechanism for ranking alternatives? Charles Phelps and I have argued that it can. Under a standard von Neumann-Morgenstem utility framework, as is widely used in decision analysis and in economics, it is possible to define a “cutoff” cost-effectiveness ratio such that interventions whose cost-effectiveness ratios exceed the cutoff are not acceptable, while those with lower cost-effectiveness ratios are. This basis for deriving the cutoff has advantages over the common and frequently uninformative practice of comparing the cost-effectiveness of common health interventions to determine whether the technology under study is itself cost-effective.

Selecting a cutoff cost-effectiveness ratio is equivalent to defining a “willingness to pay” for a change in QALYs; if the cost of obtaining a given change in QALYs by using a particular intervention exceeds the amount an individual would be willing to pay for the QALY change, the cost-effectiveness ratio of the intervention exceeds the cutoff. The cost-effectiveness ratios of common treatments and diagnostic procedures may be higher than the willingness to pay for QALYs because the cost-effectiveness ratios of the interventions are unknown. But even if such information is available, the insurance subsidy causes physicians and patients to ignore much of the cost. Thus, patients may consume more health care than they would be willing to buy in the absence of insurance.

There is no reason to believe that different people have the same willingness to pay for QALYs. People differ in their demand for QALYs for the same reasons that their demand for any good or service varies: Some people place a higher priority on good health than others, and some people have more money to spend on health care than others. Many practitioners of technology assessment recognize that the same treatment can be more cost-effective for one person than for another. But when the willingness to pay for QALYs varies among individuals, a fundamental tension between decision making for the group and choice by the individual becomes manifest. Although cost-effectiveness analysis often is used as a way to set
policies for the group, any policy for the group can be at odds with the choices that rational, fully informed persons would make for themselves.

**Appropriateness evaluation and strength of evidence.** Disappointment in the actual and potential usefulness of cost-effectiveness analysis as a tool for controlling spending growth often reflects unrealistic expectations about the contributions any such technique can make when the data are limited, the stakes are high, and values conflict. Two major approaches that eschew explicit incorporation of costs are appropriateness evaluation and strength of evidence. The former has been most fully developed and popularized by Robert Brook and colleagues at RAND and elsewhere. This approach uses a structured consensus process for defining “appropriate care,” often including formal procedures for judging the quality of evidence supporting the use of a medical intervention. Ordinarily it does not explicitly incorporate cost considerations. The former has been most fully developed and popularized by Robert Brook and colleagues at RAND and elsewhere. This approach uses a structured consensus process for defining “appropriate care,” often including formal procedures for judging the quality of evidence supporting the use of a medical intervention. Ordinarily it does not explicitly incorporate cost considerations. Some advocates for this method believe that there is so much “inappropriate care” that in the short run it will be unnecessary to eliminate any effective care, even if the care is not cost-effective. This approach has been criticized on several grounds. First, consensus criteria for appropriateness are subjective and, hence, highly dependent upon the composition of the panel of experts that devises the criteria. Second, under many circumstances, the approach overstates the amount of inappropriate care. Third, consensus ratings are unlikely to take the place of results of clinical trials. And fourth, if clinical trials have not been performed, expert ratings are not meaningful.

Methods based on strength of evidence have similar advantages and limitations. Methods based on strength of evidence have similar advantages and limitations. Advocates for the strength-of-evidence approach, in its most extreme form, would only cover and deliver health care that is of established effectiveness. Typically, evidence of effectiveness must be rigorous, such as the proof that emerges from a well-designed, randomized, controlled clinical trial. Many new (and numerous older) technologies fail this criterion. Such a criterion often will lead to the same decisions as a cost-effectiveness criterion, even though it does not explicitly introduce cost as a consideration. If a treatment is not effective, it cannot be cost-effective, and it is usually less expensive to demonstrate effectiveness if an intervention is cost-effective (which means that the treatment is inexpensive or highly effective, the two most important features in the cost of demonstrating effectiveness in a clinical trial).

Although evidence-based criteria can ensure that only effective technologies are adopted, their rigid application also can thwart efforts to provide effective care. Observational studies, which some investigators believe to be flawed and incapable of providing conclusive evidence, are occasionally so compelling that many physicians and scientists believe that a definitive randomized trial would be inappropriate and unethical. There
may never be a trial assessing whether antibiotics should be given in cases of bacterial meningitis or pneumococcal pneumonia; historical evidence suggests that the outcomes of both diseases improve dramatically with antibiotic therapy. Other technologies of interest may be used to treat diseases so rare that it is infeasible to mount a randomized clinical trial. Under such circumstances, it would seem capricious to exclude the treatment solely because a definitive clinical trial could not be performed.

Often these approaches complement one another as much as they serve as substitutes for one another. And all of them are unable to overcome the most common challenge to producing credible assessments of a health care technology: the lack of reliable and valid data about effectiveness. The crucial issue in comparing these methods is whether cost can be ignored in making a health care technology available, and if it cannot be ignored, how the analysis can incorporate it. A consensus is emerging that decisions about the use of medical technologies must reflect their costs, and that cost-effectiveness analysis, despite its limitations, offers a convenient and well-developed method for weighing costs and benefits.

Implementing Technology Assessment

Notwithstanding the recent Oregon Medicaid experience, it is unusual for cost-effectiveness considerations to be explicit determinants of the allocation of health dollars. However, even when its influence is indirect and hidden, cost-effectiveness analysis can have a significant impact, often depending on how and in what form it is to be implemented. Implementation occurs in three main areas: approval processes for drugs and devices; insurance coverage; and guideline development and application. Several other potential modes of application, such as legal standards for medical care, are less common or overlap with these areas.

Approval processes. The Food and Drug Administration (FDA) has no mandate to incorporate cost considerations into approval decisions, yet costs undoubtedly influence drug and device approval processes. Many forms of medical technology, such as laboratory tests and physician services, are not directly regulated at all, much less observed for cost-effectiveness. However, there are growing pressures to grant cost-effectiveness analysis a larger and more explicit role in the approval process because it eases decision making “downstream”—relieving physicians, payers, and patients of the responsibility of weighing the costs and benefits of individual treatments. Often third-party payers that would exclude a technology would prefer not to make coverage decisions explicitly, and certainly not case by case. Furthermore, they are often unable to deny coverage. For instance, when the FDA approves an expensive drug that has no close substitutes,
few insurers attempt to deny coverage. They would not need to deny coverage if the FDA denied approval in the first place, on the basis of lack of evidence of cost-effectiveness.

**Insurance coverage.** Insurers can decline to cover those procedures, drugs, and devices whose health effects are deemed too small to justify their costs. Alternatively, insurers can limit coverage to specific indications for which the interventions are relatively cost-effective. Indication-specific coverage requires substantial administrative oversight for implementation, so it is more feasible for expensive interventions (such as surgery) than for relatively inexpensive ones (such as antihypertensive drugs).

Sometimes the insurer is also the provider, or the provider is at risk for the costs of services, drugs, or supplies (for example, the Veterans Affairs [VA] health system, health maintenance organizations, and provider networks) and needs to decide which technologies should be covered or offered. In theory, and sometimes in practice, insurers and other purchasers of health care can use technology assessment to negotiate prices as well as to make coverage decisions. But sometimes contractual obligations limit their flexibility in using such information. Most private insurers do not routinely exclude high-price treatments from coverage, unless they are deemed “experimental.” Although the experimental exclusion can be used to delay coverage of very expensive new technologies, it applies in limited circumstances. For example, insurers cannot usually impose the experimental exclusion on a drug or device that has received FDA approval. Insurers have greater discretion in applying the experimental exclusion to surgical procedures and other physician services, for which the definition of experimental is less precise. However, the lack of precision also leaves them vulnerable to legal challenge when they deny coverage on this basis.

It would be most convenient for insurers to decide whether a given service or product should be covered at all, but typically a subset of the potential uses will meet the cost-effectiveness criterion. For example, computed tomography (CT) scans can substitute for exploratory surgery, being both effective and cost-saving in this case; they also could be used in the evaluation of every patient with abdominal pain, most of whom have benign conditions that resolve without treatment. An insurer might wish to provide coverage for CT scanning in the former but not in the latter situation. The feasibility of tying coverage to clinical indications depends, of course, on the costs of monitoring use relative to the amount of a claim. Most insurers scrutinize indications for elective surgery carefully, but not the indications for such “little-ticket” items as routine laboratory tests and inexpensive prescription drugs. Monitoring use, particularly at the level of individual tests and prescriptions, can be expensive. Utilization review and related activities appear to be responsible for a substantial fraction of the
growth in administrative expenses of health care in the United States.\textsuperscript{18}

**Guidelines.** Perhaps the best-developed application of technology assessment is medical practice guidelines. Subspecialty societies, advocacy groups, and government agencies are among the sponsors of guidelines, and many of them attempt to incorporate costs into the development of guidelines. While costs usually do not receive explicit recognition in published guidelines, the development process is only rarely conducted in complete ignorance of cost-effectiveness.

Voluntary practice guidelines based on technology assessment algorithms that describe how a health care technology should be used have been popular in part because they are advisory rather than mandatory. Under such circumstances, their impact on practices or health expenditures has been limited. Despite the authority of the groups that formulate such guidelines, physicians tend not to change their behavior to comply with guidelines when they lack direct economic incentives for doing so.\textsuperscript{19}

Even when they are under no direct pressure to comply, though, providers sometimes find guidelines based on technology assessment to be helpful in using resources effectively for the care of their patients. Furthermore, changes in the organization of health care are increasing the pressure on individual physicians to limit their expenditures. Managed care organizations have devised a variety of mechanisms to promote cost-conscious health delivery among member physicians, including methods to monitor their use of referrals, expensive procedures, and office visits. These changes can only make well-formulated guidelines more valuable to physicians.

If patients, providers, and payers knew which services provided the greatest benefit for the least cost, technology assessment would have little role to play, and guidelines would be unnecessary. But surprisingly little is known about the cost-effectiveness of even well-established health care technologies. That is why so many observers of the U.S. health care system believe that modifying incentives to discourage excessive use of technologies is not by itself sufficient; although incentives to contain costs may work, they do not necessarily provide the greatest health benefits.

**Barriers to successful implementation.** Any formal process for establishing clinical policies is subject to influences that may blunt its impact. Often the incentives to implement an analysis are weak and the disincentives compelling. The “winners” from use of a specific technology are often highly concentrated among providers and patient groups. Furthermore, the frequent association of expertise in a clinical area and self-interest can be a barrier to performing and implementing sophisticated, balanced, and impartial assessments. Although there are many examples of recommendations formulated by physicians and physician groups that call for abandonment or limited use of established, profitable practices, real or perceived
bias vitiates many assessments performed by self-interested parties.

Insurers, pharmaceutical companies, and medical device manufacturers also have assumed major roles in technology assessment. Concern about the biases that might arise in studies funded by sources that have a financial stake in the results has stimulated interest in developing standards for assessments, perhaps under the aegis of a governmental body.

Patients, particularly those with chronic diseases and disabilities, also have a stake in the results of an assessment. Insured persons may collectively prefer to have insurance that covers only cost-effective care, insofar as a cost-effective benefit package would provide the greatest expected impact on their health should they require medical services. But upon developing a disease, patients will seek coverage for any treatment that might benefit them, especially if the treatment is expensive and even if it is not cost-effective. Patients and providers whose interests are threatened by the application of assessments can, and do, exert strong pressures to modify or abandon decisions based on cost-effectiveness criteria. When the Oregon Health Services Commission applied cost-effectiveness criteria to rank treatment-indication pairs to be covered by Medicaid, the storm of criticism and protest from patient and provider groups forced it to reorder the pairs. Some of the criticism of the rankings was based on shortcomings of the data and specific methodological approaches, but some of the criticism was directed at the cost-effectiveness approach itself.20

As Oregon’s experience suggests, implementation of technology assessment often requires compromise: To have an impact, it must contain strong incentives to adopt or abandon specific health technologies, but it must not provoke overwhelming resistance. The ways in which technology assessment has been used reflect the tension between the desire to influence use and the desire to avoid confrontation.

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Assessing The Role Of Technology Assessment

Although patients and health care providers can gain from the application of technology assessment, payers are likely to put the information to use most directly, by incorporating it into cost containment programs. In doing so, they will encounter a number of challenges. Some of those challenges are technical: How should assessments be performed when only limited evidence is available about the effectiveness of an intervention? How should quality-of-life effects be measured and weighed? How should an evaluation incorporate variation in patient attitudes toward such quality-of-life effects? The rapidity of technological change in health care poses a distinct challenge, making it difficult to keep the assessment of a technology current. By the time a clinical trial is completed and analyzed,
costs have changed, alternative treatments have changed, and the intervention tested may have become obsolete. Substantial investments in technology assessment will be needed to keep pace with rapid change and to improve assessment methods.

Such an investment, however, is needed to improve the quality of care while controlling expenditures. The alternative is to proceed blindly, knowing neither the impact of the health practices that are adopted nor the potential benefits of those that are not. As better data become available and analytic methods improve, the formal evaluation of medical technology will be a vital element of strategies to confront the increasing complexity of medical care and its delivery.

Much of this work was performed while the author was a fellow at the Center for Advanced Study in the Behavioral Sciences, supported by Henry J. Kaiser Family Foundation grant 84R-2459-HPE. Additional support was provided by National Institute of Aging grant AG07651. Several persons at the Health Affairs authors’ workshop made helpful suggestions. I am particularly grateful to Earl Steinberg for his detailed and helpful comments on an earlier draft.

NOTES

3. Joseph Newhouse notes the fallacy in concluding that a technology is not welfare-enhancing simply because a person without insurance would not purchase it. Perhaps the strongest reason to purchase insurance is to enable the insured to purchase expensive health services that they might desire if they fell ill, and that they would otherwise be unable to buy. See J.P. Newhouse, “Medical Care Costs: How Much Welfare Loss?” *Journal of Economic Perspectives* 6 (1992): 3-21. However, the health care subsidy implicit in insurance can make it possible for a technology to be adopted even when it does not improve overall welfare. It appears likely that persons would not choose insurance policies that covered some expensive services, if they had better information and if there were no tax subsidies or regulatory constraints on the benefit.
4. Figures are from annual reports of the National Hospital Discharge Survey, National Center for Health Statistics.

17. For example, the United States Preventive Services Task Force, a federal advisory group convened by the Department of Health and Human Services, repudiated the use of cost information in deciding what constitutes an appropriate package of preventive services. Yet the task force drew upon a set of commissioned background papers, several of which included cost-effectiveness analyses.
18. The fraction of administrative expenses attributable to utilization review and quality assurance activities is not known precisely. Payers bear much of the costs, but hospitals devote substantial resources to these activities as well. Some data, such as the relatively high rate of growth in administrative expenditures for hospital departments with greater regulatory requirements, suggest that these activities are costly. See, for example, D.J. Shulkin, A.L. Hillman, and W.M. Cooper, "Reasons for Increasing Administrative Costs in Hospitals," Annals of Internal Medicine 119 (1993): 74-78.