4. Uses and Usefulness of CEA/CBA: General Findings

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4. Uses and Usefulness of CENCBA: General Findings

INTRODUCTION

Substantial disagreement and confusion surround the question of the potential usefulness of cost-effectiveness analysis/cost-benefit analysis (CEA/CBA) in decisions regarding medical technology and the health care system. With the continuing concern over health care expenditures, and with the advocacy of CEA/CBA by many people and groups as a means to ameliorate cost-related problems, this confusion and disagreement take on a significance that is far more than academic.

OTA believes that the potential usefulness of CEA/CBA depends very critically not only on the feasibility but also on the implications of its use. Accordingly, in this assessment, OTA examined three major issues: 1) the general usefulness (past and potential) of CEA/CBA in decisionmaking regarding medical technology; 2) the methodological strengths and limitations of CEA/CBA; and 3) the potential for initiating or expanding the use of CEA/CBA in health care decisionmaking regarding medical technology, especially in six health care programs—reimbursement coverage, health planning, market approval for drugs and devices, Professional Standards Review Organizations (PSROS), R&D activities, and health maintenance organizations (HMOS). A major aspect of the examination of the third issue is the potential implications—to the programs, to decisionmaking quality, and to society's values–of CEA/CBA use in the six program areas.

The primary focus of this assessment is on the application of CEA/CBA to medical technology—which OTA defines as the drugs, devices, and medical and surgical procedures used in medical care, and the organizational and support systems within which such care is provided. With the exception of a background paper on CEA/CBA and psychotherapy, [1] the assessment does not directly address psychosocial medicine. Other aspects of health, such as the environment, are also not covered. OTA believes, however, and it was the consensus of the advisory panel, that the findings presented in this report, and in the background paper on methodological issues,[2] may apply also to other areas such as health care resource allocation in general. With modification, the findings may also apply to areas such as environmental health regulation, occupational safety and health, and education resource allocation.

Furthermore, although the subject of the assessment was CEA/CBA, the findings should also be examined with an eye to their applicability to other types of formal analysis. Risk-benefit analysis, decision analysis, systems analysis, technology assessment, and social impact assessment, for example, are all techniques used to examine various policy questions in both public and private organizations. The usefulness and implications of each of these techniques will vary according to many of the same factors that affect the usefulness of CEA/CBA. In fact, there are only hazy distinctions between these other forms of analysis and the forms of CEA/CBA.

[1] *Background Paper #3: The Efficacy and Cost Effectiveness of Psychotherapy*, prepared by OTA.
[2] *Background Paper #1: Methodological Issues and Literature Review*, prepared by OTA.

GENERAL FINDINGS

OTA found few examples of well-conducted, sophisticated CEA/CBAs conducted for and used in decisionmaking in health care. It is likely, however, that the extent of use of CEA/CBAS in health care decisionmaking OTA found in its survey (see app. B) understates actual usage—of informal CEAS in particular, but of formal, relatively sophisticated analyses, as well. OTA'S survey was not exhaustive. The effort that was undertaken to ascertain the amount of use, though, does seem to indicate that the level of use is not substantial. Use of formal CEA/CBA in decisionmaking in health care is the exception not the rule.

It is safe to say, however, that most decisions made take into account only a subset of the potential consequences of those decisions. The inherent complexities of many decisions and the uncertainties of decision variables make it extremely difficult to identify and weigh all the consequences. In general, OTA found, the quality and validity of decisions **can be** increased by analysis that forces a structuring of the decision process, that provides a framework for identifying and considering as many of the relevant costs and benefits as is feasible.

This finding supports the two major general findings of the assessment that were presented at the end of chapter 2. **The process of CEA/CBA may be more helpful generally than would be the rigid and formal application of CEA/CBA study results in health care programs.**

Chapter 2 also set out two broad classes of health care program decisions: constrained budget ones, and nonbudget or nonconstrained ones. **CEA/CBA potentially can be more valuable for decisionmaking under a constrained budget where tradeoffs have to be made directly than when constraints are nonexistent or very indirect.** Under the budget system, the budget itself would act as a cost containing or controlling factor. Under the nonconstrained type of system, since no direct tradeoffs are required, no direct limit on expenditures is set or forced. Thus, **in neither case would CEA/CBA necessarily function as an effective cost-constraining mechanism or tool.** Advocacy of CEA/CBA as such a tool, therefore, should be regarded skeptically. CEA/CBA might, though, change the mix of expenditures. Technologies might be substituted for one another on the basis or partially on the basis of analysis—especially under a budget situation. In this regard, there is potential for CEA/CBA to help increase efficiency, even in terms of health outcome, without necessarily lowering total expenditures.

Related to this last point about the possible use of CEA/CBA in improving resource allocation within a constrained budget is the observation that this country's health care system might move closer to an overall constrained budget. This is mentioned only as a possibility. Perhaps in the future, health care expenditures may be limited (or constrained) to a fixed or specified percentage of gross national product, or to some specified absolute amount of dollars. If this situation ever comes about, or even as an increasing number of individual institutions and programs operate under budget constraints, the appropriateness of CEA/CBA may increase. In such a possible future situation, most resource allocation decisions would require explicit tradeoffs. It is conceivable, therefore, that efforts devoted to the development of a CEA/CBA-based approach to decisionmaking (not necessarily tied to numerical study results) will represent an investment in future social policymaking. The lack of direct applicability of formal CEA/CBA to many of today's decisions may then be offset by future applications of CEA/CBA.

Various sources consulted and numerous people interviewed by OTA for this assessment provided information yielding several seeming contradictions or paradoxes concerning CEA/CBA. For example, one common argument is that use of CEA/CBA may often be unethical if it does not take values and distributional issues into account adequately. There is validity to that statement. But there also seems to be validity to the argument that not considering costs and benefits in decisions on society's resources, especially in an area so basic as health, is unethical, because in the absence of the explicit consideration of consequences and of the parties on whom those

consequences may fall, inequities will very likely occur.

Another example of a seeming paradox concerns the "power" of CEA/CBA results. Some people argued that because many decisions are made in a political context, the results of any "objective" analysis would be heavily criticized and overwhelmed by other factors. Yet others argue that one of the factors in the potential misuse of CEA/CBA is its quantitative nature, allowing those involved in the decision process to "anchor" their arguments to what appear to be hard numbers. Are the results of CEA/CBA powerless? Or overly powerful?

The resolution of both these examples may lie in the distinction between the process or approach of CEA/CBA and the quantitative results of formal studies. As indicated by the two general findings of this assessment, many of the negative perceptions of CEA/CBA are based on the possible misuse or inappropriate use of formal study results. **Viewed as a method of structuring the decision process, CEA/CBA need not hide or avoid questions of ethics or values, and it need not provide a deceptively quantitative answer to** complex problems.

As an example of the difficulty of concentrating on quantifiable variables and how investigations of decision possibilities might be enhanced by thinking in CEA/CBA terms, consider the cost effectiveness of CEA/CBA itself. OTA was frequently asked whether a CEA/CBA of CEA/CBA might not be what is needed. And for a given decision situation that type of analysis might be very valuable, Approaching a CEA/CBA of CEA/CBA in order to arrive at a quantitative, traditional bottom-line result, however, might lead analysts to list as a primary "cost" of CEA/CBA the resource costs involved in conducting and interpreting the studies. Thus, resource costs such as those identified in appendix C would be included, with dollars being the measure used. If, however, the analysts were less interested in a bottom-line figure for the CEA/CBA of CEA/CBA, they might consider the opportunity costs of analyses. That is, the more important aspect of the costs of CEA/CBA may not be the dollars it takes to conduct it, but rather the alternate uses of those dollars and the alternate types of analysis and other activities that might occupy the attention of those concerned about more rational allocation of medical technologies (617). Would the funds and attention that could be devoted to CEA/CBA be more productive if applied to efficacy and safety studies? To education or consciousness-raising of physicians? To more dissemination of existing knowledge of the costs and benefits of various technologies? To regulation of the use of technology? These are the questions that probably should be asked.

FACTORS AFFECTING THE USE AND USEFULNESS OF CEA/CBA

One of the key factors affecting the uses and usefulness of CEA/CBA has already been discussed in chapter 3: the technical, methodological feasibility of the technique. These methodological factors can be inherent aspects of CEA/CBA, or they can be due to the state-of-the-art of CEA/CBA and thus more tractable.

The manner in which both types affect the usefulness of CEA/CBA, however, should be analyzed in the context or the environment of current or potential uses of CEA/CBA. In other words, the questions should be asked what is the decisionmaking context and how does it affect the strengths or limitations of the methodology, and *vice versa ?* For example, does the decision relate to a technology at an early stage in its lifecycle, such as bone marrow transplants? Or does it concern an established technology, such as appendectomy? Is the technology in question a diagnostic technology, such as the CT scanner, or a therapeutic one, such as renal dialysis?

The possibility of affecting the course of a technology's diffusion and use might be greater in early stages of its development, but the uncertainties about its health effects and its costs will generally be greater. Thus, it may be possible to

do a more valid or certain CEA/CBA later in the technology's lifecycle, but the information gained may be less valuable for public policy. The tradeoff required will vary depending on the specifics of the technology and the policy decision to be made. In addition, diagnostic technologies are often more difficult to study than other technologies because of the uncertainties involved in linking their use to health outcomes. Thus, studies of diagnostic technologies often tend toward the "net cost" end of the CEA/CBA spectrum, where the measures of outcome or benefit may be numbers of tests performed or levels of diagnostic accuracy.

In sum, the stage of development of the technology under study and the type of technology (or function of the technology) are two of the factors that will affect the specifics of analysis to be used, the uses to which analysis can be put, and the usefulness of resultant information. Other factors are the relative strength or importance of nonanalytical factors, such as politics or equity, in the decisions to be made; the ability of the sponsors of analysis to implement the results; the familiarity of sponsors and decisionmakers with formal analysis; the existence of adequate data relating to the technology, to the disease or other problem addressed by the technology, or on other possible effects of interventions based on analysis; the existence of economic incentives that match or run counter to the results of analysis, the types of decisions to be made (e.g., budget-based decisions or nonbudget-based decisions); and so on. Some of the factors that affect the use of CEA/CBA are listed in table 2.

One of the factors listed above is of particular importance: the quality and availability of data. Obviously, without data or estimates of data, there would be no CEA/CBAs. The quality of a CEA/CBA is directly related to the accuracy of the data used in it. For example, when good epidemiological data on the effects of a technology or the existence of disease are present, analysis will have a greater potential for being relevant and useful. A specific example of where epidemiological data have permitted analyses of high quality is in the area of smoking and its effects on health. Good data do not guarantee good analyses, however, because the quality of analysis is also affected by the other factors mentioned above. Similarly, the usefulness of analysis is dependent on those factors affecting quality as well as on a number of other factors (see table 2) relating to the decisionmaking and analytical contexts or environments.

Table 2.—Factors Affecting the Use of CENCBA

Stage of Development of the Technologies Under Study. —Tradeoff required between availability/validity of data and ability to affect the future use of the technologies. Both the type of analysis and the usefulness of analysis will be affected.

Nature of Technologies Under Study and Function of Tech. nologies Under Study.— In terms of function, diagnostic technologies, for example, often have indirect connections to health outcome and often lend themselves to the net cost type of CEA/CBA. In terms of the physical nature of technologies, surgery, for example, may involve additional uncertainties due to varying skills of surgeons and surgical settings. Both type and use of analysis will be affected, but especially the type or specific methodological elements.

Social, Ethical, or Value Influences in the Decision Environ. ment.—Very similar, often overlapping with the above factor. Will affect both the type and uses of the analysis. The example of renal dialysis applies here. Abortion would serve as another example.

Quality of the Analysis.— Can be of at least four types:

Analysis Subject to Inherent Methodological Limitations. —e.g., inability to adequately deal with equity concerns; influence of discount rate chosen on outcome of analysis.

Analysis Subject to State-of-the-Art Limitations.—e.g., difficulties in identifying and measuring many costs or effects.

Analysis Containing Errors of Omission or Commission. —These are errors not due to the state-of-the-art, e.g., failure to discount or perform sensitivity analysis when appropriate.

Ana/ysis Subject to Data Limitations. —This factor will affect quality even though the other factors might have been adequately dealt with. Much cost and health outcome data are uncertain, difficult to retrieve, or simply nonexistent.

All four of these factors can affect the quality of analysis, which in turn affects the usefulness of the results.

Ability of Sponsors or Users of Analysis to Implement Results.—The usefulness of analysis will naturally depend on the amount of control the user has over the particular technology or situation studied.

Experience/Familiarity of Users With the Type of Analysis Conducted.—This factor will affect usefulness in two ways: it will be a direct influence on the acceptability of results, and it will affect the ability of the users to appropriately apply the results.

Existence of Economic Incentives in the Decision Environment.— If the economic incentives relating to the use of the technology under study are in accord with the results, their acceptability will be great. If they run counter to the results, the usefulness will be limited, depending on the strength of the economic incentives.

SOURCE: Off Ice of Technology Assessment

There are many gaps in the data available for CEA/CBA, owing to such factors as methodological constraints, inadequate resources for data collection and interpretation, lack of communication between the users of data and those collecting it, and the sheer impossibility of collecting and analyzing all the data that could be used by someone, somewhere. The principal Federal agency charged with collecting and analyzing health data is the National Center for Health Statistics (NCHS). NCHS is currently involved in several developmental projects intended to clarify certain methodological issues related to the provision of data for CEA/CBA, especially in relation to cost-of-illness studies (see app. B).

POTENTIAL USERS OF CEA/CBA

Health care policies and other decisions are made at a variety of levels and in a variety of situations by an extremely broad range of individuals and groups. In theory, CEA/CBA results or approaches might be useful to any or all of these decisionmakers. Table 3 lists many of the decisionmakers—the list is not exhaustive but should provide an idea of how diverse and numerous the types of decisionmakers are. Three general classes of decisionmakers or potential users of CEA/CBA information are discussed in this assessment: individual medical practitioners, nongovernmental institutions, and governmental /quasi-governmental institutions.

Table 3.—Partial List of Individuals and Groups Making or Influencing Resource Allocation Decisions

Individual physicians and other health care professionals
Individual patients
Medical professional societies and boards
Consumer groups
Health industry representatives and organizations
Hospitals, clinics, other health care institutions
Labor organizations
Businesses
Health maintenance organizations
Medicare and medicaid
Other governmental health care programs
Health systems agencies, State agencies
Professional Standards Review Organizations
Blue Cross and Blue Shield Associations
Other health care insurers, third-party payers
Other quality assurance or utilization review groups
Food and Drug Administration
Ratesetting commissions
Voluntary health organizations
Public health departments
Other State and local health agencies
U.S. Congress, executive agencies, State legislatures
Health care systems, such as the Veterans Administration's and the Department of Defense's
Medical schools
Biomedical and health services researchers
Other health-related associations

SOURCE Office of Technology Assessment

Individual Medical Practitioners

Despite the fairly small amount of empirical research on the subject, it seems safe to say that CEA/CBA has had little direct impact on individual physicians' behavior.[3]

Discussions with academic physicians indicate a consensus regarding the above point on CEA/CBA's lack of impact. Beyond that point, however, the consensus dissolves. There is disagreement, for example, concerning whether CEA/CBA has, and if so the extent to which, significantly affected physicians' consciousness of economic issues. Explanations for the lack of impact on practice are numerous, with emphasis on their relative importance varying dramatically from one observer to the next. And the consensus on current practice impact does not translate into agreement on the future role of CEA/CBA in influencing individual physician behavior: Opinion seems to be split roughly in half between those who believe that CEA/CBA will cause many physicians to alter their medical practices and those who anticipate continuation of the current absence of significant effect.

The principal explanations for CEA/CBA's lack of impact on physicians' behavior to date can be grouped under two headings:

1. **The novelty of CEA/CBA in health care.** Until very recently, the Literature on health care

[3]The following discussion is taken from work done for OTA by Kenneth Warner of the University of Michigan (615).

CEA/CBA was sparse. As indicated in Background Paper #l, this has been particularly true in the medical literature. Relatively few physicians read the nonmedical health care literature; hence their exposure to the concepts and practice of CEA/CBA was minimal prior to the last few years. Needless to say, lack of exposure correlated highly with (and presumably caused in part) a lack of understanding of the technique and meaning of CEA/CBA.

The novelty of CEA/CBA in health care accounts for some of the quality problems in the published literature. While poor analytical quality certainly could be a barrier to application of the results of analysis, few observers cite it as a significant factor in the failure of physicians to apply findings to their practices.

In a similar vein, the uncertainties in analysis frequently prevent determination of an unequivocal conclusion in an analysis. Even when a firm "bottom line" is presented, nonquantified factors—for example, the distribution of costs and benefits—can make the conclusion far from definitive. Thus, one could argue that even high-quality analyses frequently do not produce findings that can or should be translated directly into practice by individual physician decisionmakers. This seems an attractive explanation for physicians' nonresponse to analysis, particularly combined with whatever bewilderment they may feel as a result of their unfamiliarity with CEA/CBA. It is not, however, an explanation often noted in discussions on the subject. Most likely, this explanation presupposes that other, preliminary barriers to application of analysis have been surmounted; the evidence is to the contrary. Thus, one might anticipate that such inherent technical limitations of analysis will grow in importance as other barriers fall.

2. The irrelevance of much of CEA/CBA to medical practice decisionmaking. There are two basic sources of irrelevance, one substantive, one structural. In the substantive category, many CEA/CBAs have involved assessments of the desirability of social programs where social, and not individual, decisionmaking was at issue. Examples include the several studies of communicable disease control programs (e.g., measles, swine flu, etc.), community (or industry) based screening programs (e.g., hypertension), and fluoridation of municipal water supplies. The subject matter of such studies precludes a direct practice response by individual physicians.

While this too may serve as a useful partial explanation of the absence of behavioral response by individual practitioners, it cannot explain the total absence of such response, since much of the health care CEA/CBA literature is clearly relevant to individual practice decisionmaking. Nor is this an often-cited explanation. A more cogent argument concerns structural irrelevance: According to a strict economic interpretation, most physicians' interests in "cost-effective care" deviate significantly from those of society. All physicians share an interest in understanding the efficacy and safety of medical technologies—technologies whose risks outweigh medical benefits are undesirable—but concerns with the economic side of cost effectiveness are either nonexistent or dependent on the physicians' economic environment. In general (619):

> Cost data are psychologically remote. (The physician's) one-on-one relationship with the patient is not in the context of the cost to society.

The physician's economic circumstances, however, can produce in the physician an often subconscious reaction to costs. To a fee-for-service physician whose patients are well insured, the cost of a technology may be irrelevant, at least immediately. If the physician works within the context of prepayment, however, the professional concern with cost effectiveness begins to approach the social concern. In all cases, the patient's economic wherewithall often will be a major consideration: In an environment of prepayment or adequate insurance coverage, high costs of technologies do not translate into direct economic burdens on patients; hence the high costs are something of an abstraction to both the immediate patient and the physician.

This economic interpretation—emphasized by many knowledgeable observers—attributes the lack of effect of CEA/CBA on medical practice to its irrelevancy and even inconsistency

with medical norms, irrespective of the quality or quantity of the literature. Accordingly, unless the reimbursement system is changed, this argument suggests, the future will auger little change in the application of CEA / CBA to individual practice decisionmaking. According to this explanation, physicians' nonresponse to CEA / CBA is not necessarily a reflection of physicians' selfish monetary interests, or their indifference to economic considerations. Rather, nonresponse to CEA / CBA perhaps reflects physicians' fulfilling their roles as agents of their clients—patients. A physician's major responsibility may be to weigh all the costs and benefits to the patient and to his or her medical practice—i. e., the aggregate of all the patients of the physician.

This argument is not an entirely economic one, because the ethics of the doctor-patient relationship are involved. If a patient is not harmed economically by performance of a certain procedure, even though only a small medical benefit might be expected, what are the ethics of the individual physician's denying or recommending against the procedure in order to represent society's cost and benefit priorities? The differences between social and individual economic and ethical considerations constitute the only frequently advanced explanation for physicians' nonresponse to CEA / CBA that does not imply a brighter future for the ability of analysis to alter individuals' medical practice policies. Systemwide changes in the economic environment, such as growth in HMOs or major reimbursement reforms, might more closely aline the practice of medicine with the precepts of analysis. The strength of the explanation does not depend on lack of understanding of CEA / CBA within the medical community; hence anticipated increases in familiarity with analysis need not promote the direct application of findings. Accordingly, barring external pressures, the economic incentives and ethical norms of medicine may very well continue to preclude widespread application by practitioners of the findings of health care CEA / CBAs, with the exception of the "easy" cases in which one procedure is demonstrated to be both more effective and less costly than an alternative.

Nongovernmental Institutions

A variety of nongovernmental institutions are potential consumers of CEA / CBAs. Insurers have a direct economic incentive to find and promote cost effectiveness in the provision of health care services; officials of major insurers, including Blue Cross / Blue Shield, have expressed their interest in the development of more and better CEA / CBAs to assist them with reimbursement decisions (see ch. 5). In an era of increasing restrictions on reimbursement, hospitals' interests in enhancing efficiency are obvious. HMOs also have a direct economic interest in cost-effective care: Greater efficiency translates into lower, more competitive membership rates and / or higher incomes for member physicians. Large business firms and unions have several reasons to be interested in CEA / CBA: Greater efficiency in the provision of medical services to employees implies lower business costs or room for negotiation of other fringe benefits; health promotion and disease prevention among workers may increase productivity and reduce other costs of disability and morbidity; and so on. As major financers of the costs of illness, each of these organizations has not only an interest in promoting cost-effective care, but also has the market power to translate judgments concerning cost effectiveness into changes in health practice.

Another group of nongovernmental institutions, not directly involved in the financing of care, is evidencing interest in CEA / CBA: professional associations. Among such groups are the Association of American Medical Colleges, the American College of Physicians, the Resident Physicians section of the American Medical Association, and the cost-containment committees of several State medical societies. In part, the interest of such groups reflects concerns about the social implications of inefficient medical resource allocation; in part, interest may reflect a perception that if the health care community does not control cost inflation, Government regulators may attempt to do the job for it. Regardless of the motivation, the demonstrated interest suggests a receptivity to information that CEA / CBA in theory can pro-

vide. This interest extends beyond the medical community. The American Dietetic Association has recently completed a study of the costs and benefits of nutrition care services; dentists have discussed the relative efficiency of alternative methods of preventing caries (78); and so on. Whether the efforts of such groups will ever translate into significant practice changes remains to be seen. But the "cost consciousness-raising" function of CEA/CBA seems well served by such efforts.

To date, direct application of CEA/CBAs to institutional policies has been limited. Some organizations have identified themselves as being in the market for specific analyses—for example, several businesses want to learn more about the costs and benefits of certain disease prevention/health promotion programs for employees (e.g., control of alcoholism and drug abuse, hypertension screening and treatment, executive exercise programs, antismoking programs)—and analysts have responded with CEA/CBAs tailored to the specific institutions' needs (275). Recent policy decisions of other organizations reflect a CEA/CBA mode of thinking, though the decisions have not derived from formal CEA/CBAs. For example, the national Blue Cross and Blue Shield Associations have recommended that member plans not reimburse for institutionally standardized batteries of laboratory tests on admission to a hospital.

The question remains whether, and if so how, nongovernmental institutions will use CEA/CBAS. Certainly, by virtue of its ability to clarify issues and collect and organize information, CEA/CBA could assist planning and decisionmaking within many of these organizations. Some kinds of findings might lend themselves neatly to policy decisionmaking. For example, persuasive evidence that a certain diagnostic procedure is both more expensive and less accurate than an alternative procedure could serve as solid grounds for nonreimbursement or nonacquisition of the former. A large cost differential between two equally effective procedures might also serve as support for a use-constraining policy decision, though opposition might be substantial if significant elements of the medical community questioned the procedures' equality of effectiveness. Indeed, whenever significant technical disagreement on efficacy exists within the medical community, CEA/CBAs seem unlikely to overcome opposition to the policies they might recommend, possibly barring the case of a truly dramatic cost difference.

This point deserves emphasis because of a major implication: Clear-cut, unobjectionable CEA/CBA results probably will be an exception, not the rule. Furthermore, they seem likely to reflect reasonably obvious differences between the alternatives being studied. When a CEA/CBA is undertaken out of genuine interest in evaluating alternatives, without significant prior expectations as to the outcome of the analysis, that outcome is less likely to be definitive. Competing professional opinions on technical issues (e. g., diagnostic accuracy) exacerbate the problem. Thus, definitive CEA/CBAs may *support* policy decisions, but their potential to *shape* such decisions seems limited by technical and political factors.

Governmental and Quasi= Governmental Institutions

A limitation of the preceding discussions is that they deal with the decisionmakers as classes of decisionmakers (e.g., nongovernmental institutions, not a specific institution). The discussion and arguments will vary according to individual circumstances. For this reason, and because its mandate is related to Federal programs, OTA analyzed the potential use of CEA/CBA by several individual Federal programs.

As an example of a reimbursement program, medicare is used, but Blue Cross and Blue Shield are discussed briefly (ch. 5). The drug and device market approval processes of the Food and Drug Administration are also covered (ch. **8).** There are two examples of programs that are federally sponsored, with national policies and administration to a degree, but primarily carried out by quasi-governmental organizations at the State and local levels: the health planning program (ch. 7) and the PSROS' programs (ch. **6).** The usefulness of CEA/CBA to the health care R&D activities of the Federal Government

is examined, using four Federal agencies as examples (ch. 9). Finally, a federally promoted program that is carried out by private sector organizations, HMOs, is discussed (ch. 10).

Each of these programs, or decision areas, uses somewhat different approaches to problems and decisionmaking. Specific approaches have been developed to address divergent and diverse issues. Distinct mechanisms to analyze decisions have been evolved in the various programs. Although informal and implicit analysis of costs and benefits seems to be a frequent aspect of policy formulation in most of the programs, however, OTA found very little formal use of CEA/CBA. In several of the areas, one being market approval, cost itself has played little or no role in decisions. Figure 1 provides a view of the relationship of the six programs to each other and to the lifecycle of medical technologies. Table 4 is a narrative explanation of that figure. An organization chart of the Department of Health and Human Services (DHHS), as seen from a perspective of interest in medical technology, is presented in figure 2 in order to show the organizations of chapters 6 through 10 in relation to other elements of DHHS.

The Federal Government is not the only public institution interested in analysis. Given medicaid and other health care finance programs, States share the Federal Government's concern with health cost inflation. Local governments have also invested in analytical capability (see app. B). Indeed, one of the largest and most productive government analysis staffs was housed in the New York City Health Services Administration.

To date, Government has been the principal consumer of analysis. Still, most observers of CEA/CBA consider Government's past *use* quite limited. One reviewer, however, has concluded that "there is evidence to suggest that such studies have played an important role in public policy determination" (16). According to Dunlop, two examples support this conclusion, First, Enke's mid-1960's finding that the benefits of birth control exceeded costs by a factor of 100 contributed to Congress' significant expansion of Agency for International Development funds to assist developing countries in implementing birth control programs. Second, Dunlop says, CBAS of water fluoridation have "nearly always preceded" dental health program development, with the studies being "widely disseminated to the public" prior to a public vote on fluoridation,

Other analysts are less sanguine about the effects of past analyses on policy. Jeffrey Weiss, who headed the Program Analysis staff of the New York City Health Services Administration, has concluded that, owing to political and budgetary factors, his staff analyses had little impact on broad strategies. Analyses initiated by the staff lacked a political constituency and tended to be ignored. Of analyses requested by city officials, a few were followed by policies consistent with their findings, but these tended to support policy makers' predetermined biases on the issues. Only when administrators had not worked through problems on their own, and strong political constituencies were not involved, could analyses affect the decisionmaking framework; and in most such cases, the effects were "suboptimizing," for example, resolving narrow management issues. Weiss has cited a couple of successes, however—a critical analysis of the neighborhood family care program resulted in constriction of the program; and a study of methadone treatment of heroin addicts created a strong intellectual rationale for drug detoxification efforts in New York City (355). Weiss noted that the city administrator might have gone ahead with the latter efforts in the absence of the analysis, but the study provided support for the policy action (633).

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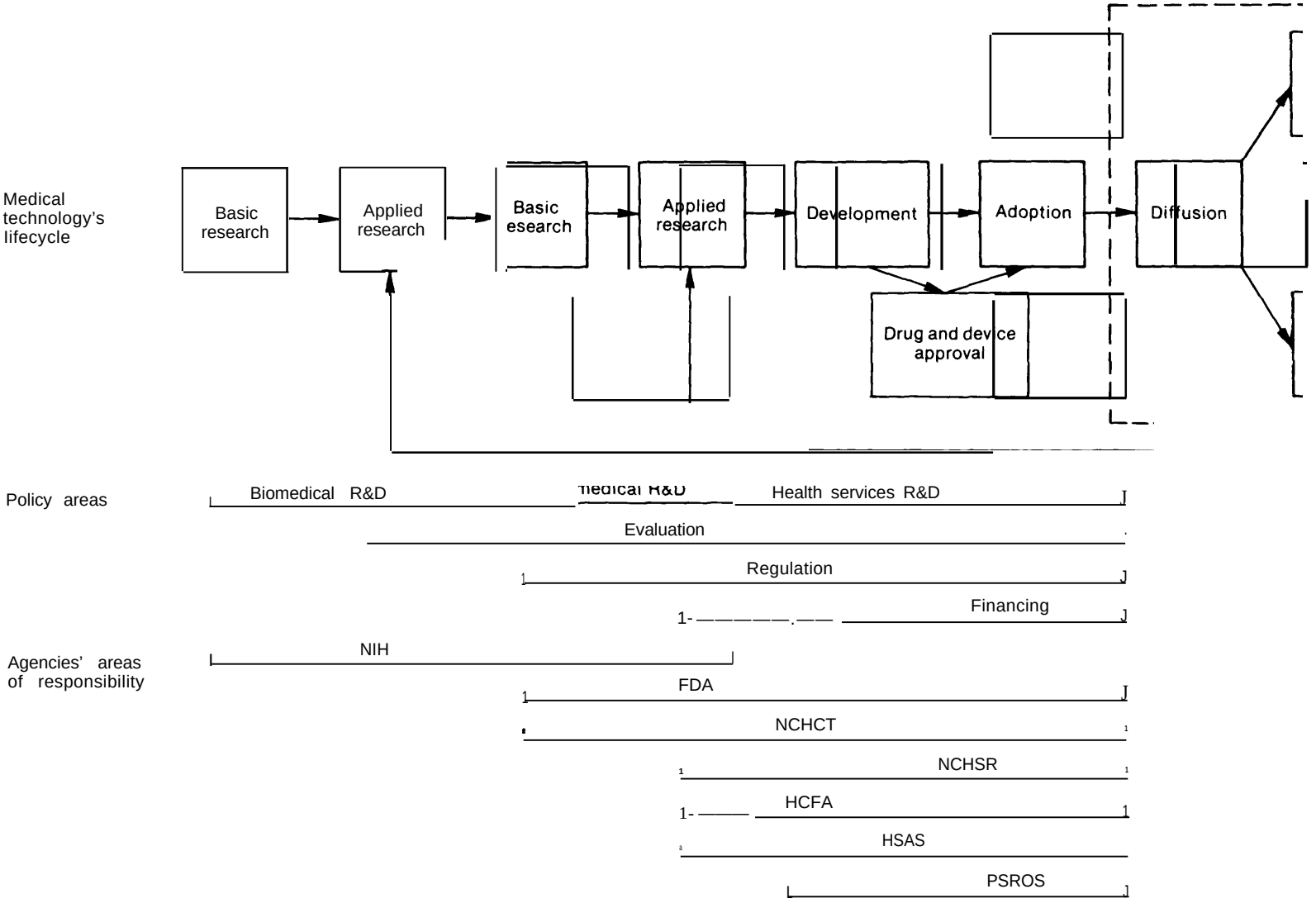
Figure 1.—Policy Levels in the Lifecycle of Medical Technology



SOURCE: Office of Technology Assessment

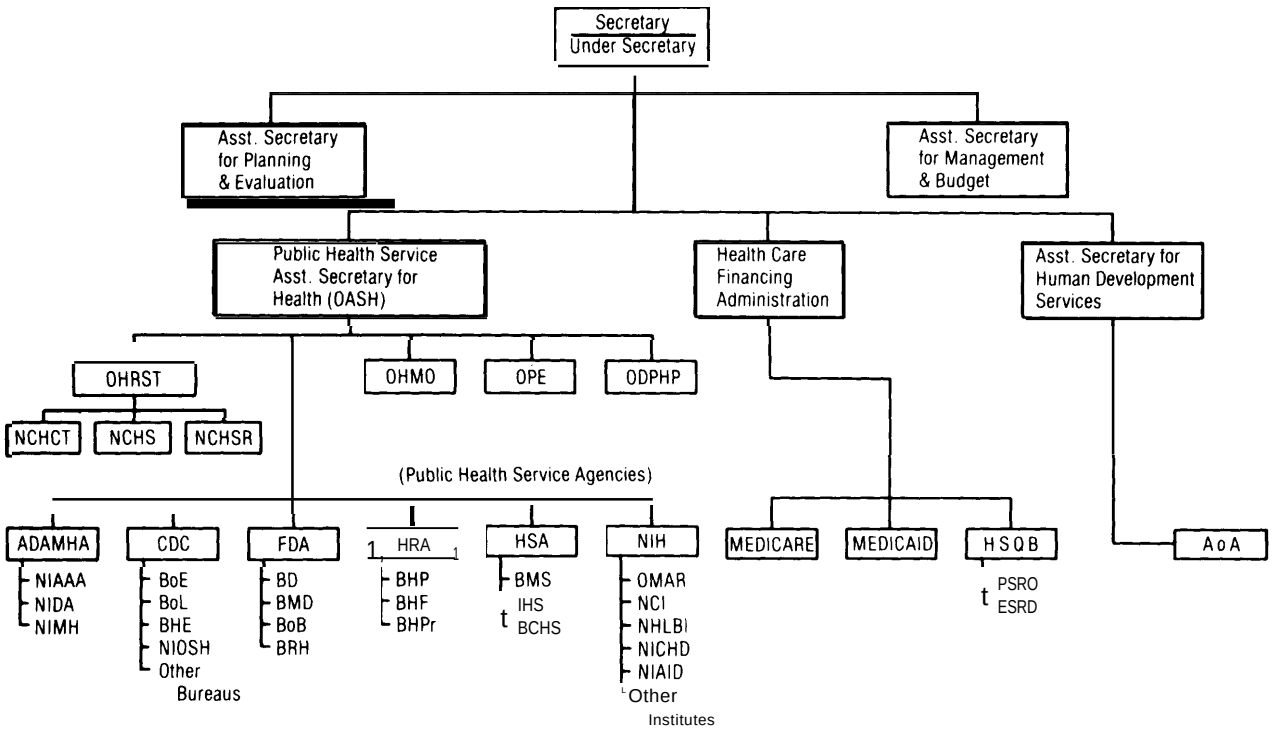
Table 4.—Overview of Agency Activities in Decisions Concerning Medical Technology

Agency/mission	Decision areas and activities: R&D	Evaluation	Regulation	Financing
NIH Improve human health by increasing medical knowledge and encouraging the development of safe and effective medical technologies	Supports and conducts basic and applied research	Establishes standards for research, clinical trials, and human experimentation Supports and conducts clinical trials Sponsors Consensus Development Conferences to evaluate medical technologies Evaluates outcomes of sponsored research		
FDA Protect the American public from unsafe and inefficacious drugs and medical devices and unsafe foods and cosmetics		Establishes regulatory requirements for demonstrations of the safety and efficacy of drugs and medical devices Evaluates safety and efficacy data from clinical trials, etc.	Regulates market approval of drugs and medical devices Regulates drug and medical device manufacturing processes Monitors the safety of marketed drugs and medical devices	
NCHCT Undertake and support assessments of health care technologies		Evaluates social, ethical, legal, medical, scientific, and economic aspects of new, emerging, and existing medical technologies Compiles and disseminates information concerning the safety and efficacy of medical technologies		Makes recommendations concerning reimbursement issues submitted by HCFA
NCHSR Support health services research on a variety of health care issues	Supports health services research, primarily on new and existing technologies			
HCFA Administer the medicare/medicaid programs, PSRO program, and support research and statistics efforts for these programs	Supports health services research on a variety of health care issues, primarily focused on areas of programmatic responsibility		Establishes reimbursement criteria for new and established medical technologies	Establishes benefits packages for medicare Makes reimbursement decisions concerning medical technologies
HSAs[a] Develop and implement local health plans and monitor the dissemination of health services			Review major capital expenditures for certificate of need Review use of Federal funds for certain programs	
PSROs[b] Assure that health care services paid for under certain Federal programs are medically necessary, meet professionally recognized standards of care, and are provided at the most economical level, possible consistent with quality care	Conduct research on quality of medical care through medical care evaluation studies and profile analyses on physicians, patients, and institutions	Review and evaluate the appropriateness of health care provided to Federal beneficiaries at acute care hospitals and long-term care facilities		Support certain Federal programs financing medical care

[a]At the national level, the Health Resources Administration's Bureau of Health Planning is responsible for providing the community or regionally based HSAs with technical assistance and guidance regarding the planning and delivery of health care services.
[b]The Health Standards and Quality Bureau of HCFA, DHHS, is the Federal level organization that provides general guidance and technical assistance to the locally controlled and operated PSROs.

SOURCE Office of Technology Assessment.

Figure 2.—Department of Health and Human Semices-Organizational Components Involved in Medical Technology



NOTE: See app. G for acronyms.

SOURCE: Office of Technology Assessment