

# Policy Formulation and Technology Assessment

H. DAVID BANTA and CLYDE J. BEHNEY

*Office of Technology Assessment,  
Congress of the United States*

**T**HE TERM “TECHNOLOGY ASSESSMENT” IS NOW part of the language of health policy. Analysts and policy makers advocate it, urge caution in its use, struggle to define its role, or, as we do, engage in all three. This paper discusses medical technology assessment, the role of experimentation in that form of policy analysis, and, most important, the evolving role of technology assessment in health policy-making.

We will be principally concerned with experimentation in its more traditional sense—as tests or trials conducted under controlled conditions in order to gain information about unknown effects. But in the medical area, and many others, there are at least two additional possible interpretations of “experimentation” and its relation to social policy. An example of one is the use of a medical technology without first gathering adequate information on its efficacy and safety (that is, the technology’s medical benefits and risks). Such use amounts to an uncontrolled and unintended experiment. In the absence of carefully planned studies, such experience may provide the medical and health policy communities with some information. Clinical judgment and other informal types of assessment may yield valuable information in these situations, but it is hard to evaluate uncontrolled experiments.

---

Milbank Memorial Fund Quarterly/*Health and Society*, Vol. 59, No. 3, 1981  
© 1981 Milbank Memorial Fund and Massachusetts Institute of Technology  
0160/1997/81/5903/0445-35 \$01.00/0

Furthermore, because these uncontrolled "experiments" are usually not considered as experiments (they are, after all, the norm and not the exception), evaluation may not be seen as critical or even necessary.

The second additional type of experimentation that we will discuss is exemplified by current efforts to create or modify existing methods of assessment. In one sense, these are experiments concerning how to experiment. The new National Center for Health Care Technology and the Medical Necessity Program of the national Blue Cross and Blue Shield associations represent experiments on how to use experimentation in social policy formulation.

Technology assessment is not equivalent to experimentation. In general, it does not consist of experiments or sets of experiments although, as we will note below, it does approach equivalency in the medical area more than in most others. Technology assessment, however, does share a common orientation with experimentation: it is a process of evaluation based on the premise that evaluating or assessing reality and assumptions about that reality will lead to more rational, well-informed decisions.

The sections that follow describe technology assessment and its application to the health field. The evaluation of efficacy, safety, and cost-effectiveness is then examined. The use of technology assessment in policy formulation, especially by federal programs, is discussed next. After this descriptive and historical background, we suggest a system for assessment of medical technologies and then make some observations about the future of technology assessment in policy-making.

## Development of the Field of Technology Assessment

The field of technology assessment is a new one and is still subject to conflicting and confusing definitions, methods, and results. Not least among these confusions is the meaning of "technology" itself. The general public seems to equate technology with machines. However, Webster's dictionary states the definition simply as "applied science." We endorse the statement by Galbraith (1977:31) that technology "means the systematic application of scientific or other or-

ganized knowledge to practical tasks." Or, as Amara (1975:55) says, "Technology can be viewed as comprising two major components: physical *artifacts* such as lasers, computers, refineries, bridges—the hardware of technology; and *social instruments* that include methods, procedures, know-how, regulations, laws—the software of technology." The Office of Technology Assessment (OTA) (1976:4) defined medical technology as "the set of techniques, drugs, equipment, and procedures used by health-care professionals in delivering medical care to individuals and the systems within which such care is delivered." Many people writing in this field since have followed the OTA definition.

Generally speaking, technology has been questioned only during the last twenty years. Until fairly recently, it was assumed that all scientific and technological change must represent progress. However, with deterioration of the physical environment, increasing population, increasing energy problems, and so forth, technology and its role in society have been increasingly questioned. Ellul (1964:325) made an even more penetrating critique:

Technique has penetrated the deepest recesses of the human being. The machine tends not only to create a new human environment, but also to modify man's very essence. The milieu in which he lives is his. He must adapt himself, as though the world were new, to a universe for which he was not created. He was made to go six kilometers an hour, and he goes a thousand. He was made to eat when he was hungry and to sleep when he was sleepy; instead, he obeys a clock. He was made to have contact with living things, and he lives in a world of stone. He was created with a certain essential unity, and he is fragmented by all the forces of the modern world.

General concerns about technology led to the development of the field of technology assessment. Technology assessment began formally in the Committee on Science and Astronautics of the House of Representatives. Working as chairman of the Subcommittee on Science, Research, and Development, Congressman Emilio Q. Daddario began a process of examining technology and its impacts in 1965. Through hearings and studies, the work of the subcommittee identified and delineated the need for new approaches to anticipating and controlling the consequences of technological change (Coates, 1977).

This work led to a number of other events. First, it stimulated the National Academy of Sciences and other organizations to become involved in examination of the issues (Brooks and Bowers, 1970). Executive branch agencies such as the National Science Foundation began to fund studies concerning technology, as well as periodic reviews of the state of the art (Coates, 1972; Coates, 1979; Armstrong and Harman, 1977; Rossini et al., 1978). An important formal step was passage of the Technology Assessment Act of 1972 (Public Law 92-484), establishing the Office of Technology Assessment as an agency to serve Congress. The bill stated that "it is necessary for the Congress to—(1) equip itself with new and effective means for securing competent, unbiased information concerning the physical, biological, economic, social, and political effects of such applications; and (2) utilize this information, whenever appropriate, as one factor in the legislative assessment of matters pending before the Congress, particularly in those instances where the federal government may be called upon to consider support for, or management or regulation of, technological applications." While the office is still new and has had considerable growing pains, there seems little doubt that it is a major focus for technology assessment.

Technology assessment is seen as a comprehensive form of policy research that examines short- and long-term social consequences (e.g., societal, economic, ethical, legal) of the application of technology. Technology assessment is an analysis of primarily social rather than technical issues, and it is especially concerned with unintended, indirect, or delayed social impacts (Daddario, 1967:28). In essence, technology assessment is simply a form of policy research broader than is commonly conducted. The goal of technology assessment, as of all policy research, is to provide decision makers with information on policy alternatives, such as allocation of research and development funds, formulation of regulations, or development of legislation.

There is considerable confusion about the term "technology assessment," and it is often used to mean different things. For example, some use it as if it were synonymous with technology-related research such as forecasting, market research, or technology transfer. Others use it to mean a political strategy to restrain or plan technological innovation. Still others use it as a general figure of speech synonymous with casual judgment about technology, such as a consumer's decision

to buy or not buy a device. Under the definition above, none of these activities can be considered to be technology assessment. Nor, it is important to add, is a strictly technical study of a technology a technology assessment.

A number of technology assessments have been completed, including offshore oil drilling (Kash et al., 1973), the automobile (Grad et al., 1975), electronic funds transfer (Arthur D. Little, Inc., 1975), and the video phone (Dickson and Bowers, 1973). The Office of Technology Assessment alone has published almost a hundred technology assessments covering virtually every area of technological change (Office of Technology Assessment, 1979). Recent reports have covered such issues as environmental contaminants of food, continuous casting in the steel industry, the potential of gasohol as an energy source, railroad safety, pest management, residential energy conservation, and energy from municipal waste. Coates (1972) was able to document that of 86 offices in federal executive agencies identified as chiefly responsible for projects and programs of a technological nature, 13 percent consistently performed or sponsored some kind of technology assessments and regarded technology assessment as their major responsibility; an additional 63 percent occasionally performed or sponsored technology assessments of some type.

Technology assessment is certainly not a panacea, and the final word on its usefulness is not yet known. Some authors argue that the process of technology assessment is more important than the product. Mendell and Tanner (1975:22), for example, stress the ambiguity of the real world, and feel that an assessment is primarily a "provocation to further study, discussion, and creative thinking." In any case, in a political world, it seems clear that any form of evaluative analysis is unlikely to become the predominant factor in most important policy decisions.

## Medical Technology Assessment

In the past five years or so, medical technology has become an important policy issue. The major issue has been the rapidly rising costs of health care and technology in particular (Altman and Blendon, 1979). But the visibility of technology in rising costs has raised other

questions: Is medical technology worth the benefits? Are the risks worth the benefits? And, in a broader sense, what is the role of medical technology in society?

The first attempt to apply the concepts of technology assessment to health care was carried out by the National Academy of Sciences in a 1973 report that examined the implications of four technologies: *in vitro* fertilization, choosing the sex of children, retardation of aging, and modifying human behavior (Committee on the Life Sciences and Social Policy, 1973). These examples seem well chosen. As Kass (1971:799) stated, "The biomedical technology works to change the user himself. . . . Biomedical technology may make it possible to change the inherent capacity for choice itself. Indeed, both those who welcome and those who fear the advent of 'human engineering' ground their hopes and fears in the same prospect: *that man can for the first time recreate himself.*" Developments such as these raise ethical and moral problems for which we can find no easy solutions in existing social, moral, or religious philosophies.

However, in the report of the academy itself, two members of the committee, Goldstein and Galston, stated that there was a need for criteria that could determine what questions ought to be asked, criteria for evaluating the answers to questions that ought to be asked, and criteria for evaluating possible societal responses to the answers given. This remains a need for the field.

Little experience has been gained since that time in the broad area of medical technology assessment. The National Institutes of Health carried out an assessment of the totally implantable artificial heart in 1973 (National Heart and Lung Institute, 1973). The National Science Foundation funded assessments of rehabilitation technologies (Texas Tech University, 1977) and life-extending technologies (Futures Group, 1977). That is the total experience with the field of what has come to be called "comprehensive technology assessment" in the health area.

The Office of Technology Assessment has not carried out a comprehensive assessment of a medical technology, in part because assessments are expensive and the office is small. We have reasoned that if we could develop methods or stimulate the Congress to provide extra money to the executive branch, we would be spending our limited resources more wisely. OTA examined the field of technology assessment in health in 1976 (Office of Technology Assessment, 1976),

and made an attempt to address Goldstein and Galston's early criticisms. We examined the assessments that were available, as well as studies and analyses that discussed social effects of medical technology (Kass, 1971; Fox and Swazey, 1974), and developed a list of questions that could be used to assess a given medical technology. We applied them to the computed tomography (CT) scanner, and predicted that the major effects of the scanner would be on patient health (through benefits and risk) and on costs of health care. We also identified potential legal problems (health planning, malpractice). We did not feel that the CT scanner had broader applications and implications such as those associated with genetic engineering (Office of Technology Assessment, 1978b). (OTA has recently issued an assessment of genetics in agricultural and industrial applications, which touched on some human applications.)

Another reason for not concentrating on comprehensive technology assessments at OTA is that we feel there may be more immediately important issues concerning health care technology. As Lederberg (1972:597) says, "We all believe that technology could be directed more beneficially than it has been toward its promise of improving the human condition." The primary purpose of health care technology is to improve human health. This seems to make it fundamentally different from many other technological applications. Health care technologies are often small and discrete, as compared with, for example, a solar-powered satellite. Many health care technologies are taken into the human body purposely, with the explicit intent of changing the human metabolism. Thus, we would argue that the central question concerning health care technology is its effect on human health. To put it in technical terms, What is a given technology's efficacy and safety? Many of those interested in medical technology assessment tend to use the term as synonymous with testing the efficacy and safety of a given technology.

Another area that should not be underemphasized is that of costs. As the number of medical technologies available has mushroomed in recent years, technology has been increasingly cited as a major cause of rising expenditures (Cooper and Gaus, 1979; Wagner and Zubkoff, 1978). So-called half-way technologies, such as renal dialysis, respirators, intensive care units, are very expensive (Thomas, 1974). Increasingly the question is asked whether the benefit received is worth the costs. Or, is the technology cost-effective?

The next two sections examine the evaluation of efficacy and safety and the evaluation of cost-effectiveness of medical technology.

### Assessing Efficacy and Safety

We define efficacy as the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. Effectiveness is similar in meaning except that it refers to average conditions of use. We define safety as a judgment of the acceptability of relative risk in a specified situation. Risk is defined as a measure of the probability of an adverse or untoward outcome occurring and the severity of the resultant harm to health of individuals in a defined population associated with use of a medical technology applied for a given medical problem under specified conditions of use. These definitions may seem bulky. It is important to remember, however, that each of the elements of the definitions is a critical aspect of the concepts and is essential for thoroughly assessing technologies.

Because of the lack of a direct and explicit relation between the rising costs of health care, the expanded use of medical technologies, and improved health, questions have been raised about the efficiency of our health care system. Evidence indicates that many technologies are not adequately assessed before they enjoy widespread use (Office of Technology Assessment, 1978a; Fineberg and Hiatt, 1979). For example, the computed tomography (CT) scanner (Banta, 1980), the electronic fetal monitor (Banta and Thacker, 1979), and radical mastectomy (National Cancer Institute, 1979) continue to be used frequently despite the lack of adequate information demonstrating the efficacy and safety of these technologies. The issue is made more dramatic by cases such as that of gastric freezing, which came into widespread use in the United States in the 1960s and was subsequently abandoned because of a total lack of benefit (Fineberg, 1979). Likewise, a number of surgical procedures on the heart to improve death rates from coronary disease have been abandoned when evidence of their lack of efficacy became available (Preston, 1977).

The key method for testing the efficacy and safety of medical technology is the clinical trial:



Taking the expression *clinical trial* in its widest possible sense—that is, to cover the test of any therapeutic procedure applied to a sick person—it is obvious that the clinical trial must be as old as medicine itself. Even the witch-doctor trying out for the first time a new and nauseating compound must surely, like Alice nibbling at the mushroom in Wonderland, have murmured to himself “Which way?”—though he would no doubt have concealed his anxiety from his patient with the customary bedside manner. Such personal observations of a handful of patients, acutely made and accurately recorded by the masters of clinical medicine, have been, and will continue to be, fundamental to the progress of medicine. (Hill, 1962:3)

Although statistical techniques to complement those of clinical judgment were used as early as the eighteenth century, the use of experiments and statistical techniques to evaluate the results is an activity of this century. Hill (1937) formulated the principles of a well-designed controlled trial in the 1930s. Because knowledge of the natural history of disease does not allow precise predictions of what will happen to an individual patient without therapy, a control is necessary in most cases for comparison. The most powerful technique for selecting the control is to randomize a group of potential patients into experimental and control groups. This area of experimentation has been discussed in an earlier paper in this issue (S.M. McKinlay).

Controlled clinical trials are still infrequently initiated. Administrative, statistical, and financial resources available to support them are small. The largest single investor, the National Institutes of Health (NIH), provided about \$110 million in 1975 to support 755 clinical trials; this figure represents 5 percent of the total NIH budget for 1975. Completion of these trials was estimated to cost another \$345 million (National Institutes of Health, 1977). For 1976, NIH spent \$147 million on 926 clinical trials (National Institutes of Health, 1979). Although other agencies, such as the Veterans Administration (VA), have carried out important clinical trials, their total investment is small. We estimate that the entire public investment in clinical trials is about \$200 million a year.

Not only is the amount small, but also the priorities are skewed, and many important technologies go unassessed. In the 1975 NIH trials, tests of therapeutic technologies predominated. Of the 755 trials, 535 were conducted to test drugs either in isolation or in

combination with another intervention. Four hundred of these trials tested drugs in isolation. More than 300 trials tested cancer chemotherapies; only 25 evaluated surgical procedures. Eighty-five trials examined diagnostic technologies, such as CT scanner for brain tumors and fluorescent scanning in thyroid disease. Few trials examined the efficacy of screening or procedures for early diagnosis. Trials of primary prevention were rare.

Of course, not all trials are funded by the federal government. As described in Nightingale (1981), the Food and Drug Administration (FDA) requires premarketing trials of drugs. There seems little doubt that this requirement has resulted in significant information for society. The 1976 Medical Devices Amendments require the testing of some medical devices in an analogous fashion. We are primarily concerned about two aspects: the lack of evaluation of medical and surgical procedures, and the lack of studies oriented to determining appropriate use of an efficacious technology.

No study has been done to indicate to what extent trials are carried out in the private sector. The best known trials have been funded either by the NIH or by the VA (Paradise, 1975; Takaro et al., 1976). It seems unlikely that the private investment in trials, other than that required by FDA, is very large. This type of research is a public good, and there is no other obvious incentive to undertake it (Rettig et al., 1974).

Given the relatively small amount of funding, which is not likely to increase substantially in the foreseeable future, it is important to set priorities for clinical trials. We feel that this problem is not being considered adequately at present. Later in this paper, we will propose a system for ensuring that important technologies are assessed in a timely fashion.

Many public and private programs, as well as health care providers, depend on information concerning efficacy and safety. Obviously, physicians want to provide the best possible medical care to their patients with minimal risk. Health planners must determine whether a particular technology or capital investment is needed in a given area. Insurance companies, as well as the public programs to provide medical care to the elderly and the poor (Medicare and Medicaid), must decide what services should be reimbursed. The federally mandated professional standards review organization (PSRO) program must determine what is appropriate use. Without good information on

efficacy and safety, the entire health care system is hampered. Thus, one crucial role that experimentation can play in policy formulation for medical care derives from the importance of controlled clinical trials in providing information for that policy.

## Assessing Cost-Effectiveness

We use the term “cost-effectiveness analysis” to refer to formal analytical techniques for comparing the negative and positive consequences of alternative projects or decisions (Office of Technology Assessment, 1980a). Beyond the brief statements that follow, we will not distinguish between cost-benefit analysis and cost-effectiveness analysis in this discussion. In cost-benefit analysis, all consequences, health outcomes as well as costs, are valued in monetary terms. In cost-effectiveness analysis, desirable program consequences are not valued in monetary terms, but are measured in some other unit. In health care cost-effectiveness analysis, common measures include years of life saved and days of morbidity or disability avoided. Cost-benefit analysis allows, at least theoretically, a comparison of projects or programs of a widely divergent nature. Cost-effectiveness permits comparison of cost per unit of effectiveness among competing program alternatives designed to serve the same purpose, but does not allow comparison of programs having different objectives. Cost-benefit analysis is the theoretical ideal, but problems of benefit valuation are myriad, especially in the health area, where such outcomes as healthy life may have to be valued in dollar terms. For this reason, cost-effectiveness analysis is gaining visibility as a tool in the health care system. We will use that term to refer to both types of studies as applicable.

Cost-effectiveness analysis can be used for purposes of planning for the future or evaluating past program performance. As planning tools, the techniques involve prospective analysis. By contrast, as evaluation tools, cost-effectiveness analyses involve retrospective assessment of the realized costs and benefits of existing or past programs. Frequently, of course, a retrospective evaluation will have a prospective or planning intent: should a program be continued into the future and, if so, how should it be modified?

Cost-effectiveness analysis is often confused with other techniques. The two parts of the analysis, assessment of the costs and of the desirable consequences, are both important. The latter, focusing on effectiveness (or efficacy), is traditionally the focal point of evaluation in health care. Similarly, though less commonly, the costs of certain programs or technologies may be assessed in a cost analysis that treats effectiveness only implicitly or not at all. Finally, risk-benefit analyses compare the desirable outcomes of a practice with the undesirable but noneconomic ones. Ideally, cost-effectiveness analysis represents a merging of all these concerns.

As a formal evaluation technique, cost-effectiveness analysis has been used to assess public sector resource allocation decisions where conventional private sector techniques will not suffice. This may occur when the subject under analysis is not traded in or part of a classically defined market system. This is an important characteristic of the health care system and has helped lead to proposals to expand the use of cost-effectiveness analysis as a decision-making tool in health care. In addition, concern with the efficacy and safety of medical technology, the rapidly growing size of the Medicare and Medicaid programs, and the lack of economic constraints on use of medical technology have come together to create a perceived need for formal evaluation of the economic as well as the medical implications of individual procedures and technologies.

Review of the medical literature indicates that widespread interest in cost-effectiveness analysis has developed during the 1970s (Office of Technology Assessment, 1980b). Before 1970, the annual number of health care cost-effectiveness analyses never exceeded 16; after 1970, the number was never less than 25. In 1977, 79 studies were identified in the literature, compared with 5 in 1967. Not only that, but many such studies have been published in prestigious medical journals beginning in 1975. Interestingly, the earlier literature focused on prevention, but recently there has been a shift toward evaluation of diagnosis and treatment.

Experimentation has played very little direct part in this type of analysis. We do not believe that any true experiments, in which data on costs and effects are gathered simultaneously under controlled conditions, have been undertaken in the health field. Where experimentation is involved, it is generally because the analysis has used

results of earlier studies of efficacy and safety, which were themselves based on experimental trials.

In an extensive study of cost-effectiveness techniques, OTA recently concluded that performing an analysis of costs and benefits has the potential to be very helpful to decision makers because the process of analysis could structure the problem, allow an open consideration of the relevant effects of a decision, and force the explicit treatment of key assumptions (Office of Technology Assessment, 1980a). However, OTA also concluded that cost-effectiveness analysis has too many methodological and other weaknesses to justify relying solely or primarily on the results of formal studies in making a decision. Examples of such weaknesses are the difficulty of predicting with precision the costs and benefits of new or not yet existing programs or technologies, fundamental problems in quantifying or valuing certain important but less tangible health benefits, controversy over the appropriate discount rate, the inability of analysis to adequately incorporate equity and political considerations, and the inevitability of significant sensitivities or uncertainties even in many perfectly managed studies. Thus, although cost-effectiveness is useful for assisting in many decisions, it should not be the sole or even a primary determinant of a decision.

### Using Technology Assessment in Policy Mechanisms

There are a variety of public policy mechanisms dealing with medical technology. The federal government funds biomedical research and technology development. It also exerts some control over the early stage of diffusion of technology through health planning and FDA approval of drugs and devices for marketing. Reimbursement policy may be the most important determinant of technology use. Third-party payment schemes have resulted in a situation in which use of a technology involves only small marginal costs to the user. This hides the full resource costs of such use and contributes to rapid and relatively uncontrolled proliferation of medical technology. There is also a federal program (PSRO) whose explicit aim is to control the utilization by physicians of certain technologies. OTA has found little

use of technology assessment as a decision-assisting tool in any of these programs except the Food and Drug Administration. Experimentation, therefore, has been little used by these programs.

Reimbursement programs such as Medicare and Blue Cross/Blue Shield, when deciding what technologies will be covered, concentrate on criteria such as efficacy, safety, stage of development of the technology, and acceptance by the medical community, that generally do not include consideration of costs or broader social implications. Under Medicare, initial responsibility for identifying questions about whether a technology should be covered lies with the system of local, private contractors who administer the program. When not resolved at the local level, the question of coverage is referred to the Health Care Financing Administration (HCFA), which may seek a recommendation from the Public Health Service (PHS). PHS has traditionally used four criteria in its recommendations: efficacy, safety, stage of development, and acceptance by the medical community. Other health insurance programs, such as Blue Cross/Blue Shield, operate similarly. When information from clinical trials on efficacy and safety is available, it is used but, as pointed out above, such information is often not available.

The possibility of expanding coverage criteria to include costs or cost-effectiveness is being examined by HCFA and PHS. The first question to be answered is whether there is a legal basis for any such inclusion. Current language of the Social Security Act requires the Medicare program to pay for services that are "reasonable and necessary." There is no definitive interpretation of whether that language means that the relative cost-effectiveness of a particular technology might make it unreasonable or unnecessary.

Current reimbursement programs are examples of programs without direct budget constraints. Each reimbursement coverage decision does not involve a trade-off. Approval of one technology does not mean that another will not be covered. In a very real sense, it is an open-ended system of financing medical care.

In contrast to the reimbursement system, the National Health Planning and Resources Development Act, with its amendments, explicitly states that resources are to be allocated in a more efficient manner and that health planners should weigh both costs and benefits in their decision processes. The Health Resources Administration, which administers the health planning program, is emphasizing a

more analytical approach to health planning, especially in regard to capital budgeting. On the other hand, OTA has found that state health planning and development agencies (SHPDAs) and local health systems agencies (HSAs) are for the most part still oriented primarily to health "needs." An OTA survey of planning agencies found that few agencies are going beyond the traditional practice of considering only capital costs (Office of Technology Assessment, 1980a). There are a few agencies, however, that consider the marginal (or incremental) costs associated with changes in utilization of a technology. The analysis that took place around the CT scanner is a good example of that. OTA discovered no HSAs that explicitly balance costs with health benefits in, for example, certificate-of-need recommendations. Thus, although there appear to be no legal barriers to its use, cost-effectiveness analysis has not been much applied. In health planning, as in reimbursement, there is no direct budget constraint. The area served by an HSA is not operating with a fixed or predetermined amount of resources to be spent on health care. Health planning agencies have no legal basis for considering broader social impacts of technology, other than relatively narrow, health care system questions such as access to care.

Market approval for drugs and medical devices, by the Food and Drug Administration, is an example of an area where Congress has specified the decision criteria, which explicitly do not include economic costs. As described in Nightingale (1981), the main basis is well-controlled studies of efficacy and safety. Thus FDA is at present the most consistent user of explicit results of experimentation.

The PSRO program was enacted to ensure that health services provided under Medicare, Medicaid, and certain other programs are medically necessary, meet professionally recognized standards of care, and are provided at the most economical level consistent with quality care. Yet cost-effectiveness criteria have not been directly incorporated into the standards of care used for review by PSROs. Indeed, experimental results in general, such as data on efficacy and safety, appear to have had little impact on PSRO standards. The standards have been developed on the basis of clinical experience and prevailing practice in the particular area. For example, many PSROs have reviewed length of stay for such conditions as myocardial infarction. In one PSRO, the average length of stay was 15.5 days. The PSRO decided that any stay over 21 days was excessive. There was no basis

in the scientific literature for the standard. Likewise, CT head scans have been scrutinized by several PSROs, using clinical criteria including known diagnoses, abnormal physical findings, and symptoms. However, there has been no attempt to relate the criteria to improvements in patient outcome, and little to ensure that the symptoms cited do in fact mean physical disease.

Some net cost techniques have been used to evaluate whether the savings achieved through the review activities of the overall PSRO program outweigh the costs of administering the program. These analyses, however, do not examine costs in relation to changes in health outcomes that may result from PSRO reviews. Interestingly, these evaluations, which sometimes show a small cost savings and sometimes show a small net cost increase, are evaluated in terms of the value of the national PSRO effort. Implicit in such a criterion is a view of PSROs as a cost-containment mechanism. Yet, if this is indeed the rationale of the PSRO program, what does it matter if the program does cost slightly less than the amount it saves? That net saving is still infinitesimal compared with the total cost of the programs that the PSROs are supposed to be constraining.

The federal health care research and development effort encompasses a range of activities, from biomedical research (e.g., National Institutes of Health) to health services research (e.g., National Center for Health Services Research, the Health Care Financing Administration). The National Center for Health Care Technology incorporates to an extent the two points of the spectrum noted above. Explicit cost-effectiveness considerations are rarely used by Research and Development (R & D) agencies to set research priorities, to allocate research resources, or to evaluate the results of research. The uncertain end-products of much of research, especially basic research, make it difficult to use formal analysis to assist decision-making. Ironically, if analysis is to influence decision-making, it is desirable that it be done early in the development of a technology.

There has been one instance of a "comprehensive technology assessment" that in part was conducted to influence research priorities. During the 1960s, a time of great faith in the powers of science and technology, a program was launched to develop an "artificial heart" (more accurately, a totally implantable artificial heart, including an implantable power source). By 1965, a five-year plan was developed by the National Institutes of Health for achieving the artificial heart,



and by 1967 this NIH program had expended \$10 million. However, two difficult problems arose: the development of biomaterials that would not cause adverse consequences with constant contact with the blood, and the development of a suitable power source. In 1972 and 1973, NIH convened a special panel to examine the social implications of the artificial heart. The panel did a reasonably comprehensive analysis, although without a defined systematic approach, and identified (but did not fully analyze) a number of potential problems. Officials of the National Heart, Lung, and Blood Institute of NIH have told OTA informally that this assessment helped change the priorities of the development program. Recently, the program has focused on the development of a left-ventricular assist device that could be used temporarily with an external power source for people with acute problems such as myocardial infarction. The full impact that the assessment had on the development effort deserves careful study (Lubeck and Bunker, 1980).

## A System for Assessing Medical Technologies

The previous section has discussed the limited use of formal assessment techniques in policy-making. This is due in part to the nature of the policy-making process, and in part to the immaturity of the field of technology assessment. But it is also due in part to the lack of information on the benefits, risks, costs, and social effects of existing or planned medical technologies. If adoption and use of medical technologies are to be based on well-validated information, such information must be developed to the extent desired and practical and must also be disseminated to individuals and groups in need of it.

The process may be viewed as an interdependent and nondiscrete flow of four types of actions (see Fig. 1):

1. Identification: Monitoring technologies, selecting those in need of study and deciding which to study.
2. Testing: Conducting the appropriate analyses or trials.
3. Synthesis: Collecting and interpreting existing information and the results of the testing step, and (usually) making recommendations or judgments of efficacy, safety, costs, and so forth.

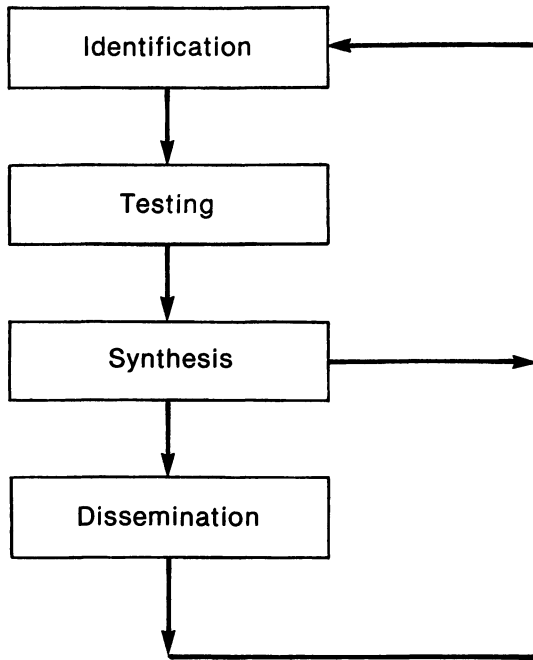


FIG. 1: Process for developing and disseminating information on medical technologies.

4. Dissemination: Providing the synthesized information, or any other relevant information, to the appropriate persons who use or make decisions concerning the use of medical technologies.

Despite recent changes in federal policy—for example, 1978 legislation establishing the National Center for Health Care Technology within the Department of Health and Human Services—the primary shortcoming in current assessment methods is still the lack of a formal or well-coordinated “system” for developing and disseminating relevant data. Some elements of the process are operating and performing well. However, the elements are not adequately linked together and do not follow each other logically.

### *Identification*

At present, there is no complete list or catalogue of either existing medical technologies or those that particularly require assessment. Partial lists do exist. The Food and Drug Administration, for example,

has lists of approved drugs and devices. The fact remains, however, that many medical procedures that are not on reimbursement schedules, but are important to assess (bed rest for certain diseases, for example), are not catalogued in one source.

No existing system adequately identifies developing technologies that will need evaluation. The National Institutes of Health does a yearly study of its clinical trials and publishes a catalogue of those trials it supports. Other agencies, such as the Veterans Administration, have similar catalogues or lists. Through its premarket approval process FDA gathers information on drugs and devices that are being developed. If medical and surgical procedures were to be evaluated before they came into widespread use, however, some comprehensive system for recognizing them in a timely fashion would be necessary. As a possible step in this direction, FDA and NIH now are required to provide the National Center for Health Care Technology (NCHCT) with lists of new and emerging technologies.

Even if funds for, and numbers of, studies were greatly expanded, setting priorities for study would still be necessary, because it is neither possible nor desirable to examine formally every aspect of every medical technology. Several considerations make such sweeping evaluation undesirable. One is the probability of diminishing marginal utility. Presumably, evaluation would reach a point where less and less additional information is gained for the substantial investments of time, money, and other resources that would be required. Another factor is the near impossibility of manipulating and successfully disseminating the tremendous masses of data that would result. Another, and potentially one of the most important issues, is the effect that total assessment might have on incentives for innovation. Even in the current assessment situation some analysts feel that the rate of innovation of medical technology has been slowed.

Priorities for assessment might include beneficial technologies that are neglected or technologies that are suspected to be useless or dangerous. Technologies that are, or are expected to be, either expensive or widely used also could be given priority. For new technologies, potentially important advances could be assessed rapidly.

One confounding variable in the process of assessment that is especially critical for the identification phase is the stage of development of the technology. Obviously, the farther along the development of a technology is, the better the information about its effects can be.

Technologies change as they move from early clinical use, e.g., through clinical refinement to early adoption and their eventual patterns of use in medical practice. Dosages are refined. New generations of devices replace older ones. Surgical techniques are modified. New uses are often added, older ones sometimes abandoned. In other words, the indications for using the technology change and its potential benefits, risks, and cost change. For example, early in the diffusion of a new technology it may not be desirable to conduct a large-scale randomized controlled clinical trial. At a later point, however, as the technology is accepted, such a trial may become highly desirable.

All this implies that criteria for selecting technologies for study need to be sensitive to stage of development and extremely flexible. Trade-offs are inherent. A study initiated too soon or on a rapidly outdated technology will be of limited use; yet delay in assessment could mean that the technology might diffuse before adequate information on its effects was collected. We do not have the answer to this dilemma. We do, however, feel strongly that this aspect of evaluation deserves considerable attention—attention that it is not receiving.

One of the most critical functions of NCHCT is to set these priorities for assessment. That agency has been developing the beginnings of such a process—for example, a priority list has been developed including such technologies as barium enema, ultrasound, and nuclear magnetic resonance—but so far the overall effort has been less than impressive. More attention needs to be placed on the criteria to be used for setting the priorities. Nonetheless, the agency and its advisory council recognize the value of such priority-setting.

In sum, there is as yet little formal process for selecting which technologies are to be studied; indeed, there is not even a widely agreed upon set of priorities for such selection. New drugs and new devices are, however, subject to the FDA market approval process and thus are automatically identified for study, at least in regard to the efficacy and safety claims of the manufacturers.

### *Testing*

The testing phase includes stimulating, requiring, funding, or conducting studies. Shortcomings related to the testing phase center

around four issues: 1) the quality of the methods for conducting controlled trials, consensus activities, and other tests; 2) the level of financial support, particularly for controlled clinical trials; 3) the relative appropriateness of the questions and technologies being studied; and 4) the number of personnel qualified to conduct such research.

There is no "correct" level of financial support for studies; no one can set an exact figure for the amount that should be invested in trials and other forms of testing. Does the current level of funding, then, represent a shortcoming? This question must be answered affirmatively because important areas of health care are not receiving adequate investigation, according to the evidence gathered by the Office of Technology Assessment (1978a). New or developing preventive and screening technologies and new procedures are studied relatively infrequently, as are existing technologies of all types.

Efficacy and effectiveness are two different concepts that are not clearly differentiated in the medical literature. In our conceptual model, all medical technologies would be evaluated for efficacy before they come into widespread use. This would involve their being tested under *optimal* conditions. For example, the most skillful surgeons should be involved in a test of a surgical technique. This model does not tell us how to ensure effectiveness—that is, the benefit from the technology when applied by an average practitioner in an average setting. Once a technology has come into widespread use, questions are seldom raised about how it is being used on a routine basis. Yet use of technologies does vary substantially, and technologies are sometimes modified through use so that they, in effect, become different technologies. Coronary by-pass surgery illustrates several of these problems. After its initial development, it diffused fairly rapidly. It was developed as a treatment for severe coronary disease of a life-threatening nature. But, once developed, it has been applied to more and different patients. Patients with angina pectoris are now commonly treated with such surgery. In addition, many surgeons whose skills are unknown are now performing the procedure. The medical literature contains virtually no analyses of the effectiveness of medical technology. Yet in some ways, this is the more important and interesting question. We predict that in the future this problem will be of great concern, and that the number of studies of effectiveness, now few in number, will increase.

### *Synthesis*

Synthesis involves a critical analysis of the results of testing (available data from preclinical to clinical experience, epidemiological studies, and experiments) and all other available and relevant information. It often takes the form of judgments or recommendations regarding the appropriate indications for use of technology. Consensus development sometimes can be considered a synthesis activity. Syntheses are commonly found as review articles in the literature. However, the literature reviewed is often of poor quality and is usually not directed toward the needs of practitioners. Moreover, reviews tend to overlook the varying quality of evidence in constructing a synthesis.

Federal government synthesis activities are expanding. How well these activities fulfill the synthesis function remains to be seen, but there is a great potential. The process by which the National Center for Health Care Technology recommends coverage decisions to Medicare may represent a new important synthesis activity. However, all synthesis activities are hampered especially by the lack of well-validated information on efficacy and safety.

### *Dissemination*

Many of the comments relating to synthesis also apply here. The success of dissemination activities does not depend only on the extent of distribution or publication of information, no matter how relevant or important those data may be. More critical is *effective distribution*—actually making contact with the intended audience and convincing that audience of the importance and validity of the information. Dissemination should be designed to influence behavior, or at least to increase the opportunity for informed behavior change by physicians or other target populations. It is frustrating to note that little satisfactory research has been conducted on methodologies for engaging in effective dissemination or for evaluating the success of dissemination activities. Much of the research that does exist is inconclusive, and the research that is well regarded is not applied to any major degree. The quality and success of dissemination, then, are the important variables here, and the simple *level* of activity is merely an unsatisfactory surrogate for them.

Federal agencies have not assigned a high priority to disseminating information. FDA sometimes sends letters to all physicians as one

mechanism for distributing important information. The National Center for Health Services Research frequently disseminates information to a wide audience by issuing research reports that describe the results of projects funded or conducted by the agency. Also, NIH has provided information, primarily to the professional community, through its demonstration and control projects, through the National Library of Medicine, and through other activities, including a regular feature in the *Journal of the American Medical Association*. One of NCHCT's mandates is to coordinate and expand dissemination of relevant information. The private sector also has multiple channels that encourage the flow of information, and professional societies have been expanding their activities in this area.

### The Future of Technology Assessment in Policy-Making

The previous section is the first in this paper to be future-oriented. The others are primarily descriptive. The section on using technology assessment, especially, described the current status of public policy mechanisms and their past or current use of technology assessment, including experimentation. We only infrequently touched on the future potential of technology assessment in those programs. Normally we would next consider that future potential, based on our impressions and on the work done to date by others. Such a discussion could follow the typical pattern in this area of "policy-analysis-related policy analysis." The theme of this issue of the *Quarterly*, however, provides an opportunity to give some attention to another critical step. And that is to ask ourselves whether we in the field of technology assessment have been doing something that we criticize more traditional policy analysts for doing—concentrating on the specifics of the subject of analysis without having first identified the subject's broader role in society and its possible broader implications. The large majority of writings in the area of the future role of technology assessment have been principally concerned with such topics as the maturity or sophistication of specific analytical methods, knowing at what stage of a technology's life cycle to apply which method, developing institutional bases for assessment, and identifying what increases in funding

and personnel might be necessary for an expanded assessment effort. Many such analyses or discussions have been excellent and have increased interest in and awareness of technology assessment and have advanced the state of the art (e.g., Bunker et al., 1977; Fineberg and Hiatt, 1979; Weinstein, 1979). This type of examination is necessary in the early stages of a new area of policy. But we feel that a more basic examination of the role of technology assessment is also required.

Therefore, we will examine the rationale for that role. To do this we present an admittedly simplistic process of social policy-making, with particular emphasis on the part played by experimentation.

The role of experimentation in social policy formulation is determined in large part by the process of developing that policy. Figure 2 provides a highly simplified and *idealized* depiction of that process. Although the process is idealized, there have been several instances when social scientists have contributed to society through the design or conduct of social experiments. Our society does not, however, typically use such methods in its policy-making processes (Saxe and Fine, 1981). Viewed as an artificially linear flow, policies should begin as perceptions of a gap between goals or desired states and the status quo or current state. Desired directions translate into attempts to use or develop mechanisms for moving in those directions. Specific manipulations of those mechanisms are designed to provide movement toward desired states. At this point, some method both of determining the necessary manipulations and of evaluating the results of the manipulations is needed. Several classes of "techniques" are available—expert opinion, historical analysis, political considerations, blind modifications to existing manipulations, experiments, other forms of assessment, and so on. Whatever technique or combination of techniques is used, though, should have some analytical relation to the initial statement of desired goals. This process and its relation to the role and form of experimentation will be examined more closely.

### *Goals or Desired States*

Individuals, society collectively, and the many subgroups of society all have goals. These goals may not always be well defined; they may only be general feelings about values or directions, but they exist. And obviously, but most critically, the goals of different groups and



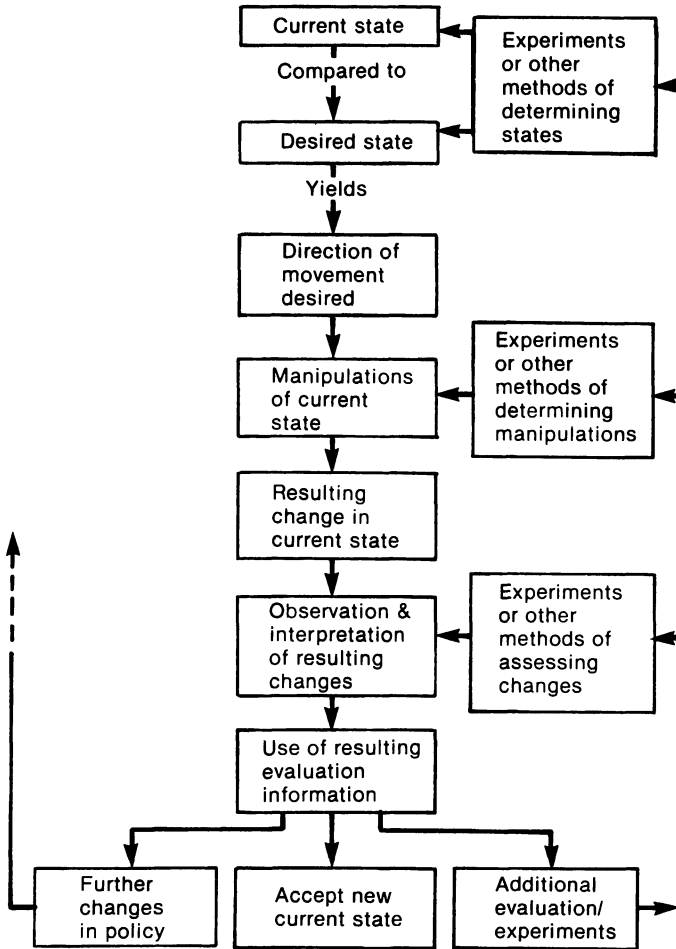


FIG. 2. Process of developing social policy.

different individuals often differ markedly. This antagonistic dynamic contributes to the defining of the role of experimentation in developing social policies, as do the existence of multiple goals, levels of goals, and goals that change over time. Clearly, when groups within society differ on basic goals it will be difficult to reach consensus on even the need for an experiment, much less on the form any experiments should take.

The medical field provides an example of agreement on a basic goal but disagreement on a subsequent level of goals. Most people find little to argue with in the statement that improved health is a basic social goal of this country. Differences arise, however, in the attempt to state intermediate or subsidiary goals. Many physicians, for ex-

ample, believe that an essential intermediate goal is that the medical profession retain a high degree of autonomy. This is a necessary goal, they feel, in order to make progress to the higher goal of improved health. Other people or groups appear to hold a somewhat different view of the level of medical professional autonomy that is necessary for maximum progress toward the higher goal. The proliferation of government and private sector programs designed to increase the amount of scientific examination of medical technologies is in some instances a lessening of professional autonomy, yet their advocates view the existence of these methods of evaluation as a desirable goal in the movement toward ensuring better health.

This example also illustrates a key aspect of intermediate goals: with the exception of ultimate goals, all goals are inextricably meshed with mechanisms for moving in desired directions. It is impossible to meaningfully separate the journey from the destination. Any statement about an intermediate goal along the path to the goal of better health involves a statement of "how" to move toward a better health state. Better health itself may be subordinate to the goal of happiness or contentment or some similar personally defined ultimate state. By stating that good health is a goal, one is indicating belief that attaining better health is a way to move toward the goal of happiness or some higher goal; it is itself a "how." Viewing most goals, then, as other ways of expressing the concept of "how to move" increases the importance of experimentation and other methods of identifying and evaluating methods of moving from the present state to a desired new state.

### *The Current State*

Perceptions of the current state of aspects of society or its institutions determine whether a policy question will be raised. Such perceptions take on meaning only when viewed against desired states or goals. One objective of policy analysis in general, including technology assessment, is to provide or improve perceptions of the current state. It may also be used, as technology assessment is in particular, to estimate or predict future states under certain assumptions. These definings or refinings of the perception of the status quo, and the consequently perceived disparities between that state and the desired

one, exert considerable influence on the role of experimentation. Those perceived disparities are in effect statements of problems or opportunities to be acted on. Will the problem be defined as one that is susceptible to experimentation during the search for solutions? Or will the problem be defined as essentially political or ethical, with respect to which experimentation is viewed as playing a lesser role?

### *Moving toward Goals or Desired States*

We have already mentioned that methods of moving toward goals are themselves intermediate goals. In this section, however, we will consider them only as mechanisms for moving from one state to another.

Many of the mechanisms are obvious. All the programs mentioned in the section of this paper on using technology assessment have been established to act as mechanisms to move society or at least the health care system in desired directions. Mechanisms are often expected to play multiple roles. The health planning program, for example, is charged with improving access while at the same time being concerned with the quality and the cost of health care services. There is disagreement on whether the health planning program is a desirable or proper mechanism. Similar disagreement is often voiced regarding many other mechanisms for change in health care. We will not enter those debates, but we will point out how well such disagreements illustrate the subjective nature of the policy process. The appropriateness of health planning as a means of implementing policy depends on a succession of value judgments: what are the desired movements to be made, what should the nature of an implementing mechanism be, how should we evaluate the resultant movement and its value, and so on. And, as Vickers (1965) argues, things resting on value judgments cannot be proven; they can only be approved as correct or disapproved as wrong on the basis of further value judgments. The legitimacy of mechanisms stems from the magnitude of societal approval they possess. Further, we believe that the extent to which experimentation and other forms of analysis represented by or used in technology assessment are accepted and used will be determined not only by how "technical" the mechanism's field is but also on the degree of value approval that the mechanism can claim.

### *Role of Technology Assessment and Experimentation*

There are three principal points in this idealized process for developing policy where assessment, including experimentation, can play a critical role. The *first* is in the identification of current or potential splits between actual and desired states of society, its institutions, or other aspects. In this sense, assessment's value lies in testing assumptions about reality. Technology assessment in particular was developed with the goal of predicting possible future implications of technological change and therefore is designed to provide perceptions of potential problems.

A *second* role is the use of experiments or other forms of assessment in the change mechanisms. An example of this role is the use of controlled clinical trials in the Food and Drug Administration's process for regulating the market introduction of drugs and devices. This represents a direct use of experimentation. An example of an indirect use is provided by the experiments in which the Health Care Financing Administration (HCFA) sometimes engages, with respect to different types of reimbursement methods. In this case, experimentation is used to help determine what specific changes could be made to improve the ways in which the mechanism, or program, operates.

Whether or not experimentation is used directly or indirectly, and whether or not some form of technology assessment is used to guide manipulations of policy-implementing mechanisms, it is essential to evaluate the impact of the mechanisms. This is the *third* area in which experimentation and technology assessment can play a role. In the case where experimentation has been used indirectly, as with the HCFA example above, those same experiments or further experiments of a similar kind can serve as one of the evaluating mechanisms. In the case of HCFA, a reimbursement method experiment could yield information on the results of the changes in those methods, while in fact being the instrument of those changes. Generalizing from this example, we would argue that demonstration programs often have the potential to serve as this kind of experiment, yet they are very often not seen as such. As a result, the sponsors of the demonstration are frequently left with a great deal of data but little usable information on, for example, what specific elements of the demonstration produced the resulting changes in the subject of the demonstration.

In the case of experimentation used directly (as by FDA), technology assessment could perhaps play a role in the evaluation of the effects of the overall FDA program for drug or device approval, including the role and effect of experiments (the controlled trials) used in the program. By emphasizing the dangers of evaluating FDA on narrow grounds of any sort—e.g., on the drug lag alone, or on the number of harmful drugs allowed on the market, or on the economic impacts of drug regulation—a technology assessment might be able at least to identify the range of medical, economic, ethical, political, and social factors affected by, and in turn affecting, the operations of FDA. These factors may not all be quantified, but they might be identified and characterized. And their open consideration in relation to one another might suggest possibilities for experiments in drug regulation reform as well as factors that should be considered in any experimental evaluation of reform.

Examination of these three roles for experimentation/technology assessment in the development of policy demonstrates one of the most obvious statements about experimentation and assessment: their prime goal is to produce not just information but to produce information that is usable in and useful to the process of developing, implementing, and evaluating policy. Obvious; but frustrating. Frustrating because the health policy process badly needs relevant and valid information. But as we pointed out earlier, that type of information, at least in regard to medical technologies, is infrequently generated, even less frequently used, and ultimately may be very difficult to generate.

An example of this dilemma is the unfulfilled promise of cost-effectiveness analysis. Decision makers in health care need information on the costs and the benefits or effectiveness of alternative programs or technological applications. Nearly every health care program of the Department of Health and Human Services currently has the authority to conduct or fund studies of cost-effectiveness. Very few, however, do so (Office of Technology Assessment, 1980a). This statement, of course, fails to take into account the, in all likelihood, large number of decisions that are in part made on informal and “unsophisticated” comparisons of positive and negative consequences, a sort of part-intuitive, part-quantified analysis. The ubiquitous back of an envelope is perhaps being passed from office to office in the Public Health Service. Yet this type of assessment is not what the proponents of

cost-effectiveness analysis have in mind, and it is not the theoretical ideal of experimentation or of technology assessment. The reluctant administrators of, for example, the Public Health Service may be representing rationality in this case, however. Just as they may not be ready for cost-effectiveness analysis, so too is cost-effectiveness not ready for them. It has serious methodological flaws, some of which are due to its newness in the health area and so might be lessened, and some of which are inherent in the technique. The theoretical ideal of using experimentation or technology assessment, in the form of cost-effectiveness analysis, becomes tarnished in varying degrees when faced with the complexities of the decision-making world, with its political undercurrents and its numerous disagreements on goals and methods of attaining them.

Which leads us to experiments on methods of experimentation or on methods of assessment. Because of the increasing attention being paid to medical technology as a policy issue, especially to the costs, efficacy, and safety of those technologies, the country has set about institutionalizing technology assessment. OTA is part of that trend; so is the National Center for Health Care Technology, the Office of Medical Applications of Research at NIH (consensus development conferences), the interagency task force on health care technology of the Department of Health and Human Services, and many other organizations in the government and in various nongovernmental organizations, such as committees within several medical specialty societies. The overall purpose of this activity is hazy, however, and at times we seem more concerned about how to organize the activities than about why we undertook them and of what value they will be in five or ten years. We are in effect combining the two special types of experimentation that were mentioned at the beginning of this paper. First, all this activity is an experiment on experimenting or assessing. All the involved agencies and groups are generating and synthesizing and, sometimes, disseminating information about poorly understood phenomena (e.g., the efficacy and safety of many medical technologies). At the same time, this activity represents an example of an uncontrolled and unintended experiment. It is not, to our knowledge, seen as an experiment by any significant number of people. This unseen experiment possesses the danger of leaving us very near where we were when it started. If it is not recognized for an experiment

in social policy-making or policy-assisting, then it will not be evaluated as such. Criteria will not have been prepared in advance for eventual use in evaluating the effects or impacts of the growing amount of activity. And those criteria can be prepared with relevance and validity only if this experiment is seen in relation to the policy process that it is intended to serve.

It is not our intent or task here to begin the design of such an evaluation. We hope that the importance of that task is recognized and that some initial efforts in that direction can be stimulated.

## Conclusion

In its comprehensive forms, technology assessment has been little used in the health policy process. When viewed as a more narrow form of policy-related research, however, technology assessment has long been a part of that process. Efficacy and safety assessment, and to a lesser extent, cost-effectiveness analysis, play an increasingly important role. And the role of experimentation in these forms of research is growing.

Although the resources devoted to assessment are increasing and its importance is being more widely recognized and accepted, the amount of effort is still small. The experience with using the results of studies of efficacy, safety, and costs in policy decisions is limited, with a few exceptions, and leaves us with serious unknowns about how best to organize the growing effort in assessment.

Thomas (1974:31) predicted this state of affairs years ago: "When, as is bound to happen sooner or later, the analysts get around to the technology of medicine itself, they will have to face the problem of measuring the relative cost and effectiveness of all the things that are done in the management of disease. They make their living at this kind of thing, and I wish them well, but I imagine they will have a bewildering time."

That statement is impossible to refute. Yet, it does not detract from the necessity of the undertaking. It highlights the unknowns and the difficulties. And it implies the critical role that experimentation must come to play as we sort our way through the planning, conduct, and use of technology assessment.

## References

- Altman, S., and Blendon, R., eds. 1979. *Medical Technology: The Culprit behind Health Care Costs?* DHEW Publication No. PHS 79-3216. Hyattsville, Md.: National Center for Health Services Research and Bureau of Health Planning.
- Amara, R. 1975. Some Observations on the Interaction of Technology and Society. *Futures* 7:515-517.
- Armstrong, J.E., and Harman, W.W. 1977. *Strategies for Conducting Technology Assessment*. Stanford, Calif.: Stanford University Department of Engineering-Economic Systems.
- Arthur D. Little, Inc. 1975. *The Consequences of Electronic Funds Transfer: A Technology Assessment of Movement toward Less Cash/Less Check Society*. Boston, Mass.
- Banta, H.D. 1980. The Diffusion of the Computed Tomography (CT) Scanner in the United States. *International Journal of Health Services* 10:251-269.
- , and Thacker, S. 1979. Assessing the Costs and Benefits of Electronic Fetal Monitoring. *Obstetrical and Gynecological Survey* 34:627-641.
- Brooks, H., and Bowers, R. 1970. The Assessment of Technology. *Scientific American* 22:13-21.
- Bunker, J.P., Barnes, B.A., and Mosteller, F. 1977. *Cost, Risk and Benefits of Surgery*. New York: Oxford University Press.
- Coates, J. 1977. Technology Assessment. In Teich, A., ed., *Technology and Man's Future*, 251-270. New York: St. Martin's Press.
- Coates, V.T. 1972. *Technology and Public Policy, Summary Report*. Washington, D.C.: George Washington University. Prepared for the National Science Foundation.
- . 1979. *Technology Assessment in Federal Agencies: 1971-1976*. Washington, D.C.: George Washington University Program of Policy Studies in Science and Technology.
- Committee on the Life Sciences and Social Policy, Assembly of Behavioral and Social Sciences, National Research Council. 1975. *Assessing Biomedical Technologies: An Inquiry into the Nature of the Process*. Washington, D.C.: National Academy of Sciences.
- Cooper, B., and Gaus, C. 1979. Controlling Health Technology. In Altman, S., and Blendon, R., eds., *Medical Technology: The Culprit behind Health Care Costs?* 242-252. DHEW Publication No. PHS 79-3216. Hyattsville, Md.: National Center for Health Services Research and Bureau of Health Planning.
- Daddario, E.Q. 1967. Statement of the Chairman. In *Technology Assessment*. U.S. Congress, House of Representatives, Committee



- on Science and Astronautics, Subcommittee on Science, Research, and Development. 90th Congress, 1st Session. Washington, D.C.
- Dickson, E.M., and Bowers, R. 1973. *The Video Telephone: Impact of a New Era in Telephone Communications*. New York: Praeger.
- Ellul, J. 1964. *The Technological Society*. New York: Vintage Books.
- Fineberg, H. 1979. Gastric Freezing: A Study of Diffusion of a Medical Innovation. In *Medical Technology and the Health Care System*, Committee on Technology and Health Care, 173–200. Washington, D.C.: National Academy of Sciences.
- , and Hiatt, H. 1979. Evaluation of Medical Practices. *New England Journal of Medicine* 301:1086–1091.
- Fox, R.C., and Swazey, J.P. 1974. *The Courage to Fail*. Chicago: The University of Chicago Press.
- Futures Group, Inc. 1977. *A Study of Life-Extending Technologies*. Prepared for the National Science Foundation. Glastonbury, Conn.
- Galbraith, J.K. 1977. *The New Industrial State*. New York: New American Library.
- Grad, F.P., et al. 1975. *The Automobile and the Regulation of Its Impact on the Environment*. Norman, Okla.: University of Oklahoma Press.
- Hill, A.B. 1937. *Medical Statistics*. Edinburgh: R. & R. Clark.
- . 1962. *Statistical Methods in Clinical and Preventive Medicine*. London: E. & S. Livingston.
- Kash, D.E., et al. 1973. *Energy under the Oceans: A Technology Assessment of Outer Continental Shelf Oil and Gas Operations*. Norman, Okla.: University of Oklahoma Press.
- Kass, L.R. 1971. The New Biology: What Price Relieving Man's Estate? *Science* 174:779–788.
- Lederberg, J. 1972. The Freedoms and the Control of Science: Notes from the Ivory Tower. *Southern California Law Review* 45:596–614.
- Lubeck, D.P., and Bunker, J.P. 1980. The Artificial Heart: Costs, Risks, and Benefits. In *The Implications of Cost-Effectiveness Analysis of Medical Technology/Background Paper #2: Case Studies of Medical Technologies*. Prepared by OTA. Washington, D.C.: Government Printing Office.
- Mendell, J.S., and Tanner, W.L. 1975. In Technology Assessment, Process Is More Important than Product; or, Throw Out the Assessment and Keep the Assessor. *Journal of the International Society for Technology Assessment* 1:22–29.
- National Cancer Institute. 1979. *The Treatment of Primary Breast Cancer: Management of Local Disease*. NIH Consensus Development Conference. Summary. Washington, D.C.: National Institutes of Health.

- National Heart and Lung Institute. 1973. *The Totally Implantable Artificial Heart*. Report of the Artificial Heart Assessment Panel. Washington, D.C.: National Institutes of Health.
- National Institutes of Health. 1977. *NIH Inventory of Clinical Trials: Fiscal Year 1975*. Volumes I and II. Bethesda, Md.: Department of Health, Education, and Welfare.
- . 1979. Personal communication.
- Office of Technology Assessment. 1976. *Development of Medical Technology: Opportunities for Assessment*. Washington, D.C.: Government Printing Office.
- . 1978a. *Assessing the Efficacy and Safety of Medical Technologies*. Washington, D.C.: Government Printing Office.
- . 1978b. *Policy Implications of the Computed Tomography (CT) Scanner*. Washington, D.C.: Government Printing Office.
- . 1979. *Annual Report to the Congress for 1979*. Washington, D.C.: Government Printing Office.
- . 1980a. *The Implications of Cost-Effectiveness Analysis of Medical Technology*. Washington, D.C.: Government Printing Office.
- . 1980b. *The Implications of Cost-Effectiveness Analysis of Medical Technology/Background Paper #1: Methodological Issues and Literature Review*. Washington, D.C.: Government Printing Office.
- Paradise, J.L. 1975. Pittsburgh Tonsillectomy and Adenoidectomy Study: Differences from Earlier Studies and Problems and Execution. *Annals of Otolaryngology, Rhinology, and Laryngology* 84:15–20.
- Preston, T. 1977. *Coronary Artery Surgery: A Critical Review*. New York: Raven Press.
- Rettig, R., et al. 1974. *Criteria for the Allocation of Resources to Research and Development: A Review of the Literature*. Washington, D.C.: National Science Foundation.
- Rossini, F.A., et al. 1978. *Frameworks and Factors Affecting Integration within Technology Assessment*. Atlanta: Georgia Institute of Technology.
- Saxe, L., and Fine, M. *Toward the Experimenting Society: Methods for the Design and Evaluation of Social Experiments*. Beverly Hills: Sage. In press.
- Takaro, T., et al. 1976. The VA Cooperative Randomized Study of Surgery for Coronary Arterial Occlusive Disease. *Circulation* 54 (Supplement 3). III-107–III-117.
- Texas Tech University. 1977. *Human Rehabilitation Techniques: A Technology Assessment*. Prepared for the National Science Foundation. Lubbock, Tex.
- Thomas, L. 1974. *The Lives of a Cell*. New York: Viking.
- Vickers, G. 1965. *The Art of Judgment: A Study of Policy Making*. New York: Basic Books.

- Wagner, J.L., and Zubkoff, M. 1975. Medical Technology and Hospital Costs. In Zubkoff, M., Raskin, I.E., and Hanft, R.S., eds., *Hospital Cost Containment*, 263–289. New York: Prodist.
- Weinstein, M. 1979. Economic Evaluation of Medical Procedures and Technologies: Progress, Problems and Prospects. In Wagner, J.L., ed., *Medical Technology*, 52–68. DHEW Publication No. PHS 79-3254. Hyattsville, Md.: National Center for Health Services Research.

---

*Acknowledgments:* This paper is based in part on a number of reports from the OTA Health Program. A number of OTA staff and consultants have made contributions to those reports, and we are grateful for this assistance. We are also grateful for constructive comments from Joyce Lashof.

*Address correspondence to:* Dr. H. David Banta, Office of Technology Assessment, Congress of the United States, Washington, DC 20510.