Social Values in Technology Assessment

The very success of science has ended its pleasant isolation.

—Robert Sinsheimer
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Social Values in Technology Assessment

INTRODUCTION

Any decision to develop or use a medical technology, or not to do so, inevitably rests on value judgments, though such values may not be explicitly acknowledged. One goal of technology assessment, therefore, is (63):

. . . the identification of [social] implications possibly overlooked by decisionmakers who, by their own values, would not want them overlooked or implications that decisionmakers cannot afford to ignore, even if they so desire, because many other people, by their own values, may find them important.

This chapter explores the role of values in medical technology assessment. The first section examines the value premises of the assessment process itself. Implicit value judgments permeate every stage of a technology assessment, and it is important to recognize these when conducting or examining a specific assessment. The second section of this chapter considers the role of value analysis in assessing the social and ethical implications of policy decisions regarding the development and use of medical technologies. The third section reviews the efforts of some past and present Federal bodies to consider these implications.

VALUE PREMISES OF MEDICAL TECHNOLOGY ASSESSMENT

Technology assessment and other types of policy analysis can never be totally objective or value-free. Even at the most fundamental level, technology assessment is based on the value assumptions that: 1) it is better for society to systematically analyze the far-reaching consequences of technological change and development for its effect on economic, social, and ethical values; and 2) it is better for society, in terms of maximizing benefits, minimizing risk, and promoting efficiency, to have the information that technology assessments can provide. That these things are “better” represents a fundamental assumption, an unspoken value judgment.

Indeed, although they are rarely made explicit, value judgments enter into every phase and aspect of technology assessment. Such judgments determine: 1) which technologies will be assessed and at what stage of their development, 2) what the scope of assessments will be, 3) what kinds of data will be collected and how these data will be analyzed, 4) what methods will be used in an assessment, and 5) how the results of an assessment will be presented and interpreted.

The first thing to consider, perhaps, is the genesis of the assessment process. Assessments of medical technologies are requested by decisionmakers concerned with questions relating to their safety and efficacy, reimbursement, and appropriateness. The factors and perceived needs that lead to a specific request should be clearly understood by those conducting or examining an assessment. The constraints inherent in the request should also be understood. What types of issues is the assessment not expected—or not permitted—to consider? Finally, the assessment should be put into a larger perspective. Why is the technology a concern to society? Where does the assessment topic fit into the current cultural and political setting?

Also important to consider are the values of the assessors and of the analytic methods, goals, and objectives they choose to employ. Here the issues are most numerous. First, there is a need to determine the boundaries and scope of the assessment. What values should the assessment include? If value judgments are organized into a hierarchy/continuum of abstractions, running from
generalities to specifics, a technology assessment begins at some point in this hierarchy/continuum, with the implicit assumption being that only the value implications below that point will be considered. Values above that point (i.e., those considered more abstract or general) are prior assumptions that are accepted, laying a foundation for the analysis that follows. In other words, an agreed upon set of decisions is in some sense "final," at least from the perspective of the analysis at hand, so that the analysis is only concerned with specific policies or refinements (214).

In some sense, establishing a hierarchy of value judgments incorporates the values of the individuals performing the assessment. Nevertheless, the values of the assessors warrant special attention on their own. It is unreasonable to presume that one can begin to appreciate, in any worthwhile fashion, the psyches of those conducting an assessment. The concern, however, should not so much be what the assessors’ individual biases are as with ensuring that their values do not overly bias the outcome of the assessment. Thus, it is important to build into the assessment measures to correct for possible value distortions. Bioethicists have been particularly successful in this regard, bringing a broader set of values—more representative, perhaps, of those held by the public—to the fore in technology assessment. The key is to look for values that have been consciously or unconsciously omitted from the analysis. Attempts to broaden the values represented in an assessment can also be made by performing an assessment under public scrutiny. In conducting its assessments, for example, OTA uses multidisciplinary advisory panels that include interested parties.

The “tools” of technology assessment—e.g., the methods of collecting and evaluating data—must be applied with great caution and with the broadest possible understanding of the kinds of distortions they can create. One danger in technology assessment is that problems may be reduced to terms that mistake their underlying structure and ignore their total character. Indeed, the problem of using too narrowly defined objectives is of concern in all policy analysis. Convenience for the analyst often leads to inaccurate definitions of problems.

The measurement and analysis of data are tasks involving more than technical procedures, and carry implicit value systems and orientations (140). In assembling data and information relevant to an assessment subject, value judgments are incorporated in the choices of what to look for, the manner in which data are measured, and the manner in which information is presented.

For example, in measuring improvements in health status, changes are frequently expressed in levels of resource inputs. It is not clear, however, that inputs such as more doctors, more hospital beds, more computed tomography (CT) scanners directly translate into improved health status. Furthermore, even if one assumes that more of a resource input is “better,” one still cannot measure the improvement in health status that results from the addition of each resource unit. If decision-makers are attempting to determine which resource is needed more, they must know the levels of effectiveness involved in the addition of doctors, beds, or CT scanners. Otherwise, there is no basis for choosing among programs emphasizing one of these resources. In addition, measuring health status in this fashion carries the implication that the development of any new programs must be biased in favor of such measurable goals, or the new programs cannot be compared against older programs (140).

The methods available to assess medical technologies also have normative underpinnings. If, upon examination, the underlying normative assumptions are found to be unsatisfactory, the conclusion of the analysis must be rejected. OTA’s report on cost-effectiveness analysis (270) discussed in detail the inappropriateness of aggregating costs and benefits in economic analyses. Thus, for example, the technique of cost-benefit analysis is of concern, because it requires aggrega-
tion which tends to ignore the distributional effects of the costs and benefits that the technique attempts to measure. Encouraging the conduct of randomized clinical trials implicitly signals a willingness to subject a relatively small number of individuals to varying degrees of risk, hoping that greater benefits will accrue to society as a whole (19). The danger here is that one small group (e.g., the urban poor) may bear a disproportionate share of the risks of experimentation, raising serious questions of equity and autonomy.

Thus, throughout an assessment there is a need for constant inquiry into the nature of the questions being asked. Despite deficiencies in measurement techniques and the difficulty of translating social principles and values into practical terms, technology assessment can contribute to better judgments regarding appropriate responses to technological change and development when social values are explicitly considered.

SOCIAL IMPLICATIONS OF MEDICAL TECHNOLOGIES

To varying degrees, medical technologies may directly or indirectly influence the quality of the lives of individual patients and their families; the structure of medical, legal, political, and economic systems; and the fundamental values on which these social systems rest, including society’s sense of ethics and morality. * These “social implications” cannot easily be quantified, but they can be identified and rigorously analyzed.

An important task in medical technology assessment is to identify the conflicting social values that underlie policy alternatives. This assessment task is sometimes referred to as “value analysis.” In the broadest sense, the task of value analysis in examining social implications is to bring into focus the compromises that are made with society’s preexisting goals, values, and institutions when choices are made between policy alternatives. Often, value analysis may simply provide a more conceptually clear understanding of policy problems by describing the complex interaction of interests within the confines of established social—economic, medical, legal, and cultural—values.

Some work has been done in the area of suggesting techniques for assessing social implications. In 1976, OTA developed an illustrative list of questions that could be asked regarding a medical technology (269):

- What are the implications of the technology for the patient?
- What are the implications for the patient’s family?
- What are the implications for society?
- What are the implications for the medical care system?
- What are the implications for the legal and political systems?
- What are the implications for the economic system?

Wolf has suggested that certain economic analytic techniques (e.g., cost-benefit analysis) could be modified and applied as value analysis (397).

Jensen and Butler have suggested that value analysis specifically in the area of ethical implications should be structured by the following three tasks (205):

1. articulation of relevant moral principles;
2. elucidation of proposed policy options in light of the identified principles; and
3. rank ordering of policy options for choice.

The first task is to identify the moral and ethical principles around which the policy issue turns, and to set these principles into the center of the discussion in as definite form as possible. In setting public policy to guide the conduct of biomed-
cial research on fetuses, for example, two apparently conflicting concerns overwhelm the debate: respect for the autonomy of individuals v. the knowledge (and hence the benefits) society gains through such research efforts. The second task is to examine how policy options interact with the various identified ethical principles and theses. This task involves identifying and isolating the subtleties of ethical questions. Finally, the third task is to rank the policy options to show how each policy would look and what its probable outcome might be if one moral principle were ranked over another. This ranking is similar to economists' arraying of tradeoffs in costs and benefits when comparing alternative policies (270,383).

Public policies in the United States are not directed toward a single set of objectives. Different policies reflect different social goals, which may often appear to be in conflict. In determining whether to further the development or use of a medical technology, questions of safety, efficacy, and cost effectiveness are centrally important, but in some cases—even when the technology brings two or more of society's values and goals into conflict—these may be outweighed by a broader set of costs and consequences. Such conflicts are illustrated by the technologies discussed below.

### End-Stage Renal Disease Program

This year, the Federal Government will spend over $1.2 billion to provide dialysis treatment and kidney transplants to some 50,000 patients suffering from end-stage renal disease (ESRD) (see case study in app. E). Without such treatment, these patients would die from renal failure. Although no one denies that the Federal ESRD program provides medically necessary services to people in dire need, the program is surrounded by agonizing questions for policymakers faced with decisions about allocating medical resources. Because of their enormous costs, disease-specific programs (like that for ESRD) cannot be publicly funded for all patients whose medical needs are equally pressing or more ambiguous (48).

The ESRD program was enacted as a humanitarian response to the vivid impact of dialysis and transplants and the plight of needy patients. In that it does not offer guidance for selecting among equally needy groups of patients suffering from other diseases, the enactment of this program does not reflect a guiding ethical principle. The absence of analytic foresight in this instance makes the ESRD program appear to be a political accident. Because choices among programs competing for scarce resources inevitably do and should rest on value judgments, more coherent public policies might evolve if attendant analyses represent a careful working through of the ethical underpinnings of policy alternatives.

### Maternal Serum Alpha-Fetoprotein

Maternal serum alpha-fetoprotein (MSAFP) (see case study in app. E) is the first in a series of diagnostic tests used to screen and diagnose two types of fetal neural tube defects: anencephaly (absent or undeveloped brain) and open spina bifida (failure of the spine and overlying skin to fully close over the spinal cord). Initially, attention was focused on MSAFP because of profound social implications inherent in its diffusion and use. The test is given to expectant mothers to provide them with information about the fetus, the value assumption being that it is better for them to know in advance if their children are to be born with neural tube defects. Since some mothers given information that such defects are present might be expected to terminate their pregnancies voluntarily, MSAFP was thrust into the ethical argument over abortion.

The test has also raised questions of distributive justice, particularly with regard to entitlement programs. For example, the Health Care Financing Administration was concerned with the ethical implications of reimbursable MSAFP tests for Medicaid recipients. Women receiving Medicaid were not entitled to abortions. Thus, the dilemma arose: If Medicaid agrees to reimburse physicians for providing MSAFP tests, what happens to women with test results indicating fetal defects when abortions are not reimbursable?

### Artificial Heart

Another medical technology that illustrates the importance of social implications is the artificial
heart. In 1972, the National Heart and Lung Institute convened a panel of physicians, ethicists, lawyers, and social scientists to identify and evaluate the “economic, ethical, legal, medical, psychiatric, and social implications of a totally implantable artificial heart.” The institute was concerned about the broader implications of such an innovation, implications which the institute’s physicians and administrators recognized were “beyond the limits of their own expertise” (204).

The panel primarily focused on two sets of questions, both related to the ethical problem of distributive justice. First were questions concerning access to the device and the selection of patients to receive what would most likely be a scarce, expensive medical resource—problems endemic to modern medicine. Second were questions applicable only to an artificial heart powered by nuclear energy. (The National Heart and Lung Institute had been developing three power systems for its device: an electric motor powered by a biological fuel cell, a motor powered by rechargeable batteries, and a nuclear engine fueled with plutonium.) The panel noted that patients faced with imminent death from heart disease might be willing to accept the attendant risks of prolonged exposure to radiation from the nuclear device, but it expressed greater concern for persons exposed to “slight though significant risks” through contact with recipients. A majority of the panel’s members doubted that a decision to make a nuclear-powered artificial heart widely available would be “ethically justified when measures to improve the health and extend the life of specific individuals pose a risk to the health and lives of the population generally, including unborn future generations” (204).

**General Comments**

Not every new medical technology warrants a full-scale technology assessment with an examination of social implications. Some technologies probably do not even warrant a formal assessment. In the area of values and social implications, however, the lack of sound, effective criteria for determining which technologies to assess is decidedly evident.

Despite the abundance of offerings from bioethics on microallocation issues, the methods for assessing values and classifying social effects have thus far received little attention in the literature. Macroallocation issues are well described in the literature, but more apt to be ignored in an analysis. The panel that examined the development of the artificial heart, for example, focused its discussion on the microdistribution issue of which individuals would receive this scarce, expensive technology. The panel was criticized for failing to consider the artificial heart as an experimental device raising profound questions of patients’ abilities to meet informed consent criteria (46). However, this concern misses an even larger social question: Is the development of technologies such as the artificial heart, which benefit only a few, a proper way to spend social resources? What then are the implications, the social costs and benefits—and how are these distributed—to society? Developing and maintaining an effective concern for the social implications of medical technology will be extremely difficult unless further work is devoted to important questions such as these.

Systematic consideration of relevant social and ethical values will not necessarily lead to conclusive answers about which policies decision-makers should adopt. Nevertheless, choices and compromises need to be identified so that decision-makers can see which ethical principles will be sacrificed or compromised by specific policy options. Value analysis cannot determine what the policymakers’ values should be, but it can bring into focus the impact of choices on established goals and institutions (373). By describing the complex interaction of interests within the confines of the economic, legal, social, and cultural values, and technical facts prevailing at the time and anticipated in the future, value analysis can provide a more focused, conceptually clear understanding of policy problems. Value analysis can show decisionmakers where they disagree and why they disagree, as well as identify the longrun social implications of their decisions.

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*Microallocation issues are concerned with single specialized economic units (e.g., individual, hospital, household).

*Macroallocation issues are related to larger or multiple economic units which make up the economy (e.g., government, business, health care).
POLICY- RELATED ACTIVITIES FOR CONSIDERING SOCIAL EFFECTS OF TECHNOLOGIES

Congress has explicitly recognized both the value of technology assessment and the importance of considering the social implications of technological change and development. This recognition is manifest, at least in part, in legislation establishing the Office of Technology Assessment (OTA), the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission), the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President’s Commission), and the National Center for Health Care Technology (NCHCT). The activities and efforts of these bodies are reviewed briefly below. Also reviewed are the activities of the Ethics Advisory Board in the Department of Health, Education, and Welfare (DHEW). *

Office of Technology Assessment

OTA was established in 1972 as an analytic support agency of Congress to conduct policy research on science and technology issues for congressional committees. OTA clarifies the range of policy options available on a given set of issues, and assesses the potential physical, biological, economic, legal, and social impacts that might result from adopting each option. OTA has conducted assessments in wide-ranging areas of congressional interest, including energy, international security and commerce, materials, food and renewable resources, biological applications, communication and information technologies, oceans and environment, space, transportation, innovation, and health. Although OTA reports have only rarely been directly translated into policy or legislation, they do serve to provide comprehensive background information on complex issues related to scientific and technological developments.

As exemplified by this report, OTA’S health reports have primarily focused on “generic” issues in the use and assessment of medical technology.

OTA has studied specific technologies (e.g., CT scanners) as illustrative issues in technology assessment and policy.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

The National Commission was established in 1974 to develop ethical guidelines for conducting research on human subjects, and to recommend applications of these guidelines for research conducted or supported by DHEW (now DHHS). In establishing the National Commission, Congress also requested recommendations regarding the protection of human subjects in research conducted outside DHEW’S purview.

The National Commission’s work, which ended in 1978, was prodigious. Reports and recommended guidelines were generated covering research on human fetuses, children, prisoners, and the institutionalized mentally infirm, and on the appropriate utilization of psychosurgery. The National Commission proposed guidelines for protecting patients in DHEW-funded health care centers. It also recommended the establishment of institutional review boards in research centers as a means of ensuring that biomedical and behavioral research efforts were conducted in an ethically acceptable fashion. Many of the National Commission’s proposals were recommended, revised, and adopted by DHEW, particularly those governing the protection of human subjects.

The National Commission completed two reports that have been important resource documents to later studies of human experimentation and biomedical technology. One, The Belmont Report (88), reviewed and clarified the ethical underpinnings of research conducted with human subjects, removing much of the conceptual confusion and semantic misunderstanding that had confounded previous attempts at rational policy for human research. Ethical analyses were developed for the distinction between research and practice, the lack of distinction between thera-
peutic and nontherapeutic research, the notion of risk, and the purpose and use of informed consent.

The National Commission also conducted a special study of the social, ethical, and legal implications of advances in biomedical and behavioral research and medical technology (89). The study addressed the implications of computer applications to medicine, life-extending technologies, genetic screening, and reproductive engineering. The report offered no definitive recommendations and was less easily translated into policies than some of the commission’s other works (349).

**Ethics Advisory Board**

One of the National Commission’s recommendations to the Secretary of Health, Education, and Welfare resulted in the establishment of the Ethics Advisory Board in 1978. The board was given a broad mandate to review ethically questionable research protocols and research involving human subjects. Its most formidable efforts focused on in vitro fertilization and embryo transfer (the National Commission determined that under certain specified conditions, such research could be conducted in an ethically acceptable manner). The board also examined ethical questions raised by use of fetoscopy for diagnosing sickle cell anemia and hemoglobinopathies.

Because it was established in the Office of the Secretary, the Ethics Advisory Board often fielded queries from other DHEW agencies. Conducting research with human subjects raised particular problems for agencies in handling inquiries generated under the requirements of the Freedom of Information Act. The Centers for Disease Control (CDC) and the National Institutes of Health (NIH) were especially concerned about releasing specific types of research and epidemiologic data, because the data were supplied voluntarily by health care providers and institutions. CDC was afraid that its sources would dry up if the data were released. NIH wanted to avoid disclosing incomplete or preliminary findings from its ongoing clinical trials and observational studies. The Ethics Advisory Board focused attention on the need for those agencies to withhold information under the provisions of the Freedom of Information Act. Funding for the board was eliminated in 1980.

**President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research**

The President’s Commission was established as the successor to the National Commission in 1978. Its enabling legislation directs the Secretaries of Health and Human Services and Defense, the Administrator of the Veterans Administration, and Directors of the Central Intelligence Agency, National Science Foundation, and White House Office of Science and Technology Policy to appoint representatives as liaisons with the President’s Commission. Thus, the president’s Commission’s sphere of influence is much broader than was that of the Ethics Advisory Board.

The President’s Commission is mandated to conduct studies in the broad areas of medical practice and biomedical research. The President’s Commission is also to examine five specific subjects for their legal and ethical implications and their importance to public policy:

1. the requirements of informed consent for participation as human research subjects and for receiving medical treatment;
2. the procedures designed to assure the privacy of human subjects, the confidentiality of individually identifiable patient records, and appropriate access for patients to information contained in medical records;
3. the issue and advisability of developing a uniform definition of death;
4. voluntary screening, counseling, information, and education programs concerned with genetic diseases, and the fundamental equality of all human beings, born and unborn; and
5. the differences in availability of and access to health services as determined by such variables as income and residence.

In its first year, much of the President’s Commission’s work focused on the protection of human subjects. It examined proposed DHEW regulations (which had been based largely on the guidelines of the National Commission), specific
problems inherent in social science research, and
the operations of institutional review boards. The
President’s Commission paid particular attention
to an issue originally raised by the Ethics Advisory
Board: compensation for subjects injured in bio-
medical and behavioral experimentation. This is
the only activity of the former Ethics Advisory
Board carried on by the President’s Commission;
the President’s Commission does not review ques-
tionable protocols for DHHS-funded research.

The first formal report of the President’s Com-
mission was released in July 1981 (296). A land-
mark examination of the medical, legal, and
ethical issues surrounding the determination of
death, the report is expected to serve as a model
in formulating a uniform statute defining death.

In keeping with the legislative requirement that
it respond to specific Presidential requests, the
President’s Commission has been studying issues
related to genetic engineering. At the urging of
religious leaders, the President’s Commission was
asked to address the social and ethical implica-
tions of the new technology. A draft report, focus-
ing on questions of safety, technical capabilities,
and specific issues in therapeutic and diagnostic
use, was in preparation at the time of this writing.

The President’s Commission has spent most of
the past year looking at the distribution of health
care resources, particularly as it differs among
population groups. To date, the discussion has
included barriers in access to care, disparities and
differentials in the utilization of health services,
an attempt to identify relevant ethical principles
aimed at defining equity of access, the nature of
special health care facilities, cost considerations,
and freedom of choice for both patients and pro-
viders.

National Center for Health Care
Technology

NCHCT was established in 1978 to undertake
and support assessments of medical technologies,
including questions of their safety, effectiveness,
and cost effectiveness and their economic, ethical,
legal, and social implications. Funding for
NCHCT was not provided for fiscal year 1982.
Congress had envisioned two primary missions
for NCHCT: 1) stimulating increased scrutiny of
new and existing health care technologies to en-
sure that the questions listed above were thor-
oughly explored; and 2) encouraging the dissemi-
nation of new technologies proven safe, effective,
and cost effective (277).

NCHCT had no regulatory authority. Its pur-
pose was to provide current evaluations of health
care technologies to individuals and agencies with
regulatory and decisionmaking responsibilities.
NCHCT funded and conducted two types of as-
sessments—“focused” and “full”—but did no ac-
tual testing of technologies.

“Focused” assessments examined the scientific
and medical aspects of a technology to evaluate
the technology’s safety and efficacy. Such assess-
ments were prompted by coverage questions
raised by HCFA. NCHCT gathered and evaluated
data, then made a recommendation to HCFA as
to whether the technology should be covered by
Medicare. By 1981, NCHCT had completed more
than 60 focused assessments.

“Full” assessments examined the technology’s
safety, effectiveness, cost effectiveness, and social
implications of a technology. Full assessments
were integrated analyses conducted by NCHCT
in cooperation with other interested Federal agen-
cies, representatives of appropriate private sec-
tor organizations, and individuals from a broad
range of relevant disciplines. When possible, par-
ticipants attempted to reach agreement and pro-
vide recommendations for appropriate utilization
of the technology. NCHCT identified technologies
for full assessments with the assistance of an ad-
visory council. Such assessments were conducted
for coronary artery bypass surgery, cesarean de-
livery, and dental radiology.
CONCLUSION

Value analysis has a dual role in medical technology assessment. The first is to consider the effects on society’s cultural, ethical, and political values that may result from the introduction, modification, or extension of medical technologies. Such effects cannot easily be measured and balanced, yet can profoundly affect determinations of a technology’s worth. Like any form of policy analysis, technology assessment is founded on value premises. The second role of value analysis is to ensure that these value premises are made explicit and do not unduly influence the outcome of the assessment.

There is no established set of methods or techniques for conducting value analyses, nor is there a coherent, agreed upon set of principles an analysis should incorporate. Government efforts to promote value analysis probably do not require coherent sets of methods or principles. In considering the social implications of medical technology, Government promotes more comprehensive policy analysis; and in making the value premises of assessments explicit, it furthers accountability for its decisions.

Methods for synthesizing information about the health effects of medical technologies and for combining this information with information about such technologies’ economic and social effects are discussed in the next chapter. Also discussed are methods for dealing with uncertainty.