Chapter Iv

THE IMPACTS OF MEDICAL BE ASSESSED?

Chapter IV

HOW CAN THE IMPACTS OF NEW MEDICAL TECHNOLOGIES BE ASSESSED?

The preceding chapters of this report have demonstrated the variety and nature of impacts that may accompany or follow the introduction of new medical technologies. It might be valuable to introduce some consideration of these impacts into the decisionmaking processes that govern the development and early use of such technologies. If these impacts are to be systematically considered, one will require methods of prospective analysis—that is, methods that can be applied while the technology is still being developed, to define and evaluate the potential impacts of its eventual introduction into use. The first three parts of this chapter describe one such method, technology assessment, discuss some limitations of this method, , and outline several alternate modes of assessment. The final section describes how the general methodology of technology assessment could be applied to developing medical technologies.

TECHNOLOGY Assessment

Technology assessment is a comprehensive form of policy research that examines the short- and long-term social consequences (e.g. societal, economic, ethical, legal) of the application or use of technology. It is an analysis of *social* rather than technical issues, and it is especially concerned with unintended, indirect, or delayed social impacts (203, p. 28). Technology assessment is neither a panacea nor a new discipline. In essence, it is simply a broader form of policy research than is commonly conducted. The goal of technology assessment, as of all policy research, is to provide decisionmakers with information on policy alternatives, such as allocation of research and development funds, formulation of regulations, or development of new 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 to buy a device. While such activities maybe vital, they do not constitute technology assessment by this definition.

The term "technology assessment" was first used by the Subcommittee on Science, Research, and Development of the House Science and Astronautics Committee of the U.S. Congress in 1965. Hearings were held at a time of rising public alarm over alleged hazards to life and health resulting from contamination of the

[1] A draft concept paper by Sherry R. Arnstein, delivered at a staff seminar of the National Center for Health Services Research on May 12, 1976, was helpful in preparation of this section.

environment by byproducts of chemical and industrial processes. Since that time many academic and professional seminars have explored the concept, numerous publications have described elements of a technology assessment, technology assessments have been carried out (42, 51, 133, 189), and congressional hearings and reports have further explored the developing field (159, 200). By 1972, V. Coates was able to document that of 86 offices in Federal executive agencies identified as chiefly responsible for projects and programs of technological nature, 13 percent consistently performed or sponsored technology assessments and regarded technology assessment as their major responsibility; an additional 63 percent occasionally performed or sponsored technology assessments of some type. Approximately 100 such studies had been done by 1972 (36).

Technology assessment has several features that distinguish it from other ways of examining the societal impacts of a proposed new technology. These features are important both in the process of doing a technology assessment and in the product that emerges. Some of the most important features of technology assessment are:

- Technology assessment is based on an explicit analytic framework, which is specified before the study begins. Although this framework may be modified as the study proceeds, its existence helps to insure that the implications of introducing a new technology will be systematically identified and examined.
- Technology assessment is comprehensive in its scope, examining impacts on social, ethical, legal, and other systems that may not be immediately obvious. Furthermore, a technology assessment considers "higher order impacts" (that is, impacts of the impacts). Some impacts are presently examined in the planning stage (e.g., through economic evaluations), but technology assessment considers a wider range of factors.
- Technology assessment is carried out by a multidisciplinary group, because it requires wider expertise than any individual or single disciplinary group could be expected to possess.
- Technology assessment explicitly identifies the groups that will be affected by the proposed technology (the "parties at interest") and evaluates the impacts of the technology on each party.

Technology assessment can be "problem-driven" or "technology -driven." In other words, a technology assessment could start from a problem—in medical care, a disease, such as lung cancer-and attempt to assess alternative solutions to that problem. These might include policy actions going far beyond the medical-care system, such as abating air pollution or banning cigarettes. A problem-driven assessment might, however, be confined to the medical-care system, and attempt to compare only traditional and proposed medical therapies. A technology-driven assessment would start from the technology itself and attempt to measure its impacts.

One important question in technology assessment is how to handle the societal values on which the analysis is based. Some argue for value-free assessments, in which facts and analysis are presented in as objective a way as possible. Others argue that values will necessarily be implicit in any analysis and should be made explicit from the beginning (4, pp. 171–172). One method for dealing with

value differences is to involve as broad a group as possible in preparing the assessment, including adversaries on certain issues. In many cases, it may be desirable to represent the interests of each party, including (or especially) the general public, in some way as the assessment is prepared. For example, an advisory board might include representatives of different affected groups (14).

Whatever the approach taken or the technology to be examined, a comprehensive assessment would include the following elements (4, pp. 13–14):

1. A statement of the problem to be considered—usually restated or recast after analysis is underway.
2. A definition of the system (technology) and specific alternatives that could accomplish the same objectives.
3. Identification of potential impacts.
4. Evaluation of potential impacts.
5. Definition of the relevant decisionmaking apparatus.
6. Presentation of options for decisionmakers.
7. Identification of parties of interest, potential "winners" and "losers," ineluding both overt and latent interests.
8. Definition of "macroalternatives", not alternative technologies as considered in 2, but broader alternative solutions to the medical problem that the new technology is designed to solve.
9. Identification of exogenous variables, systems, or events that may affect the system.
10. Conclusions-and possibly recommendations.

THE LIMITATIONS OF TECHNOLOGY ASSESSMENT

Although technology assessment is important and promising as a method of predicting and dealing with societal impacts of technology, there are problems in applying technology assessment in practice:

1. The field is still a new one. There is no standard, usable method for performing a technology assessment.
2. Medical technologies are diverse and have complicated patterns of development. Therefore, it is uncertain that there will ever be a standard format for assessing medical technologies.
3. Technology assessments are hampered by weaknesses in the tools and techniques of social science (4) that must be used to calculate social impacts.
4. Groups carrying out technology assessments have had great difficulty establishing boundaries for their studies.
5. Study groups have had difficulty achieving profitable cooperation and communication among experts from different disciplines working on research teams.
6. Coates found that the average cost of comprehensive technology assessments was $381,000, with an average elapsed time of 16 months (36). This investment automatically limits the use of technology assessment to particularly troubling problems or technologies.

It must be emphasized that technology assessment is a new field, and many of its problems relate to this fact. It would be unrealistic to expect consistently ex-

cellent results from a field that is less than 10 years old. Few assessments have been done so far and little time has elapsed since their completion. It is too early to know how useful technology assessment has been and what purposes it can serve. The process of actually performing assessments will surely contribute to the solution of troubling methodological problems.

ALTERNATIVES TO COMPREHENSIVE TECHNOLOGY ASSESSMENT

A comprehensive technology assessment, costing hundreds of thousands of dollars and lasting for more than a year, cannot be performed for each developing technology. It is possible, however, to perform limited assessments (sometimes called "mini" or "micro-assessments"), either in preparation for or in lieu of efforts on a larger scale. There are also a number of less comprehensive methods for assessing impacts that might precede, be included in, or take the place of a complete technology assessment; such analyses are sometimes called "Partial" technology assessments.

In the economic sphere, cost-benefit, cost-effectiveness, or other analyses introduce considerations that mere cost comparisons neglect (110-111). Cost-benefit studies are exceedingly difficult to do in the medical-care area because of the difficulty in quantifying benefits in monetary terms. Cost-effectiveness studies, however, requiring nonmonetary quantification of relative benefit, are more frequently feasible (126, 127, 162, 179).

Other academic or disciplinary assessments are also done, often on Government grant or contract. Sociological, ethical, public health, economic, and other discipline-oriented studies have provided insights into the process of introduction of new technologies, as well as their benefits and negative impacts. Such studies, coming from outside of the medical establishment, have provided some critical and objective evaluations of new medical technologies (69, 71, 187, 192).

Even within the boundaries of the scientific-medical establishment, there are ways to introduce broad considerations into the assessment protocol, albeit in an unstructured way. For example, the national advisory councils of the NIH categorical institutes include nonscientists who consider nontechnical issues as part of their charge. The Director's Advisory Committee at NIH has broad functions relating to NIH as an institution and has considerable potential for assessment of new research findings, a potential realized, for example, when the Advisory Committee recently made recommendations to the Director of NIH on guidelines for recombinant DNA research (150). Similarly, human experimentation committees that oversee and regulate clinical investigations on human subjects in medical schools, hospitals, and research establishments are intended to consider ethical as well as medical implications of the proposed research procedures (8). Finally, proposals to include impact statements in NIH grant or contract proposals would fall into this class of assessment.

Broader assessments are possible when input is obtained from interested, concerned, or knowledgeable parties outside of the medical establishment. Some familiar forms are (28, 108):

Public hearings: Public testimony was solicited and presented during the Director's Advisory Committee meeting at NIH on recombinant DNA research mentioned above.

- Publicly funded workshops for interested citizens: The National Academy of Sciences is sponsoring a series of forums for citizens on science.
- Public ombudsmen: This mechanism seems to have been little used in the area of the public role in science.
- Congressional hearings: With the growing role of Congress in the health-care system, the importance of such public hearings has already increased (106, p. 129).

ASSESSING MEDICAL TECHNOLOGIES

Perhaps the best way to define methods for technology assessment is to use the experience gained from assessments that have already been completed. Despite the steadily increasing number of available assessments, however, only a few medical technologies have so far been formally assessed:

. Preliminary and incomplete assessments of four medical technologies (in vitro fertilization, methods for choosing the sex of children, ways to retard aging, and technological ways to modify behavior) were sponsored by the National Academy of Sciences (134).

. An assessment of the totally implantable artificial heart (discussed in detail in chs. II and III of this report) was supported by the National Institutes of Health (142).

. Two assessments of medical technological areas (rehabilitation technologies and life-extending technologies), funded by the National Science Foundation, are currently underway.

These efforts, although valuable, provide a sparse background for further work. If medical technologies are to be more frequently, completely, or systematically assessed, three questions must be answered:

. How will medical technologies be selected for assessment?

. How will assessments be conducted?

ž How will the results of assessments be used?

Selecting Technologies for Assessment

In planning to implement programs of technology assessment, one must first complete a list of candidate technologies and then adopt some criteria to select among them. Certainly a large number of minor innovations or modifications of medical practice would not merit assessment, and one does not know whether the list of candidates would be long or short. For example, a preliminary list of candidates might include:

. Immunotherapeutic and immunosuppressive drugs.

. Remote medical monitoring equipment.

. Techniques for electrical stimulation of the central nervous system to modify behavior.

- Artificial organs, such as implantable hearts, kidneys, livers.
- Neural prostheses (see case 8 in ch. II for a specific example).
- Male contraceptives.
- Automated physical examinations.
- Gene modification therapy for inherited diseases.
- Techniques for fetal monitoring and amniocentesis.
- Reversible surgical contraception,
- Self-administered chemical abortifacients.
- Bone-marrow transplants for cancer or immune-deficiency diseases.
- Vaccines for new strains of flu and other viral diseases.
- Limb prostheses.
- Methods to determine or choose the sex of children.
- Fertilization and/or embryonic development outside of the body.
- New imaging devices for diagnostic use (e.g., emission tomography, and new developments in ultrasonography and transmission tomography).
- Rational development of psychotropic drugs for mental illness or other behavioral or affective anomalies.
- "Intelligence testing" by electrophysiological means.
- Organ and organ system banks.

On the assumption that initial lists of candidate technologies for assessment are often unworkably long, Coates (35) and others have proposed criteria for setting priorities and making selections among the candidates. Nearly all of the criteria, however, are subsumed by two simple questions: *Can the technology be assessed, and is it worth assessing?*

Can the technology be assessed?

In some cases, the data that would be required for analysis and assessment might be unavailable completely, or available in only an unusable form. The generation of new data or reorganization of old data might, according to Coates, sometimes be so difficult that it would obviate the possibility of effective assessment. Even if data are available, one must ask whether their analysis is within the competence of the agency or institution being asked to perform the assessment. Finally, some preliminary consideration must be given to the question of whether assessment of a particular technology holds the possibility of reducing uncertainty, defining issues, or structuring arguments; in some cases, it may not.

Is the technology worth assessing?

Although the scale of a proposed technology and the scope of its impacts will be largely unknown before assessment is attempted, it may be possible to make some preliminary estimates. In general, the greater the scale of an enterprise, the wider the scope of its impacts, and the higher its projected cost, the more suitable a candidate for assessment it is. Other factors may also play

a role in deciding whether a technology is worth assessing. In some cases, similar technologies already will have been assessed, obviating the need for completely new effort. Conversely, some technologies may epitomize problems ‘or impacts common to many technologies, and the potential for generating transferable information may make them especially suitable for assessment. Whether anyone will listen to or be affected by the results of an assessment should also be considered.

If the formulation of policy related to a technology is politically sensitive, inappropriate to Government agencies, or clearly beyond the responsibility of any identifiable institution, then there may be little value in assessing that technology. Finally, the stage of development of each technology must be considered. Some technologies may be so poorly developed or speculative that it would be difficult to intelligently define their characteristics, forecast their impacts, or formulate rational policy. In other cases, technologies may be so completely developed or even implemented that assessment would come too late to have significant utility.

Conducting a Technology Assessment

The tools and techniques that have been used in the assessment of nonmedical technologies have been described extensively **(4, 34, 91).** Possible institutional formats for assessing medical technologies will be discussed in chapter V. It will be the first duty of whatever institutions may be chosen to consider the range of techniques available, and to adapt them for the purposes of assessing medical technologies. Whatever the methodology and the institution, however, comprehensive technology assessment will undoubtedly entail applying the 10 elements described above (p. 47) to the medical technology in question:

. Define” the medical problem addressed, and the medical technologies proposed (elements 1 and 2). Ask questions about the aims, technical characteristics, and developmental stage of the technology, such as those enumerated on pages 32-33 (“Preliminary considerations, ” ch. III). Consider alternative forms of the technology available, proposed, or being developed so that different but related technological solutions to a common problem can be compared.

. Identify and evaluate impacts (elements 3 and 4). Chapter III includes a list of questions designed to elicit information about the implications of a new medical technology for the individual and for family, social, medical, legal, economic, and political systems. These questions may provide a way to begin searching for impacts of a medical technology and may suggest other impacts that would not otherwise have been apparent. Evaluation of the possible impacts may require calling on the expertise of lawyers, sociologists, psychologists, economists, and other professionals, as well as on medical personnel and representatives of the public.

. Identify the decisionmakers and consider the decisions that they might make (elements 5 and 6). Find the people or institutions, either in the Government or in the private sector, that are responsible for formulating policies that relate to the technology being assessed. Determine what scope of responsibility and authority each one has, and what types of decisions each could make to affect the development and use of the technology being assessed. In some cases, the available policy options might be presented explicitly and in some detail.

. Identify the "parties at interest" (element 7). Identify all of the people, groups, and institutions that will be affected by the new technology or by decisions relating to it. For medical technologies, obvious candidates include patients, physicians and other health personnel, hospitals and medical centers, third-party payers, and public and private developers of technology. Identification of the impacts of the new technology (element 3) and of the decisionmaking apparatus (element 5) will reveal other, possibly less obvious parties at interest. The explicit identification of parties at interest is important, not only because it focuses attention on the potential "winners" and "losers" resulting from technological innovation, but also because it specifies the range of interests and viewpoints that will have to be considered as policy is eventually formulated.

. Define "macroalternatives" to the technology being assessed (element 8). In element 2, alternative technological tactics to solution of a medicaI problem will have been identified and compared. It is important to consider alternative strategies that purport to solve the same medical problem in very different ways, and to consider the effect that the technology in question will have on the development and implementation of these alternatives. For example, in assessing a therapeutic technology, one might consider proposals for prevention of the disease in question. It would be legitimate, in this context, to ask how reasonable, feasible, or desirable these alternatives are and whether heavy investment in or implementation of the therapeutic technology would encourage, discourage, or complement their development and implementation. Excessively detailed assessment of "macroalternatives" could lead to undesirable expansion of the scope of the technology assessment being performed. However, ignoring such macroalternatives entirely might result in subordinating the problem at hand to the particular technology, and in ignoring an important class of policy alternatives. .

. Identify variables, systems, or events that may affect the development or use of the technology being assessed (element 9). This step has two important purposes. First, it requires that assumptions underlying the evaluation of impacts be made explicit. Assumptions about institutional structure and stability, about economic and manpower trends, or about population, lifestyle, and social values almost inevitably underlie each assessment, and it is worthwhile to examine these assumptions, both to question their validity and to see how supposedly objective analysis depends on them. Second, this exercise may help to identify previously unanticipated changes (for example, in social systems) or events (for example, economic depressions) that may materially affect the way in which the new technology will be developed or used.

. Conclusions and recommendations (element 10) are demanded in some assessments, while in other cases political considerations dictate that these elements be omitted. Their inclusion and form will, in any program of technology assessment, be dictated by the institutional position and responsibility of the team doing the assessments.

Even among technologies selected for assessment, many will not merit *comrehensive* technology assessment. One might begin to identify and evaluate the impacts of each new technology (elements 3 and 4) in an informal way by asking questions such as those listed in chapter III of this report. Appropriate further steps could then be planned, whether they be specialized economic analyses, attempts to

gather public opinion, or perhaps even comprehensive technology assessment. For example, OTA's Health Assessment Program recently initiated a study of the CAT scanner, a new diagnostic technology (Case 2 in ch. II). The staff began by conducting a "micro-assessment" which consisted of studying the technical and medical aspects of CAT scanning and asking the impact questions in chapter III. Although there are ethical, legal, and societal implications, most of the important impacts that could be identified related to medical and economic issues. Further OTA efforts will therefore be concentrated in these two areas; comprehensive assessment will not be attempted at this time.

Using the Results of a Technology Assessment

As noted above, too few technology assessments have been completed to know how the information they elicit and the recommendations they propose will be used. Furthermore, even when more assessments are available, their uses will vary with their scope and quality as well as with a variety of other endogenous factors including political considerations and the institutional setting of the group performing the assessment. However, it is already possible to imagine a number of possible outcomes of technology assessment.

Two outcomes that are frequently predicted and sometimes feared are:

- Nothing will happen. The assessment may fail to identify workable and beneficial policy changes or may conclude that the present policy is, in fact, the most desirable. Alternatively, the results of the assessment, however solid and well documented, may be overshadowed by political, economic, or other considerations.
- Development of the technology will be blocked. The assessment may find sufficient unintended or unanticipated consequences of the new technology to justify termination of all programs for its development. In some cases the drawbacks, however limited or qualified, maybe sufficient to arouse public opinion and force termination of the project.

Between these two extremes are a large number of possible outcomes of technology assessment that might modify relevant policy in other ways:

- Development or use of the technology might be expedited if new, unanticipated benefits are revealed by the assessment.
- The technology might be applied to new or expanded ends, if assessment reveals aspects or uses that had not been envisioned by the original developers.
- The assessment might provide useful information to parties at interest, including developers, that could be used as development and implementation proceed.
- Potential providers of the new technology and other parties in the marketplace may be able to plan ahead for the implementation of the new technology. If changes in systems (including reimbursement schemes, other technologies, or institutions) will be required, the groups responsible for making these changes will have a headstart in formulating policy.

. The assessment may reveal ways to implement (or develop) the new technology in an incremental fashion. For example, limited experimental programs of use might profitably precede large-scale implementation in some cases. In other cases, there might be ways to develop and test portions of the new technology (e.g., a left ventricular assist device instead of a totally implantable artificial heart) instead of adopting an all-or-nothing approach.

. If potential drawbacks to the new technology are identified but cannot be adequately evaluated, the assessment might stimulate research aimed at better understanding of such risks.

. If drawbacks to the new technology can be predicted with some confidence, the assessment might stimulate new programs of R&D aimed at developing alternative forms of the technology that minimize its drawbacks and maximize its benefits.

. If the risks or drawbacks are intrinsic to the technology, but the benefits are large, assessment might stimulate development of programs of technologies to counteract or correct the drawbacks.

• Assessment may reveal the need for new controls related to the development or use of the new technology. Agencies or legislative bodies might profitably use the results of assessment in considering if and what new regulations, taxes, prohibitions, or laws would be socially desirable.

. In many cases, assessment may reveal impacts of the new technology but may not be able to evaluate their importance. Programs of continued surveillance might then be instituted to monitor the continued development and implementation of the technology to insure that appropriate information will be made available to responsible parties in a timely fashion.

. If uncertainty about the drawbacks of the new technology is sufficiently great, or if it is difficult to balance large benefits and drawbacks, assessment may cause delays in development or use of the technology, while more information is gathered or while public response and opinion is measured. These "moratoria," whether short or long, formal or informal, could provide a desirable alternative to a policy of proceeding with expensive programs that would be wasteful, costly, difficult, or politically impossible to "turn off" at a later stage.

Whether technology assessment would have any or all of these outcomes is, at present, a matter of speculation. Any decision to implement programs of assessment must rest on the belief that more and better information is needed in making decisions about medical technology and the hope that the results of assessment can be profitably intercalated into what is already a complex decisionmaking process.