Chapter V

WHAT ARE SOME OPPORTUNITIES FOR ASSESSING THE IMPACTS OF NEW MEDICAL TECHNOLOGIES?

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This report has described a broad range of impacts that might accompany or follow the introduction of new medical technologies into the medical-care system and has discussed some methods for identifying and evaluating these impacts. The impacts range from psychological effects on the patient or his or her family to threats to the environment, from requirements for new types of medical manpower to changes in society's concept of death and dying. Methods for evaluating these impacts include the new field of technology assessment, as well as a variety of less comprehensive methods.

If technology assessment is applied more often and more effectively to medical technologies during their development, information could be gathered that would be useful in—

- Making decisions about priorities for research and development, and
- . Planning for the eventual introduction of new medical technologies.

In addition, technology assessment might provide a new forum for communication of biomedical scientists and policy makers with each other and with the public. Effective programs of assessment could—

- Encourage more effective education of and communication with the public on issues concerning medical technology;
- Allow opportunities for more effective public input to decisions dealing with the development and use of new medical technology;
- Improve technical input to political decisions about research policy; and
- Tap the resources of social responsibility already present in the scientific community.

Technology assessments could be conducted in a variety of ways and in any of a variety of places, either within or outside of the Government. The initial policy decision that must be made is whether or not the Federal Government should conduct, administer, or support programs of medical technology assessment. If these activities are considered desirable, then one must decide which organizations or agencies should be responsible for such programs. The following options identify several organizations within the Federal Government that might be considered. The options are not mutually exclusive-one could select none, any, or *several* of them. Furthermore, within each organization, assessments could be conducted in any of a variety of ways. For example, Government employees could conduct the assessments, or the organizations could award grants or contracts to groups in universities or consulting firms. The options that follow do not discuss or compare these approaches.

TECHNOLOGY ASSESSMENT AT THE NATIONAL INSTITUTES OF HEALTH

Funding of biomedical research is largely Federal, and 63 percent of Federal support is administered by the National Institutes of Health (NIH). NIH carries out its responsibilities through 11 categorical institutes, each of which awards grants and contracts for "extramural" research (at universities or other institutions) as well as carrying out "intramural" research (in NIH-operated laboratories and clinics).[1] Each categorical institute is charged with supporting or conducting research aimed at understanding and amelioration of a particular class of diseases. Determination of priorities, embodied in allocation of funds, occurs at three levels: among institutes (by congressional appropriations), within each institute (by line items in appropriation bills, at various levels of the executive branch, and by administrators and advisory councils within each institute), and among competitors for research funds (by peer review groups for grants and by NIH staff for contracts).[2]

As the leading Federal agency involved in biomedical research and medical technology development, NIH might be considered as a site for programs of medical technology assessment. The administrative and intramural staffs have, collectively, a wide range of expertise in matters pertaining to medical technologies. This expertise often extends to areas in which NIH is not directly conducting or supporting programs of technology development. In many cases, NIH supports research on, and thus has knowledge of, new medical technologies that are being developed in clinically useful form elsewhere (for example, see Case 8 in ch. II). Even if development is occurring exclusively in other agencies or in the private sector, NIH staff might provide a central repository of knowledge and informed judgment. Thus, groups at or supported by NIH could assess technologies being developed at NIH, technologies being developed elsewhere with NIH support through the extramural grants and contracts programs, and some technologies whose development is supported by other sources of funds,

Programs of technology assessment at NIH could be implemented at several levels:

Option 1: Programs of medical technology assessment could be conducted or administered by staff in the Office of the Director of NIH. This staff could be expanded as necessary to carry out such a program. The Director has an Advisory Committee, with members from within and outside of the scientific community; this Committee could play a role in oversight and review of assessments performed through the Director's Office.

Option 2: A new unit could be formed at NIH. NIH already has administrative entities such as the Division of Research Grants (DRG) and the Division of Research Services (DRS). These units are separate from the 11 categorical

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[1] One institute, the National Institute of General Medical Sciences, has no intramural program.

[2] The organization of NIH is discussed in more detail in sec. D of app. A.

institutes, but work with them to carry out specialized functions. Such a unit could be formed to conduct or administer programs of medical technology assessments.

Option 3: Technology assessments could be conducted in or administered through the offices of the directors of the categorical institutes. Like the Director of NIH, each institute director has a staff and an advisory council which could be involved in assessments. If this option were adopted, each institute would have the responsibility of assessing technologies whose development it supports or about which it has special expertise. The National Heart, Lung, and Blood Institute, for example, might assess not only innovations in cardiovascular medicine that it is developing (see Case 9 in ch. II), but also other technologies addressed to medical problems that fall within its categorical mandate (see Case 7 in ch. II).

Option 4:. Many of the activities conducted or supported by each categorical institute are organized as programs, divisions, or task forces. Research on the artificial heart, for example, is supported by the Artificial Heart Program in the National Heart, Lung, and Blood Institute (see Case 9 in ch. II), research on breast cancer is overseen by the Breast Cancer Task Force in the National Cancer Institute (see Case 4 in ch. II), and research on cortical prostheses is administered by a Neural Prostheses Program in the National Institute of Neurological and Communicative Disorders and Stroke (see Case 8 in ch. II). Assessments of many developing medical technologies could be conducted or administered by the staffs of the appropriate administrative units within each institute.

Option 5: Technology assessments could be conducted or administered by groups composed of members drawn from the staffs of several categorical institutes or of several programs or divisions. Often several institutes have interests in a particular medical technology; for example, the National Cancer Institute and the National Institute of Neurological and Communicative Disorders and Stroke are both involved in work on the CAT scanner (see Case 2 in ch. II). Groups with representatives of involved programs or divisions could be permanently constituted, or ad hoc groups could be created for specific assessments. In either case, a small permanent administrative staff might be required to set up, maintain, and support such groups.

Choosing among these five options involves two converse considerations. On the one hand, assessments conducted close to the research programs could be expected to ask more precise and meaningful questions and to obtain more reliable and useful information. On the other hand, assessments conducted at some distance from the programs might be somewhat more objective, less preoccupied with parochial concerns, and more able to include a wide variety of disinterested parties and viewpoints.

Another mechanism could be used, either in addition to or instead of the options listed above, to identify new medical technologies at the earliest possible stage of their development, and to identify some of their potential social impacts. The investigators performing grant-supported basic research are perhaps in a good position to identify potential applications or social implications of their work. It might be desirable to tap this rich source of information. Presently, NIH grant applications request some statement about the significance and relevance of the proposed

research; however, the information elicited is often vague, there is a powerful incentive for applicants to make self-serving statements, and the relevance must be assessed before the research is done. Alternatively, NIH or other agencies that award grants might request a forecast or "impact statement" from investigators as part of the grant completion reports, which are already routinely required. By divorcing such speculation from the grant application process, one would encourage researchers to be more realistic. By requesting the information *after* the research project is complete, one would allow investigators to reflect on initially unforeseen outcomes, applications, or implications of their work.

Such reports might provide a sound basis for assessing the implications of potential technological advance after new knowledge is acquired through basic research but before it is applied. Serving as an "early warning system" for technological innovation, these statements could be used to help NIH in setting priorities, to encourage researchers to be aware of the societal implications of their work, and to give policy makers time to prepare for unanticipated technological advances in medical care.

Option 6: NIH grant and contract recipients could be required to submit a forecast or "impact statement" concerning their research as part of their completion reports.

It must be recognized, however, that one can seldom predict either which line of research (if any) will lead to a particular medical advance, or which medical area (if any) a particular line of research will eventually benefit. Although the mechanism outlined in Option 6 provides a method for discovering medical technologies whose development is feasible, the unpredictability of basic research might make it preferable to withhold more formal assessments until actual technology development has begun, or until targeted developmental programs have been organized.

Option 7: Assessments could be restricted to medical technologies being developed through targeted programs. Technologies whose feasibility has been postulated, but whose development into a clinically useful form has not yet been attempted would not be candidates for assessment under this option.

Any formal program of technology assessment runs the risk of creating a large and expensive bureaucracy whose product may not be useful. Because technology assessment is a new field, this danger is increased. Because few medical technologies have been assessed, the usefulness of such assessments is difficult to predict (see ch. IV). One might prefer, therefore, to maintain the present system of evacuating social impacts and setting priorities until methods for technology assessment are more firmly established. The present system includes congressional hearings and the congressional appropriations process, decisionmaking in the executive branch, oversight by advisory committees at NIH, and judgment by institute staffs and study sections.

Option 8: Do not implement any formal programs of technology assessment at NIH.

A decision to maintain the status quo does not necessarily imply that technology assessment is not an important activity or that social impacts of new medical technologies should not be assessed. Option 8 could be adopted if it were felt that present methods of evaluation and assessment are adequate, that programs of

assessment should be implemented slowly and cautiously, or that NIH is not an appropriate institution to conduct or supervise programs of technology assessment.

TECHNOLOGY ASSESSMENT AT OTHER FEDERAL AGENCIES THAT SPONSOR BIOMEDICAL RESEARCH AND MEDICAL TECHNOLOGY DEVELOPMENT

Although perhaps the best known, NIH is not the only source of Federal Government funds for biomedical research and technology development. Other Federal organizations that support development and/or testing of new medical technologies include the National Science Foundation (NSF), the Veterans' Administration (VA), the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), and the Energy Research and Development Administration (ERDA) (see app. A). The administrative structures and responsibilities of these departments have not been examined during the course of this study. However, it seems reasonable to assume that programs of technology assessment, similar to those described above for NIH, could be implemented in some or all of these agencies.

Option 9: Programs of technology assessment could be implemented at some or all of the Federal institutions that support the development of new medical technologies. Programs would be similar to those outlined in Options 1 to 7 above, although their precise nature would depend on the structure and function of each agency or department.

TECHNOLOGY ASSESSMENT IN THE WHITE HOUSE OFFICE OF SCIENCE AND TECHNOLOGY POLICY

The programs specified in the options presented above would all involve technology assessment administered by organizations that conduct or support the development of medical technology. The assessments might be conducted either internally ("in-house") by staff members, or outside the Government, with grant or contract support. Assessments might focus on medical technologies being developed by the agency or department in question, or on technologies being developed in part or entirely elsewhere. In any case, however, assessments would be supported by organizations with a direct stake in the development of new medical technologies.

Such an arrangement has both advantages and disadvantages. One advantage is that assessments done by R&D organizations would have the best access to sources of technical expertise. Information about new developments or technical progress would be readily available and could be easily incorporated into each assessment. Questions could be asked with precision and the types of information that would be most useful could be specified. The results of each assessment could be used in making decisions that would modify the course of technology development in fairly subtle ways.

On the other hand, assessments done through agencies and departments that support technology development might raise problems of conflict of interest. These organizations have some reason to encourage further technology development and their assessments might reflect this bias. Furthermore, in cases where technology development is proceeding in several places, one agency might have difficulty in obtaining information from or making recommendations to other agencies.

Some of the disadvantages could be ameliorated, at the risk of losing some of the advantages, by performing assessments in or through a more central authority. A logical candidate is the Office of Science and Technology Policy in the White House, which was established by Public Law 94–282. This Office has the responsibility for furnishing the executive branch in general and the President in particular with advice on scientific and technological matters. One does not yet know how easy it will be for this Office to obtain information from agencies that fund medical technology development. By virtue of its central position, however, it might have access to many or all such agencies, and could take a broad view of new technologies and of their implications.

Option 10: Programs of technology assessment could be conducted or administered by the White House Office of Science and Technology Policy.

TECHNOLOGY ASSESSMENT IN THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

A number of offices and agencies in the Department of Health, Education, and Welfare (DHEW) that do not conductor support biomedical research are nevertheless involved in making policy related to the development and/or use of medical technologies. Some of these groups could conductor administer programs of medical technology assessment. Such an arrangement would share many of the advantages and disadvantages of programs of assessment at the Office of Science and Technology Policy (Option 10). It would, however, have the additional advantage that the assessments would be conducted in institutions concerned with areas that might benefit from the results of technology assessment. Groups in HEW have the responsibility for making decisions about biomedical R&D and technology development (for example, at NIH), and for making policies related to the introduction and use of new medical technologies in the service system (for example, through Medicare and Medicaid). Thus, assessments done in DHEW would be available to many agencies that might be interested in using their results.

Groups within HEW that might be considered as candidates for carrying out assessments include the National Center for Health Services Research (NCHSR), the Office of the Assistant Secretary for Health, and the Office of the Assistant Secretary for Planning and Evaluation. The Social Security Administration (SSA), which pays for the use of new medical technologies through the Medicare program, might also have an interest in conducting medical technology assessments.

Option 11: Programs of technology assessment could be conducted or administered by offices or agencies in DHEW that are not directly involved in supporting the development of new medical technologies.

TECHNOLOGY ASSESSMENT AND THE FOOD AND DRUG ADMINISTRATION

The options presented above deal primarily—although not exclusively—with the assessment of medical technologies being developed in the public sector or with public support. Many medical technologies, including a large number of drugs and devices are, however, developed largely or wholly in the private sector. (See ch. II for examples and discussion, and app. A for details.) Information about the

development of such technologies is considered proprietary and confidential, and thus might be inaccessible to many Federal departments or agencies.

Programs to assess some of these privately developed and marketed medical technologies could be administered by FDA. This agency has the power to require private corporations to submit information about safety and efficacy of new drugs. Under the recently enacted Public Law 94–295, this authority has been extended to cover medical devices. New drugs and some classes of medical devices must be approved by FDA as safe and effective before they can be marketed.

The requirements for certification could be expanded legislatively to include some form of social-impact assessment of new technologies that companies plan to market. The mandated assessment might, for example, be modeled on the environmental impact statements now required for some technologies. The companies themselves might be required to assess their products, or FDA could conduct the assessments.

This arrangement would have the advantage of providing a mechanism for assessing some-although not all-of the new medical technologies that are not developed in Federal programs. There are also drawbacks. One is that some technologies, such as surgical procedures, would still escape detection and assessment (see ch. II). Another is that manufacturers assessing or providing information about the products from which they hope to profit might be biased. Finally, it would be difficult for FDA to develop criteria to judge the results of an assessment. Unlike safety and efficacy, which can to some extent be quantified, social impacts are by nature nonquantitative, and necessarily involve prediction, speculation, and value judgment. Detailed protocols would be required to insure that appropriate standards are set and met.

Option 12: Some form of social-impact statement or technology assessment could be required as part of the procedure by which FDA approves certain new medical technologies for marketing and use.