
8 Policy Options

The great end of life is not knowledge but action.

—Thomas Henry Huxley

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8.

Policy Options

INTRODUCTION

As described in the previous chapter, the present “system” of assessing medical technologies exhibits deficiencies in a number of areas. One of the problems is that there has been no strategy or systematic plan for developing an effective system:

1. to identify technologies to be assessed;
2. to ensure that high-quality, relevant assessments are carried out;
3. to synthesize or coordinate the synthesis of the resulting information; and
4. to disseminate the information to Federal agencies, health care providers, third-party payers, patients, and other health care decisionmakers.

Elements of an effective system are already in place—e.g., the Food and Drug Administration’s (FDA’s) processes for the regulation of drugs and the National Institutes of Health’s (NIH’s) support for clinical trials. The problem is that these elements have not become part of a coherent overall system. The most important need is to bring forth, from the present multiplicity of agencies and activities, a more rational and systematic approach to promote and coordinate medical technology assessment.

Achieving the goal of an effective system for assessing medical technologies will require a more integrated structure than now exists. An integrated system for assessing medical technologies need not be centrally managed or controlled. However, an integrated system will require strong links between multiple organizations and agencies. Candidate technologies for assessment could be identified by a number of Federal organizations—including NIH, FDA, Professional Standards Review Organizations (PSROs), health planning agencies, the Health Care Financing Administration (HCFA), the Veterans Administration, and the Department of Defense—as well as private sector organizations. To ensure that the

most significant technologies are assessed, all involved organizations could participate in a priority-setting exercise. Many medical technologies needing assessment are already in widespread use. In setting assessment priorities, therefore, it might be useful to establish new links to nongovernment bodies such as medical specialty societies.

Mechanisms to fund assessments of high-priority technologies would have to be developed. Federal research organizations, such as NIH and the National Center for Health Services Research (NCHSR), should be involved. Private organizations may also be interested in participating in assessments.

An important function of any system for assessing medical technologies would be to select appropriate testing methods. Although the randomized clinical trial (RCT) is accepted as the optimal method for testing efficacy in most situations, resource and other constraints make it impossible to test every technology by this method. In some cases, alternative study designs may be more useful.

Syntheses of information could be done by both Government and private organizations to meet their respective needs. Information could be fed back to organizations participating in the assessment process in a form most useful or acceptable to them. HCFA, for example, in making reimbursement decisions, might be most interested in the question of whether, on the basis of scientific evidence, a specific technology could be considered to be efficacious.

To imagine how a coordinated technology assessment system could work, consider the assessment of a hypothetical high-priority medical technology about which relatively little is known. First, it would be necessary to gather and synthesize information about the technology. The process of synthesis, by pointing to gaps in

available knowledge about the technology, might suggest a need for further research. It might be, for example, that the extent of use of the technology is not known; in that case, a simple data-gathering exercise by the health insurance system might be useful. It might be that the technology had been tested in normal subjects, but not in elderly people with chronic disease; in that case, its safety in the latter might need to be investigated by surveillance.

All agencies and organizations participating in the system could contribute to the assessment of this technology. Thus, for example, HCFA could provide information from its data base about the extent of the technology's use. If questions arose concerning benefits in the usual practice of medicine, selected PSROs might be asked to evaluate these. Different testing methods could be used simultaneously to complement one another. For instance, a small RCT could be used to establish causation, while an observational survey could be used to detect associations within a more diverse population. Unlike RCTs, which generate their own data for analysis, observational studies typically rely on existing, often large-scale, data collection systems (e.g., Medicare claims files, vital statistics). For purposes of analysis, it is important that these data systems be compatible with one another and be accurate.

When policy decisions about the technology needed to be made, the evidence of safety, efficacy, and effectiveness would be synthesized, and the information disseminated to the appropriate decisionmakers. The system would require mechanisms to determine when a rigorous assess-

ment was needed and when a more informal review was sufficient. If controversy existed concerning appropriate patterns of use for the technology, group decision techniques such as those described in chapter 5 would be useful.

The initial concept of the 1978 legislation establishing the National Center for Health Care Technology (NCHCT) resulted from a recognition in Congress of the need for a systematic approach to the assessment of medical technologies. However, the NCHCT legislation left certain problems unaddressed, e.g., who would set research priorities for the Government. Furthermore, NCHCT's mandate to perform assessments was curtailed by its austere budget. Consequently, NCHCT's impact on the health care system has been fairly small. If NCHCT's funding is not restored, however, an organization potentially able to carry out or coordinate the tasks mentioned above will have been lost.

The policy options that follow are intended to address the deficiencies of the existing system for assessing medical technologies. The options are divided into two broad categories: legislative and oversight. OTA finds that there are few realistic legislative options necessary for Congress to consider. In most of the deficient areas noted within this report, congressional oversight may suffice. There is already substantial statutory authority vested in the Secretary of Health and Human Services to develop a coherent system of medical technology assessment. The options below are not presented in any particular order of importance, nor should they be regarded as mutually exclusive.

LEGISLATIVE OPTIONS

Organizational Options

- 1. Sponsor a private-public body or grant a charter to an organization to undertake medical technology assessment activities.**

An organization could be chartered either as a separate nonprofit corporation or as part of an organization (e.g., the Institute of Medicine of the National Academy of Sciences) to undertake assessment activities that would complement Federal

activities and serve the needs of consumers, providers, and third-party payers. The organization could be composed of a number of groups concerned with the evaluation of health care: physician and hospital professional associations, consumers represented through industry and labor, private health insurers, and academic centers.

One of several objectives that such an organization could have would be to stimulate the devel-

opment of uniform and accessible data bases for medical technology assessment. This could include encouraging the use of uniform diagnostic and procedure coding, encouraging commonality of patient registration and claims forms, and developing clinical data banks. A second objective would be to identify technologies for assessment and to establish assessment priorities. A third would be to develop and refine methods of assessment, including scientific, economic, and social tools. This objective could include development of community-based collaborative studies, improved clinical data banks, better measures of quality of life, etc. A fourth objective would be to conduct comprehensive assessments of medical technologies, considering their scientific, economic, social, ethical, and legal implications; and to perform scientific and economic analyses at the request of providers and third parties. The performance of such assessments would include the generation of new data as needed. A fifth objective would be to disseminate new information and to serve as a clearinghouse of information on new technologies, assessments of technologies, etc.

Initial funding for the organization could come from private foundations. Ongoing support might include some support from foundations, contributions from insurers for support of assessment activities, congressional appropriations for special assessments of interest to the Federal Government, and support from hospital associations for advice on use and distribution of technologies.

One of the advantages of this option's general approach is that it would capitalize on private sector initiative and interest and would rely on private as well as possible public funding. A combination of private and public sector involvement may be essential for any system of medical technology assessment to be acceptable to all parties concerned. Apart from the very real possibility that an effective arrangement could not be forged, disadvantages of this approach include potential legal problems with funding—e.g., possible, though not likely, antitrust violations, and interference with State laws governing the health insurance industry.

A variation of this option, presented in appendix F, would establish a private-public body termed an "Institute for Health Care Evaluation."

A limitation to the particular model proposed in appendix F is that it deals with medical technology assessment primarily as it relates to the reimbursement system. Thus, it may be unnecessarily restrictive. Both the legal issues noted above and ethical concerns associated with selectively reimbursing for health care technologies are discussed in appendix F.

2. Maintain the authority of and fund NCHCT.

Several advantages would result from refunding NCHCT. In the few years of its operation, NCHCT was making progress on several fronts. Perhaps most importantly, the Technology Coordinating Committee of the Department of Health and Human Services (DHHS), chaired by the Director of NCHCT, provided a valuable framework for the coordination of technology assessment within the Government; NCHCT's conference (e.g., on coronary artery bypass surgery) were successful as a needed adjunct to the more medically oriented NIH conferences; NCHCT provided an important focal point for HCFA to interact with the Public Health Service (PHS) for coverage determinations. Refunding NCHCT would allow it to continue this work and to mature as a Federal agency. Furthermore, even if option 1 above were implemented, the Federal involvement would still require interagency coordination.

The disadvantages of this option include most of the arguments which recently led Congress not to fund NCHCT for fiscal year 1982. A major concern at that time were the assertions by the medical devices industry that NCHCT's "emerging technology list" inhibited innovation. The other major concern was that NCHCT's activities might not be needed, because professional medical societies are increasingly active in technology assessment and PHS may be able to manage many of NCHCT's former responsibilities.

Research Funding Options

3. Change the statutes so that HCFA can selectively reimburse for experimental technologies in return for clinical data on these technologies.

This option has several potential advantages. First, the actual implementation of this option

would not necessarily involve additional costs. Second, the implementation of this option might prove over the long run to be an effective method of cutting costs. Decisions to reimburse for many technologies which are essentially experimental are now made before adequate safety, efficacy, and cost-effectiveness information is available. If implemented properly, this option could substantially increase the quality of information available for reimbursement coverage decisions, thereby yielding substantial budgetary savings.

The possible disadvantages of this option are also substantial and are similar to some of those of option 1. Primarily, the problems concern the legal and ethical implications of selectively reimbursing for health care. Before Congress seriously considers exercising this option, therefore, it would probably need to conduct extensive hearings concerning possible adverse consequences. Possibly, elements of PHS could be involved in developing research protocols and in interpreting research evidence from the resulting experiments. If option 2 above is exercised, NCHCT could perform these duties.

Educational Options

4. Increase funding to train researchers in methodological and statistical principles.

This option is a general one that could be accomplished through a variety of existing educational programs. One advantage of this option is that the quality of both privately and publicly funded research could be expected to improve over time; the quality of the synthesis of research findings could be expected to improve as well. The disadvantages are that this option would require additional funding and would not produce immediate results.

5. Increase efforts to train health professionals in methodological and statistical principles.

This option could be exercised either by categorical funding for additional training or through congressional oversight with respect to the educational curricula of professional and continuing educational programs. One advantage of this option is that it would help to increase the quality of research performed by clinical professionals. Perhaps more importantly, it would help to ensure that such professionals are more informed about the value and limitations of research literature in their respective fields. Disadvantages might be the cost of increased training efforts and the lack of immediately observable results.

CONGRESSIONAL OVERSIGHT OPTIONS

An option involving the private sector and eight other options involving the powers already vested in the Secretary of the Health and Human Services are discussed below. Congress could exercise these options by using its oversight powers.

Private Sector Oversight Option

6. Encourage the private sector to take the lead in assessing medical technologies.

As noted in chapter 6, there is evidence that the private sector is increasing its technology assessment activities. The advantages of this option are that it would require no additional funding, would probably be more attractive to ele-

ments of the private sector than other options, and would capitalize on an existing trend at an early stage. Disadvantages of this approach include the problem of differing private and public objectives; because of these differing objectives, much of the research conducted by the private sector may not be of high priority to Congress or the Secretary of Health and Human Services. A further problem may be a low level of funding. Since technology assessment is apt to be very expensive and since the information it produces is generally regarded as a public good, any one private party has an incentive to let someone else pay for it. Finally, the private sector does not have an impressive record in the assessment field; most past efforts have been Federal ones or have been required by Federal law.

Identification of Medical Technologies for Assessment

7. Examine how Federal research institutes (e.g., NIH), agencies (e.g., NCHSR), and research programs of operating agencies within DHHS (e.g., the Office of Research and Demonstrations of HCFA) could identify technologies better when setting their research agendas; and how the PSRO program and the reimbursement system itself could be used to more advantage for identifying candidate technologies.

As discussed in chapter 7, Federal programs do an inadequate job of identifying technologies which need assessment, especially medical and surgical procedures. This option is intended to address that problem.

Testing Medical Technologies

8. Continue to conduct oversight hearings concerning the duplication and fragmentation of health-related data collection activities.
9. Examine the ability of operating agencies within DHHS (e.g., HCFA) to generate sufficient information for their decisions related to medical technologies, and the extent to which the Secretary of Health and Human Services utilizes the department's other research arms (e.g., NCHSR, NIH) to procure that information in a timely manner.
10. Examine the activities, plans, and potential for elements of DHHS (e.g., NIH) in utilizing various research methods to determine the appropriate use of medical technologies.

The duplication and fragmentation of health-related data collection has been discussed in previous OTA reports and is well known to Congress. If Congress believes there is a continuing need to evaluate data collection activities and to match their value with both research and operating needs, it may wish to exercise option 8.

As discussed in chapters 6 and 7, operating agencies of DHHS (including HCFA), PSROs (within HCFA), and State and local health planning agencies require information for the decisions which they make, yet they all have limited ability (funding, expertise, and/or legal mandate) to

secure such information. Option 9 would allow Congress to investigate this matter further.

Option 10 addresses research methods. As discussed in chapter 3, the selection of optimal research methods for evaluating different technologies at different stages in their lifecycle is very complex. Although an RCT is often ideal for studying efficacy, other methods may be more appropriate for such things as safety or for technologies in widespread use. This option would permit Congress to encourage the use of appropriate methods.

Synthesizing Research Information and Group Decisionmaking Activities

11. Explore how research evidence could be better evaluated by HCFA and its carriers and fiscal intermediaries when making reimbursement decisions, by PHS when making recommendations to HCFA on coverage policy, by PSROs when setting standards for care, and by the Office of Medical Applications of Research of NIH when conducting consensus development conferences; and monitor the progress and potential costs and benefits of the National Library of Medicine's (NLM's) knowledge base prototype.

As discussed in chapters 6 and 7, many decisions are currently being made by Federal agencies regarding premarket approval, reimbursement, and appropriate use of medical technologies. As discussed in chapter 5, however, there is good reason to believe that the evidence from research is seldom carefully and objectively analyzed before these decisions are made. This option would help ensure that these decisions are better informed and would assist in establishing research agendas for Federal agencies.

Dissemination Activities

12. Examine the disposition of federally generated reports to determine the degree to which they have been useful both to private and public researchers and policymakers; specifically conduct an oversight hearing on the

ability of researchers and policymakers to locate, retrieve, and use these reports.

13. **Examine whether NLM's literature base** should be further expanded, especially to include more Government research reports and other nonserial literature; **and examine whether there** are more useful ways to index articles which contain findings from research.

Federal agencies that conduct or fund research generate reports that may be useful for technology assessment. As discussed in chapter 2, numerous agencies and other organizational units of DHHS are involved in disseminating Government reports and other health-related information that is useful for medical technology assessment. The deposition of all research reports and other Government documents to distributing organizational units is not mandatory. Option 12 would allow Congress to ascertain whether, and the degree to which, federally generated information is useful and accessible to the people and agencies conducting medical technology assessments and making related health policy decisions.

As discussed in chapter 2, NLM is primarily oriented toward the biomedical research community. Increasingly, however, the health services research community is looking to NLM for assistance in locating and retrieving health services information. Option 13 suggests two areas that Congress may wish to explore. *

Establishing a Coordinated System of Technology Assessment

14. Encourage use of the powers vested in the Secretary of Health and Human Services to develop a coherent system of medical technology assessment.

As already discussed, a recent decision was made by Congress not to fund NCHCT. If Congress does not choose to restore NCHCT funding (see option 2), it may wish to consider this option.

*NLM's role in the dissemination of health-related information is explored at greater length in OTA's technical memorandum entitled *MEDLARS and Health Information Policy* (276).