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A Consortium for Assessing Medical Technology

Planning Study Report

Division of Health Sciences Policy

INSTITUTE OF MEDICINE

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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education.

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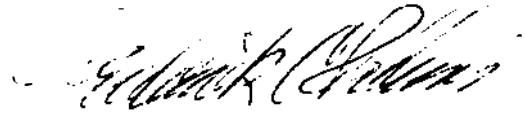
FREDERICK C. ROBBINS, M. D.
PRESIDENT

This report, "Medical Technology Assessment: A Plan for a Private/Public Sector Consortium," was prepared by an Institute of Medicine committee headed by Jeremiah A. Barondess, M.D. The planning project was undertaken in response to growing concerns in both the private and public sectors expressed at a meeting convened by the Institute of Medicine in June 1982 about the lack of a coordinating entity for the assessment of medical technologies.

There is presented a reasoned approach to the kind of an organization needed to foster a private/public partnership in medical technology assessment, and an outline of the functions, governance, and possible funding mechanisms of the enterprise. Many persons from each sector of interest contributed perspectives to the committee's deliberations, and their work is greatly appreciated.

The committee's recommendations constitute only a plan for an organization. The Institute's governing Council as well as the similar bodies of the National Academy of Sciences and National Academy of Engineering will consider whether to implement the recommendations of the committee and, if so, in what manner.



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With collaboration and assistance of the Director of the Division of Health Care Services, Karl Yordy.

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ACKNOWLEDGMENTS

The brief working life of the Committee to Develop a Plan for a Private/Public Sector Entity to Assess Technology in Medical Care was characterized by the dedication of committee members and liaison panel members alike. Jeremiah Barondess was an eloquent maestro of this consensus-building enterprise, aided by the creative industry of subcommittees chaired by Richard Johns, Saul Farber, William Anlyan, and Margaret McClure. The large number of participants and the diversity and force of individual views on this subject posed some potential stress on the deliberative process in such a short-term effort, but the commitment of everyone on the committee and panels facilitated arrival at the concord expressed in this report.

The beginnings of this project were developed by participants of a one-day meeting convened by the Institute and chaired by Frederick Robbins on June 16, 1982. That meeting framed the broad outlines of inquiry, and many of its participants later served on this project's primary committee or its liaison panels. Drawing upon the discussions at that exploratory meeting, Enriqueta Bond and Karl Yordy designed the proposal for this follow-up project.

Funding for this project was the result of a deliberate effort to draw many of the potential constituents of a medical technology assessment entity into a shareholder relationship with the problem-solving/planning process. The generous support of the following corporations and agencies is gratefully acknowledged:

Aetna Life and Casualty
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Public Health Service, United States Department of Health and Human Services
The Commonwealth Fund
The Equitable Life Assurance Society of the United States

Gratitude is also expressed to Enriqueta C. Bond for her administrative support of the project, and to Talitha D. Shipp, who bore the primary and very substantial secretarial burden in this endeavor.

Alton Hodges
Senior Scholar-in-Residence
Project Director

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PREFACE

The mission of the committee that produced this report was stated clearly in its name: Committee to Develop a Plan for a Private/Public Sector Entity to Assess Technology in Medical Care. In constructing the plan, the committee affirmed the need for such an entity and developed a rationale for what it believes is the most practical set of organizational characteristics. The committee's major recommendation is for the establishment of a Medical Technology Assessment Consortium associated with the Institute of Medicine.

Although members of the committee were concerned about the rudimentary state of some technology assessment methods, a critique of assessment methods was not appropriate here. Another Institute committee, the Committee for Evaluating Medical Technologies in Clinical Use, under the chairmanship of Frederick Mosteller, is charged in this respect and the work of that committee continues at this time.

The individuals involved in the design and execution of the project reported here are listed in the previous pages. The members of the committee and of the liaison panels, all extraordinarily busy and distinguished people, were animated by a belief in the need for the type of entity described, by a concern for the quality of medical care, by a desire for the continued development of appropriate medical technology, and by a concern for the validity of the technologic procedures involved in patient care. They met their task with intelligence, energy and good humor; it is a pleasure to acknowledge my lasting gratitude to each of them.

Because of the inherently judgmental elements involved in this report, and the wide disparity of participants, not everyone on the committee or the liaison panels subscribes to every aspect of the conclusions and recommendations that are made. Nevertheless, the report does represent the overwhelming consensus of the committee. The staff effort for any study of this kind is considerable. In this instance it was especially so in view of the large number of individuals on the committee and liaison panels and the number of constituencies involved. We are especially fortunate in having the willing and expert assistance of Enriqueta C. Bond and Alton Hodges and their coworkers. Their efforts in organizing, coordinating and systematizing our work were central to the entire effort, and permitted us to conclude our work within the six-month time frame available to us. On behalf of the entire committee I acknowledge with pleasure our indebtedness to the IOM staff and to Drs. Bond and Hodges particularly.

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Further, I wish to acknowledge my appreciation of the editorial assistance of Wallace K. Waterfall, who helped immensely in our efforts to make this report clear and, above all, useful.

Jeremiah A. Barondess
Chairman

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SUMMARY

The Institute of Medicine established the Committee to Plan a Private/Public Sector Entity to Assess Technology in Medical Care in December 1982, and charged it with the development of a plan for a technology assessment organization that would be based in the private sector but supported by both government and non-governmental parties. This initiative grew out of an exploratory meeting convened by the Institute on June 16, 1982, in response to growing concerns in both public and private sectors about the proliferation of technologies in medical care. The concerns have several aspects: pressures to eliminate technologies that may be obsolete, harmful, or ineffective; desires to affirm the benefits of other technologies; and stringencies of the need to slow the growth of costs while maintaining and improving tne quality of American medical care.

The committee completed its work on June 30, 1983, recommending the creation of a Medical Technology Assessment Consortium as a part of the Institute of Medicine. Based in the private sector, the consortium is to seek support that would be approximately evenly divided between governmental and non-governmental resources. The functional priorities of the consortium call for it, first, to establish and maintain an information clearinghouse in medical technology assessment. This clearinghouse function would build a communications network among the principal parties to technology assessment--other technology assessment entities, manufacturers of drugs and devices, the professional users of technologies, third party payers, and the major health care providers. The clearinghouse function would serve to reduce unneeded or unrecognized redundancies in evaluation, establish a central repository of information on completed and ongoing assessments, provide a forum for all the parties at interest in the development and validation of technologies, and facilitate the dissemination of information on medical technology assessments. The consortium is not intended as a competitor or as a replacement for any existing entity involved in assessing medical technologies. Rather, it is to be complementary and facilitative of the efforts of others involved in responsible assessments of medical technologies.

Second, the consortium should develop a capability to synthesize, evaluate, and interpret the reports and data generated by others involved in medical technology assessment. This is an activity of "secondary" assessment, which adds to the information retrieval and dissemination tasks of the clearinghouse function.

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Third, the consortium should be prepared to stimulate, coordinate, conduct, or commission original assessments of medical technologies. This function is generally termed "primary" assessment--the generation of new facts upon which to base direct judgments. Recognizing this as a major research need in the field, the committee chose the broadest possible role for the consortium in original research.

Fourth, the consortium should function in the identification of needs for technology assessment, conducting consensus-building activities on the specific question of which technologies are in need of evaluation or re-evaluation. Along with this, in the committee's view, is a responsibility of the consortium to help identify areas in which more technologic development would be desirable.

Fifth, the consortium should contribute to the development and evaluation of criteria and methods for assessment of technologies in medical care. The committee does not provide a definitive review and evaluation of assessment methods in this report, but it wishes the consortium to be capable of such examination so as to improve the quality of research in assessment.

Sixth, and last, the consortium should become involved in education and training, and provide technical assistance to others interested or engaged in medical technology assessment. This function attempts to round out the desired range of services that might be offered through the consortium by allowing it to complement primary and continuing education efforts of others, and to serve as a resource for improving the technology of technological evaluation.

The consortium should seek at least $300,000 for its first year of operation, and should have an annual budget of at least $1 million in its third year. The clearinghouse function should be initiated in the first year and be fully operational by the third. A $1 million budget should be sufficient to support the clearinghouse activities, but as the consortium activates its other intended functions, particularly those of conducting or commissioning primary data-based research, the annual budget must increase substantially. Several funding possibilities are proposed, including congressional appropriations, fee-for-service work, or combinations of those.

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BACKGROUND

> "... in medicine, it is characteristic of our technology that we do not count the cost, ever, even when the bills begin coming in....It is, in part, explainable by our history, by the brand newness of any kind of technology at all in this field, and our consequent unfamiliarity with any methods, or indeed, any incentive in the first place, for technology assessment in medicine." (Thomas, 1972)

In a relatively short span of recent years medical technology* has developed at an awesome rate, presenting new ways to prevent, detect, and treat disease. But those same technological developments also have alerted us to the necessity that we "count the cost," in Lewis Thomas's phrase, and have provided "incentive...for technology assessment in medicine."

Hundreds of new technologies enter the health care system each year, and the pace of their development indicates no slackening in the foreseeable future. The benefits of the new technologies often are clear and convincing. Computed axial tomographic (CAT) scanners can reveal more clearly than prior techniques the anatomic abnormalities of a brain tumor, and now positron emission tomographic (PET) scanners can trace the chemical abnormalities created by disease. Antibiotics and vaccines have removed infectious diseases from their paramount position as a cause of death in industrialized nations. Surgical equipment and procedures enable the restoration of a damaged heart or the replacement of a failing kidney. In many instances the new technologies have improved the results of care, have reduced the cost of care, and even have increased access to care.

In other instances the new technologies have posed risks to patients. Some risks are intrinsic to the technology; others are related to the skill with which it is applied or to the setting in which it is used. Some new technologies are increasing the cost of health care, sometimes dramatically (Altman, Blendon, 1979; Moloney, Rogers, 1979). Health care costs are now at an all-time high, representing more than 10 percent of the gross national product (U.S. Public Health Service, 1982). Costs of the Medicare program and the federal

*For purposes of this report, medical technology is defined as a drug, device, medical or surgical procedure, or combination of the above and the knowledge necessary for their appropriate use in the delivery of patient care.

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portion of Medicaid increased from $31.5 billion in 1976 to more than $70 billion in 1981 (Health Care Financing Administration, 1983). Although there are many explanations for the increase in expenditures, some of it is related to the use of technology. More costly care, particularly in a time of economic strain, should force attention on the appropriateness of all health care procedures, including the technologies involved. A new technology is not necessarily synonymous with an improved technology, but its use can spread rapidly and widely. Only later may well-designed research validate that new is better--or show that it is less efficacious (Office of Technology Assessment, 1978).

There clearly is a need to develop better methods and better organizational strategies for distinguishing useful new medical technologies from those that are wasteful or even harmful. The principal objective in assessment of medical technology is the improved health of people (Institute of Medicine, 1977). A timely scientific assessment of new medical technologies can help (1) to promote the use of technologies that have been shown to be more efficacious or equally efficacious but less costly than others, (2) to ensure that new technologies are made available only after they are shown to have benefits that outweigh their risks, (3) to curb the use and spread of technologies that lack efficacy or cause preventable harm, and (4) to provide evidence to guide appropriate use of all technologies, new and old (Institute of Medicine, 1979).

The worth of technology assessment in medicine goes far beyond its warranty to the patient and its utility to the health care professional. The results of assessment are also needed by the hospitals and other facilities that buy and apply technologies, by industries that develop technologies, by the professional societies that disseminate information to health care practitioners, and by the insurance companies, government agencies, and corporate health plans that pay for the applications of technologies. A strategy for assessing medical technology, therefore, must take into account not only the methods of assessment, but also the needs, demands, and resistances of the participants and beneficiaries in the process and products of assessment.

The fairly recent appreciation of the need for medical technology assessment has created numerous efforts to satisfy that need. In the private sector, for example, professional societies such as the American Medical Association and the American College of Physicians developed formal mechanisms for accumulating evidence on the proper use of technology and for disseminating this information. Hospital groups and associations such as the Alliance for Engineering in Medicine and Biology and the Association for the Advancement of Medical Instrumentation have an interest in and contribute to the assessment of technologies in clinical practice.

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In the public sector, the Food and Drug Administration of the U.S. Public Health Service has as a principal activity assuring the safety and efficacy of pharmaceuticals and medical devices. The National Institutes of Health several years ago began efforts in technology assessment by means of awarding grants for clinical trials and consensus development conferences. The Office of Technology Assessment (OTA), an arm of the U.S. Congress, operates a program to assess medical technology for the main purpose of providing accurate information and practical alternatives for congressional decision makers in developing health policies. Other federal agencies whose activities include health care, such as the Veterans Administration and the Department of Defense, also have become engaged in medical technology assessment.

Congress passed legislation in 1978 establishing the National Center for Health Care Technology (NCHCT) to conduct, sponsor, and coordinate the assessment of new and existing technologies. The government's Health Care Financing Administration, as well as other third-party payers used the information generated by the NCHCT to help in making decisions about coverage and payments. However, the NCHCT was abolished in 1981. The Office of Health Technology Assessment, based in the National Center for Health Services Research of the U.S. Public Health Service, has assumed some functions of the NCHCT.

The end of the NCHCT, however, did not signal an abatement of congressional interest in new approaches to assessment of medical technology. The 1983 amendments to the Social Security Act (P.L. 98-21) authorize the creation of a Prospective Payment Assessment Commission, appointed by the director of the congressional Office of Technology Assessment, and give it broad powers, including medical technology assessment and the evaluation of the appropriateness of medical practice patterns. The commission, recently activated, could have considerable impact on technology assessment and its relationship to federal payments for health care. The body already has gained the sobriquet of "DRG Commission" for its planned relationship to the diagnosis-related groups that will form the basis for prospective payments for health care services under the federal Medicare program.

Specifically, the DRG Commission is to collect and assess information on costs, productivity, technological advances, and cost-effectiveness of hospital services. The commission is expected to synthesize existing data in framing its recommendations on reimbursement rate setting, where those data are available, but it is also empowered to carry out research and to award grants and contracts for research purposes, specifically research that will inform its judgments about diagnosis related groups and prospective payment rates. A major provision of this legislation allows the commission to obligate Medicare Trust Fund resources for external research activities, with the approval of the DHHS Secretary. The range of responsibilities of the commission, and its power for

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awarding external grants and contracts for projects in technology assessment, make it likely that the proposed body will become a major contractor for assessment projects.

Two other recent and germane Congressional developments may be cited. Rep. Henry Waxman, Democrat of California and chairman of the House Energy and Commerce Subcommittee on Health and the Environment, introduced a bill (H.R. 2350) to reauthorize the National Institutes of Health that included a $4 million item to re-establish the National Center for Health Care Technology. And Sen. Edward Kennedy, Democrat of Massachusetts and ranking minority member of the Senate Committee on Labor and Human Resources, introduced a bill (S. 814) to "control health's escalating costs," which also would create an "Advisory Committee on Health Care Technologies and Procedures" under the administrative supervision of the Institute of Medicine and funded as an administrative cost of the Medicare program.

Although there are many agencies and organizations conducting programs in assessment and dissemination of information about medical technology, there currently is no private or public sector entity charged to coordinate and syntnesize information produced by the various agencies and organizations and to provide a meeting ground apart from the regulatory framework for purposes of technology assessment. Most existing entities are not positioned to approach technology assessment with both a scientific and a social perspective. For example, government agencies such as National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control (CDC), and the Health Care Financing Administration (HCFA) are limited in their mandates. FDA's legislative charge is the safety and efficacy of drugs and devices; it does not deal with procedures or with economic and ethical issues. HCFA, on the other hand, is a major payer whose efforts are addressed primarily to cost issues associated with the Medicare and Medicaid programs. Private sector organizations--American Medical Association, American Hospital Association, the Blue Cross and Blue Shield Association, tne Health Insurance Association of America, and others--serve constituents with a variety of focused concerns.

University faculty and research groups conduct many of the assessments of medical technologies based on primary data, principally by means of controlled clinical trials. Several university research units conduct other types of quality medical technology assessment, but, their efforts tend toward detailed examinations of a few areas of interest.

Consequences of these many and varied approaches to medical technology assessment include hampering the emergence and application of potentially valuable new technologies and tardiness in retiring obsolete technologies, as well as compromised credibility with the health professions and the public. Promotion of promising procedures and techniques

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in health care may be more likely to depend on perceived marketability than on potential or proved contributions to patient care. The identification of an outmoded technology is cumbersome at best, and depends on the gradual accretion of reports in the literature and at professional society meetings until they constitute a consensus for change.

Poor dissemination of information from good technology assessment contributes to the rising costs of health care. Conversely, the Blue Cross and Blue Shield Association, for instance, estimates that its Medical Necessity Program has saved premium payers as much as 500 million dollars in its first five years. Studies at UCLA and Harvard commissioned by the NCHCT estimated that 100 to 200 million dollars per year could be saved by the Medicare program if NCHCT recommendations not to reimburse for six technologies were followed (Harvard, 1981; UCLA, 1981). Also, in the training of health professionals, the lack of coordinated dissemination of valid technology assessment information means that curricula quite possibly will not include current clinical knowledge.

The lack of an organization with the credentials to coordinate and complement existing efforts in medical technology assessment has prompted several proposals for the formation of an entity that could assume those functions (Bunker, 1982; Perry, 1982; Relman, 1980, 1982). Government officials, members of the Institute of Medicine, practicing physicians, and other health industry leaders have requested at various times that the Institute call together the parties appropriate to a discussion of the feasibility of a new entity to lead medical technology assessment efforts. Further, there were suggestions that the conferees consider a role for the Institute in the establishment of such a new entity.

The Institute was viewed as an appropriate convener partly because it is designed by its charter to have a membership of expertise and authority in many disciplines of health care and the related professions. One of the Institute's principal functions is the assembling of the most appropriate and knowledgeable persons from the membership and elsewhere to conduct studies and produce objectively balanced reports on issues of health policy. The Institute for a decade has provided a neutral forum where representatives of public and private interests can meet, removed from parochial involvements, to discuss mutual concerns. In addition, the Institute has a long history of activities in the assessment of medical technology, beginning with a policy statement in February 1968 that heart transplantation was a research venture and not an accepted routine clinical procedure (Board on Medicine, 1968). Later the Institute (1973) produced reports cautioning against the adverse economics of the artificial heart, setting an application and payment framework for computed axial tomographic (CAT) scanning (1977), examining

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policy and research issues basic to the impacts of new technology on the health care system (with the Assembly of Engineering) (1979), and developing research methods for evaluating technologies in clinical use (1981). Also, the Institute recently convened a conference on cost-effective medical care, part of which centered on increased efficiency in practice through the application of new technologies.

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FIRST CONSIDERATIONS

In response to the interest expressed in re-establishing a forum for medical technology assessment, the Institute on June 16, 1982, convened representatives from professional societies, industry, academia, government, and third-party payers for health care. They were to initiate consideration of such questions as what assessment functions were needed, what organizational structure might best meet the need, what auspices might best suit the structure, and what might be the source of funds for such an organization.

Participants variously suggested that functions of a new organization might include (1) the setting of priorities for the conduct of medical technology assessments, (2) supporting and/or conducting such assessments, (3) widely disseminating the results of assessments, (4) supporting research and development of assessment methods, (5) acting as a catalyst for the discussion of assessment issues, and (6) providing a clearinghouse for information about assessment. There was ready consensus about the need for timely information that could be used by a variety of organizations and individuals in making decisions appropriate to their own concerns.

The meeting made it clear that much further effort would be necessary to develop widely acceptable definitions of technology assessment, to outline the scope of activity of any new entity hoping to coordinate asessment, and to develop a plan of action for establishing and funding such an entity. Success in attracting funding was seen as heavily dependent on the creation of a specific proposal that would cover the six tasks listed above.

Important functions not now being adequately performed in various technology assessment efforts were identified by the meeting participants. Included were the lack of a central clearinghouse, the lack of an entity with prime responsibility for coordination and synthesis of assessment information for wide dissemination and education, and the lack of any significant entity responsible for supporting research in assessment.

Conferees discussed several advantages of basing a new entity in the private sector and supporting it with both private and public funds. First, a private base could attract broader support from health care professionals and the industry as a whole by being outside of government and its regulatory activities. Second, an essentially private-sector organization would be less subject to political pressures than would a government agency, and therefore could conduct its activities in a more neutral and stable context. Last, a private entity could be seen as more accessible and responsive to its supporters, and could be hoped to

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perform with more alacrity and effectiveness.

Possible disadvantages to an entity based in the private sector, conferees conceded, could include considerable difficulty in securing adequate long-term support for the establishment of effective programs, and an inference of bias in favor of the marketing and profit incentives of private enterprise.

Participants requested the Institute to take the lead in developing a plan for the establishment of a private/public sector activity in medical technology assessment.

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FORMATION OF THE COMMITTEE

In response to the requests of the participants of the June 1982 meeting, Institute president Frederick C. Robbins arranged for the apppointment of a 24-member committee.

The committee was established January 1, 1983, and was charged with the development in the ensuing six months of a plan for a private/public entity in the assessment of technology related to medical care. The committee's charge included defining the mission of the new entity, identifying the composition of its governing body, outlining possible short-term and long-term roles of the Institute of Medicine in the effort, formulating a budget, and suggesting mechanisms for support of the continuing effort.

In developing the plan the committee specifically was to examine these issues:

- the possible roles of the proposed organization in gathering and disseminating information on technology assessment, recommending priorities for assessment, and synthesizing the results of studies
- whether this new organization should support specific assessments and methodologic studies or should confine its activities to synthesis of the work of others
- whether existing technologies as well as new ones would be considered
- whether the scope of concern would include appropriate use of technologies as well as safety and efficacy
- the structure and governance of a proposed new organization
- sources of support for the entity.

As broadly representative as the committee was, the breadth of the community of interests in this undertaking seemed to call for even greater representation. Thus, two panels auxiliary to the committee were created and their members invited to each committee meeting (Appendix 2 and 3). A Public Sector Liaison Panel had members from appropriate government agencies and the legislative branch; a Private Sector Liaison Panel had members from the medical profession, hospital and health tecnnology industry, professional societies, insurers, academic health institutions, and the engineering profession.

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Members of the liaison panels also joined members of the committee in work on various subcommittees responsible for structuring major aspects of a new entity in technologic assessment (Appendix 4).

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CONCLUSIONS AND RECOMMENDATION

The committee's conclusions, overall recommendation, and components of the recommendation follow.

Organization

THE COMMITTEE RECOMMENDS THE ESTABLISHMENT OF A MEDICAL TECHNOLOGY ASSESSMENT CONSORTIUM ASSOCIATED WITH THE INSTITUTE OF MEDICINE.

In searching for the appropriate organizational structure, the committee was especially interested in the extent of governmental control, responsiveness to the needs of potential constituencies, and funding of various organizational models that were public, private, or some hybrid of the two.

Reasonable and effective approaches to such technical issues as energy regulation, consumer product safety, occupational health and safety, and technology assessment require that business and government become successful partners in accommodating divergent views (Fox, 1981). Various government agencies approach technology assessment from different perspectives and with different needs. Likewise, industry and the professional groups have differing needs, concerns, and goals. One way to bring all these interests together, in the committee's view, is to establish an organization or forum outside the formal judicial, legislative, and regulatory processes of government.

Two examples of organizations that have successfully accommodated divergent industry and government views are the National Institute of Building Sciences (NIBS) and the Health Effects Institute (HEI).

NIBS is a private non-profit organization established by Congress to provide for the evaluation of building technology, and to facilitate the introduction and acceptance of desirable technologies at the federal, state and local levels (Fox, 1981). NIBS received an initial five-year congressional authorization, and was mandated to provide its own financial support by no later than 1983 (PL 93-383, 1974). Its first board of directors was appointed by the President of the United States but later was to be nominated by the housing and building industry and voted upon by the NIBS board.

HEI was formed in 1980 as an independent entity to conduct assessments of the health effects of emissions from automobiles and trucks. Its research informs both the vehicle manufacturers and the Environmental Protection Agency, which writes and enforces air pollution

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regulations. HEI is directed by a board whose three members come neither from the affected industry nor from government (Fox, 1981). It was given an initial federal line of credit in 1981 to begin developing its organizational and research capacity, and has secured agreement of 24 private companies to reimburse 50 percent of its operational expenditures, within the federal credit limit. This support--half public, half private--is expected to continue indefinitely (Powers, 1983).

The committee chose to blend these two examples, deciding that a private/public partnership for technology assessment could best be fostered under the auspices of a private non-profit organization, established either de novo or as an appendage to an existing private non-profit corporation. A privately based organization was seen as likely to attract broader support from the private sector because it would be less subject to governmental pressures and perhaps more accessible and responsive to its supporters. Better coordinated, more balanced, and less polarized assessments should be possible when conducted outside of a regulatory framework and in a neutral setting. The committee chose to name the new entity the Medical Technology Assessment Consortium.

The committee recommends that the Medical Technology Assessment Consortium begin under the auspices of the Institute of Medicine, because of the expense and difficulties of establishing a new organization and because there are decided advantages for such a new effort if located in this component of the National Academy of Sciences. Such a locus would provide visibility and credibility for the new entity, would offer a clear indication of neutrality and objectivity, and would facilitate the recruitment of board members, senior staff, and panel members of high caliber. In addition, prior Institute experience with issues of technology assessment would be a resource for the activity of the new entity.

The committee recognizes that a permanent relationship between the consortium and the Institute of Medicine may neither be desirable nor necessary and that the consortium might become an independent entity after a period of development. A reasonable developmental period, the committee felt, would be five years. Careful monitoring of growth and potential for independence should be formalized on an annual review basis while the consortium is in the Institute.

One of the documents used by the committee in developing the organization of the new entity was a chart describing the mission, scope, role, funding, and functions of other existing or proposed technology assessment organizations (Appendix 1). The committee determined that the following characteristics would be a desirable statement of the mission, scope, role, operations, and financial support of the new entity.

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Mission

THE MISSION OF THE ENTITY IS MEDICAL TECHNOLOGY ASSESSMENT. FOR THE PURPOSES OF THIS ENTITY, MEDICAL TECHNOLOGY IS DEFINED AS A DRUG, DEVICE, MEDICAL OR SURGICAL PROCEDURE, OR COMBINATION OF THE ABOVE AND THE KNOWLEDGE NECESSARY FOR THEIR APPROPRIATE USE IN THE DELIVERY OF PATIENT CARE.

Scope

MEDICAL TECHNOLOGY ASSESSMENT INCLUDES THE DEVELOPMENT AND EVALUATION OF EVIDENCE, OR THE EVALUATION OF EVIDENCE DEVELOPED BY OTHERS, CONCERNING EFFECTIVENESS, SAFETY, COST, COST-EFFECTIVENESS, UNINTENDED CONSEQUENCES, AND, WHEN APPROPRIATE, THE POLICY IMPLICATIONS OF THE DEVELOPMENT AND/OR USE OF A SPECIFIC TECHNOLOGY, COMMENSURATE WITH ITS STAGE OF DEVELOPMENT. IT MAY ALSO INCLUDE THE EVALUATION OF KNOWLEDGE, PROFESSIONAL COMPETENCE, INDICATIONS, FACILITIES, AND PERSONNEL NECESSARY FOR APPROPRIATE USE.

Role

THE ROLE OF THE ENTITY IS TO PROMOTE THE EMERGENCE AND APPLICATION OF APPROPRIATE MEDICAL TECHNOLOGIES, AND THE RETIREMENT OF INAPPROPRIATE OR OBSOLETE MEDICAL TECHNOLOGIES BY:

- SERVING AS A CLEARINGHOUSE OF INFORMATION ON MEDICAL TECHNOLOGIES AND MEDICAL TECHNOLOGY ASSESSMENT
- ASSEMBLING AND EVALUATING INFORMATION AND MAKING RECOMMENDATIONS CONCERNING INDIVIDUAL MEDICAL TECHNOLOGIES
- ACTING WHEN NECESSARY AND APPROPRIATE TO STIMULATE, COORDINATE, UNDERTAKE, OR COMMISSION MEDICAL TECHNOLOGY ASSESSMENT, INCLUDING ACTIVITIES THAT WOULD COMPLEMENT THOSE OF OTHERS
- IDENTIFYING NEEDS IN THE ASSESSMENT OF SPECIFIC MEDICAL TECHNOLOGIES
- DEVELOPING AND EVALUATING ASSESSMENT CRITERIA AND METHODS
- PROVIDING EDUCATION, TRAINING, AND TECHNICAL ASSISTANCE IN THE USE OF MEDICAL TECHNOLOGY ASSESSMENT METHODS AND RESULTS.

In identifying the breadth of functions of the proposed consortium, the committee chose to endow it with enough flexibility to be maximally responsive to its users. This flexibility should enable the consortium

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to evolve into as comprehensive an institution as is commensurate with its operational concept and finances. The committee recognized the breadth of the role it had defined, and consequently ordered the six primary functions by priority, both in terms of perceived need within the technology assessment community and in terms of the probability of funding for early implementation.

Expecting that the consortium's initial operating capital may be relatively small, the committee proposes the clearinghouse function be established first. The principal components of the clearinghouse function, as described in the OPERATIONS section later in this report, are an information management system and a scanning and surveillance function. The committee recognized the complexity of setting up a truly expert clearinghouse, but that complexity would be greatly reduced by the consortium's association with the IOM/NAS.

Current resources of the NAS complex that would aid the consortium's clearinghouse function include: the NAS Library, with state-of-the-art bibliographic and electronic retrieval capability; the IOM experience in convening its members and other experts for specific inquiries; and the information-gathering experience gained by this committee and the parallel Committee on Evaluating Medical Technologies in Clinical Use, which have become conversant with most other existing technology assessment entities and with rosters of entities in other countries developed by staff of the congressional Office of Technology Assessment.

The committee endorses pluralism in technology assessment, believing that the involvement of multiple entities in technology assessment is desirable. The proposed consortium is not intended to replace or eliminate other assessment entities, but should be complementary to them. The consortium's products--evaluations, recommendations, reports--should be available both to other assessment entities and to the public.

Because the consortium should have the capability to consider societal, ethical, legal, and other aspects of technology assessment, the statement of scope provides for the development and evaluation of all kinds of evidence about technological policy implications. Addressing policy implications, however, is deemed secondary to the consortium's prime task of providing evaluation information with which other entities can formulate policy.

Although the committee did not delve into specific methods used in "technology assessment", it noted that the greatest research need is for the generation of primary data for analysis. The most prevalent method of conducting assessments entails the synthesis and interpretation of primary research done by others--secondary analysis. However great the need for primary data development and analysis, the very high costs of such assessments require funding at a rate substantially greater than

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that which the committee felt the consortium could attract at the onset of its activities. Assessments requiring primary data likely would be conducted later in the consortium's existence.

Governing Board

THE INITIAL GOVERNING BOARD OF THE CONSORTIUM WILL BE APPOINTED BY, ITS TERMS OF OFFICE DETERMINED BY, AND ITS CHAIR DESIGNATED BY THE PRESIDENT OF THE NATIONAL ACADEMY OF SCIENCES, ON RECOMMENDATION OF THE PRESIDENT OF THE INSTITUTE OF MEDICINE, FOLLOWING APPROPRIATE CONSULTATION. OFFICERS, OTHER THAN THE INITIAL CHAIR AND NEW BOARD MEMBERS, WILL BE NOMINATED AND ELECTED BY THE BOARD IN ACCORDANCE WITH SUCH BYLAWS AND OTHER RULES OF CONDUCT AS THE BOARD SHALL HAVE ADOPTED. THE BOARD WILL CONSIST OF 15 MEMBERS DRAWN FROM THE PUBLIC AND PRIVATE SECTORS.

It is the intention of the committee that board members will be representative of an array of expertises, but should not be representative of specific organizational entities. Board members, selected from both private and public sectors, should be knowledgeable in such matters as the financing of health care, the provision of health care, the management of health care institutions, and research, development, and marketing of health care technologies.

The responsibilities of the board will be to:

- adopt by-laws for the consortium
- set policy for the consortium
- establish broad priorities for the consortium
- employ the chief executive officer
- approve the budget.

The members of the initial board will take whatever actions are necessary to establish the consortium.

Professional Staff

The new entity will require a highly qualified and committed staff.

The chief executive officer, appointed by the board, will have responsibility for:

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- recommending the organizational and operational structure of the consortium
- managing the operations of the consortium, including developing budgets
- employing staff
- developing specific priorities and tasks consistent with board approval
- developing and recommending to the board technical review and evaluation panels
- developing funding sources
- entering into contracts authorized by the board.

Operations

The management of the consortium will involve the interaction of several basic functions discussed briefly below. The organization should be able to accept and sort requests and problems, draw upon and manage relevant information, make evaluations, and report findings and recommendations. The organization should be able to evaluate and learn from its own performance. The organization also should be able to detect trends and developments that could affect the development, diffusion, and utilization of medical technology and the need for its assessment. The operations described below may be implemented in any of a number of organizational frameworks, depending upon such factors as the resources available to the consortium, its relationship to a parent organization, and preferences of its governing board and administration.

- Information Management The organization should have the capability to acquire, process, store, retrieve, and disseminate information. The acquisition of information includes the capability of seeking new information by conducting or sponsoring studies and other inquiries, as required by the decision making operation.
- Scanning/Surveillance Beyond acquiring and managing information, the organization should have the capability of discerning indications that merit its attention. These include trends, cycles, and new and projected developments in medical technology and other relevant fields. Changes in technology utilization patterns, relevant developments in biology, engineering, elec-

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tronics, and communications, population trends and disease patterns, political and international developments all are examples of indications to be picked up by the scanning operation and provided to other organizational operations as appropriate.

- o Issue Identification and Triage The organization will receive from both external and internal sources a broad variety of requests, problems and issues. It should be capable of accepting, identifying, clarifying, and sorting these. Some will be handled on a routine basis by staff, some will be referred to the decision making operation of the organization, and certain inquiries will be referred to outside agencies better able to handle them.

- o Recommendations The organization should have the capability of conducting evaluations or assessments in a timely and effective manner, and of rendering findings and recommendations. Decision processes and findings should be recorded in ways that facilitate performance evaluation.

- o Performance Evaluation The organization should have the capability of monitoring its own decisions, findings, and recommendations for internal management purposes. This entails maintaining records of information and processes used in making decisions and any expected outcomes or effects of those decisions, and comparing these with actual outcomes. Besides documenting the decision process, performance evaluation would provide information to the organization's decision makers to enable them to identify ways of improving their performance.

Financial Support

THE CONSORTIUM SHOULD BECOME SELF-SUFFICIENT AS SOON AS POSSIBLE. IN MOVING TOWARD SELF-SUFFICIENCY, IT SHOULD SEEK BOTH PUBLIC AND PRIVATE SECTOR FINANCIAL SUPPORT.

The committee determined that several different strategies should be used to secure sufficient funds for operating the Medical Technology Assessment Consortium. Two kinds of funds would be required: core support and project or program support. Ideally the private/public partnership in the enterprise would be reflected by 50 percent of funds coming from each sector. However, the ratio could vary depending on the organization's functions. The committee believes that an endowment would provide the most stability for the organization. One approach to an endowment would be to solicit a congressional appropriation to initiate the entity.

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Both the National Institute of Building Sciences (NIBS) and the Health Effects Institute (HEI) began with appreciable federal funding, NIBS through direct appropriations, and HEI through budgeted contributions from the Environmental Protection Agency (Fox, 1981). The NIBS Congressional commitment for support extended five years in declining appropriations of one million dollars in the first year to one-half million dollars in the fifth (PL 93-383, 1974). In 1983, technically the sixth year, NIBS received a "last appropriation" of $1.42 million and was expected to be self-sufficient thereafter (Dillon, 1983). This last appropriation may be the closest approximation to a congressionally appropriated "endowment".

HEI had an initial one million dollar "line of credit" from the federal government, administered through the EPA, and the agreement of 24 automakers (8 domestic and 16 foreign) to contribute half of HEI's operational expenditures. Federal budgetary reauthorizations in subsequent years have extended HEI's line of credit to $2.5 million, although its operational expenditures currently amount to only $640,000. With its major research efforts only beginning, HEI will have rapidly increasing costs. The current federal budget will provide HEI with a $3 million line of credit in fiscal year 1984, and private sector agreements will match the federal share of HEI's expenditures (Powers, 1983).

Other than the consortium's receiving a start-up congressional appropriation, an endowment might be obtained by pooling funds solicited from a number of interested parties, including industry, third-party payers, professional associations, foundations, and the like. Such sources and pooling of funds would permit maximum freedom of operation to the new entity.

Another source of revenue for the organization might be in grants, contracts, or other research or fee-for-service arrangements. Such support for specific programs or projects might be available from both public and private sources. Most government support of the entity probably would come in the form of grants or contracts for specific projects.

Once launched, the entity would have the ability to raise additional funds from publication fees, subscriptions, and conference registration fees. Potential users or supporters of services and products of the consortium might include:

- federal, state, and local governmental agencies
- health care financing organizations
- health and medical care professionals and related associations

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- health care institutions
- manufacturers of health industry devices, drugs, and other products
- employers
- labor and consumer groups
- academic and research institutions
- individuals

Membership fees or assessments were seen as less desirable sources of support because they might restrict the freedom of the organization by creating direct relationships with a given health industry, or because assessments would be very difficult to implement in a fair manner.

In contemplating possible budget figures for such an organization, the committee found the budgets of other proposed or existing entities instructive (See Appendix 1). The NCHCT had a yearly budget of approximately $3 million when it ceased to exist. During start-up years, the budget had been substantially smaller but was programmed to grow in size. Over its three-year life the NCHCT engaged in approximately 75 technology evaluations (Perry, 1982).

A budget was unspecified in the authorizing legislation for the proposed new DRG Commission, although a ceiling of 25 staff personnel was stipulated. Appropriation legislation recently passed by the Congress provides $1.5 million for the first year of that commission's operation. The largest budget for any entity was proposed by Relman (1980), who suggested that an assessment of two-tenths of one percent of total expenditures by private and public third-party payers would yield $100-$200 million for a new national program of support for a comprehensive system of technology assessment.

The committee believes that because it would take time to hire staff, develop programs, and establish the consortium, first- and second-year operations might call for budgets of one-third and two-thirds of a million dollars, respectively. In the third year of development the consortium should have an operating budget of approximately $1 million. In subsequent years the consortium might require annual budgets substantially greater than $1 million, but such estimates might be better made during the first three years of development. An initial budget of $300,000 could support a small professional and clerical staff (including the chief executive

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officer), cover travel costs for the board members and a small number of panels, and would cover officing, supplies, telephone, printing, etc. This budget should be sufficient to support preliminary efforts needed to develop the coordinating and clearinghouse functions. As activities of the new entity grow, additional funds could be raised to parallel increasing functions. The committee felt that the new entity would have a better chance of surviving if it began as an organization of modest size, growing as its services increased in importance and effectiveness.

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APPENDIX 1

Summaries of Five Selected Previously Existing or Proposed Health Care Technology Assessment Organizations

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	INSTITUTE FOR HEALTH-CARE EVALUATION "IHCE" (Bunker; 1,2)	INSTITUTE FOR THE ASSESSMENT OF ADVANCED MEDICAL EQUIPMENTS, DEVICES, AND TECHNOLOGY "IMPAMEDT" (AEMB; 3)	CENTER FOR ASSESSMENT OF HEALTH CARE TECHNOLOGY "CAHCT" (Perry; 4)	NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY "NCHCT" (U.S. Congress; 5)	PRIVATE-PUBLIC BODY TO UNDERTAKE MEDICAL TECHNOLOGY ASSESSMENT (Office of Technology Assessment; 6)
PURPOSE	To generate cost-effectiveness data with a strong emphasis on the measurement of outcomes of therapeutic intervention.	To identify, review, critique, plan, perform, synthesize, and report on assessments of new medical technologies and equipments in order to generate core information and associated decision models required by health care institutions, practitioners, third-party payers, and public agencies as a basis for making decisions to acquire, use, improve, or provide reimbursement for such technologies and equipments.	To concern itself with conducting assessments of health care technologies from the standpoint of safety, clinical effectiveness, and ethical and legal considerations.	To undertake and support (by grant and contract) assessments of health care technology ... (taking) into account the safety, effectiveness, and cost-effectiveness of, and the social, ethical, and economic impact of health care technologies.	To undertake (medical technology) assessment activities that would complement federal activities and serve the needs of consumers, providers, and third party payers.
OBJECTIVES/MAJOR ACTIVITIES	Establishment of a uniform data base Systematic identification of agenda issues Generation of new data and analyses Dissemination of information to carriers, professionals, and the public Responsibilities would rest solely with data collection and analysis; should not have responsibility for making policy (eg, making reimbursement decisions).	Conduct assessments of medical technologies Review and critique assessments Report results of assessments, reviews/critiques Develop methods and models for conducting primary assessments, and for applying results of primary assessments in secondary assessments Develop guidelines for application of assessment models, and the use and improvement of technology, equipment and devices Conduct educational program for understanding and use of assessment results, and how to conduct primary and secondary assessments Provide technical assistance in applying results of assessments, and conducting primary or secondary assessments.	Respond to requests for assessments by contributingmember organizations, and possibly from other groups (on a fee basis). Make available results of all evaluations to sponsor organizations. Other possible (eg, contingent on funds) activities include: provide membership periodically with information concerning new and emerging technologies; provide interpretations and appraisals of policy decisions; concerning technologies in federal and other agencies; develop grant-supported research program for obtaining primary evaluative data; mount programs to improve data bases currently available and to delineate utilization patterns of specific technologies study development of improved assessment methodologies; collect clinical data on new technologies as they enter practice.	Encourage, undertake, and support (by grant or contract) research, evaluations, and demonstrations respecting the safety and efficacy of particular health care technologies. Establish priorities for such activities, considering a technology's risks, benefits, cost, rate of use and stage of development. Make recommendations (to DHHS), including recommendations regarding reimbursement policy. Develop and disseminate information concerning the use of particular health care technologies. Assist public and non-profit entities in meeting the costs of planning and establishing new centers, and operating existing and new centers, for carrying out related activities. Shall not unreasonably inhibit the innovation of new technologies. Shall attempt not to duplicate the activities of other (federal) units.	Stimulate the development of uniform and accessible data bases for medical technology assessment. Identify technologies for assessment and establish assessment priorities Develop and refine methods of assessment, including scientific, economic, and social tools. 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. Disseminate new information and serve as a clearinghouse of information on new technologies, assessment of technologies, etc.

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COMPOSITION	Composed in equal parts of members of the groups in the private sector that are concerned with the evaluation of health care: the public (employers, employees, consumers); the profession (researchers, academicians, and clinical practitioners, eg, CHSS, AHA, AAMC); and the service (eg, BC/BS) and commercial (eg, HIAA) insurers.	Founded jointly by AEMB (the Alliance for Engineering in Medicine and Biology, an alliance of over 20 professional organizations in the areas of medicine, engineering and biology) and AMSER (Analytic Services Inc., a non-profit organization engaged in analysis and evaluation).	not addressed as such; see governance	not directly applicable; see governance	A number of groups concerned with the evaluation of health care: physicians and hospital professional associations, consumers represented through industry and labor, private health insurers, and academic centers.
GOVERNANCE/STAFF	Governed by a council composed of representatives (in equal parts) from its major groups: private insurance carriers, HMOs, professional associations, consumers, and state and federal governments. The government, a major source of funding, would be represented either ex-officio or as a full voting member. In addition to topical subgroups, there would be appointed specific departments for legal affairs, communication, and publications.	Governed by a 12-member board of trustees, with three members appointed each by AEMB, AMSER, AEMB/AMSER jointly, and the membership. The staff would include: chief executive, core administrative staff (AEMB subcontract), core technical management staff (AMSER subcontract), and requisite project staffs supplemented with advisory panels as appropriate.	Governed by a blue ribbon advisory panel, composed of experts in a variety of fields such as health care economics, medicine and surgery, law, hospital administration, biomedical technology, ethics, health insurance, information dissemination, etc. Staff would initially include a physician director, two physicians, a biomedical engineer, an administrative officer, and public relations person. In subsequent years, the staff would be expanded modestly to include other disciplines, eg, health economics.	Governed by the National Council on Health Care Technology, consisting of the heads of nine designated federal agencies, including NIH, VA (Chief Medical Director), FDA, CDC, and HCFA; 18 other members appointed by DHHS, including individuals representing medicine, health care technology industry, hospital administration, economics, law, ethics, and consumer interests; and other federal officials by DHHS (as non-voting, ex-officio members).	not specified

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	INSTITUTE FOR HEALTH-CARE EVALUATION "IHCE" (Bunker; 1,2)	INSTITUTE FOR THE ASSESSMENT OF ADVANCED MEDICAL EQUIPMENTS, DEVICES, AND TECHNOLOGY "INFAAMEDT" (AEMB; 3)	CENTER FOR ASSESSMENT OF HEALTH CARE TECHNOLOGY "CAHCT" (Perry; 4)	NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY "NCHCT" (U.S. Congress; 5)	PRIVATE-PUBLIC BODY TO UNDERTAKE MEDICAL TECHNOLOGY ASSESSMENT (Office of Technology Assessment; 6)
FUNDING AND BUDGET	A non-profit organization funded by per capita assessment/levy from qualified health plans. (Federal government would participate through grants/contracts, eg, HCFA demonstrationfunds, plus its per capita assessment.) Funding basis could be either mandatory or voluntary. With mandatory system, health plans would be required to support IHCE as a condition of recognition as "qualified," thereby being eligible to receive tax credits, vouchers, or Medicare payments. With voluntary funding, a membership fee would still be required of participants to cover IHCE's administrative costs. Members would also subscribe in advance to cover costs of conducting specific research studies. An appropriate method for funding of projects (would be to have) funds generated only as the potential users of information judge appropriate. Helmer (7) has suggested that two-tenths of one percent of total third party expenditures for medical care (ie, approximately $300M, currently) might be an appropriate ultimate budget.	A non-profit organization funded by individual contributions ($2M at equilibrium), corporate contributions ($2M), subscriptions from hospitals, clinics and other health care institutions ($4M), government agency grants ($2M), and foundation grants($2M) for a total budget of $12M.	A non-profit organization with funding derived from multiple sources, eg, private foundations, third party payers and health insurance alliances, group health and hospital associations, and corporations and labor unions with major health insurance programs for employees. Funds could be obtained under contract from HCFA for evaluations to be used in coverage decisions and from other federal (eg, CHAMPUS) or state agencies requiring similar services. Estimated budget for first year would come to approximately $0.75M, including 100% overhead and provision for consulant fees.	Federally funded; Federal appropriations: '79 (fiscal year): $15M, '80: $25M, '81: $33M, '82: $3M, '83: $4M, '84: $5M.	A federally chartered, non-profit organization, which could be funded initially by 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. No specified budget.

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SUMMARIES OF FIVE SELECTED PREVIOUSLY EXISTING OR PROPOSED HEALTH CARE TECHNOLOGY ASSESSMENT ORGANIZATIONS

NOTES:

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APPENDIX 2

PRIVATE SECTOR LIAISON PANEL

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APPENDIX 3

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APPENDIX 4

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