Appendix C.—Selected Activities in Medical Technology Assessment

Introduction

Medical technology assessment in health policy today typically refers to an evaluation of the efficacy and safety, and sometimes costs, of medical technology. Medical technology assessments are a source of information needed by government officials in formulating legislation and regulations, by health professionals in managing patients, by industry in developing products, by private insurers in creating benefit packages, and by consumers in making personal health decisions (359). Furthermore, medical technology}? assessments can yield information for hospitals functioning under Medicare's new Diagnosis Related Group (DRG) hospital payment system. [1]

Currently, there are numerous activities in medical technology assessment. Multiple participants from both the public and private sector perform or use medical technology assessments (359). However, there is little, it any, coordination among the various organizations, and because of a lack of funds, many organ i-zations neither assess as many technologies nor perform as comprehensive assessments as they desire. Assessments are used for different purposes, including coverage, payment, purchasing, and management decisions, The focus of this appendix is on assessments made or used for coverage purposes.

In the past 2 years, the private and nonprofit sectors have increased their involvement in assessing medical technology. However, many of their assessments are limited to specific organizational objectives and have limited value for national policy decisions. Safety and efficacy criteria are usually used in technology assessments; economic, legal, social, and ethical criteria are sometimes used.

Public Sector Activities

OTA has estimated that Federal expenditures on evaluating health technologies in general are approximately $200 million a year (361). Only a small fraction of this amount is spent for evaluating medical technologies specifically to determine their eligibility for Medicare payment. By way of contrast, it is interesting to note that fiscal year 1982 reimbursement for Medicare services totaled $50.9 billion (135).

Currently, the body with explicit responsibility for evaluating selected medical technologies to assist the Health Care Financing Administration (HCFA) in determining what diagnostic and therapeutic techniques ought to be covered by Medicare is the Office of Health Technology Assessment (OHTA), of the National Center for Health Services Research in the Public Health Service (PHS). [2] OHTA's budget for fiscal year 1983 was approximately $1 million.

The Medicare program has called on PHS to provide technical medical advice for making coverage decisions since the late 1960's. The coverage advice process established initially was a loosely structured one, relying mainly on informal contacts with experts at the National Institutes of Health (NIH) or medical specialty societies for opinions about the safety and effectiveness of medical technologies. In 1977, the Administrator of HCFA and the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) formalized the PHS role in providing advice through the Office of the Assistant Secretary for Health.

In recent years, the increasingly rapid development and use of sophisticated and expensive medical technologies has increased the number and complexity of Medicare coverage determinations. Thus, Congress passed the National Health Services Research, Health Statistics, and Health Care Technology Act of 1978 (Public Law 95-623). That act established the National Center for Health Care Technology (NCHCT).

One of NCHCT's mandated assignments was to provide scientific / medical assessments to HCFA on Medicare coverage for specific medical procedures and technologies, The agency's overall mission, however, was much broader: it was to "stimulate increased scrutiny of new and existing health care technologies to insure that their safety, efficacy, cost-effectiveness, social, ethical and economic impacts are more completely explored" and to encourage the "rapid dissemination of newly developed health care technologies which have proved their worth in terms of safety, efficacy, (and) cost-effectiveness. " NCHCT's staff was officially limited to never more than 20, but "creative management" by its director, Dr. Seymour Perry, enabled the center to obtain the services of 39 individuals (45). In December 1981, however, NCHCT ceased to function because of a lack of congressional funding.

OHTA, formed as NCHCT's successor, has been assigned a variety of duties (see table C-1). Generally, however, its activities have been confined to evaluating

[1] For more information on DRGs, see OTA s July 1983 technical memorandum *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology* (343).

[2] Despite the similarities in their names the Office of Health Technology Assessment OHTA and the congressional Office of Technology Assessment (OTA) are two different offices

Table C-1 .—Activities of the Office of Health Technology Assessment (OHTA)

- Provide national leadership, coordination, and administration of a comprehensive program for health care technology assessment and transfer to improve the quality and reduce the cost of medical care
- Establish criteria for public and private organizations and individuals both within and outside OHTA to identify the critical technologies to be assessed
- Administer a program of assessments of health care technologies which take into account their safety; efficacy; cost effectiveness; and social, ethical, and economic impacts
- Make recommendations 01 health care technology issues i n the administration of the laws under the Assistant Secretary for Health's jurisdiction, including preparation of the PHS position regarding appropriateness of Medicare coverage of health care technology
- Publish and disseminate the information obtained as a result of activities supported by OHTA, and undertake programs to develop new and improved methods for making such information available
- Provide technical assistance and consultation to organizations and individuals within and outside DHHS engaged in or concerned with the results of health care technology assessments, research, evaluations, and demonstrations
- [b] Coordinate PHS research, evaluations, and demonstrations relating to the assessment of health care technology undertaken and supported by DHHS components.

SOURCE *Federa/ Regisfer* **48(13} 2444 Jan 19 1983**

technologies in response to requests from HCFA. When HCFA has a simple inquiry about the regulatory and research standing of a particular technology, the staff of OHTA provides background information obtained from other PHS agencies, including the Food and Drug Administration (FDA), NIH, the Centers for Disease Control (CDC), and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

HCFA may also request full assessments from OHTA. OHTA's assessment process, which involves synthesizing the available information about a technology and transmitting the results to HCFA, requires 12 to 18 months for completion. As of June 1983, OHTA had a backlog of 12 months or more on 23 technologies requiring assessment—some from 1979 (211). OHTA completed 26 assessments in 1982. The OHTA Director reported that as of June 1983, 16 assessments had been completed, 30 assessments were in progress, and 40 were expected to be completed by the end of the 1983 fiscal year (211).

In performing a full assessment, the OHTA staff first reviews the coverage issue with HCFA, clarifies the original request, and defines appropriate questions. It also initiates a literature search and data collection effort, gathering information from a wide spectrum of sources. Working under a philosophy that it should hear from all interested parties, OHTA advertises an impending assessment in the *Federal Register.* Although notices and advertisements regarding particular coverage issues also appear in professional and trade publications, notices in the *Federal Register* are PHS's primary access to the "general public" and are used to obtain the views of a broad mix of interested parties. Responses to such notices have generally come from industry and physicians.

For available scientific information, clinical trial data, bibliographic materials, and other relevant materials, OHTA solicits the advice and assistance of Federal agencies such as NIH, FDA, ADAMHA, and CDC, Each agency has developed a formal plan for responding to such evaluations. Furthermore, PHS routinely announces the assessment through DHHS's Technology Coordinating Committee, which informs other interested Federal agencies. OHTA also contacts the Council on Medical Specialty Societies, the organization representing all medical specialty societies, as well as the relevant specialty societies for information on the specific technology (or in some cases, a list of technologies) being considered.

The OHTA staff then analyzes and synthesizes the medical and scientific evidence and professional opinions collected. OHTA's assessment, primarily of the safety, efficacy, and clinical effectiveness, of the technology in question is conducted according to specific criteria (399). The types of acceptable information range from qualified medical opinions derived from personal experience, to well-designed clinical studies, to controlled clinical trials, Although OHTA's guidelines emphasize the value of controlled clinical trials, few evaluations have had the benefit of such rigorous evidence (352).

Like its predecessor NCHCT, OHTA provides recommendations to HCFA about the appropriateness of providing Medicare coverage for a technology which it has assessed. OHTA does not release its assessment until HCFA has taken action on the recommendation. The assessments, but not the recommendations, are published and disseminated.

The formation of the Prospective Payment Assessment Commission (ProPAC), mandated with the passage of the Social Security Amendments of 1983 (Public Law 98-21), initiates a new Government involvement in medical technology assessment for payment purposes. ProPAC members were appointed in November 1983, and the body's activities started in the early part of 1984. ProPAC is an independent advisory committee that is empowered to collect and assess information on hospital costs and productivity, technological advances, and the cost effectiveness of hospital services. It is required to use existing informa-

tion where possible but is also given authority to carry out research and to award grants and contracts. ProPAC will make recommendations to the Secretary of DHHS concerning the appropriate payment rate under Medicare's DRG payment system for inpatient hospital services. ProPAC also has broad powers to assess medical technology and the appropriateness of medical practice patterns.

Private Sector Activities

In the private sector, the Blue Cross and Blue Shield (BC/BS) associations often rely on evaluations of medical technology in arriving at coverage and reimbursement decisions. Like Medicare, the BC/BS associations make a majority of coverage decisions through a decentralized and loosely structured process that places key emphasis on two criteria used in Medicare's coverage policy: stage of development and acceptance by the medical community.

Some BC/BS member plans use informal methods to evaluate medical technologies. The medical advisors of individual plans may make coverage determinations based on immediate personal knowledge or may survey the literature and consult with advocates of the procedure, local specialty societies, the county medical society, and other area insurers. If the plan functions as a contractor for Medicare, as an agent for Medicaid, or as an agent for the armed services CHAMPUS program, the medical advisor will generally review the coverage determinations of these programs. Similarly, the medical advisor will usually study the coverage recommendations of the national BC/BS Association and other member plans, although he or she may not follow any previous rulings (353).

On the other hand, there are BC/BS plans that follow an extremely formal procedure for assessment. A particularly active State affiliate, Blue Shield of California, established a Medical Policy Committee in 1966 to assess the scope and limits of Blue Shield's standard medical insurance policies with respect to new diagnostic and therapeutic procedures (52). This committee has continued its interest in evaluating technologies in the interest of cost containment.

Blue Shield of Massachusetts is actively involved in technology assessment, as well. A separate committee, the Interspecialty Medical Advisory Committee, is incorporated into its decisionmaking structure. One of the advisory committee's main duties is to make recommendations concerning medical, surgical, or therapeutic procedures, i.e., to determine the "general acceptability" of a new service or procedure. Only those services or procedures deemed "generally accepted" by Blue Shield are reimbursed. The "generally accepted" guidelines promulgated by Blue Shield of Massachusetts are very similar to those used by OHTA in performing its assessments for coverage purposes (see ch. 5). According to the Blue Shield guidelines (41):

> . . . a generally accepted surgical or medical procedure is a procedure which:
> a) has completed the research or experimental stage of development;
> b) does not involve, as an integral part of the procedure, the use of any drug, substance or device which has not been released by the Food and Drug Administration or other governmental licensing agencies for general use by qualified physicians;
> c) is in general use for patient care by physicians qualified to perform the procedure;
> d) is of demonstrated value for the diagnosis or treatment of an illness, injury, or bodily function.

There are very specific definitions and clarifications for the administration of the Massachusetts Blue Shield guidelines, including a requirement for factual material such as the rates of mortality and morbidity associated with the technology. A health care provider (or group of providers) contacts his or her specialty society committee concerning coverage of a new technology. There are 30 such committees. The specialty society committee then assesses the surgical or medical procedure according to the guidelines just described. If the new technology is approved, the recommendation with all necessary supporting information is presented to Blue Shield's Interspecialty Medical Advisory Committee, which then decides on a fair reimbursement level for the service/procedure. After going through additional steps in the organizational structure, the recommendation is formalized. If coverage is denied, there is opportunity for a request for reconsideration.

The assessment performed by Blue Shield of Massachusetts differs from that performed by OHTA in a number of ways. One important way is that attention is paid in the Blue Shield evaluation to other established procedures that are equal to the procedure under consideration in merit or effectiveness as well as in their morbidity and relative cost. Another important consideration in performing a Blue Shield evaluation is the cost of the prosthesis/device/drug/substance which is an integral part of the proposed procedure.

The coverage recommendations of the national BC/BS Association are made using two mechanisms: the Medical Advisory Subcommittee and the Medical Necessity Program. The Medical Advisory Subcommittee, composed of six medical directors from individual affiliates, meets four times a year to make coverage decisions. Requests for coverage determinations may originate either directly from a manufacturer or provider or indirectly from one of the local plans. After the national BC/BS staff conducts research on the product or service, which may include

collecting the opinions of professional medical associations, the Medical Advisory Subcommittee either reaches a coverage decision or postpones a decision until further information on the product or service is available for review (141).

Cost considerations are more likely to be explicitly included in the evaluation of a technology by the Medical Advisory Subcommittee than they are in evaluations for Medicare. During the initial review for the Medical Advisory Subcommittee, the BC/BS staff gathers information about the reimbursement level for the product or services, or similar product or services, where possible. Furthermore, when a decision is reached, it is reviewed by the Providers Affairs and Cost Containment Review Committees and then by the National Blue Goss and Blue Shield Board Review, The coverage determinations, which go out as a recommendation to the 106 local U.S. BC/BS plans, usually concern new technology and are expressed in broad terms. However, sometimes they specify indications for use.

The Medical Necessity Program was developed in 1977 in conjunction with the American College of Physicians (ACP), the American College of Surgeons (ACS), and the American College of Radiology. It was designed to curtail reimbursement for obsolete, duplicated, and outmoded procedures (4 I). In 1977, the Medical Necessity Program advised BC/BS plans to discontinue routine payment for a group of 42 procedures unless physicians provided special medical justification for their use. Since 1977, the original list of 42 procedures has been expanded to nearly 100 (41). In 1979, on the basis of the recommendations of ACP and ACS, the Medical Necessity Program advised BC/BS plans to pay for diagnostic tests performed at the time of admission to hospitals only when the tests had been specifically ordered by a physician.

The stated objectives of the Medical Necessity Program—cost containment and the improvement of quality of care—remain the same as in 1977. The focus of the program, though, was expanded in 1980 from evaluating possibly obsolete procedures to examining procedures that may be overutilized or inappropriately utilized. In October 1982, the BC/BS national associations recommended new guidelines to member plans "intended to raise the level of cost consciousness" about the unnecessary use of certain respiratory care procedures, with expectations of potential savings of hundreds of millions of dollars annual]y (326).

In arriving at its recommendations, the Medical Necessity Program draws on the advice of national medical specialty organizations including ACP. Indeed, ACP's involvement in evaluating the safety, efficacy, and effectiveness of clinical tests, procedures, and therapies began with its participation in the project (230).

Commercial insurance companies make independent coverage decisions regarding the coverage of new and emerging technologies. When a coverage question arises, a company may contact the Health Insurance Association of America (HIAA). HIAA is a trade association of 338 commercial insurance companies. It will provide information to its member companies on the medical appropriateness of diagnostic and therapeutic procedures. HIAA does not conduct technology assessments, but reports opinions rendered by the Council of Medical Specialty Societies (CMSS) through its program for clinical procedure review (193). In late 1977, CMSS agreed to accept questions from insurers with HIAA acting as the intermediary between the many insurance companies and CMSS. HIAA will transmit the information to the requesting insurer and publish the CMSS opinion in its "Medical Relations" bulletin. Each company makes its own coverage policy decision using its discretion.

Some prepaid group practices have also had experience with medical technology assessment. The Department of Medical Methods Research of the Kaiser-Permanente Medical Care Program (KPMCP) of Northern California has conducted research on the utilization of modern technology for the development of improved methods of providing and delivering medical care within the KPMCP (72). The primary purpose of the department's Division of Technology Assessment is to aid in the selection of the most cost-effective technology. The process of assessment the division uses is quite different from that employed elsewhere, primarily because of the unique financial structure of prepaid group practices, In a prepaid group practice, an increase in the use of a technology often increases expenses and does not generate revenues as it might in fee-for-service or cost-reimbursement programs. In addition, there are no savings from the purchases of equipment that could increase cash flow. Thus, the incentives are for low-cost technology that maintains or improves the effectiveness of medical care.

Assessments at the KPMCP begin with the identification of a technology that uses substantial resources. Next, the characteristics of the population utilizing the technology and the workloads for its utilization are determined. Alternative technologies used for the same specified objectives are evaluated as to important intended and unintended consequences. The technology assessments use epidemiological methods, controlled studies, medical record studies, literature reviews, consensus development, and sensitivity analyses, The results of the assessments are presented as important consequences of alternative technologies so that management can make more rational decisions.

A number of medical specialty societies are interested in technology assessment. ACP is now conduct-

ing the Clinical Efficacy Assessment Project (CEAP), a major effort to study the efficacy, clinical effectiveness, and safety of tests, procedures, and therapeutic interventions. CEAP evaluated 50 procedures and tests from January 1981 through November 1983 and as of March 1984 had 11 other evaluations in process. Almost all the technologies that have been evaluated to date were submitted by the Federal Government or insurance companies who generally use the result in their coverage and reimbursement decisions (21).

The steps in ACP's evaluation process are similar to those used by OHTA. CEAP draws on its membership for information on the technology under evaluation, and after developing a draft statement, sends the statement to outside experts for review. The final statement is written by staff with the help of ACP's Clinical Efficacy Subcommittee.

In addition to ACP, other medical specialty societies and medical associations have either initiated or intensified existing activities involved with medical technology assessment during the past few years. Among these are the American College of Cardiology (ACC), the American Medical Association (AMA), and the American Hospital Association (AHA).[3] Although the assessment activities of these organizations are not as directly linked with coverage and reimbursement decisions as ACP's have been, their findings are often used by public and private insurers.

ACC has three activities related to technology assessment. First, it responds to requests from Federal agencies as well as from the private sector (e. g., hospitals, clinics, third-party carriers) about the standards, criteria, and appropriateness of procedures usually performed in a hospital setting by physicians treating cardiovascular diseases, Second, it has a Joint Task Force in conjunction with the American Heart Association that undertakes in-depth technology assessments. The assessments include criteria of contribution uniqueness, sensitivity, specificity y, indications and contraindications, and cost effectiveness.

The third activity of ACC is new and under development. A Cardiovascular Norms Committee is being formed, to "establish and obtain consensus on dynamic norms (defined as factors essential for quality care decisionmaking) for the diagnoses and management of the most common cardiac diagnoses, including cost effectiveness of alternate plans or diagnostic techniques. " The first step of this ambitious undertaking is to investigate a mechanism for developing dynamic norms (a type of criteria setting) (196).

[3]The American Academy of Pediatric, the American Public Health Association the American College of Radiology are among the other professional associations used that have taken part in evaluating technologies Their activities <ire discussed in the OTA report *Strategies for Medical Technology Assessment* 359

AMA has been involved in evaluating and providing information of technologies through its scientific publications; through a series of reports published by its Council of Scientific Affairs dealing with diagnostic, therapeutic, and other medical technologies; and by responding to thousands of inquiries that involve information on assessment of medical technologies, particularly those that are well established. AMA just began a new project, Diagnostic and Therapeutic Technology Assessment (DATTA), whose purpose is to "expeditiously and effectively examine medical technologies that are passing from experimental or investigational to accepted forms of treatment and define, where possible, indication for their use. " It is intended that the assessments will be limited to the evaluation of the safety and effectiveness of a technology (196).

Other private sector parties with a longstanding involvement in medical technology assessment, especially to determine safety and efficacy, are manufacturers of drugs and devices, They initiate research and are required by FDA to conduct tests for premarket approval of their products. Large private clinics, e.g., the Cleveland and Mayo Clinics, also perform some assessments' (359).

Recently, AHA and other members of the hospital community have become actively involved in evaluating technologies, but mainly from the perspective of planning for new health care services and in reviewing existing services. AHA has played a catalytic role in this authority by issuing the manual, *Technology Evaluation and Acquisition Methods for Hospitals (TEAM),* in 1979 (13). The program described in the manual not only provides a mechanism for hospitals to evaluate technologies for financial reasons but also emphasizes evaluation with respect to community needs and hospitals' role in the community,

AHA has continued to involve its members *in re*cent developments in technology and technology assessment through its Hospital Technology Series Guidelines Reports, published as part of the Hospital Technology Series, which are individual reports devoted mainly to specific technologies. They usually examine the key factors a hospital should include when evaluating a particular technology for purchase, as well as product information on commercially available models of the technology.

In addition, hospitals and hospital chains, such as Humana and the Hospital Corporation of America, are examining technologies more carefully than before. However, when they evaluate technology, it is most often with respect to an "overall risk management program for the identification, evaluation, and treatment

[4]See *Strategies for Medical Technology Assessment* for a description of their activities '359

of risk or financial loss" (292). The Hospital Corporation of America, for example, recommends the formation of a Product Selection Committee by each of its member hospitals. The committee's purpose is to evaluate the degree of inherent risk to each patient and/or employee posed by material that may be introduced into or is already being used within the hospital (171). Prepaid group practices, such as Kaiser-Permanente of Northern California, conduct technology assessments in order to improve their methods of providing and delivering medical care within their organization.

Finally, ECRI (formerly the Emergency Care Research Institute) is a nonprofit organization primarily involved in comparative product evaluations of diagnostic and therapeutic devices and hospital equipment and supplies. ECRI provides a type of "consumer report" service for hospital administrators that gives ratings to comparable medical technologies based on performance safety, ease of use, and cost effectiveness. An emphasis on the larger economic, social and ethical issues surrounding health care technologies has recently been added. Further, ECRI maintains a computerized health devices data base on over 6,000 categories of devices and hospital equipment (28).

Public/Private Sector Activities

There are some indications of cooperation between the public and private sector and among members of the private sector in evaluating medical technologies. Massachusetts Blue Shield, for example, has been sending its Interspecialty Medical Advisory Committee's monthly agenda to HCFA's Office of Coverage Policy for 2 years (436). This mechanism informs the Office of Coverage Policy of current issues pertaining to technology assessments considered in Massachusetts by Massachusetts Blue Shield's Interspecialty Medicare Advisory Committee. The monthly agendas are also exchanged with the Blue Shield of New Jersey's Medical Advisory Committee and with the National Blue Cross and Blue Shield Medical Advisory Committee and their staff. Furthermore, the national BC/BS Association has begun a comprehensive medical policy manual that will be the basis for a uniform medical policy for all of the Blues nationwide (436).

The activities just mentioned are but a few of the numerous efforts underway to evaluate medical technologies. The proliferation of medical technologies and the absence of an organization to coordinate and complement existing technology assessment activities prompted the Institute of Medicine (IOM) to appoint a committee to develop a plan for a technology assessment organization that would be based in the private sector and supported by both governmental and nongovernmental funds (234). The IOM report recommended the establishment of a medical technology consortium that would function under the auspices of IOM during an initial period of development, and then, after approximately 5 years, function as an independent entity in the private sector. The functions of the medical technology consortium would be as follows:

- to serve as a clearinghouse of information on medical technologies and medical technology assessment;
- to assemble and evaluate information and make recommendations concerning individual medical technologies;
- to act when necessary and appropriate to stimulate, coordinate, undertake, or commission medical technology assessments, including activities that would complement those of others;
- to identify needs in the assessment of specific medical technologies;
- to develop and evaluate assessment criteria and methods; and
- to provide education, training, and technical assistance in the use of medical technology assessment methods and results.

The IOM report noted that the "consortium is not intended as a competitor or replacement for an 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. The report recommended that when the consortium first starts to function, initial emphasis should be placed on the clearinghouse function because of expected financial constraints. A proposal for the creation of the consortium awaits funding (169).