# The Federal Role in Health Technology Assessment

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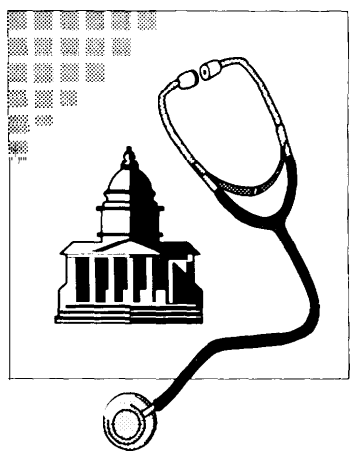
Health technology assessment has been a direct concern of the federal government since at least 1976, the year the Office of Technology Assessment (OTA) published its first report on the topic (778). Interest during the ensuing years has waxed and waned as Congress and other interested parties debated the appropriate uses of health technology assessment and the government's role in this activity,

The debate has been complicated somewhat by the diversity of activities that are sometimes labeled "technology assessment." Although in the context of health care this phrase has been defined comprehensive y at times, to include an analysis of the "evidence of [a technology 's] safety. efficacy. cost. cost-effectiveness, and ethical and legal implications" (597 ), it is also often applied to evaluations of only some of these components. Health technology assessment has been used to describe activities as diverse as hospital purchasing decisions (477a). randomized clinical trials (165), and the cost-effectiveness evaluation of public health programs (348). Indeed. the association of technology assessment with cost-effectiveness analysis (CEA) has led some researchers to consider health technology assessment and CEA to be nearly synonymous (270).

OTA's definition of technology assessment is broader and more policy-oriented than many of the uses of this term elsewhere. In this report. as in previous OTA reports, "health care technology" comprises drugs. devices, procedures, and the organizational and supportive systems within which health care is delivered (780). The inclusion of "organizational and supportive systems" is an acknowledgment that the implications of a health technology depend on its context, and that clusters of individual



technologies organized in a specific way can themselves become a more complex technology--e.g., an intensive care unit.

**"Health technology assessment" as used in this report is a structured analysis of a health care technology, a set of related technologies, or a technology-related issue performed for the purpose of providing input to a policy decision.** Requisite components of a health technology assessment include the collection or generation of information about the technology (including, e.g., information about its effectiveness and cost-effectiveness); a synthesis and critical analysis of that information in the context of the policy decision being addressed; and presentation of the result in language that is relevant to the decision.

In this framework. the perspective and breadth of a given technology assessment is determined by the policy decision to be made. If the decision relates to insurance coverage, for example, the assessment might address issues of effectiveness, utilization, costs to the insurer, effects on the costs and use of other services, and potential for legal liability in the case of noncoverage. In contrast, an assessment of the same technology as part of a national research and development policy might place much more emphasis on factors that influenced the technology's development, and on the broad social consequences of its application.

CEA (discussed in the previous chapter) is often an important component of technology assessment, but the two activities are not synonymous. A CEA alone is only an adequate technology assessment when costs and effectiveness are the sole issues relevant to a policy decision, as might be true for a few clinical management or coverage policies. But CEA is a powerful tool for technology assessment, and interest in assessing medical technologies was a major impetus behind the initial development of the field (780). The two activities are clearly closely linked.

This chapter describes the federal government's involvement in health technology assessment and the relationship of technology assessment to clinical practice guidelines. It also describes the escalating private interest in health technology assessment.

## GROWTH OF HEALTH TECHNOLOGY ASSESSMENT

### Debating the Federal Role

As originally conceived, technology assessments were to be aids to public policy makers. The term itself was coined by legislators concerned about the social impacts of technologies (box 6-1). Despite this history, the federal government role in health technology assessment has been a subject of intense controversy from the beginning.

The earliest reports about health technology assessment (778,779) drew attention to the fact that most medical technologies were introduced and widely adopted without undergoing any rigorous evaluation. Few were adequately evaluated even for their safety and efficacy, much less their broader effectiveness, costs, and social implications. Although the Food and Drug Administration (FDA) evaluated evidence that drugs were safe and efficacious as part of its regulatory responsibi - lities, similar responsibilities relating to medical devices were enacted only in 1976 and were much more limited. No systematic process of evaluation of medical or surgical procedures existed at all. Nor has the FDA generally viewed its authority or responsibilities as extending to the examination of economic or social issues.

Because they largely escaped FDA scrutiny, medical devices and procedures were a natural first target for federal technology assessment efforts. At a time when rapidly rising health care expenditures were becoming a matter of increasing concern, the introduction and diffusion of expensive medical devices was considered a major contributor to medical costs (597). The federal government's support for health planning, and its financial interests in the Medicare and Medicaid programs, made devices such as the computed tomography scanner particularly attractive targets for assessment (see, e.g., reference 782). The association of technology assessment with the valuation of expensive devices for the purposes of government health planning and technology man-

## BOX 6-1: The Origins of Technology Assessment

The concept of "technology assessment" is rooted in the political and social debates o? the 1960s and 1970s, when the environmental and social consequences of technologies such as the pesticide DDT and the supersonic transport plane were prime topics for political discussion at every level Credit for Introducing the phrase is traditionally assigned to Emilio Daddario, former chairman of the Science, Research and Development Subcommittee of the House Science and Astronautics Committee of the U S Congress, who defined it in 1967 as" ...a form of policy research which provides a balanced appraisal to the policy maker It is a method of analysis that systematically appraises the nature, significance, status, and merit of a technological progress" (1 47)

Early uses of the term specifically required that technology assessments should identify indirect effects of technological innovations and assess these effects for the purpose of improving decisions regarding the social use of technology (428a,774). The idea that "technology in this context should be broadly defined was explicit, an early report to Identify candidate technologies for assessment included such items as acupuncture for pain relief, early tests for fetal deformities, and compulsory heroin treatment clinics (554).

The concern regarding the impact of technology on society led directly to the creation of a small legislature support agency, the Off Ice of Technology Assessment (OTA), to assist Congress in making decisions that revolved science- and technology-related issues The OTA Health Program issued its first report, on Development of *Medical Technology Opportunities for Assessment?,* in 1976 OTA continues to produce assessments of both Individual technologies and broader technology-related issues at the request of Congress

SOURCE Off Ice of Technology Assessment 1994, based on sources as shown Full citations are at the end of the report

agement, however, meant that from the beginning the activity was often considered directly counter to the interests of the health products industry and the autonomy of professional medicine.

The federal government took several steps in the 1970s to fill its perceived need for information about potentially problematic health care technologies. In 1972, Congress created OTA to perform technology assessments and related analyses for the purpose of assisting with legislative decisionmaking (Public Law 92-484). The Health Program was created within OTA in 1975 and released its first report, on opportunities for assessing medical technologies. in 1976 (778). OTA continues to perform assessments of health care technologies and technology-related issues, but because it is located in the legislative branch of the government, its role in producing health technology assessments is limited to those requested by Congress.

In 1977, NIH (at the urging of Congress) established the Office of Medical Applications of Research and its Consensus Development Program. Its stated goal was to bring together physicians, consumers, scientists, and others "in an effort to reach general agreement on whether a given medical technology is safe and effective" (864). The first Consensus Development Conference, on breast cancer screening. took place in September 1977 (866).

Then, in the following year, Congress established the National Center for Health Care Technologies (NCHCT) (Public Law 95-623). NCHCT had an ambitious mandate that embraced a broad role for the federal government in con-

ducting and facilitating health technology assessments. Its mandated activities included setting priorities for technology assessments, conducting assessments, developing standards for the use of technologies, and advising the Medicare program regarding coverage for new technologies (68, 241 ,598). Its mechanisms for carrying out this mandate included not only intramural staff analyses but clinical studies and the use of panels of expert advisors.

NCHCT was confronted with immediate opposition from medical and industry organizations (63 1). The establishment of standards particularly concerned these groups. During hearings preceding the reauthorization of the center in 1981, the American Medical Association (AMA) testified that NCHCT would interfere with the practice of medicine (76), and the Health Industry Manufacturer's Association argued that NCHCT's functions were unnecessary, would stifle innovation, and duplicated those of NIH (674,675). Congress did reauthorize the center, with an abbreviated role that eliminated the standards mandate. The administration did not request funding for NCHCT, however, and Congress elected not to appropriate the authorized budget.

After NCHCT's political demise in October 1981, a vestige of the center became the Office of Health Technology Assessment (OHTA) in the National Center for Health Services Research (NCHSR). The duties of this small office were reduced to advising the Medicare program regarding the safety and effectiveness of medical technologies being considered for coverage. OHTA assessments relied largely on staff-conducted literature reviews, surveys of other agencies' activities and evaluations, and on unpublished clinical evidence provided by manufacturers and others.

Although OHTA was responsive to Medicare concerns, it did not address other interests that were also initially behind the creation of NCHCT. States, private insurers, and federal policy makers with broader concerns in the social, economic, and health care implications of medical technology still lacked access to assessments that incorporated these concerns.

Congress created the Prospective Payment Assessment Commission in 1983 to address some of the federal needs for technology assessment in light of changes to the way Medicare paid hospitals (Public Law 98-21 ).} Unlike NCHCT, the Commission was supported politically by industry, which saw it as a way to have a voice in Medicare payment policies that would affect the adoption of expensive new technologies (363a). Over time, however, the technology assessment component of the Commission's work has declined, and this activity is now manifested primarily through efforts to assess the extent to which hospital payments should be changed to account for technological innovation (3,785).

Congress found a temporary home for broader efforts in 1984 with the establishment of the Council on Health Care Technology Assessment (Public Law 98-55 1), which was placed under the auspices of the Institute of Medicine (IOM). The IOM had previously been quite active in addressing the issue of medical technology assessment, including the development of a report on technology assessment and its component techniques (366). The Council was charged with operating a "clearinghouse" for technology assessments, conducting assessments, and furthering methodological development (259). Its contributions included a directory of organizations that performed medical technology assessment (367) and several publications on conceptual and methodological issues (368,374,375). The Council found it difficult to raise the private funds necessary to help support its activities, however (635), and its authorization was allowed to expire in 1989, the year that the

[1] Beginning in 1983, Medicare ceased reimbursing hospitals for their Medicare-related inpatient expenses on the basis of actual cost and began paying for them under a prospective payment system based on diagnosis-related groups (Public Law 98-21 ).

Agency for Health Care Policy and Research (AHCPR) was created.

In AHCPR's mandate, Congress re-established a more direct role for the federal government in conducting health technology assessments for brooder purposes. Along with its mandate to support effectiveness research, AHCPR inherited the old NCHSR[2] and most of its functions, including those of OHTA. To date, OHTA technology assessments have been done only in response to requests from federal health program policy makers—specifically, the Medicare program and the Department of Defense's CHAMPUS insurance program for military dependents (351). The output of the office is accordingly small, averaging fewer than five assessments or reviews (more limited evaluations) per year (box 6-2). The 1992 legislation reauthorizing AHCPR now permits the agency to perform individual technology assessments for more general reasons (Public Law 102-41 O), but whether the agency will have the resources and the desire to do so is still unclear.

## Health Technology Assessment in the Private Sector

For all of the federal government's 15 years of involvement in health technology assessment, it has never really carried out the central technology assessment repository function originally envisioned for NCHCT. A recent, briefly contemplated proposal to augment OHTA's funds with private funds and cater to a larger clientele—particularly the needs of private health insurers—was dismissed as politically and administratively infeasible (440,521).

But in the private as well as the public sector, the demand for timely and relevant technology assessments has increased. Rather than information on broad social implications or regional health planning efforts, private users of health technology assessment want targeted information to help them make coverage, purchasing, and management decisions. Ironically, the interest in assessing technologies in order to monitor and control their use remains a major impetus for the demand for this activity, but the planners are now often private managed care organizations and multihospital systems rather than governments.

Stimulated by this demand, a small but explosive private market for health technology assessments produced by and for health care providers. payers. and manufacturers is flourishing. In this market, activities have largely abandoned technology assessment initial emphasis on broad social and ethical impacts and focused instead on more local and user-specific needs.

Private organizations have been involved in their own versions of health technology assessment for some time. In 1981, for example, the American College of Physicians (ACP) established a Clinical Efficacy Assessment Project to evaluate procedures, tests, and therapeutic interventions within the purview of internal medicine ( 16). Although primarily intending its guidelines to be used by physicians to eliminate obsolete and unnecessary tests and procedures, ACP also specified that the guidelines might be helpful to others for policymaking and for setting research agendas.

In 1982. the AMA established its Diagnostic and Therapeutic Technology Assessment Program (DATTA). Unlike the ACP effort, AMA's assessments were based on opinion surveys of selected panels of up to 70 physicians, and they were specifically aimed at assessing the acceptability and effectiveness of new technologies (20). Although the immediate purpose of the program was to provide information on technologies to physicians "in a timely manner," it was also a defense against the assessments of nonphysicians and was intended "to represent the views and concerns of the practicing medical community to public policy makers" (508). Both the ACP and AMA

[2] In 19X9. when NCHSR was folded into the newly created AHCPR, its full name was the National Center for Health Services Research and Health Care Technology Assessment.

## BOX 6-2: The Activities of AHCPR's Office of Health Technology Assessment, 1991-94

*Reviews* [1]

1991 Laparoscopic Cholecystectomy

1992 Home Uterine Monitoring
Procuren: A Platelet-Derived Wound Healing Formula
Cochlear Implantation in the Outpatient Setting

1993 Lymphedema Pumps: Pneumatic Compression Devices
Intradialytic Parenteral Nutrition for Hemodialysis Patients
Small Intestine and Combined Liver-Small Intestine Transplantation
External and Implantable Infusion Pumps

1994 Electrical Bone Growth Stimulation and Spinal Fusion

*Assessments*

*1991* Intermittent Positive Pressure Breathing Therapy
Hyperthermia in Conjunction with Cancer Chemotherapy
Cardiac Rehabilitation Programs
Polysomnography and Sleep Disorder Reports
Single and Double Lung Transplantation
Measuring Cardiac Output by Electrical Bioimpedance

*Forthcoming assessments*

Heart-Lung Transplantation
Plethysmography
Combined Kidney-Pancreas Transplantation

[1] In the terminology used by OHTA, 'Technology Reviews are brief evaluations of health technologies prepared by the Office of Health Technology Assessment, Agency for Health Care Policy and Research (OHTA/AHCPR) of the Public Health Service Reviews may be composed in lieu of a technology assessment because the medical or scientific questions are limited and do not warrant the resources required for a full assessment the available ewdence is limited and the published medical or scientific literature is insufficient in quality or quantity for an assessment. or the time frame available precludes utilization of the full. formal assessment process" (825)

SOURCE B Gordon Off Ice of Health Technology Assessment, Agency for Health Care Policy and Research Public Health Service, U S Department of Health and Human Services, Rockville, MD personal communication May 25 1994, U S Department of Health and Human Services, Public Health Ser'wee, Agency for Health Care Policy and Research Off Ice of Health Technology Assessment OHTA Assessment and Reviews Published 1981-, unpublished document Rockville MD February 1994

technology assessment activities still continue (see appendix C).

The extent of the blossoming of the private sector market is hard to evaluate precisely. In 1988 (he IOM attempted to document all U.S. producers of health technology assessments in its Medical Technology Assessment Directory (367). At that time IOM identified seven governmental and 30 nongovernmental organizations that performed assessments (table 6-1 ). Of the private-sector organizations, over half ( 16) were provider or payer organizations, such as the AMA, the

## TABLE 6-1: Organizations Involved in Health Technology Assessment Activities, 1988

| Type of organization | Name of organization |
|---|---|
| **Government** | U S Congress |
| | Prospective Payment Assessment Commission |
| | Off Ice of Technology Assessment |
| | U S Department of Health and Human Services |
| | Agency for Health Care Policy and Research |
| | Food and Drug Administration |
| | Health Care Financing Administration |
| | National Institutes of Health |
| | U S Department of Veterans Affairs |
| **Academic** | Brandeis University |
| | Health Policy Center, Organ Procurement Project |
| | Duke University |
| | Center for Health Policy Research and Education |
| | Georgetown University Medical Center |
| | Institute for Health Policy Analysis |
| | Harvard University |
| | School of Public Health, Institute for Health Research |
| | Johns Hopkins University |
| | Program for Medical Technology and Practice Assessment |
| | University of California, San Francisco |
| | Institute for Health Policy Studies |
| | University of Pennsylvania |
| | Leonard Davis Institute of Health Economics |
| **Provider/payer organization** | American Academy of Neurology |
| | American Academy of Ophthalmology |
| | American Academy of Pediatrics |
| | American College of Cardiology/American Heart Association |
| | Task Force on Assessment of Cardiovascular Procedures |
| | American College of Obstetricians and Gynecologists |
| | American College of Physicians |
| | American College of Radiology |
| | American Dental Association |
| | American Diabetes Association |
| | American Gastroenterological Association |
| | American Hospital Association |
| | American Medical Association |
| | American Society for Gastrointestinal Endoscopy |
| | Blue Cross and Blue Shield Association |
| | California Medical Association |
| | College of American Pathologists |
| **Other private** | Battelle Memorial Institute |
| | ECRI |
| | Lewin and Associates, Inc |
| | Medical Technology and Practice Patterns Institute |
| | Policy Analysis, Inc |
| | Project HOPE Center for Health Affairs |
| | U S. Administrators Inc |

SOURCE Institute of Medicine, Council of Health Care Technology *Medical Technology Assessment Directory* C Goodman (ed ) (Washington DC National Academy Press 1988)

ACP, and the American Hospital Association. Another seven were university-based centers (e.g., the Johns Hopkins University Program in Medical Technology and Practice Assessment), and seven were private consulting or research organizations (367) (table 6-1 ).

Since IOM's inventory, the organizations it described all still appear to exist, and at least some have grown considerably. Among the largest private firms is ECRI,[3] which in 1988 produced primarily technical reports on the capabilities of medical devices. It has doubled in size and has greatly expanded its breadth of assessments, producing about 40 assessments per year for clients ranging from providers to purchasers of health care ( 128,579). It also operates a technology assessment clearinghouse funded by the World Health Organization.

Entirely new firms have sprung up as well, capitalizing on the interest in effectiveness research, cost-effectiveness analysis, and assessments of individual technologies. Technology Assessment Group, Inc., for instance, incorporated in 1990, markets its expertise in cost-effectiveness analysis and quality-of-life studies (885). One novel company, MetaWorks, offers meta-analyses of clinical studies (652). An upcoming directory produced by ECRI will list over 200 organizations in the United States and elsewhere that undertake health technology assessments or related activities (579). The rapid growth of these activities attests to the increasing importance given to knowledge of the costs and health effects of specific medical technologies in private sector (and state-level) decisionmaking.

Activity in the private sector is especially interesting in light of the fact that it was opposition by manufacturers and health care providers that helped bring about the demise of NCHCT in 1981 (68,598). Ten years later, a collaborative group of manufacturers. payers, and providers in Minnesota has published a consensus document advocating technology assessment that is being used in State health reform efforts (329,5 18).

Growth is not confined to proprietary consulting firms. Hospitals and managed care providers are now entrenched consumers of technology assessment. Although relatively few individual hospitals conduct formal assessments (900), hospital organizations are producing them in significant numbers. The American Hospital Association, for example, issues a periodical *(Technology Reports)* that offers in-depth commentary on new technologies. The University Hospitals Consortium, an association of academic teaching hospitals, has had an in-house technology assessment office since 1989 (498). The Hospital Association of New York State recently produced a detailed manual for hospitals on how to do and use technology assessments for hospital decisionmaking (121 ).

Insurers have likewise begun to turn to formal technology assessments to assist their decisionmaking. In some of the most striking examples:

- Blue Cross and Blue Shield Association's Medical Necessity Program is now in its 18th year of operation. The Association has also expanded its Technology Evaluation and Coverage program through a cooperative technology assessment venture with Kaiser Permanence Medical Care Program, and in a major change from past policy the organization will make these assessments available to the public (282) (box 6-3).
- Other major insurers such as Cigna, Prudential, and Aetna now also have their own full y staffed technology assessment divisions (1 78).
- A managed care organization, The HMO Group, established its TEMINEX project in 1989 to assess technologies on behalf it its members (258).
- The Health Insurance Association of America, whose members tend to be somewhat smaller insurance companies, has investigated an

[3] ECRI (formerly the Emergency Care Research Institute) is now the full name of this organization.

**BOX 6-3: The Technology Assessment Activities of the Blue Cross and Blue Shield Association**

One of the earnest organized private technology assessment efforts was the Blue Cross and Blue Shield Associations (BCBSA's) Medical Necessity Program, which began in 1976 The Medical Necessity Program identified lists of medical and surgical procedures which contributed to the cost of health care but, in many Instances, did not make parallel contributions to the quality of care'" (67) The program's purpose was to inform member plans regarding specific coverage decisions and participation questions Physician organizations, such as the American College of Physicians, the American College of Radiology, and the American College of Surgeons, assisted in the identification of procedures that were either unproven, redundant when performed in conjunction with others, or repeated without clinical value The technology assessment process Included a literature review of articles and the creation of a guideline that was reviewed by the appropriate medical specialty society and the BCBSA Medical Advisory Panel Once approved, the guideline represented the official recommendation of the Blue Cross and Blue Shield Association to its member companies (67)

The Medical Necessity Program continues but has been augmented by a separate Technology Evaluation and Coverage Program, established in 1985 This programs goal is to assist member plans in determining the clinical status of emerging technologies and to aid in the coverage and reimbursement decisions The TEC Program evaluates medical and surgical procedures for specific conditions, focusing on the diagnostic and treatment value Unlike the Medical Necessity Program, it is explicitly concerned with costs as well as health effects Recently, Blue Cross and Blue Shield Association announced its decision to undertake its TEC efforts in collaboration with Kaiser Permanente Medical Care Program, a major prepaid care provider (282)

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agreement with a private company to perform technology assessments for its members (329).

## Clinical Practice Guidelines and Technology Assessment

Clinical recommendations based on the deliberations of groups have become commonplace, as advances in medical knowledge have increased the complexity of decisonmaking and made it difficult for individual clinicians to keep abreast of the emerging literature. Many health professional associations themselves produce practice guidelines: AMA's *Directory of Practice Parameters* lists 1,500 guidelines of some kind produced by more than 45 organizations (22).

Clinical practice guidelines have a diverse array of potential roles and applications, reflected in the many definitions of guidelines that exist. Probably the most widely cited definition is one developed by the IOM. Here. practice guidelines are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (371 ). This definition emphasizes the traditional role of guidelines in assisting in individual clinical decisionmaking.

Other definitions have emphasized the role of clinical practice guidelines as clinical policy statements about the proper way to practice clinical care. Woolf, for example, uses "practice guidelines" to refer to "the official statements or policies of major organizations and agencies on the proper indications for performing a procedure or treatment or the proper management for specific clinical problems" (944). Eddy distinguishes among different types of "practice policies, " which range from "standards" to "opinions, " ac-

cording to the level of certainty that underlies their respective recommendations (200).

Clinical practice guidelines clearly serve policy purposes other than establishing clinical policies and aiding in individual clinical decision - making. In its 1992 report on the topic, the IOM identified fivc major purposes of guidelines (371 ):

1. to assist clinical decisionmaking by patients and practitioners:
2. to educate individuals or groups;
3. to assess and assure the quality of care (e.g., by establishing clinical indicators for quality assurance programs);
4. to guide allocation of resources for health care (e.g., insurance payment decisions): and
5. to reduce the risk of legal liability for negligent care (e.g., through laws that restrict the liability of physicians who were following practice guidelines).

Clinicians have frequently viewed guidelines developed for some of these roles, particularly those associated with payment, with some suspicion. Guidelines promoted by insurers are regarded by physicians as less credible than guidelines promoted by the physicians' own organization (768). Much of the antagonism against the old NCHCT related to the agency charge to develop "'standards" for the use of particular technologies (68).

Guidelines less associated with payment have inspired less concern, even if those guidelines are sponsored by government agencies. In fact, federal agencies have sponsored the development of clinical practice guidelines for topics within their purviews for years. The Centers for Disease Control and Prevention (CDC), for example. has been promoting recommendations regarding vaccinations since the 1960s, in its role as protector of the public health. The National Heart, Lung, and Blood Institute's cholesterol, asthma, and blood pressure guidelines are likewise well known (663,854,856,857). Until recently, the National Cancer Institute published and disseminated screening recommendations for many cancers (361).[4]

When Congress established AHCPR in 1989, it created a new, separate, and very visible additional guidelines effort through its mandate that AHCPR establish a Forum for Quality and Effectiveness in Health Care to produce clinical practice guidelines. The theory was that the panels developing the guidelines would use the results of effectiveness research, augment these findings with their own expert judgment, and come up with templates for the best qua] it y medicine. AHCPR's guidelines and effectiveness research efforts were purposefully located outside of the Health care Financing Administration (HCFA) to enhance their acceptability to providcrs by minimizing their association with Medicare's cost control objectives (295).

The federal government dive into broad-spectrum clinical guidelines at AHCPR in 1989 undcrlined the split that had gradually been growing between the activities labeled "health technology assessment" and those involving clinical practice guidelines development. At AHCPR, the split is evidenced in three ways. First, the guidelines development office was established as an entity entirely separate from OHTA, with little apparent overlap in activities between the two. Second, in contrast to the technology-specific focus of OHTA's work, AHCPR's clinical practice guidelines focus on the broad sets of interventions used in the management of a particular clinical condition, rather than on individual technologies. Third, AHCPR "technology assessments" are staff-generated. while guidelines are developed by external expert groups sponsoed by the agency. The extent of the conceptual split between guidelines and technology assessment at the agency is demonstrated by the fact that staff in the guidelines office are quite insistent that clinical practice guidelines and technology assessment are entirely different activities (501 ).

[4] NCI now assembles and evaluates evidence regarding screening tests but does not make recommendations (see appendix C).

Yet much of the distinction between health technology assessment and clinical practice guidelines is artificial. Like other technology assessments, guidelines can focus either on a single technology (e.g., the acceptable applications of a particular procedure) or on a technology-related issue (e.g., alternative technologies for managing a particular medical condition). NIH's Consensus Development Program was explicitly designed as a method of assessing medical technologies that produced statements for clinicians about the appropriate use of those technologies. Both the ACP and AMA technology assessments efforts described above also share these characteristics.

And, like other technology assessments, guidelines can be used for policymaking, including payment and other resource allocation policies. In fact, all clinical practice guidelines represent resource allocation decisions on the part of the persons creating the guideline. Those decisions may be to underscore current practice—i.e., resources should best be allocated as they are at present-or to change resource allocation—i.e., in favor of different practices, which use different resources. RAND's expert panels examining the appropriateness of different indications for particular procedures, described in chapter 2, are particularly explicit attempts to create guidelines to influence the resource allocation associated with technologies they assess.

Thus, in the context of public policymaking, clinical practice guidelines can be considered a particular form of technology assessment, where the assessors are an expert panel and the audience comprises not only program decisionmakers but individual clinical decisionmakers as well. When guidelines are sponsored by the federal government, the different potential "roles" of guidelines are simply the mechanisms by which the government can attempt to influence the content of clinical care. The technologies examined in the guidelines may be individual products or procedures, or they maybe the sets of technologies used within a management strategy.

The government's goals in developing guidelines are presumably to improve the effectiveness and quality of care, constrain the costs of care, or achieve other social objectives (e.g., improve the equitability of access to care). One of the attractions of guidelines development as an assessment mechanism is the fact that it involves representatives of some of those affected by the guidelines through their inclusion in the expert group creating the guideline.

All guidelines are not equally valid or equally effective. The IOM has suggested some of the attributes of a guideline that it considers desirable. including reproducibility, applicability, and clarity (box 6-4). IOM's criteria do not address the implications of how costs are considered (or not considered) when creating guidelines. Their criteria also do not address the interactions of the expert group and how group members consider the information available to them, another important contributor to the validity and reliability y of guidelines. These and other components of guidelines development are discussed in chapter 7. Chapter 8, in turn, discusses the impact of different strategies for implementing guidelines on clinical practice.

## CONCLUSIONS

**One of the most remarkable developments in the field of health technology assessment has been its transition from the public to the private sector.** Certainly, a few individual private sector payers and providers have been involved in health technology assessment for years. What is new is the degree to which technology assessments are becoming a standard ingredient in private-sector decisionmaking. While the federal government's investment in individual technology assessments has been largely unchanged in degree over the past decade, the private market in technology assessments has become a full-fledged economic activity in its own right.

Two seemingly opposing trends in this market are notable. The first is the increasing number of payers and providers, or groups of providers, performing their own technology assessments and with staff dedicated to that purpose. This trend is illustrated, for example, in Aetna's dedicated

## BOX 6-4: The Institute of Medicine's Attributes of a "Good" Guideline

The Institute of Medicine has proposed several attributes that a "good" guideline should have.

- *Validity* — when followed, practice guidelines should lead to the health and cost outcomes projected for them,
- *Reliability* — given the same evidence and methods for guidelines development, another set of experts should produce essentially the same statements and given the same clinical circumstances, the guideline should be interpreted and applied consistently by practitioners.
- Clinical *applicability* — practice guidelines should be as inclusive of appropriately defined patient populations as evidence and expert Judgment permit, and they should explicitly state the population to which statements apply,
- *Clinical flexibility* — practice guidelines should identify the specifically known or generally expected exceptions to their recommendations and discuss how patient preferences are to be Identified and considered.
- *Comprehensiveness* — practice guidelines should include all likely clinical alternatives or indications for the use of an Intervention.
- *Specificity* — guidelines should have detailed descriptions of the circumstances for which an intervention IS recommended, is appropriate, or for which there is inadequate information to form an opinion.
- *Soundness* — guideline recommendations must be based on good evidence
- *Ease of use* — guidelines should be concise, unambiguous, and in a format which makes it easy for clinicians to use them,
- *Scheduled review* — guidelines should include a statement about when they should be reviewed for revisions,
- *Documentation* — the procedures followed in developing guidelines, the participants involved, the evidence used, the assumptions and rationales accepted, and the analytic methods employed must be documented and described meticulously,

SOURCE Off Ice of Technology Assessment, 1994, based on information from Institute of Medicine, *Guidelines for C/mica/Practice from Development to Use* (Washington DC National Academy Press, 1992), L L Leape, "Practice Guidelines and Standards An Overview, " Qua/@ *Review Bulletin*, 16(2) 42-49 1990

technology assessment section and the creation of a technology assessment shop in the University Hospital Consortium. Dedicated in-house divisions such as these enable the organizations to develop technology assessments specifically tailored to the needs of their users—in these cases, an insurer and academic medical centers.

At the same time, consulting firms and academic centers specializing in technology assessments are flourishing. Rather than tailoring their assessments exclusively for the interests of one particular user, these organizations market a relatively more uniform product to multiple users. (Individual assessments, however, may be tailored for a specific client.) What both these trends-dedicated in-house technology assessment and greater use of external assessors—have in common is

their demonstration of the enormous and growing demand for assessments.

Health technology assessments generally require multiple areas of expertise (e.g., clinical, statistical, economic, etc.). While only relatively large organizations can justify many staff dedicated to the endeavor, private firms have responded to the market demand for health technology assessments by assembling the needed expertise in consulting firms and marketing that expertise to organizations that cannot sustain in-house efforts. The recent changes in the Blue Cross and Blue Shield Association's dedicated technology assessment division illustrate this nicely: the organization is now collaborating jointly with Kaiser Permanence in this effort, and it is marketing its assessments for the first time to outside organizations.

OHTA has been instructed by Congress to set priorities for technologies to assess in the event it can conduct some private assessments (Public Law 102-410), and it has taken steps to establish these priorities (827). Given the vastly expanded private sector capability for individual technology assessments, however, payers, providers, and others wanting assessments of particular technologies are not dependent on the government to obtain them. Thus, rather than expanding its activities to cater to the private market, one possible future role for OHTA would be to continue to perform assessments for government programs only. The Office could, however, also expand its usefulness to other government decisionmakers (e.g., Medicaid programs). Exceptions could be made for unusual circumstances in which an assessment is believed to be vitally needed and for some reason is not being conducted, or cannot be adequately conducted, in the private sector.

Alternatively, Congress may consider that developments in health reform underscore the need for reliable assessments from a single source. so that private payers and providers are not faced with conflicting conclusions from assessments by different sources, and so that critiques of the assessments can be both public and focused. If this is the case, OHTA (or another federal body) would need to greatly increase its size and scope to accommodate user needs.

Even if a more limited role is envisioned for OHTA, its usefulness might be improved by encouraging it to assess technologies with greater impact. Many of its past assessments have been on fairly technical and esoteric topics (e.g., the Rehfuss test for gastric acidity and the debridement of mycotic toenails). By broadening the scope of its assessments (and staff expertise) to include cost and other impacts, and extend the breadth of technologies it assesses, OHTA would be more likely to be able to help fill future needs under health reform.

In both its legislative origins and its organizational placement, the new federal guidelines effort is much more closely aligned with effectiveness research than with health technology assessment. At present, AHCPR guidelines tend to be viewed as distinct from technology assessments by virtue of their focus (management- vs. technology-focused); their purpose and audience (educational advice to clinicians vs. coverage decisions for payers); and their source of production ('*expert group" vs. staff-produced).

In fact, however, federal guidelines development efforts arc simply a different manifestation of the need to assess the impacts of health technologies. Even if guidelines are intended primarily for individual educational purposes, they constitute decisions about the best use of medical technologies that are implicitly supported by the federal government. From the perspective of public policymaking, the distinction between guidelines and technology assessments is not a valid one.

Guidelines do have some unique attributes. In particular, unlike other federal technology assessments, they involve clinical experts or other public representatives of affected groups as the assessors themselves. Because guidelines are important to many of the proposals to improve the health care system, in both the private and the public sectors, the methods by which they are derived and the impact they have on practice deserve considerable attention,